

PATIENT INTERFACE

TECHNICAL FIELD

[0001] The present invention relates to a patient interface for delivering respiratory therapy to a patient. In particular, the present invention relates to a non-invasive
5 patient interface for delivering pressurised respiratory gasses to a patient.

BACKGROUND

[0002] One current treatment for respiratory diseases, such as thoracic restrictive diseases, acute respiratory failure, advanced neuromuscular diseases, chronic obstructive pulmonary disease (COPD - which includes emphysema, refractory
10 asthma, and chronic bronchitis), is non-invasive ventilation (NIV) therapy. There is some evidence to suggest that NIV therapy may be useful for assisting respiration after intubation, including reducing the chances of re-intubation. The NIV therapy applies a positive airway pressure to the lungs throughout the inhalation and exhalation cycles. This improves the flow of respiratory gas into and out of the lungs.

15 [0003] However, one side effect of the positive pressures applied in current NIV treatments is that the therapy pressures applied can make patients uncomfortable and, therefore, less willing to undergo the treatment. A follow-on effect of the positive pressure is that it requires the patient interface to be secured firmly to the patient to for a seal sufficient to minimize leakages and, thereby ensure that the pressure can
20 be maintained in both the patient interface and the respiratory system. Such firm application of the patient interface to the patient's face can cause pressure sores, particularly for patients that are semi-conscious or unconscious and, therefore, are unable to provide feedback on any soreness caused by the pressure of the patient interface on their skin.

25 [0004] For at least the reasons above, NIV therapy gives rise to two prominent challenges, namely compliance (the extent to which patients are willing to submit to the therapy) and pressure sores created for contact between the patient interface and the patients skin. In addition to these challenges, a further challenge for patients with obstructive respiration diseases or acute respiratory failure is flushing exhaled
30 carbon dioxide from their anatomical dead space. Specifically, the end of the exhalation cycle is characterised by a reduction in pressure of the patient's airway. This means that the carbon dioxide-loaded respiratory gas remains in the throat,

nose, and mouth of the patient and is pulled back into the lungs at the commencement of the next inhalation cycle. Replacing the carbon dioxide-loaded respiratory gas in these regions with fresh respiratory gas that includes lower levels or carbon-dioxide (and higher levels of oxygen) than the carbon dioxide-loaded respiratory gas therefore assists patients in achieving improved respiration via improved ventilation efficiency.

[0005] It is believed that this improved ventilation efficiency may enable a reduction in therapy pressures which may lead to a reduction in pressure sores and an improvement in patient compliance. Alternatively, it may provide improved ventilation at the same therapy pressures and lead to improved patient outcomes and a reduction of time spent undergoing NIV therapy.

[0006] It is desirable to provide a patient interface that improves patient comfort and that reduces pressure sores by improving ventilation of the patient.

[0007] It is also desirable to provide a patient interface that assists with flushing anatomical dead space.

SUMMARY OF DISCLOSURE

[0008] Aspects of a patient interface for delivering respiratory therapy to a patient will now be described by way of a set of embodiments. However, it will be appreciated that further aspects may be defined by combining the features of two or more of the embodiments.

[0009] In a first aspect a cushion module for a patient interface for delivering positive pressure respiratory therapy to a user may comprise:

- a seal for forming a seal around the user's mouth and nares;
- a housing connected to the seal, the housing and seal forming a cavity configured to receive a flow of pressurized gas;
- at least one opening in the seal to communicate the pressurized gas with the user;
- an inlet through which the pressurized gas is received into the cavity;
- an outlet through which gas is exhausted from the cushion module; and
- an exhaust conduit configured to draw gas from the user's nares through at least one exhaust conduit inlet and conduct it to the outlet of the cushion module.

[0010] In a second aspect a cushion module for a patient interface for delivering positive pressure respiratory therapy to a user may comprise:
a seal for forming a seal around the user's mouth and nares;
a housing connected to the seal, the housing and seal forming a cavity configured to
5 receive a flow of pressurized gas;
at least one opening in the seal to communicate the pressurized gas with the user;
an inlet for receiving pressurized gas into the cavity;
an outlet for exhausting gas from the cushion module; and
an exhaust conduit located within the cavity, the exhaust conduit having at least one
10 exhaust conduit inlet through which gas is received into the exhaust conduit, the
exhaust conduit extending from the at least one exhaust conduit inlet to the outlet of
the cushion module.

[0011] Each exhaust conduit inlet may be configured to be positioned within one or a
respective one of the user's nares or to be positioned at a position that is below the
15 one or the respective one of the user's nares and adjacent a lip superior of the user,
when the patient interface is fitted to the user.

[0012] The cross-sectional area of the at least one exhaust conduit inlet may be less
than the cross-sectional area of the inlet to cause gas entering the exhaust conduit
to accelerate as it flows from the cavity into the exhaust conduit.

20 [0013] The exhaust conduit and the at least one exhaust conduit inlet may be
configured to accelerate gas as it flows from the cavity into the exhaust conduit and
to entrain surrounding gas into the exhaust conduit.

[0014] The entrainment of surrounding gas into the exhaust conduit may entrain
respiratory gas from within the one or the respective one of the user's nares when
25 the at least one exhaust conduit inlet is positioned within the one or respective one of
the user's nares or positioned at the position that is below the one or the respective
one of the user's nares and adjacent the lip superior of the user.

[0015] The at least one opening of the seal may comprise a first opening
encompassing the mouth of the user and a second opening encompassing the nares
30 of the user.

[0016] The exhaust conduit may be configured to conduct exhaled gas from the mouth and/or nares of the user or to conduct excess gas from the cavity or both to the outlet.

5 [0017] The exhaust conduit may be configured to exhaust the exhaled gas from the mouth and/or nares of the user or the excess gas from the cavity or both from the cushion module.

[0018] The exhaust conduit may be adjustably mounted to the housing such that the orientation and/or position with respect to the seal can be adjusted.

10 [0019] The exhaust conduit may comprise a body which is pliable to allow the orientation and/or position with respect to the seal to be adjusted.

[0020] The exhaust conduit may be an enclosed passageway extending from the at least one exhaust conduit inlet to the outlet.

15 [0021] The exhaust conduit may be configured to prevent ingress of gas from the cavity, other than via the at least one exhaust conduit inlet, and to prevent egress of gas into the cavity.

[0022] The exhaust conduit may be surrounded by the cavity.

[0023] The exhaust conduit may be a separate structure from the seal.

20 [0024] The exhaust conduit may comprise at least one prong, and wherein the at least one exhaust conduit inlet may be located at a free end of the at least one prong.

[0025] The at least one prong may be configured to extend into the one or respective one of the user's nares.

[0026] The at least one prong may be a sealing prong configured to form a seal with the one or respective one of the user's nares.

25 [0027] The at least one prong may be formed of an elastomeric material.

[0028] The elastomeric material may be silicone.

[0029] The at least one exhaust conduit inlet may comprise a first exhaust conduit inlet configured to be positioned within a first nare of the user's nares or to be positioned at a position that is below the first nare of the users nares and adjacent a

lip superior of the user and a second exhaust conduit inlet configured to be positioned within a second nare of the user's nares or to be positioned at a position that is below the second nare of the users nares and adjacent a lip superior of the user, when the patient interface is fitted to the user.

- 5 [0030] The at least one prong may comprise a first prong and a second prong, the first exhaust conduit inlet located at a free end of the first prong, and the second exhaust conduit inlet located at a free end of the second prong.

[0031] The first prong may be configured to extend into the first nare of the user and the second prong may be configured to extend into the second nare of the user,

- 10 when the patient interface is fitted to the user.

[0032] The exhaust conduit may comprise a manifold, the first and second prongs extending from the manifold.

[0033] At least a portion of the exhaust conduit may be pliable to allow the position of the first and second prongs to be adjusted.

- 15 [0034] The first exhaust conduit inlet and the second exhaust conduit inlet may have different cross-sectional areas.

[0035] The ratio of the cross-sectional area of the first exhaust conduit inlet to the cross-sectional area of the second exhaust conduit inlet may be between 1:1.1 and 1:4.

- 20 [0036] The ratio of the cross-sectional area of the first exhaust conduit inlet to the cross-sectional area of the second exhaust conduit inlet may be 1:3.

[0037] At least part of the exhaust conduit may be incorporated into a nasal interface which includes a flushing conduit having at least one flushing conduit inlet within the cavity and at least one flushing conduit outlet at or adjacent to at least one of the first

- 25 or second exhaust conduit inlets.

[0038] The nasal interface may be located within the cavity. The nasal interface may be a separate structure to the seal. The nasal interface may be a separate structure to the housing. The nasal interface may be connectable to the seal, the housing or both the seal and the housing.

[0039] Each of the first and second prongs may be a sealing prong configured to form a seal with a respective one of the user's nares.

[0040] The flushing conduit may have a first flushing conduit outlet at or adjacent to the first exhaust conduit inlet and a second flushing conduit outlet at or adjacent to
5 the second exhaust conduit inlet.

[0041] The flushing conduit may be configured to conduct gas from within the cavity to the one or respective one of the user's nares.

[0042] The flushing conduit may be configured to accelerate gas from the at least one flushing conduit inlet towards the first flushing conduit outlet and second flushing
10 conduit outlet and direct the accelerated gas into the respective nares of the user's nares.

[0043] The first and second prongs may be formed of an elastomeric material.

[0044] The elastomeric material may be silicone.

[0045] The cushion module outlet may be in fluid communication with a filter such
15 that gas exiting the cushion module through the outlet will pass through the filter.

[0046] The filter may be located externally of the cushion module.

[0047] The filter may be attached to the cushion module.

[0048] The cushion module outlet may comprise a bias flow vent.

[0049] The cushion module outlet may be configured to connect to, or be in fluid
20 communication with, an exhalation conduit.

[0050] The bias flow vent may comprise a plurality of apertures.

[0051] The cushion module may be configured to only receive the flow of pressurized gas through the inlet and to only exhaust gas through the outlet.

[0052] The cushion module may comprise a supplementary bias flow vent, the
25 supplementary bias flow vent in fluid communication with the cavity.

[0053] The supplementary bias flow vent may be configured to have a flow rate, in use, that is less than the flow rate through the cushion module outlet.

[0054] The supplementary bias flow vent may be configured to have a resistance to flow, in use, that is higher than the resistance to flow through the cushion module outlet.

5 [0055] The supplementary bias flow vent may comprise at least one aperture, the at least one aperture having a cross-sectional area and the cross-sectional area of the at least one aperture being less than a cross-sectional area of the cushion module outlet.

[0056] The housing may comprise a plastics material. The plastics material may be polycarbonate.

10 [0057] The seal may comprise an elastomeric material. The elastomeric material may be silicone.

[0058] The seal and housing may be mechanically connected.

[0059] The housing may comprise the cushion module inlet.

[0060] The housing may comprise the cushion module outlet.

15 [0061] The seal may comprise the cushion module outlet.

[0062] The seal may comprise the cushion module inlet.

[0063] The seal may be a full-face over-nose seal configured to form a seal on a bridge of the user in use.

20 [0064] The seal may be a full-face undernose seal configured not to form a seal on a bridge of the user in use.

[0065] The seal may be a total-face seal configured to form a seal circumscribing a mouth, nose, and eyes of the user in use.

[0066] The seal may be a helmet style seal configured to form a seal on a neck of the user in use.

25 [0067] A patient interface may comprise the cushion module of any prior aspect, the patient interface may further comprise a frame configured to be attached to the cushion module, the frame comprising a plurality of headgear connectors configured to be connected to a headgear for retaining the patient interface on the users face in use.

[0068] The patient interface may further comprise a conduit connector configured to be connected to the inlet of the cushion module, the conduit connector comprising an anti-asphyxiation valve and a pressure port and further being configured to be removably attached to a respiratory therapy conduit.

- 5 [0069] The conduit connector may be configured to be connected to a single-limb respiratory circuit.

[0070] The conduit connector may be configured to be connected to a dual-limb respiratory circuit.

- 10 [0071] The conduit connector may be configured to be connected to a dual-limb respiratory circuit via a Y-piece.

- [0072] In a third aspect a patient interface for delivering positive pressure respiratory therapy to a user may comprise: (a) a cushion module defining a first cavity configured to be pressurized, the cushion module comprising an inlet configured to receive a flow of pressurized gas into the cavity, an opening configured to encompass a mouth and nares of the user to communicate the pressurized gas with the user, and an outlet configured to exhaust gas to externally of the cushion module,

- 20 (b) an exhaust conduit located within the first cavity, the exhaust conduit extending from the outlet of the cushion module to at least one exhaust conduit inlet, the at least one exhaust conduit inlet configured to be positioned within a first nare of a one or respective one of the user's nares when the patient interface is fitted to the user, wherein the exhaust conduit comprises at least one prong configured to form a seal with the first nare of the one or respective one of the users nares, the at least one exhaust conduit inlet being located at a free end of the at least one prong.

- 25 [0073] In a fourth aspect a patient interface for delivering positive pressure respiratory therapy to a user may comprise:

- (a) a cushion module defining a first cavity configured to be pressurized, the cushion module comprising an inlet configured to receive a flow of pressurized gas into the cavity, an opening configured to encompass a mouth and nares of the user to communicate pressurized gas with the user, and an outlet configured to exhaust gas to externally of the cushion module,
- 30 (b) an exhaust conduit located within the first cavity, the exhaust conduit extending

from the outlet of the cushion module to a first exhaust conduit inlet and a second exhaust conduit inlet, the first exhaust conduit inlet configured to be positioned within a first nare of the user's nares and the second exhaust conduit inlet configured to be positioned within a second nare of the user's nares, when the patient interface is
5 fitted to the user.

[0074] In a fifth aspect a cushion module for a patient interface for delivering positive pressure respiratory therapy to a user may comprise:

- (a) a cavity to communicate respiratory gas to a mouth and nares of the user, and
- (b) an exhaust conduit to communicate exhaled gas from the mouth and/or nares of
10 the user or to communicate excess respiratory gas from within the cavity or both to externally of the cushion module,
wherein the exhaust conduit is configured to accelerate respiratory gas as it flows from cavity into the exhaust conduit.

[0075] In a sixth aspect a non-invasive patient interface which is configured to seal
15 about the mouth and nares of a patient may comprise:

- (a) an outer wall defining an interior volume which comprises a first chamber having an oral opening to communicate gas with the mouth and a second chamber having a nasal opening to communicate gas with the nares; and
- (b) a dividing wall that separates the first chamber from the second chamber; and
20 (c) one or more flow directors which enable gas to flow into the second chamber from the first chamber and which flow directors are configured to direct the gas flow into the nares; and
wherein the outer wall is configured to extend over a nasal bridge of the patient.

[0076] In a seventh aspect a non-invasive patient interface which is configured to
25 seal about the mouth and nares of a patient may comprise:

- (a) an outer wall defining an interior volume of the patient interface, the outer wall having a patient contacting surface comprising an oral opening which communicates gas with the mouth and a nasal opening which communicates gas with the nares; and
- 30 (b) a dividing wall that separates the interior volume into a first chamber having the oral opening and a second chamber having the nasal opening; and
(c) one or more flow directors extending from the dividing wall which enable gas to

flow into the second chamber from the first chamber and which flow directors are configured to direct the gas flow into the nares; and
wherein the flow directors are spaced apart by a spacing element which maintains a spacing between the flow directors; and

- 5 wherein the patient contacting surface engages a dorsum nasi of the patient.

[0077] In an eighth aspect a non-invasive patient interface which is configured to seal about the mouth and nares of a patient may comprise:

- (a) an outer wall defining an interior volume of the patient interface, the outer wall having an oral opening which communicates gas with the mouth and a nasal
10 opening which communicates gas with the nares;
(b) a dividing wall that separates the interior volume into a first chamber having the oral opening and a second chamber having the nasal opening; and
wherein the dividing wall includes one or more spaced apart flow directors which enable gas to flow into the second chamber from the first chamber and which flow
15 directors are configured to direct the gas flow into the nares; and
wherein the outer wall engages the nasal bridge of the patient.

[0078] In a ninth aspect a patient interface for delivering positive pressure respiratory therapy to a user may comprise:

- a cushion module comprising a seal and a housing which together define a cavity
20 configured to receive a flow of pressurized gas,
the seal configured to form a seal with a user's mouth and nares and comprising at least one opening to communicate the pressurized gas with the user's mouth and nares,
a cushion module inlet through which the pressurized gas is received into the cavity,
25 a cushion module outlet through which gas is exhausted from the cavity, and
a dividing wall insert configured to be inserted within the cavity of the cushion module and comprising a dividing wall and one or more flow directors,
wherein when the dividing wall insert is inserted within the cavity of the cushion module:
30 the dividing wall extends across the cavity and intersects the at least one seal opening to separate the cavity into a first chamber comprising an oral opening to communicate the pressurized gas with the user's mouth and a second chamber

comprising a nasal opening to communicate the pressurized gas with the user's nares; and
the one or more flow directors enable gas to flow into the second chamber from the first chamber through the dividing wall.

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[0079] The cushion module inlet may deliver the pressurized gas into the first chamber.

[0080] The cushion module outlet may exhaust gas from the second chamber.

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[0081] The dividing wall may comprise an outer periphery which contacts the housing and/or the seal to sufficiently seal the first chamber from the second chamber around the outer periphery.

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[0082] The dividing wall may comprise an outer periphery which is shaped to substantially match the internal geometry of the housing and/or seal to limit gas flowing between the first chamber and the second chamber around the outer periphery.

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[0083] The outer periphery of the dividing wall may be configured to be spaced from the housing and/or seal to allow a predetermined amount of gas flow between the outer periphery and the housing and/or seal.

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[0084] The outer periphery of the dividing wall may be bonded, adhered, or mechanically attached to the housing and/or seal.

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[0085] The dividing wall insert may comprise a connector configured for removable connection to the housing to secure the dividing wall insert within the cavity of cushion module.

[0086] The connector of the dividing wall insert may comprise a sleeve configured for connection with a sleeve of the housing.

[0087] The one or more flow directors may comprise a first flow director comprising a first flow director inlet in fluid communication with the first chamber and a first flow director outlet in fluid communication with the second chamber.

- 5 [0088] The first flow director outlet may be configured to be positioned near to and/or directed towards a user's nare when the patient interface is worn by a user.

- [0089] The one or more flow directors may further comprise a second flow director comprising a second flow director inlet in fluid communication with the first chamber
10 and a second flow director outlet in fluid communication with the second chamber.

- [0090] The first flow director outlet and the second flow director outlet may each configured to be positioned near to and/or directed towards a respective one of the user's nares when the patient interface is worn by a user.

- 15 [0091] The first flow director and the second flow director may be shaped differently to one another in at least one way.

- [0092] The first flow director outlet and the second flow director outlet may comprise
20 cross-sectional areas that are unequal.

[0093] The dividing wall may comprise a rigid portion and an elastomeric portion.

- [0094] The connector may be attached to the rigid portion and the one or more flow
25 directors may extend from the elastomeric portion.

- [0095] The elastomeric portion may comprise a deformation region, the deformation region comprising a thin region located between a first thickened region and a second thickened region.

- 30 [0096] The deformation region may allow for controlled deformation of the dividing wall within the thin region in response to forces applied to the dividing wall in use.

[0097] The seal may be a full-face over-nose seal configured to contact the nasal bridge of the user.

5 [0098] The seal may be a full face undernose seal configured not to contact the nasal bridge of the user.

[0099] In a tenth aspect a patient interface for delivering positive pressure respiratory therapy to a user may comprise:

10 a cushion module comprising a seal and a housing which together define a cavity configured to receive a flow of pressurized gas,
the seal configured to form a seal with a user's mouth and nares and comprising a nasal opening to communicate the pressurized gas with the user's nares and an oral opening to communicate the pressurized gas with the users mouth,
a cushion module inlet through which the pressurized gas is received into the cavity,
15 a cushion module outlet through which gas is exhausted from the cavity, and
a dividing wall insert configured to be inserted within the cavity of the cushion module and comprising a dividing wall and one or more flow directors,
wherein when the dividing wall insert is inserted within the cavity of the cushion module:
20 the dividing wall extends across the cavity and separates the cavity into a first chamber comprising the oral opening and a second chamber comprising the nasal opening; and
the one or more flow directors enable gas to flow into the second chamber from the first chamber through the dividing wall.

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[0100] The cushion module inlet may deliver the pressurized gas into the first chamber.

[0101] The cushion module outlet may exhaust gas from the second chamber.

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[0102] The dividing wall may comprise an outer periphery which contacts the housing and/or the seal to sufficiently seal the first chamber from the second chamber around the outer periphery.

[0103] The dividing wall may comprise an outer periphery which is shaped to substantially match the internal geometry of the housing and/or seal to limit gas flowing between the first chamber and the second chamber around the outer periphery.

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[0104] The outer periphery of the dividing wall may be configured to be spaced from the housing and/or seal to allow a predetermined amount of gas flow between the outer periphery and the housing and/or seal.

- 10 [0105] The outer periphery of the dividing wall may be bonded, adhered, or mechanically attached to the housing and/or seal.

- [0106] The dividing wall insert may comprise a connector configured for removable connection to the housing to secure the dividing wall insert within the cavity of
15 cushion module.

[0107] The connector of the dividing wall insert may comprise a sleeve configured for connection with a sleeve of the housing.

- 20 [0108] The one or more flow directors may comprise a first flow director comprising a first flow director inlet in fluid communication with the first chamber and a first flow director outlet in fluid communication with the second chamber.

- [0109] The first flow director outlet may be configured to be positioned near to and/or
25 directed towards a user's nare when the patient interface is worn by a user.

- [0110] The one or more flow directors may further comprise a second flow director comprising a second flow director inlet in fluid communication with the first chamber and a second flow director outlet in fluid communication with the second chamber.

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[0111] The first flow director outlet and the second flow director outlet may each configured to be positioned near to and/or directed towards a respective one of the user's nares when the patient interface is worn by a user.

[0112] The first flow director and the second flow director may be shaped differently to one another in at least one way.

5 [0113] The first flow director outlet and the second flow director outlet may comprise cross-sectional areas that are unequal.

[0114] The dividing wall may comprise a rigid portion and an elastomeric portion.

10 [0115] The connector may be attached to the rigid portion and the one or more flow directors may extend from the elastomeric portion.

[0116] The elastomeric portion may comprise a deformation region, the deformation region comprising a thin region located between a first thickened region and a second thickened region.

15 [0117] The deformation region may allow for controlled deformation of the dividing wall within the thin region in response to forces applied to the dividing wall in use.

20 [0118] The seal may be a full-face over-nose seal configured to contact the nasal bridge of the user.

[0119] The seal may be a full face undernose seal configured not to contact the nasal bridge of the user.

25 [0120] In an eleventh aspect a patient interface for delivering positive pressure respiratory therapy to a user comprises:
a cushion module comprising a seal and a housing which together define a cavity configured to receive a flow of pressurized gas,
the seal configured to form a seal with a user's mouth and nares and comprising a
30 nasal opening to communicate the pressurized gas with the user's nares and an oral opening to communicate the pressurized gas with the users mouth,
a cushion module inlet through which the pressurized gas is received into the cavity,
a cushion module outlet through which gas is exhausted from the cavity, and

a dividing wall that separates the cavity into a first chamber having the oral opening and a second chamber having the nasal opening,
wherein the dividing wall includes a flow director aperture configured to receive a flow director insert, and

- 5 wherein the flow director insert comprises one or more flow directors which enable gas to flow into the second chamber from the first chamber when the flow director insert is received within the flow director aperture.

[0121] The cushion module inlet may deliver the pressurized gas into the first
10 chamber.

[0122] The cushion module outlet may exhaust gas from the second chamber.

[0123] The flow director aperture may be configured to removably receive the flow
15 director insert.

[0124] The flow director insert may comprise a channel around a periphery of the flow director insert which is configured to receive a rim of the flow director aperture to removably attach the flow director insert to the dividing wall.

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[0125] The flow director insert may comprise an elastomeric material.

[0126] The one or more flow directors may comprise a first flow director comprising a first flow director inlet in fluid communication with the first chamber and a first flow
25 director outlet in fluid communication with the second chamber.

[0127] The first flow director outlet may be configured to be positioned near to and/or directed towards a user's nare when the patient interface is worn by a user.

30 [0128] The one or more flow directors may further comprise a second flow director comprising a second flow director inlet in fluid communication with the first chamber and a second flow director outlet in fluid communication with the second chamber.

[0129] The first flow director outlet and the second flow director outlet may each configured to be positioned near to and/or directed towards a respective one of the user's nares when the patient interface is worn by a user.

- 5 [0130] The first flow director and the second flow director may be shaped differently to one another in at least one way.

[0131] The first flow director outlet and the second flow director outlet may comprise cross-sectional areas that are unequal.

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[0132] The ratio of the cross-sectional area of the first flow director outlet to the cross-sectional area of the second flow director outlet may be in a range from 1:1.1 to 1:4.

- 15 [0133] The flow director insert may comprise one or more flow director apertures extending through the flow director insert.

[0134] The dividing wall may comprise an elastomeric portion.

- 20 [0135] The elastomeric portion may comprise a deformation region, the deformation region comprising a thin region located between a first thickened region and a second thickened region.

- 25 [0136] The deformation region may allow for controlled deformation of the dividing wall within the thin region in response to forces applied to the dividing wall in use.

[0137] The seal may be a full-face over-nose seal configured to contact the nasal bridge of the user.

- 30 [0138] The seal may be a full-face undernose seal configured not to contact the nasal bridge of the user.

[0139] Ordinal references (e.g. first, second, third) to aspects disclosed above serve to differentiate aspects from one another only. The ordinal references are not to be interpreted as the order of importance of the aspects.

- 5 [0140] Although various features are disclosed above in relation to one or more aspect, it will be appreciated that one or more features of one aspect may be combined with other aspects to arrive at additional embodiments. It follows that disclosure of features in the preceding statements should not be interpreted as meaning that the features are limited in application to the aspects in respect of which they are disclosed.

10 **BRIEF DESCRIPTION OF THE DRAWINGS**

[0141] The aspects of the patient interface disclosed above are described in detail below by reference to embodiments, which serve as examples only, and with reference to the accompanying drawings, in which:

- 15 [0142] Figure 1 is perspective view of a patient interface according to a first embodiment.

[0143] Figure 2 is an exploded perspective view of the patient interface of Figure 1.

[0144] Figure 3 is an exploded side view of the patient interface of Figure 1.

[0145] Figure 4 is a front view of the patient interface of Figure 1.

[0146] Figure 5 is a side view of the patient interface of Figure 1.

- 20 [0147] Figure 6 is a rear view of the patient interface of Figure 1.

[0148] Figure 7 is a top view of the patient interface of Figure 1.

[0149] Figure 8 is an underneath view of the patient interface of Figure 1.

[0150] Figure 9 is a cross-sectional side view of the patient interface of Figure 1 along line AA' as shown in Figure 4.

- 25 [0151] Figure 10 is a perspective view of a patient interface according to a second embodiment.

[0152] Figure 11 is an exploded perspective view of the patient interface of Figure 10.

- [0153] Figure 12 is an exploded side view of the patient interface of Figure 10.
- [0154] Figure 13 is a front view of the patient interface of Figure 10.
- [0155] Figure 14 is a side view of the patient interface of Figure 10.
- [0156] Figure 15 is a rear view of the patient interface of Figure 10.
- 5 [0157] Figure 16 is a top view of the patient interface of Figure 10.
- [0158] Figure 17 is an underneath view of the patient interface of Figure 10.
- [0159] Figure 18 is a cross-sectional side view of the patient interface of Figure 10 along line BB' as shown in Figure 13.
- [0160] Figure 19 is a cross-sectional perspective view of the patient interface of
- 10 Figure 10 along line BB' as shown in Figure 13.
- [0161] Figure 20 is a further cross-sectional perspective view of the patient interface of Figure 10 along line BB' as shown in Figure 13.
- [0162] Figure 21 is a cross-sectional top view of the patient interface of Figure 10 along line CC' as shown in Figure 13.
- 15 [0163] Figure 22 is a perspective view of an exhaust conduit of the patient interface of Figure 10.
- [0164] Figure 23 is a schematic cross-sectional side view of the patient interface of Figure 10 along line BB' as shown in figure 13 fitted to a patient while their mouth is open.
- 20 [0165] Figure 24 is a schematic cross-sectional side view of the patient interface of Figure 10 along line BB' as shown in Figure 13 fitted to a patient while their mouth is closed.
- [0166] Figure 25 is a perspective view of a patient interface according to a third embodiment.
- 25 [0167] Figure 26 is an exploded perspective view of the patient interface of Figure 25.
- [0168] Figure 27 is an exploded side view of the patient interface of Figure 25.

- [0169] Figure 28 is a front view of the patient interface of Figure 25.
- [0170] Figure 29 is a side view of the patient interface of Figure 25.
- [0171] Figure 30 is a rear view of the patient interface of Figure 25.
- [0172] Figure 31 is a top view of the patient interface of Figure 25.
- 5 [0173] Figure 32 is an underneath view of the patient interface of Figure 25.
- [0174] Figure 33 is a cross-sectional side view of the patient interface of Figure 25 along line DD' as shown in Figure 30.
- [0175] Figure 34 is a cross-sectional perspective view of the patient interface of Figure 25 along line DD' as shown in Figure 30.
- 10 [0176] Figure 35 is a cross-sectional side view of the patient interface of Figure 25 along line EE' as shown in Figure 30.
- [0177] Figure 36 is a cross-sectional perspective view of the patient interface of Figure 25 along line EE' as shown in Figure 30.
- [0178] Figure 37 is a perspective view of an exhaust conduit of the patient interface
- 15 of Figure 25.
- [0179] Figure 38 is a rear view of the exhaust conduit of Figure 37.
- [0180] Figure 39 is a cross-sectional side view of the exhaust conduit of Figure 37 along line FF' as shown in Figure 38.
- [0181] Figure 40 is a cross-sectional side view of the exhaust conduit of Figure 37
- 20 along line GG' as shown in Figure 38.
- [0182] Figure 41 is a schematic cross-sectional side view of the patient interface of Figure 25 along line EE' as shown in Figure 30 fitted to a patient while their mouth is open.
- [0183] Figure 42 is a schematic cross-sectional side view of the patient interface of
- 25 Figure 25 along line EE' as shown in Figure 30 fitted to a patient while their mouth is closed.
- [0184] Figure 43 is a perspective view of a patient interface according to a fourth embodiment.

- [0185] Figure 44 is a front view of the patient interface of Figure 43.
- [0186] Figure 45 is a side view of the patient interface of Figure 43.
- [0187] Figure 46 is a rear view of the patient interface of Figure 43.
- [0188] Figure 47 is a top view of the patient interface of Figure 43.
- 5 [0189] Figure 48 is an underneath view of the patient interface of Figure 43.
- [0190] Figure 49 is a cross-sectional side view of the patient interface of Figure 43 along line HH' as shown in Figure 44.
- [0191] Figure 50 is a cross-sectional perspective view of the patient interface of Figure 43 along line HH' as shown in Figure 44.
- 10 [0192] Figure 51 is a cross-sectional perspective view of the patient interface of Figure 43 along line II' as shown in Figure 44.
- [0193] Figure 52 is a cross-sectional top view of the patient interface of Figure 43 along line II' as shown in Figure 44.
- [0194] Figure 53 is a schematic cross-sectional side view of the patient interface of Figure 43 along line HH' as shown in Figure 44 fitted to a patient while their mouth is open.
- 15 [0195] Figure 54 is a schematic cross-sectional side view of the patient interface of Figure 43 along line HH' as shown in Figure 44 fitted to a patient while their mouth is closed.
- 20 [0196] Figure 55 is a perspective view of a patient interface according to a fifth embodiment.
- [0197] Figure 56 is a perspective view of the cushion module of the patient interface of Figure 55.
- [0198] Figure 57 is a front view of the cushion module of the patient interface of Figure 55.
- 25 [0199] Figure 58 is a side view of the cushion module of the patient interface of Figure 55.

[0200] Figure 59 is a rear view of the cushion module of the patient interface of Figure 55.

[0201] Figure 60 is a side view of the cushion module of the patient interface of Figure 55.

- 5 [0202] Figure 61 is a cross-sectional side view of the cushion module of the patient interface of Figure 55 along line JJ' as shown in Figure 57.

[0203] Figure 62 is a cross-sectional perspective view of the cushion module of the patient interface of Figure 55 along line JJ' as shown in Figure 57.

- 10 [0204] Figure 63 is a cross-sectional perspective view of the cushion module of the patient interface of Figure 55 along line JJ' as shown in Figure 57.

[0205] Figure 64 is a perspective view of a dividing wall assembly of the patient interface of Figure 55.

[0206] Figure 65 is a side view of the dividing wall assembly in Figure 64.

[0207] Figure 66 is a rear view of the dividing wall assembly in Figure 64.

- 15 [0208] Figure 67 is a cross-sectional side view of the dividing wall assembly along line KK' as shown in Figure 66.

[0209] Figure 68 is a top view of the dividing wall assembly in Figure 64.

[0210] Figure 69 is a perspective view of a patient interface according to a sixth embodiment.

- 20 [0211] Figure 70 is a perspective view of the cushion module of the patient interface of Figure 69.

[0212] Figure 71 is a top view of the cushion module of the patient interface of Figure 69.

- 25 [0213] Figure 72 is a rear view of the cushion module of the patient interface of Figure 69.

[0214] Figure 73 is a cross-sectional side view of the cushion module along line LL' as shown in Figure 71.

[0215] Figure 74 is a cross-sectional perspective view of the cushion module MM' as shown in Figure 72.

[0216] Figure 75 is a perspective view of the dividing wall assembly of the patient interface of Figure 69.

5 [0217] Figure 76 is a rear view of the dividing wall assembly in Figure 75.

[0218] Figure 77 is a side view of the dividing wall assembly in Figure 75.

[0219] Figure 78 is a cross-sectional side view of the dividing wall assembly along line NN' as shown in Figure 76.

10 [0220] Figure 79 is a perspective view of a patient interface according to a seventh embodiment.

[0221] Figure 80 is a perspective view of the cushion module of the patient interface of Figure 79.

[0222] Figure 81 is a front view of the cushion module of the patient interface of Figure 79.

15 [0223] Figure 82 is a rear view of the cushion module of the patient interface of Figure 79.

[0224] Figure 83 is a cross-sectional side view of the cushion module along line OO' as shown in Figure 82.

20 [0225] Figure 84 is a cross-sectional perspective view of the cushion module along line OO' as shown in Figure 82.

[0226] Figure 85 is a cross-sectional perspective view of the cushion module with a flow director insert removed along line OO' as shown in Figure 82.

[0227] Figure 86 is a cross-sectional perspective view of the cushion module along line PP' as shown in Figure 82.

25 [0228] Figure 87 is a cross-sectional perspective view of the cushion module with the flow director insert removed along line PP' as shown in Figure 82.

[0229] Figure 88 is a perspective view of the flow director insert of the patient interface of Figure 79.

[0230] Figure 89 is a top view of the flow director insert of Figure 88.

[0231] Figure 90 is a perspective view of an alternative flow director insert of the patient interface of Figure 79.

[0232] Figure 91 is a top view of the flow director insert of Figure 90.

- 5 [0233] Figure 92 is a perspective view of a further alternative flow director insert of the patient interface of Figure 79.

[0234] Figure 93 is a top view of the flow director insert of Figure 92.

DESCRIPTION OF EMBODIMENTS

- 10 [0235] Embodiments will now be described in the following text which includes reference numerals that correspond to features illustrated in the accompanying figures. Where possible, related reference numerals have been used to identify the same or substantially the substantially similar features in the different embodiments. To maintain clarity of the figures, however, all reference numerals are not included in each figure.

- 15 [0236] The aspects of the patient interface disclosed above will be described in detail below by reference to embodiments of a patient interface in the general form shown in Figures 1 to 9. The embodiments described following this are variations on that general form. However, it will be appreciated that the scope of the aspects should not be limited by reference to that general form or to the specific
- 20 embodiments described below, and, instead, the aspects should be interpreted as relating as well to other forms of patient interfaces that also deliver pressurised respiratory gas to a patient, including full face patient interfaces that do not contact the bridge of the nose (over the nose oro-nasal masks), total-face masks, helmet interfaces, and where suitable, nasal masks that seal with the patients nasal cavity.

- 25 [0237] The term “respiratory gas” or “respiratory gasses” as used throughout this specification is taken to mean a gas used in human respiration or human ventilation. The term “inhaled respiratory gas” as used throughout this specification is taken to mean respiratory gas that is inhaled during the inhalation phase of the breathing cycle. The term includes within its scope ambient air or air that is conditioned for
- 30 treating a patient, such as having elevated humidity or oxygen levels, or both compared to ambient air. The term “exhaled respiratory gas” as used throughout this

specification is taken to mean respiratory gas that is exhaled from the lungs and airways of a patient during the exhalation phase of the breathing cycle. It, therefore, includes respiratory gas from the lungs and gas which occupies the anatomical dead space of the patient at the end of the exhalation phase of the breathing cycle.

5 **General Form**

- [0238] Having regard to Figures 1 to 9, the general form comprises a patient interface 1000 which includes a cushion module 1010, a frame 1400 and a conduit connector 1300. The conduit connector 1300 comprises structural components for connecting the cushion module 1010 to a source of pressurised respiratory gas,
- 10 such as a ventilator, humidifier, flow generator or wall source. In this embodiment, the patient interface 1000 is in the form of a full-face mask where the cushion module 1010 comprises a resilient seal 1100 and a housing 1200. Collectively, the resilient seal 1100 and the housing 1200 form a cushion module 1010 having an internal cavity 1012 configured to be pressurised.
- 15 [0239] The housing 1200 is formed of a substantially rigid plastics material to provide structural support to the seal 1100. Additionally, the housing 1200 provides an interface for connecting the seal 1100 to the frame 1400 and/or the conduit connector 1300.
- [0240] In an alternative configuration, the housing 1200 may be formed of an
- 20 elastomeric material, textile, or foam sufficient to provide the rigidity needed to structurally support the seal 1100. It may also be formed of any of the aforementioned materials and reinforced with a secondary more rigid material to provide the required structural support to the seal 1100.
- [0241] The housing 1200 includes a sleeve 1230 that is sized and shaped to
- 25 connect with a frame 1400. The connection between the housing 1200 and frame 1400 is detailed further below. The sleeve 1230 defines an inlet 1220 through which respiratory gas can be communicated from the conduit connector 1300 to the cavity 1012 of the cushion module 1010.
- [0242] Respiratory gas may be communicated from the conduit connector 1300 to
- 30 the cavity 1012 of the cushion module 1010 via either: an inhalation conduit of a single-limb NIV circuit which is configured to deliver fresh pressurised respiratory gas

from a gas source to the conduit connector 1300, or via a wye-piece of a of a dual-limb NIV circuit which is configured to deliver fresh pressurised respiratory gas from a gas source along an inhalation conduit to the conduit connector 1300 and to return at least some of the excess or exhaled respiratory gas from within the cushion module 1010 through the conduit connector 1300 and along an exhalation conduit to the gas source. It is envisioned that while connecting a wye-piece of a dual-limb circuit to the conduit connector, the patient interfaces disclosed herein would maintain outlets on the housing 1200 through which at least some of the exhaled and excess respiratory gasses would be exhausted from within the cushion module 1010 to external of the cushion module 1010.

[0243] The sleeve 1230 includes key formations 1232. The frame 1400 interacts with the key formations 1232 to ensure correct alignment of the frame 1400 with the housing 1200 when they are connected. It will be appreciated that these key formations 1232 may be substituted with any other suitable structure to ensure correct alignment of the frame 1400 with the housing 1200 or may be omitted entirely.

[0244] The housing 1200 includes a series of tabs 1240 which project outwardly around its perimeter. The outer ends of the tabs 1240 are linked to a bead 1245 which runs continuously across all the tabs 1240, thereby forming a series of discrete overmould windows 1250 between the tabs 1240 and the bead 1245. The seal 1100 is integrally formed with the housing 1200 by overmoulding a resilient material onto the housing 1200 to fill the series of windows 1250. Therefore, the tabs 1240 and the bead 1245 become embedded in the resilient material and are mechanically interlocked with the seal 1100. The seal 1100 and the housing 1200, therefore, form a unitary cushion module 1010 structure.

[0245] The housing 1200 includes an outlet 1210 through which exhaled and excess respiratory gasses can be exhausted from the cushion module 1010 and/or anatomical dead space of the patient's airways to external of the cushion module 1010. In the general form, the outlet 1210 comprises a bias vent 1215 comprising a plurality of apertures extending through the housing 1200. Exhaled and excess respiratory gasses can therefore be exhausted from within the cushion module 1010 through bias vent 1215 to external of the cushion module 1010, or to atmosphere.

[0246] In alternative configurations, the outlet 1210 and bias vent 1215 may be distinct structures located at positions spaced apart from each other. In further alternative configurations the patient interface 1000 may also include a supplementary bias vent 1216.

5 [0247] In a further alternative configuration, the outlet 1210 of cushion module 1010 may be in the form of an outlet configured to connect to, or be in fluid communication with, an exhalation conduit of a respiratory circuit. Such an exhalation conduit may be used in dual-limb NIV therapy. In this configuration exhaled and excess respiratory gasses can be exhausted from the cushion module 1010 and/or from the
10 patient's anatomical dead space and be transported away from the patient interface 1000 where they may be filtered, or received by the ventilator, flow generator, or other gas source which supplies fresh respiratory gas to the cushion module 1010. In such a configuration the outlet 1210 is, or is in fluid communication with, an exhalation conduit connector configured for connection with an exhalation conduit.

15 [0248] The seal 1100 is formed of soft, resilient material, such as a silicone or other suitable elastomer. The seal 1100 comprises a seal opening 1110. When fitted to a patient, the seal opening 1110 circumscribes the patient's mouth and nose. A patient contacting surface 1120 of the seal 1100 forms a seal about the mouth and nose of the patient. The seal formed by the patient contacting surface 1120 is sufficient to
20 contain, at least substantially, pressurized gas within the cavity 1012. Some leakage of pressurized gas may occur, but such leakage is relatively small so that the supply of pressurized gas to the patient is maintained at levels sufficient to deliver NIV therapy. Accordingly, respiratory gas at elevated pressure can be delivered from the cavity 1012 of the cushion module 1010 to the patient's mouth and/or nares via the
25 seal opening 1110.

[0249] Although this embodiment of the cushion module 1010 includes a single seal opening 1110, it will be appreciated that other configurations may include an oral opening for delivering pressurised respiratory gas to the patient's mouth and a nasal opening for delivering pressurised respiratory gas to the patient's nose. Alternatively,
30 the cushion module may include more than one oral opening. Alternatively, the cushion module may include more than one nasal opening. In a further alternative, the cushion module may include multiple oral openings and multiple nasal openings.

[0250] As mentioned above, it will be appreciated that in alternative embodiments the seal 1100 may be an undernose full face seal comprising an oral opening and at least one nasal opening. In this configuration the oral opening of the seal 1100 is defined by a portion of the patient contacting surface 1120 that surrounds a patient's mouth and the at least one nasal opening is defined by a portion of the patient contacting surface 1120 that surrounds the patient's nares, and which is configured to cradle the base and sides of the patient's nose without extending over or contacting the bridge of the nose. The patient contacting surface 1120 of the seal 1100 therefore forms a seal about the mouth and nares of a patient without contacting the patient's nasal bridge. Accordingly, respiratory gas at elevated pressure can be delivered from the cavity 1012 of the cushion module 1010 to the patient's mouth and nares via the oral opening and at least one nasal opening.

[0251] The undernose full face seal 1100 may comprise a single nasal opening, two nasal openings, or more than two nasal openings. In the configuration comprising a single nasal opening the single nasal opening is configured in use to surround both of the patient's nares. In the configuration comprising two nasal openings, each of the two nasal openings is configured in use to surround a respective one of the patient's nares.

[0252] In a further embodiment, the seal 1100 may be a total face seal 1100 in which, when fitted to a patient, the seal opening 1110 circumscribes the patient's mouth, nose, and eyes. In this embodiment, a patient contacting surface 1120 of the seal 1100 forms a seal about the mouth, nose, and eyes of the patient. Accordingly, respiratory gas at elevated pressure can be delivered from the cavity 1012 of the cushion module 1010 to the patient's mouth and/or nares via the seal opening 1110.

[0253] In a further embodiment, the seal 1100 may be a helmet style seal 1100 in which when fitted to a patient, the seal opening 1110 surrounds and seals with the patient's neck and the patient's head is to be located within the cavity 1012 of the cushion module 1010, in use. Accordingly, respiratory gas at elevated pressure can be delivered from the cavity 1012 of the cushion module 1010 directly to the patient's mouth and/or nares.

[0254] The conduit connector 1300 of the patient interface 1000 comprises a hollow connector body 1320 defining a lumen having a ball connector 1322 at a first end

1324, a swivel connector 1350 at a second end 1326 and an anti-asphyxiation valve (AA valve) 1330 located between the first and second ends. The connector body 1320, swivel connector 1350, and ball connector 1322 form a flow path for respiratory gas into the cushion module 1010 from a conduit of a respiratory circuit.

5 [0255] The ball connector 1322 includes a convex spherical segment that is configured to be received in a corresponding concave spherical segment of a ball socket 1402 of the frame 1400 to form a ball-and-socket joint which allows three degrees of rotational movement between the frame 1400 and the conduit connector 1300. The swivel connector 1350 is configured to be connected to a conduit of a
10 source of respiratory gas to supply pressurised respiratory gas to the cushion module 1010. The swivel connector 1350 can rotate with a single degree of freedom, otherwise known as swiveling. Together, the swivel connector 1350 and ball connector 1322 serve to decouple forces applied by the conduit from the patient interface 1000.

15 [0256] The connector body 1320 comprises a bend between the first end 1324 and second end 1326 such that gas flow through the conduit connector 1300 undergoes a change in direction from the first end 1324 to the second end 1326. Said another way, the longitudinal axes of the first end 1324 and the second end 1326 of the connector body 1320 are set at an oblique angle.

20 [0257] It will be appreciated by those skilled in the art that the connector body 1320 may, in alternative embodiments, be provided without a bend between the first end 1324 and second end 1326 such that the flow path through the connector body 1320 is substantially straight or linear.

[0258] In an alternative embodiment, the conduit connector 1300 may comprise a
25 ball connector 1322 at each end of the connector body (replacing the swivel connector 1350), a swivel connector 1350 at each end of the connector body (replacing the ball connector 1322), a single swivel connector 1350 or single ball connector at one of the first end 1324 or second end 1326 of the connector body 1320. Alternatively, the conduit connector 1300 may omit the ball connector 1322
30 and swivel connector 1350 entirely to form a fixed connector body 1320 between the cushion module 1010 and a conduit.

[0259] The second end 1326 of the conduit connector 1320 further includes a structure configured to co-operate with an anti-asphyxiation valve 1330 to permit ambient air into the patient interface if the source of respiratory gas fails or the conduit for conveying the gas from the gas source to the patient interface 1010 becomes obstructed. More specifically, the second end 1326 includes an opening 1327. A spine 1328 is disposed adjacent the opening 1327 and supports a panel 1329 that is spaced from the opening 1327. The spacing of the panel from the opening 1327 creates a gap through which ambient air can access the opening.

[0260] The anti-asphyxiation valve 1330 includes a valve seat 1331 and a valve seal 1336. The valve seat 1331 includes a sealing surface 1332 against which the valve seal 1336 seals the anti-asphyxiation valve 1330. The valve seat 1331 further includes a sleeve 1333 with a radially outwardly projecting bead 1334. The bead 1334 is at the end of the sleeve 1333. The valve seat 1331 further includes a spigot 1335 for coupling with the valve seal 1336.

[0261] The valve seal 1336 includes a flap 1337 which can transition between an open position in which the conduit connector 1300 is open to flow of respiratory gas from a gas source and a closed position in which the conduit connector 1300 is closed to flow of respiratory gas from a gas source. In the open position, access of ambient air to the inside of the conduit connector 1300 is inhibited and, in the closed position, access of ambient air to the inside of the conduit connector 1300 is permitted. In the illustrated embodiment, the flap 1337 is formed of a flexible material. The flap 1337 is joined to a lug 1338 by a hinge 1339. The hinge 1338 comprises a section of flexible material with a reduced wall thickness. The lug 1338 is configured to assist with locating the valve seal 1336 within the end of the second end 1326 of connector body 1320. Additionally, the lug 1338 includes a recess 1340 which is adapted to receive the spigot 1335. Mating of the spigot 1335 within the recess 1340 correctly orients the valve seal 1336 on the valve seat 1331.

[0262] When pressurised respiratory gas is supplied from a source, it flows through the conduit connector 1300 and into the cushion module 1010. The elevated pressure of the respiratory gas causes the flap 1337 to swing about the hinge 1339 to cover the opening 1327 in the second end 1326 of the connector body 1320. This represents the "open position" described above in that the flap 1337 prevents

ambient air from entering the conduit connector 1300 via the opening 1327. In the event that the source of respiratory gas fails or the conduit connecting to the source becomes obstructed, the anti-asphyxiation valve 1330 closes because the air pressure in the conduit connector 1300 equalizes with the air pressure outside the conduit connector 1300 so that the flap 1337 transitions to the "closed position" described above owing to the inherent resilience in the flexible material which forms the hinge 1339. In the closed position, the opening 1327 is revealed to the interior of the conduit connector 1300 so that the natural breathing cycle of the patient will draw air into the conduit connector 1300 and the cushion module 1010 via the opening 1327.

[0263] The valve seat 1331 includes a radially projecting step which is configured to couple with the conduit connector 1300. In particular, the step is configured to fit within the second end 1326 of the connector body 1320. The coupling may comprise a snap-fit connection or may comprise a permanent fixing, such as welding or fixing with adhesive.

[0264] The valve seat 1331 couples with the swivel connector 1350 which is configured to connect with a conduit from a respiratory gas source. The swivel connector 1350 includes a radially inwardly projecting shoulder 1352 which is co-operable with the step of the valve seat 1331 to connect the valve seat 1331 to the swivel connector 1350. The connection is a snap-fit connection. The snap-fit connection may be removable or may be a one-time connection. In other embodiments, however, the connection may comprise a permanent fixing, such as welding or fixing with adhesive.

[0265] The frame 1400 includes a central body portion 1401 that includes one or more channels for conveying respiratory gas from a gas source via the conduit connector 1300 to the cushion module 1010 and therefore to the patient. The frame 1400 includes one or more upper headgear connectors 1410 and one or more lower headgear connectors 1420 which are configured to co-operate with a headgear 1900 (such as resilient straps) for fitting the patient interface 1000 to the patient. The one or more upper headgear connectors 1410 are configured to co-operate with respective one or more upper straps of a headgear 1900 while the one or more lower headgear connectors are configured to co-operate with respective one or more lower

straps of a headgear 1900. The headgear 1900 operates by pulling the patient interface 1000 into contact with the patients face to form a substantially air-tight seal when respiratory gas at elevated gas pressure is delivered to the patient via the patient interface 1000.

5 [0266] In the illustrated embodiment the one or more upper headgear connectors 1410 comprise a first upper headgear connector slot 1412 on a first lateral side of a notional midplane (denoted generally along the line AA' in Figure 4) of the frame 1400 and a second upper headgear connector slot 1414 on a second lateral side of the notional midplane of the frame 1400. Each slot being configured to receive a
10 respective upper strap of a headgear 1900. The strap may be received within the slot either permanently or removably such as by being inserted through the slot, looped back on itself, and fixed in place with a hook and loop connection. In alternative embodiments, the slots 1412, 1414 may be replaced by any suitable structure for permanently or removably co-operating with an upper headgear strap. Suitable
15 connection structures may include connectors to releasably receive clips of a respective strap either through a mechanical, magnetic, or adhesive connection.

[0267] In the illustrated embodiment, the one or more lower headgear connectors 1420 comprise a first lower headgear connector 1422 on the first lateral side of the notional midplane of the frame 1400 and a second lower headgear connector 1424
20 on the second lateral side of the notional midplane of the frame 1400. Each headgear connector 1420 being configured to receive a respective lower strap of a headgear. Each lower headgear connector 1422, 1424 comprises a bar configured to removably receive a clip of the respective lower headgear strap via a mechanical connection such as a hook and post connection. In an alternative embodiment, the
25 connector may be replaced by any suitable structure for permanently or removably co-operating with a lower headgear strap and/or a clip of a lower headgear strap, such as the connection methods described above in relation to the upper straps and one or more upper headgear connectors 1410. Specifically, suitable connection structures may include one or more lower headgear connectors 1420 on the frame
30 1400 to releasably receive clips of a respective lower strap either through a mechanical, magnetic, or adhesive connection.

[0268] While the illustrated embodiment includes the frame 1400, the headgear connectors 1410, 1420 may be integrated with or connected to the housing 1200 in alternative configurations. If so, the frame 1400 is not necessary and could be omitted from such configurations while the housing 1200 integrates these features. It
5 will therefore be appreciated that all features described with relation to the frame 1400 in this specification could alternatively be incorporated into the housing 1200.

[0269] The frame 1400 further includes a connector sleeve 1430 that includes one or more arcuate fingers 1432. In the illustrated embodiment the connector sleeve 1430 includes four arcuate fingers 1432. The connector sleeve 1430 has an inner
10 wall 1434 which comprises the ball socket 1402 which is configured to receive the ball connector 1322 of the conduit connector 1300. The outer wall of the connector sleeve 1436 is shaped to fit within the sleeve 1230 of the housing 1200. The arcuate fingers 1432 are shaped and spaced apart to form a complementary fit with the key formations 1232. The alignment of the key formations 1232 between the fingers
15 1432 ensures that the frame aligns correctly with the housing 1200 when they are fitted together.

[0270] It will be appreciated that, as mentioned above, the connector sleeve 1430 of the frame 1400 may receive the conduit connector 1300 in fixed manner without the need for a ball socket 1402. In such an embodiment, the conduit connector 1300
20 would connect permanently, either directly or indirectly, or be integrally formed with the connector sleeve 1430.

[0271] Each arcuate finger 1432 has an end with an arcuate flange portion 1433 which forms a snap-fit with a radially inwardly projecting lip 1231 of the sleeve 1230. The snap-fit holds the frame 1400 to the housing 1200. The snap-fit may be
25 releasable or may be a permanent fit between the frame 1400 and the housing 1200.

[0272] Alternatively, the arcuate fingers 1432 of the frame 1400 and/or the radially inwardly projecting lip 1231 of the housing may be omitted. Instead, the frame 1400 may be connected to the housing 1200 by any conventional means, such as with adhesives or welding. For example, the frame 1400 may be permanently connected
30 to the housing 1200 by ultrasonically welding the housing 1200 and the frame 1400 together.

[0273] As foreshadowed above, the general form of the patient interface 1000 may vary. One such variation of the general form, and which is applicable to the embodiments described below, is where the housing 1200 and the frame 1400 are formed integrally. In other words, the patient interface 1000 may include a unitary structure that performs the same function of the housing 1200 and frame 1400. While the housing 1200 and the frame 1400 are described as being separate components of the patient interface 1000, the description should be read as including the option of an integrally formed component that functions in the same way as both the housing 1200 and frame 1400.

[0274] Having further regard to variations on the general form of the patient interface 1000, another variation of the general form, and which is applicable to embodiments described below, is where the housing 1200 and the seal 1100 are formed integrally of the same material. In other words, the patient interface 1000 may include a unitary structure of a single material that performs the same function as both housing 1200 and seal 1100. In such an embodiment, the housing 1200 could be formed of the same material as the seal 1100, for example an elastomer material such as silicone. It is contemplated that in a variation where additional rigidity is required in the unitary elastomer housing 1200 and seal 1100, the thickness and/or hardness of the elastomer material may be varied in localized regions to provide such rigidity. The varying hardness may be achieved by any suitable known manufacturing technique such as two shot injection moulding, or overmoulding.

[0275] Having regard to Figures 10 to 24, a patient interface 2000 of a second embodiment is shown. The patient interface 2000 is a variation of the patient interface 1000 of the general form and incorporates all components and functions with the patient interface 1000 unless stated otherwise. More specifically the patient interface 2000 incorporates at least the frame 1400, conduit connector 1300 and seal 1100 of the patient interface 1000. The patient interface 2000 has a housing 2200 that differs slightly from housing 1200 of patient interface 1000. The housing 2200 is configured for connection with an exhaust conduit 2500. This difference in housing 2200 will be described below, otherwise it should be appreciated that housing 2200 includes all features and functions of housing 1200.

[0276] Furthermore, due to the modification of housing 2200, the reference numerals for the cushion module 2010, which is formed of the housing 2200 and seal 1100, and the cavity 2012, which is defined by the cushion module 2010, have been updated. However, it is to be appreciated that the description of cushion
5 module 1010 and cavity 1012 are equally applicable to cushion module 2010 and cavity 2012 and that all features and functions are to be incorporated. Features of the housing 2200 which are the same as the features of the housing 1200 are denoted with the same reference numeral, but the leading number is “2” instead of “1”.

10 [0277] As described above, patient interface 2000 differs primarily from patient interface 1000 in that it further comprises an exhaust conduit 2500. The exhaust conduit 2500 is located within the cavity 2012 of cushion module 2010. The exhaust conduit 2500 comprises an exhaust conduit inlet 2510 located at a first end of the exhaust conduit 2500. The exhaust conduit 2500 also comprises an exhaust conduit
15 outlet 2505 located at a second end of the exhaust conduit 2500. The exhaust conduit 2500 defines an exhaust flow passage 2501 extending between the exhaust conduit inlet 2510 and exhaust conduit outlet 2505. The exhaust conduit outlet 2505 is configured to be in fluid communication with the outlet 2210 of cushion module 2010. Consequently, the exhaust conduit inlet 2510 is in fluid communication with
20 the outlet 2210 of cushion module 2010 via the exhaust flow passage 2501.

[0278] Exhaust conduit 2500 comprises a body 2560, a manifold 2550 connected to the body 2560, and one or more prongs 2530 extending from the manifold 2550. These may be separate components that are permanently or removably connected to each other or may be portions of an integral exhaust conduit 2500. Each of the
25 body 2560, manifold 2550 and one or more prongs 2530 define a portion of the exhaust flow passage 2501 through exhaust conduit 2500.

[0279] Referring to Figure 18 for example, the patient interface 2000, and as a result the exhaust conduit 2500, are shown in cross-sectional side view. The body 2560 comprises a base 2566 at a first end. The base 2566 is configured to be connected
30 to an internal surface of the housing 2200. The base 2566 connects with the housing 2200 at a position surrounding outlet 2210. The connection may be removable or permanent and may be achieved by any suitable means such as a welded

connection, overmoulded connection, mechanical connection, a magnetic connection, or an adhesive connection.

[0280] In one embodiment, the connection between the base 2566 and housing 2200 is a mechanical connection wherein the connection comprises a plurality of mating features that are formed on the base 2566 and the housing 2200, respectively. The mating features on the base 2566 and the housing 2200 engage with each other in a complementary and interlocking manner. The mating features may include, but are not limited to, grooves, ridges, tapers, hooks, slots, pins, channels, or any combination thereof. The plurality of mating features may engage each other in a removable and repeatable manner, or in a permanent manner such as a one-time engagement.

[0281] In an example of the plurality of mating features, the base 2566 may comprise a male connector and the housing 2200 may comprise a female connector configured to removably receive the male connector of the base 2566. This connection between the base 2566 and housing 2200 creates a seal that is substantially airtight at the intended gas pressures to which the cushion module 2010 is subjected for use. The connection between the male connector of the base 2566 and female connector of the housing 2200 may be a snap-fit connection. Alternatively, the housing 2200 may comprise a male connector while the base 2566 comprises a female connector configured to receive the male connector of the housing 2200. This alternative connection between the female connector of the base 2566 and male connector of the housing 2200 may also be a snap-fit connection. It is also envisioned that the connection between the respective male and female connectors may be a permanent one-time connection instead of a removable connection.

[0282] In another embodiment, the connection between the base 2566 and housing 2200 may be a taper connection wherein the housing 2200 comprises a male taper connector having a tapered external surface and the housing 2200 comprises a female taper connector having a tapered internal surface configured to removably receive the tapered external surface of the male taper connector of the base 2566. This taper connection between the base 2566 and housing 2200 forms a seal that is substantially airtight at the intended gas pressures to which the cushion module

2010 is subjected for use. Alternatively, the housing 2200 may comprise a male taper connector while the base 2566 comprises a female taper connector configured to receive the male taper connector of the housing 2200.

[0283] In another embodiment, the connection between the base 2566 and housing
5 2200 may be a welded connection. In this embodiment, the base 2566 is ultrasonically welded to the housing 2200 to form a permanent connection.

[0284] In another embodiment, the connection between the base 2566 and housing 2200 may be an adhesive connection. In this embodiment, the base 2566 is adhered to the housing 2200 to form a permanent connection.

10 [0285] In another embodiment, the base 2566 may be omitted. In this embodiment, the body 2560 or a portion of the body 2560 may be integrally formed with the housing 2200. The integral formation therefore requiring no additional connection means between the body 2560 and housing 2200. This integral formation may be achieved for example by moulding the housing 2200 and body 2560 in a single
15 moulding process or may be formed by moulding the body 2560 onto housing 2200 in a two-shot or overmould moulding process to form an integral structure.

[0286] It is to be understood that, in the illustrated embodiment, the body 2560, and specifically the base 2566, are connected to the housing 2200 as a result of the outlet 2210 of the cushion module 2010 being located on the housing 2200.

20 However, in alternative embodiments where the outlet 2210 is located on the seal 1100, or on a unitary frame-housing cushion module 2010, then the body 2560, and specifically the base 2566, may connect to whichever component, or components, comprise the outlet 2210, at a position surrounding said outlet 2210. In other words, the body 2560 is intended to connect at a position surrounding outlet 2210
25 regardless of the location of outlet 2210.

[0287] Body 2560 extends between housing 2200 and manifold 2550. In the illustrated embodiment, body 2560 is in the form of a tubular structure having the base 2566 at the first end, manifold connector 2564 at the second end, and a central portion 2562 extending between the base 2566 and manifold connector 2564. Body
30 2560 allows for gas flow passage between the first end and the second end. As previously mentioned, the body 2560 defines a portion of the exhaust flow passage

2501 of exhaust conduit 2500. Body 2560 in the illustrated embodiment can be described as a hollow conduit, duct, or pipe.

[0288] In an alternative embodiment, a portion 2565 of the body 2560 may be pliable. Such pliability enables it to be repeatably deformed without structural failure occurring. The portion 2565 allows for the exhaust conduit 2500 to be adjustable. That is, the orientation and/or position of the exhaust conduit 2500, or specifically of the manifold 2550 of exhaust conduit 2500, with respect to the seal 1100. The portion 2565 enables the orientation and/or position of the one or more prongs 2530 to be adjusted. The pliable portion 2565 may be located within the central portion 2562 of the body 2560. Alternatively, substantially the entire central portion 2562 may be pliable such that it can be repeatably deformed without structural failure occurring. To achieve the desired pliability the body 2560 may be constructed of, for example, but not limited to, a plastics material, an elastomeric material, a metal material, or a combination of one or more such as an elastomeric conduit comprising a metal reinforcing wire or embedded metal wire.

[0289] It will be appreciated by those skilled in the art that in alternative embodiments, the size and/or locations of the manifold 2550 and one or more prongs 2530 may render the body 2560 redundant. In such embodiments, the manifold 2550 may connect or extend directly from housing 2200. In this situation any of the above-described features and/or functions of the body 2560 could be incorporated into either of the housing 2200, manifold 2550, or both.

[0290] In the illustrated embodiment, the manifold 2550 connects to and/or extends from the body 2560, and the one or more prongs 2530 connect to and/or extend from the manifold 2550. Manifold 2550 comprises a manifold outlet 2552 which is configured to connect to the manifold connector 2564 of body 2560 such that the manifold outlet 2552 and body 2560 are in fluid communication.

[0291] The manifold 2550 may be removably or permanently connected to body 2560. Such connection may be via any conventional means such as mechanical fasteners, adhesives, welding, two-shot moulding, overmoulding, or a taper connection. For example, the manifold connector 2564 and manifold outlet 2552 may be connected via ultrasonic welding, a permanent or removable snap-fit connection, or via adhesive applied to the mating surfaces of the two components. The manifold

2550 may also be overmoulded onto the body 2560 wherein the body 2560 is formed in a first moulding process and then placed into a mould tool where the manifold 2550 is formed by overmoulding the manifold 2550 onto the body 2560 to create a permanent connection. Alternatively, the body 2560 and manifold 2550 may be
5 formed separately and then joined by an overmoulding process wherein a material is overmoulded over both components to form a permanent connection between the manifold 2550 and body 2560.

[0292] A portion, or an entirety of the manifold 2550 may be formed integrally with the body 2560 as a singular component. In such an embodiment, it will be
10 appreciated that the body 2560 and the manifold 2550 may be understood as portions of an integral structure that comprises both the body 2560 and manifold 2550. The manifold connector 2564 and manifold outlet 2552 may therefore be omitted if not required or taken as transitional portions between the body 2560 and manifold 2550 of the integral structure. Features and/or functions otherwise
15 disclosed in relation to the body 2560 and manifold 2550 are retained in this integral structure.

[0293] The manifold 2550 forms a portion of the exhaust flow passage 2501. The manifold 2550 is configured primarily to receive gas from the one or more prongs 2530 and deliver the gas to the body 2560 where it is ultimately delivered to the
20 outlet 2210 of the housing 2200. From there, the gas flows through the outlet 2210 to externally of the cushion module 2010. In this embodiment, the outlet 2210 is a bias vent 2215. In other embodiments, the outlet 2210 may be configured for connection with an exhalation conduit.

[0294] In the illustrated embodiment the manifold 2550 further comprise a face
25 contacting portion 2554. The face contacting portion 2554 is configured to contact one or more of the upper lip, philtrum, or nares of a patient. Such connection may aid in supporting or locating the one or more prongs 2530 in the desired position. The face contacting portion 2554 comprises a relatively soft material which may help avoid or minimize discomfort to the patient. For example, the face contacting portion
30 2554 may comprise an elastomeric material such as a silicone or a rubber material. In the illustrated embodiment the manifold 2550 is a dual material construction. In this embodiment, the manifold 2550 comprises a rigid plastic portion which

comprises the manifold outlet 2552 and an elastomeric portion which comprises the face contacting portion 2554. Alternatively, the entirety of the manifold 2550 may comprise an elastomeric material. Further alternatively, substantially the entirety of the manifold 2550 may comprise an elastomeric material with only minimal rigid components providing support where necessary. In such an embodiment, substantially the entirety of the manifold 2550 may comprise an elastomeric material with only the manifold outlet 2552 being formed of a rigid material.

[0295] In an alternative embodiment, the face contacting portion 2554 may not be configured to contact the face of the patient in use but may still be formed of an elastomeric material and configured instead to avoid discomfort should any unintentional contact between the manifold 2550 and the face of the patient occur.

[0296] In the illustrated embodiment, at least a portion of the face contacting portion 2554 of the manifold 2550 is concave when viewed in the proximal-distal direction to conform to the shape of a patient's upper lip or philtrum.

[0297] The one or more prongs 2530 extend from the manifold 2550 to the exhaust conduit inlet 2510. In the illustrated embodiment exhaust conduit 2500 comprises a first prong 2532 and a second prong 2540, the first prong 2532 extends from the manifold 2550 to a first free end 2532, the first free end comprising a first exhaust conduit inlet 2515, and the second prong 2540 extends from the manifold 2550 to a second free end 2542, the second free end comprising a second exhaust conduit inlet 2520.

[0298] In the illustrated embodiment the first prong 2532 and second prong 2540 are non-sealing nasal prongs. Non-sealing nasal prongs are not configured to form a seal with respective nares or nostrils of a patient in use. Said another way, the cross-sectional area of the first prong 2532 and second prong 2540 at their respective free ends 2532, 2542 are both designed to be less than the cross-sectional area of an intended patient's nares. It is intended that gas can flow in and out of the patient's nares through a gap defined between the outer surface of the first and second prongs 2532, 2540 and an interior surface of the user's nares.

[0299] In an alternative embodiment, exhaust conduit 2500 may comprise only a single prong 2532 and therefore only a single exhaust conduit inlet 2515. In this

configuration the first prong 2532 extends from manifold 2550 to first free end 2532, the first free end comprising the first exhaust conduit inlet 2515.

[0300] In the embodiment comprising only a single prong, the first prong 2532 may be either of a non-sealing nasal prong or a sealing nasal prong. In an embodiment
5 where the first prong 2532 is a sealing prong, the first prong 2532 is configured to engage and form a seal with an internal surface or a rim of a respective nare of the patient's nares. In the embodiment where the first prong 2532 is a non-sealing prong, as discussed above, the first prong 2532 is designed to have a cross-sectional area that is less than the cross-sectional area of an intended patient's
10 nares such that no seal is formed between the first prong 2532 and an internal surface of the respective patients nare.

[0301] The exhaust conduit inlet 2510 has a cross-sectional area comprising the first exhaust conduit inlet 2515 and where applicable the second exhaust conduit inlet 2520. This cross-sectional area of the exhaust conduit inlet 2510 is configured to be
15 less than the cross-sectional area of the inlet 2220 of housing 2200. In the illustrated embodiment, all gas entering the cushion module 2010 enters through the inlet 2220, and excluding unintentional leaks, substantially all gas exiting the cushion module 2010 exits through the outlet 2210. The exhaust conduit 2500 is in sealed fluid communication with the outlet 2210 of the housing 2200, and as such the reduced
20 cross-sectional area of the exhaust conduit inlet 2510 compared with the inlet 2220 of housing 2200 creates a flow restriction which accelerates gas flow into exhaust conduit 2500 when pressurised gas flows into the cushion module 2010 via the inlet 2220 and then into the exhaust conduit 2500 in order to exit the cushion module 2010. The reduced cross-section in the flow path creates a pressure drop which
25 accelerates gas flow entering exhaust conduit 2500. The significance of this acceleration of gas is explained in the following paragraphs.

[0302] In the illustrated embodiment, the flow restriction mentioned in the above paragraph is created by the exhaust conduit inlet 2510 having a cross-sectional area that is less than the cross-sectional area of the inlet 2220 of the housing 2200.
30 However, it is contemplated that this flow restriction could be placed elsewhere in the exhaust conduit 2500, or more specifically, elsewhere in the one or more prongs 2530, manifold 2550 or body 2560.

[0303] In the illustrated embodiment of patient interface 2000, the ratio of the cross-sectional area of the first exhaust conduit inlet 2515 to the second exhaust conduit inlet 2520 is 1:1. That is, the cross-sectional area of both exhaust conduit inlets 2515, 2520 is equal. However, in alternative embodiments, the cross-sectional area of the first exhaust conduit inlet 2515 may be unequal to the cross-sectional area of the second exhaust conduit inlet 2520. The ratio of the cross-sectional area of the first exhaust conduit inlet 2515 to the cross-sectional area of the second exhaust conduit inlet 2520 can range from 1:1.1 to 1:4. In one embodiment, the ratio of the cross-sectional area of the first exhaust conduit inlet 2515 to the cross-sectional area of the second exhaust conduit inlet 2520 is 1:3.

[0304] In addition to, or instead of, the differing exhaust conduit inlet cross-sectional areas, the first prong 2532 and the second prong 2540 may differ in shape and/or size in at least one aspect, such as the prong diameter, length, or shape. Such an embodiment where the first prong 2532 and second prong 2540 have differing shapes and/or sizes may be described as having asymmetrical first and second prongs 2532, 2540.

[0305] In the illustrated embodiment, exhaust conduit 2500 is configured to prevent ingress of gas from the cavity 2012 of cushion module 2010 into exhaust flow passage 2501 other than via the exhaust conduit inlet 2510, and to prevent egress of gas from exhaust flow passage 2501 into the cavity 2012. The exhaust conduit 2501 is an enclosed passageway extending from the exhaust conduit inlet 2510 to the exhaust conduit outlet 2505.

[0306] In the preceding paragraphs the exhaust conduit 2500 has been described in relation to the sub-components of the body 2560, manifold 2550 and one or more prongs 2530. However, in an alternative embodiment, the exhaust conduit 2500 may comprise a body 2560 which is integrally formed with the housing 2200 as a single rigid component while the one or more prongs 2530 may be constructed of an elastomeric or flexible material and connected to integral housing 2200 and exhaust conduit body 2560. For example, the body 2560 of the exhaust conduit 2500 may be integrally formed with the housing 2200. The integrally formed body 2560 and housing 2200 may comprise a rigid plastics material. The one or more prongs 2530

may be formed of an elastomeric material separately and then connected to the integrally formed housing 2200 and body 2560 of the exhaust conduit 2500.

[0307] In the illustrated embodiment, the exhaust conduit 2500 is connected permanently or removably to housing 2200 and is not in direct contact with the seal 1100. Said another way, the exhaust conduit 2500 is a separate structure from seal 1100. Furthermore, the exhaust conduit 2500 is surrounded by the cavity 2012 of cushion module 2010. It is believed this may be beneficial to improving patient comfort by reducing interference or interaction with the supply seal 1100, which is configured to contact the patient's face. However, it is to be appreciated that in alternative configurations the exhaust conduit 2500 may contact or be connected to the seal 1100 in one or more locations without significantly impacting patient comfort. For example, the exhaust conduit 2500 may connect to a portion of the seal 1100 away from the patient contacting surface 1120.

[0308] The exhaust conduit 2500 may be designed such that it may be retrofitted to existing patient interfaces. This enables the exhaust conduit to be sold separately from the remainder of the patient interface 2000. In such circumstances, the exhaust conduit 2500 is located within the cavity 1012 of the existing patient interface and the exhaust conduit outlet 2505 is in fluid communication with the outlet or bias vent of the existing patient interface. In this way, existing patient interfaces may be fitted with exhaust conduit 2500 to improve the performance of these existing patient interfaces.

[0309] Referring to Figures 23 and 24 for illustrative purposes, the patient interface 2000 is shown in cross-section along line B-B' fitted to an anatomical model of a patient (also shown in cross-section). In Figure 23 the patient interface 2000 is illustrated fitted to a patient with their mouth open. In Figure 24 the patient interface 2000 is illustrated fitted to a patient with their mouth closed. Arrows indicate the direction of gas flow into the cushion module 2010 via inlet 2220, and out of the cushion module 2010 via outlet 2210, while fitted to a patient without respiration occurring. The relative size of the arrows should not be interpreted as an indication of gas flow rate or velocity. It will be appreciated that during respiration there will be additional gas flow paths formed beyond which are described. However, for the purpose of explanation it is believed the general operation of patient interface 2000

can be adequately described while ignoring respiration because the effect of the patient interface 2000 is believed to be most prominent at the end of the exhalation cycle, which can be realistically likened to a situation in which no respiration is occurring.

5 [0310] When the patient interface 2000 is fitted to a patient, the exhaust conduit 2500 is positioned such that exhaust conduit inlet 2510 is positioned within one or a respective one of a patient's nares, or positioned at a position that is below the one or the respective one of the patient's nares and adjacent a lip superior of the patient, or positioned at a position that is immediately adjacent to the one or the respective
10 one of the patient's nares. Said another way, the exhaust conduit inlet 2510 is located within, adjacent to, or proximal to, the one or the respective one of a patient's nares.

[0311] More specifically, in embodiments comprising a first exhaust conduit inlet 2515 and a second exhaust conduit inlet 2520, the first exhaust conduit inlet 2515 is
15 configured to be positioned within a first one of a patient's nares, or to be positioned at a position that is below the first one of a patient's nares and adjacent a lip superior of the patient, or to be positioned at a position that is immediately adjacent the first one of the patient's nares, while the second exhaust conduit inlet 2520 is configured to be positioned within a second one of a patient's nares, or to be positioned at a
20 position that is below the second one of a patient's nares and adjacent a lip superior of the patient, or to be positioned at a position that is immediately adjacent the second one of the patient's nares.

[0312] In embodiments comprising a single exhaust conduit inlet 2515, the first exhaust conduit inlet 2515 is configured to be positioned within a first one of a
25 patient's nares, or to be positioned at a position that is below the first one of a patient's nares and adjacent a lip superior, of the patient or to be positioned at a position that is immediately adjacent the first one of the patient's nares.

[0313] Referring to Figure 23, where the patient interface 2000 is fitted to a patient with the patient's mouth open, without respiration occurring, and where pressurised
30 gas is being delivered to the patient interface 2000 via conduit connector 1300. The flow of pressurised gas enters the cushion module 2010 via inlet 2220, excess pressurised gas from within cushion module 2010 and/or from within the patient's

airways then flows into the exhaust conduit 2500 via the exhaust conduit inlet 2510, the gas then travels along exhaust flow passage 2501 and through outlet 2210 of cushion module 2010 to exit the cushion module 2010. Due to the intended positioning of the exhaust conduit inlet 2510 relative to a patient's nare(s) (including the positioning of either or both the first exhaust conduit inlet 2515 and second exhaust conduit inlet 2520) described above, a first significant flow path and a second significant flow path are formed for gas to enter the exhaust conduit 2500 via the exhaust conduit inlet 2510.

[0314] The first significant flow path extends from within the cushion module 2010 into the patient's oral cavity via their mouth, through the patient's throat, into the patient's nasal cavity and: (1) into the exhaust conduit inlet 2510 when the exhaust conduit inlet 2510 is positioned within a nare or nares of the patient, or (2) out of the one or more nares of the patient and into the exhaust conduit inlet 2510 when the exhaust conduit inlet 2510 is positioned at a position adjacent the one or more nares of the patient, or positioned at a position that is below the one or more nares of the patient and adjacent a lip superior of the patient, or positioned at a position that is immediately adjacent the one or more nares of the patient. In all instances this flow of gas entering the patient's oral cavity and exiting through the nasal cavity is believed to cause anatomical dead space flushing of at least some of the patient's oral cavity, throat, and nasal cavity.

[0315] The second significant flow path extends from within the cushion module 2010 and: (1) through the one or more nares of the patient and into the nasal cavity of the patient where the gas flow decelerates and/or the direction of the gas flow changes so that the gas flow can enter the exhaust conduit inlet 2510 when the exhaust conduit inlet 2510 is positioned within the one or more nares of the patient, or (2) through a space defined between the lip superior and/or outer nares of the patient and the exhaust conduit 2500 and into the exhaust conduit inlet 2510 when the exhaust conduit inlet 2510 is positioned at a position immediately adjacent the one or more nares of the patient or positioned at a position that is below the one or more nares of the patient and adjacent a lip superior of the patient. In the first instance, it is believed that the gas flow into the nasal cavity and then into the exhaust conduit inlet 2510 will cause anatomical deadspace flushing of at least some of the patient's nasal cavity. In the second instance, the gas flow being directed

between the patient's lip superior and/or outer nares and the exhaust conduit 2500 will cause acceleration of the gas flow due to the restricted cross-sectional area of the flow path. It is believed this acceleration will likely cause at least some gas flow to enter the patient's nasal cavity via the one or more nares before decelerating and/or changing direction and exiting the nasal cavity via the one or more nares and then entering the exhaust conduit inlet 2510. It is believed that this portion of gas flow entering the nasal cavity will create some anatomical dead space flushing of the patient's nasal cavity.

[0316] Referring to Figure 24, where the patient interface 2000 is fitted to a patient with the patient's mouth closed, without respiration occurring, and where pressurised gas is being delivered to the patient interface 2000 via conduit connector 1300. The flow of pressurised gas enters the cushion module 2010 via inlet 2220, excess pressurised gas from within cushion module 2010 and/or from within the patient's airways then flows into the exhaust conduit 2500 via the exhaust conduit inlet 2510, the gas then travels along exhaust flow passage 2501 and through outlet 2210 of cushion module 2010 to exit the cushion module 2010. However, due to the patient's mouth being closed, only the second significant flow path is formed. The second flow path is discussed in detail in the paragraph immediately preceding this.

[0317] Because gas flow through the first significant flow path and the second significant flow path are both thought to cause anatomical dead space flushing to some extent, it is believed that the patient interface 2000 provides a significant benefit beyond traditional non-invasive ventilation masks. The ability to provide pressure support and simultaneous dead space flushing with the patients mouth open or closed is advantageous in NIV therapy. Additionally, in embodiments where the exhaust conduit 2500 is removable it is envisioned that the patient interface 2000 with the exhaust conduit 2500 removed could be used to provide standard NIV therapy should such an outcome be desired. For example, it is envisioned that a patient may only require anatomical dead space flushing during discrete periods of time of the day. This enables the patient interface 2000 to be utilized for alternating periods of time with the exhaust conduit 2500 in place, and with the exhaust conduit 2500 removed.

[0318] In an alternative embodiment of exhaust conduit 2500 comprising a single prong 2532 that is a sealing prong, it will be appreciated that the second significant flow path will be different to that described in the paragraphs preceding this. In such an embodiment, the second significant flow path extends from within the cushion module 2010, through the first nare of a patient and into the patient's nasal cavity on a first side of the septum, then exiting the patient's nasal cavity on a second side of the septum by entering the exhaust conduit inlet 2510 which is positioned within the second nare of the patient. Said another way, gas enters the nasal cavity from the cushion module 2010 via a first nare and exits the nasal cavity via the exhaust conduit inlet 2510 located within a second nare. In this situation it is believed that the one-way gas flow through the patient's nasal cavity causes anatomical dead space flushing of the patient's nasal cavity.

[0319] In the preceding paragraphs, dead space flushing of the anatomical dead space of a patient has been discussed as an intended benefit of patient interface 2000. The anatomical dead space of a patient consists of the total volume of the respiratory tract segments of a patient that are responsible for conducting air to the alveoli and respiratory bronchioles but do not take part in the process of gas exchange itself. The anatomical dead space is therefore the total volume of the conducting airways from the nose or mouth to the terminal bronchioles of a patient including the oral cavity, nasal cavity, and pharynx (also referred to as the throat).

[0320] During respiration by a patient, lower CO₂ content air is inhaled into the lungs and higher CO₂ content air is exhaled from the lungs. At the end of an exhalation cycle a portion of the exhaled higher CO₂ content air remains in the anatomical dead space of the patient. This higher CO₂ content air is then inhaled, or rebreathed, during the next respiration cycle. This rebreathing of high CO₂ content air leads to a reduced efficiency in the gas exchange occurring within a patient's lungs.

[0321] The process of dead space flushing replaces at least a portion of the exhaled higher CO₂ content air present in the anatomical dead space of a patient with fresh lower CO₂ content air so that during the following inhalation cycle a reduced amount of exhaled higher CO₂ content air is inhaled, or rebreathed. This reduction in rebreathing of higher CO₂ content air improves the efficiency of gas exchange occurring within a patient's lungs.

[0322] As mentioned in proceeding paragraphs, the exhaust conduit inlet 2510 has a cross-sectional area that is configured to be less than the cross-sectional area of the inlet 2220 of housing 2200. The smaller cross-sectional area of the exhaust conduit inlet 2510 compared with the inlet 2220 of housing 2200 forms a flow restriction which creates a pressure drop and therefore an acceleration of gas flow into the exhaust conduit 2500, when pressurised gas is supplied to the cushion module 2010 of patient interface 2000 in use. It is believed that this acceleration of gas flow into exhaust conduit 2500 may also cause entrainment of surrounding gas into the exhaust conduit 2500.

[0323] The entrainment of gasses at a position surrounding exhaust conduit inlet 2510 into exhaust conduit 2500 may be beneficial to the anatomical dead space flushing of a patient when the exhaust conduit inlet 2510 is positioned within one or a respective one of the patient's nares or is positioned at a position immediately adjacent the patient's nares or is positioned at a position that is below the patient's nares and adjacent a lip superior of the patient. As gas flow is accelerated into the exhaust conduit inlet 2510 higher CO₂ content gas present in the patient's anatomical dead space may be entrained into exhaust conduit inlet 2510 due to a combination of the acceleration of gas flow and/or the localized pressure drop. It is believed that this may provide anatomical dead space flushing instead of or in addition to the anatomical dead space flushing described above in relation the significant flow paths formed during use.

[0324] Having regard to Figures 25 to 42, a patient interface 3000 of a third embodiment is shown. The patient interface 3000 is a variation of the patient interface 1000 of the general form and incorporates all components and functions with the patient interface 1000 unless stated otherwise. More specifically the patient interface 3000 incorporates at least the frame 1400, headgear 1900, conduit connector 1300 and seal 1100 of the patient interface 1000. The housing 3200 of patient interface 3000 differs slightly from housing 1200 of patient interface 1000 in that it is configured for connection with a nasal interface 3600. This difference in housing 3200 will be described below, otherwise it should be appreciated that housing 3200 includes all features and functions of housing 1200. Features of the housing 3200 which are the same as the features of the housing 1200 are denoted with the same reference numeral, but the leading number is "3" instead of "1".

[0325] Furthermore, due to the modification of housing 3200, the reference numerals for the cushion module 3010, which is formed of the housing 3200 and seal 1100, and the cavity 3012, which is defined by the cushion module 3010, have been updated. However, it is to be appreciated that the description of cushion
5 module 1010 and cavity 1012 are equally applicable to cushion module 3010 and cavity 3012 and that all features and functions are to be incorporated. Features of the cushion module 3010 which are the same as the features of the cushion module 1010 are denoted with the same reference numeral, but the leading number is “3” instead of “1”.

10 [0326] The patient interface 3000 is also a variation of the patient interface 2000 and includes exhaust conduit 3500 which functions in substantially the same way and incorporates all the features of exhaust conduit 2500 unless stated otherwise. However, patient interface 3000 differs from patient interface 2000 in that the exhaust conduit 3500 is incorporated into a nasal interface 3600. The nasal interface
15 3600 comprises both the exhaust conduit 3500 and a flushing conduit 3610. The nasal interface 3600 is connected permanently or removably to housing 3200 and is not in direct contact with the seal 1100. Said another way, the nasal interface 3600 is a separate structure from the seal 1100. The nasal interface 3600 is surrounded by the cavity 3012 of cushion module 3010.

20 [0327] Exhaust conduit 3500 is located within the cavity 3012 of cushion module 3010 and comprises an exhaust conduit inlet 3510 located at a first end of the exhaust conduit 3500, and an exhaust conduit outlet 3505 located at a second end of the exhaust conduit 3500. The exhaust conduit 3500 defines an exhaust flow passage 3501 extending between the exhaust conduit inlet 3510 and exhaust
25 conduit outlet 3505. The exhaust conduit outlet 3505 is configured to be in fluid communication with the outlet 3210 of cushion module 3010. Consequently, the exhaust conduit inlet 3510 is in fluid communication with the outlet 3210 of cushion module 3010 via the exhaust flow passage 3501.

[0328] Flushing conduit 3610 is located within the cavity 3012 of cushion module
30 3010 and comprises a flushing conduit inlet 3612 located at a first end of the flushing conduit 3610 and a flushing conduit outlet 3613 located at a second end of the flushing conduit 3610. The flushing conduit 3610 defines a flushing flow passage

3611 extending between the flushing conduit inlet 3612 and flushing conduit outlet 3613. The flushing conduit inlet 3612 is configured to be in fluid communication with the cavity 3012 of cushion module 3010. Consequently, the flushing conduit outlet 3610 is in fluid communication with cavity of cushion module 3010 via the flushing
5 flow passage 3611.

[0329] In the illustrated embodiment, the flushing conduit outlet 3613 comprises a first flushing conduit outlet 3614 and a second flushing conduit outlet 3615. In the illustrated embodiment, the flushing flow passage 3611 therefore extends from the flushing conduit inlet 3612 to both the first flushing conduit outlet 3614 and the
10 second flushing conduit outlet 3615. In alternative embodiments, the flushing conduit outlet 3613 may comprise only the first flushing conduit outlet 3614.

[0330] The flushing conduit outlet 3613 is configured to be located near, or adjacent to, the exhaust conduit inlet 3510 such that the exhaust conduit inlet 3510 and the flushing conduit outlet 2613 are located at a first end of the nasal interface 3600, the
15 exhaust conduit outlet 2505 is located at a second end of the nasal interface 3600, and the flushing conduit inlet 3612 is located between the first end and the second end of the nasal interface 3600.

[0331] In the illustrated embodiment the flushing conduit inlet 3612 is located in the manifold 3550 at a position adjacent to, or near to, the manifold outlet 3552 such that
20 a rigid or semi-rigid portion of the manifold 3550 may partially surround, or completely surround, both the manifold outlet 3552 and flushing conduit inlet 3612. This relatively small rigid or semi-rigid portion of the manifold 3550 may beneficially provide structural integrity to both the manifold outlet 3552 and flushing conduit inlet 3612 without providing unwanted rigidity to the remainder of the manifold 3550 which
25 may otherwise comprise a soft elastomeric material.

[0332] Alternatively, the flushing conduit inlet 3612 may be located in the manifold 3550 at a position distinct from the manifold outlet 3552. If located at a position distinct from the manifold outlet 3552, the flushing conduit inlet 3612 may be partially surrounded, or completely surrounded, by an additional rigid or semi-rigid portion of
30 the manifold 3550 separate to that which partially surrounds, or completely surrounds, the manifold outlet 3552.

[0333] In further alternative embodiments, the flushing conduit inlet 3612 may be located in the body 3560 or in the one or more prongs 2530. It is envisioned that the flushing conduit inlet 3612 should be in fluid communication with the cavity 3012 of cushion module 3010 but may be located at any suitable location on the nasal interface 3600 which enables this fluid communication. Locating the flushing flow inlet 3612 in the body 3560 or in a portion of the manifold 3550 near a rigid or semi-rigid structure provides structural integrity to the flushing flow inlet 3612 which may stop or minimize unwanted occlusion or deformation in use.

[0334] Nasal interface 3600 comprises a body 3560, a manifold 3550 connected to the body 3560, and one or more prongs 3530 extending from the manifold 3550. These may be separate components that are permanently or removably connected to each other or may be portions of an integral nasal interface 3600.

[0335] Each of the body 3560, manifold 3550 and one or more prongs 3530 define a portion of the exhaust flow passage 3501 through exhaust conduit 3500.

[0336] One or more of the one or more prongs 3530, manifold 3550 and body 3560 define a portion of the flushing flow passage 3611 through flushing conduit 3600. In the illustrated embodiment, the one or more prongs 3530 and manifold 3550 each define a portion of the flushing flow passage 3611.

[0337] Referring to Figure 35 for example, the patient interface 3000, and as a result the nasal interface 3600, are shown in a cross-sectional side view. The body 3560 of nasal interface 3600 is configured to be connected to the cushion module 3010. A first end of the nasal interface 3600 is connected to an internal surface of the cushion module 3010 at a position surrounding outlet 3210. In the illustrated embodiment, the body 3560 is connected to the housing 3200 at a position surrounding outlet 3210 as the outlet 3210 is located on the housing 3200. The body 3560 comprises a base 3566 at the first end and the base 3566 is configured to be connected to the housing 3200 at the position surrounding outlet 3210. The connection may be removable or permanent and may be achieved by any suitable means such as a welded connection, overmoulded connection, mechanical connection, magnetic connection, or an adhesive connection.

[0338] In one configuration, the base 3566 and housing 3200 are mechanically connected. The connection comprises a plurality of mating features that are formed

on the base 3566 and the housing 3200, respectively. The mating features engage with each other in a complementary and interlocking manner. The mating features may include, but are not limited to, grooves, ridges, tapers, hooks, slots, pins, channels, or any combination thereof. The plurality of mating features may engage
5 each other in a removable and repeatable manner, or in a permanent manner such as a one-time engagement.

[0339] In an example of the plurality of mating features, the base 3566 may comprise a male connector and the housing 3200 may comprise a female connector configured to removably receive the male connector of the base 3566. This
10 connection between the base 3566 and housing 3200 creates a seal that is substantially airtight at the intended gas pressures to which the cushion module 2010 is subjected for use. The connection between the male connector of the base 3566 and female connector of the housing 3200 may be a snap-fit connection. Alternatively, the housing 3200 may comprise a male connector while the base 3566
15 comprises a female connector configured to receive the male connector of the housing 3200. This alternative connection between the female connector of the base 3566 and male connector of the housing 3200 may be a snap-fit connection. It is also envisioned that the connection between the respective male and female connectors may be a permanent one-time connection such as a one-time snap-fit
20 instead of a removable connection.

[0340] In another embodiment, the connection between the base 3566 and housing 3200 may be a taper connection. In this embodiment, the housing 3200 comprises a male taper connector having a tapered external surface and the housing 3200 comprises a female taper connector having a tapered internal surface configured to
25 removably receive the tapered external surface of the male taper connector of the base 3566. This taper connection between the base 3566 and housing 3200 forms a seal that is substantially airtight at the intended gas pressures to which the cushion module 2010 is subjected for use. Alternatively, the housing 3200 may comprise a male taper connector while the base 3566 comprises a female taper connector
30 configured to receive the male taper connector of the housing 3200.

[0341] In another embodiment, the connection between the base 3566 and housing 3200 may be a welded connection wherein the base 3566 is ultrasonically welded to the housing 3200 to form a permanent connection.

[0342] In another embodiment, the base 3566 may be omitted. The body 3560 or a
5 portion of the body 3560 may be integrally formed with the housing 3200. The integral formation therefore requiring no additional connection means between the body 3560 and housing 3200. This integral formation may be achieved, for example, by moulding the housing 3200 and body 3560 in a single moulding process or may be formed by moulding the body 3560 onto housing 3200 in a two-shot or overmould
10 moulding process to form an integral structure.

[0343] It is to be understood that in the illustrated embodiment the body 3560, and specifically the base 3566, are connected to the housing 3200 as a result of the outlet 3210 of the cushion module 3010 being located on the housing 3200. However, in alternative embodiments where the outlet 3210 is located on the seal
15 1100, or on a unitary frame-housing cushion module 3010, then the body 3560, and specifically the base 3566, may connect to whichever component, or components, comprise the outlet 3210, at a position surrounding said outlet 3210. In other words, the body 3560 is intended to connect at a position surrounding the outlet 3210 regardless of the location of outlet 2210.

[0344] The body 3560 extends between the housing 3200 and the manifold 3550. In
20 the illustrated embodiment, the body 3560 is in the form of a hollow structure with a varying cross-section having the base 3566 at the first end, manifold connector 3564 at the second end, and a central portion 3562 extending between the base 3566 and the manifold connector 3564. The body 3560 allows for gas flow passage between
25 the first end and the second end and as previously mentioned, defines a portion of the exhaust flow passage 3501 of exhaust conduit 3500. The body 3560 in the illustrated embodiment can be described as a hollow conduit, duct, passage, or pipe.

[0345] In an alternative embodiment, a portion 3565 of the body 3560 may be pliable. Such pliability enables the portion 3565 to be repeatably deformed without
30 structural failure occurring. The portion 3565 allows for the nasal interface 3600 to be adjustable. That is, the orientation and/or position of the nasal interface 3600 with respect to the seal 1100 of the manifold 3550. The portion enables the orientation

and/or position of the one or more prongs 3530 to be adjusted. The pliable portion 3565 may be located within the central portion 3562 of the body 3560. Alternatively, substantially the entire central portion 3562 may be pliable such that it can be repeatedly deformed without structural failure occurring. To achieve the desired

5 pliability the body 3560 may be constructed of, for example but not limited to, a plastics material, an elastomeric material, a metal material, or a combination of one or more such as an elastomeric conduit comprising a metal reinforcing wire or embedded metal wire.

[0346] It will be appreciated by those skilled in the art that in alternative

10 embodiments, the size and/or locations of the manifold 3550 and the one or more prongs 3530 may render the body 3560 redundant. In such embodiments, the manifold 3550 may connect or extend directly from housing 3200. In this situation, any of the above-described features and/or functions of the body 3560 could be incorporated into either of the housing 3200, manifold 3550, or both.

15 [0347] In the illustrated embodiment, the manifold 3550 connects to and/or extends from the body 3560, and the one or more prongs 3530 connect to and/or extend from the manifold 3550. Manifold 3550 comprises a manifold outlet 3552 which is configured to connect to the manifold connector 3564 of body 3560 such that the manifold outlet 3552 and body 3560 are in fluid communication. Manifold 3550

20 additionally comprises a flushing conduit inlet 3612 which is in fluid communication with the cavity 3012 of cushion module 3010.

[0348] The manifold 3550 may be removably or permanently connected to body 3560. The connection may be via any conventional means such as mechanical fasteners, adhesives, welding, two-shot moulding, overmoulding, or a taper

25 connection. For example, the manifold connector 3564 and manifold outlet 3552 may be connected via ultrasonic welding, a permanent or removable snap-fit connection, or via adhesive applied to the mating surfaces of the two components. The manifold 3550 may also be overmoulded onto the body 3560 wherein the body 3560 is formed in a first moulding process and then placed into a mould tool where the manifold

30 3550 is then formed by overmoulding the manifold 3550 onto the body 3560 to create a permanent connection. Alternatively, the body 3560 and manifold 3550 may be formed separately and then joined by an overmoulding process. For example, a

material may be overmoulded over both components to form a permanent connection between the manifold 3550 and body 3560.

[0349] A portion, or an entirety, of the manifold 3550 may be formed integrally with the body 3560. In such an embodiment, it will be appreciated that the body 3560 and
5 the manifold 3550 may be understood as portions of the integral structure that comprises both the body 3560 and manifold 3550. The manifold connector 3564 of the body 3560 and manifold outlet 3552 of the manifold 3550 may therefore be omitted if not required or taken as transitional portions between the body 3560 and manifold 3550 of the integral structure. Features and/or functions otherwise
10 disclosed in relation to the body 3560 and manifold 3550 will be incorporated into this integral structure.

[0350] In the illustrated embodiment the manifold 3550 defines a portion of both the exhaust flow passage 3501 of exhaust conduit 3500 and of the flushing flow passage 3611 of the flushing conduit 3610. Manifold 3550 is configured to receive gas from
15 the one or more prongs 3530 and to deliver the gas through manifold outlet 3552 to the body 3560. The gas is ultimately delivered to the outlet 3210 of the housing 3200 and to externally of the cushion module 3010. This may be via either a bias vent 3215 or an outlet configured for connection with an exhalation conduit. The manifold 3550 is additionally configured to receive gas from the cavity 3012 of cushion
20 module 3010 into the manifold 3550 through the flushing conduit inlet 3612 and deliver it to the one or more prongs 3530.

[0351] The manifold 3550 comprises a manifold dividing wall 3553 which defines a manifold exhaust cavity 3554 and a manifold flushing cavity 3555. The manifold exhaust cavity 3554 defines a portion of the exhaust flow passage 3501. The
25 manifold flushing cavity 3555 defines a portion of the flushing flow passage 3611.

[0352] The manifold 3550 is therefore configured to receive gas from the one or more prongs 3530 and transport the gas through the manifold exhaust cavity 3554 and out of the manifold outlet 3552 into the body 3560. The manifold 3550 is also configured to receive gas from the cavity 3012 of cushion module 3010 and transport
30 the gas through the flushing conduit inlet 3612 into the manifold flushing cavity 3555 and deliver it to the one or more prongs 3530.

[0353] In the illustrated embodiment, the manifold exhaust cavity 3554 and the manifold flushing cavity 3555 are formed by the manifold dividing wall 3553 bifurcating the internal cavity of the manifold 3550. However, it will be appreciated that the formation of these two cavities could be achieved without the manifold
5 dividing wall 3553. For example, in an alternative embodiment, the manifold 3550 comprises a distinct manifold exhaust cavity 3554 and a distinct manifold flushing cavity 3555 which do not share any walls and/or are not defined by the boundaries of each other. Said another way, the manifold 3550 may comprise a body comprising the manifold exhaust cavity 3554 and the manifold flushing cavity 3555 with each of
10 the cavities formed separately of one another. In a further alternative embodiment, the manifold 3550 may comprise a first body comprising the manifold exhaust cavity 3554 and a second body comprising the manifold flushing cavity 3555.

[0354] In the illustrated embodiment, the manifold 3550 further comprises a face contacting portion 3556 which is configured to contact one or more of the upper lip,
15 philtrum, nasal bridge, or nares of a patient. Such contact aids in supporting or locating the one or more prongs 3530 in the desired position. The face contacting portion 3556 comprises a relatively soft material. This may help avoid or minimize discomfort to the patient. For example, the face contacting portion 3556 may comprise an elastomeric material such as a silicone or rubber.

20 [0355] In the illustrated embodiment the manifold 3550 has a dual material construction comprising a rigid plastic portion which comprises at least a portion of each of the manifold outlet 3552 and the flushing conduit inlet 3612, and an elastomeric portion which comprises the face contacting portion 3556.

[0356] Alternatively, the entirety of the manifold 3550 may comprise an elastomeric
25 material. Further alternatively, a majority of the manifold 3550 may comprise an elastomeric material with only minimal rigid portions providing support where necessary. In such an embodiment, a majority of the manifold 3550 may comprise a resiliently deformable elastomeric material with only the manifold outlet 3552 being formed of a rigid plastic material or only the manifold outlet 3552 and the flushing
30 conduit inlet 3612 being formed of a rigid plastic material.

[0357] In an alternative embodiment, the face contacting portion 3556 may not be configured to contact the face of the patient in use but may still be formed of an

elastomeric material and configured instead to avoid discomfort should any unintentional contact between the manifold 3550 and the face of the patient occur.

[0358] In the illustrated embodiment at least a portion of the face contacting portion 3556 of the manifold 3550 is concave when viewed in the proximal-distal direction to conform to the shape of a patient's upper lip, philtrum, and/or nares.

[0359] The one or more prongs 3530 extend from the manifold 3550 to the exhaust conduit inlet 3510 and the flushing conduit outlet 3613. In the illustrated embodiment, the nasal interface 3600 comprises a first prong 3531 and a second prong 3540. The first prong 3531 extends from the manifold 3550 to a first free end 3532. The first free end 3532 comprising a first exhaust conduit inlet 3515 and a first flushing conduit outlet 3614. The second prong 3540 extends from the manifold 3550 to a second free end 3542. The second free end 3542 comprising a second exhaust conduit inlet 3520 and a second flushing conduit outlet 3615.

[0360] The exhaust conduit inlet 3510 comprises both the first exhaust conduit inlet 3515 and the second exhaust conduit inlet 3520. The flushing conduit outlet 3613 comprises both the first flushing conduit outlet 3614 and the second flushing conduit outlet 3615.

[0361] In the illustrated embodiment, the first prong 3531 is bifurcated by a first prong dividing wall 3534 to form a first prong exhaust cavity 3536 and a first prong flushing cavity 3538. The second prong 3540 is bifurcated by a second prong dividing wall 3536 to form a second prong exhaust cavity 3546 and a second prong flushing cavity 3548.

[0362] The formation of separate exhaust cavities and flushing cavities within each of the one or more prongs 3530 allow portions of each of the exhaust flow passage 3501 and flushing flow passage 3611 that extend through the first prong 3531 and second prong 3540 respectively to be separated from each other.

[0363] In the illustrated embodiment, each of the first prong dividing wall 3534 and the second prong dividing wall 3536 are configured to connect to, abut with, join with, or be continuous with, the manifold dividing wall 3553. This allows for continuous separation of the portions of the exhaust flow passage 3501 and flushing flow

passage 3611 that are defined by the manifold 3550 and the one or more prongs 3530.

[0364] The first prong 3531 is therefore configured to receive gas through the first exhaust conduit inlet 3515 and transport it through the first prong exhaust cavity 3536 into the manifold exhaust cavity 3554. The first prong 3531 is also configured to receive gas from the manifold flushing cavity 3555 and transport it through the first prong flushing cavity 3538 and out of the first flushing conduit outlet 3614.

[0365] Likewise, the second prong 3540 is configured to receive gas through the second exhaust conduit inlet 3520 and transport it through the second prong exhaust cavity 3546 into the manifold exhaust cavity 3554. The second prong 3540 is also configured to receive gas from the manifold flushing cavity 3555 and transport it through the second prong flushing cavity 3548 and out of the second flushing conduit outlet 3615.

[0366] In an alternative embodiment, the first prong dividing wall 3534 and second prong dividing wall 3546 may be omitted. In this embodiment, the portions of the respective exhaust flow passage 3510 and flushing flow passage 3611 that extend through the first prong 3531 and second prong 3540 may be separated by any suitable structure that stops the mixing of gas flow occurring between the two passages.

[0367] In the illustrated embodiment, the first prong dividing wall 3534 and second prong dividing wall 3546 form the first prong exhaust cavity 3536, first prong flushing cavity 3538, second prong exhaust cavity 3546, and second prong flushing cavity 3548 respectively. However, it will be appreciated that the formation of these cavities could be achieved without the dividing walls of each of the prongs. For example, in an alternative embodiment, the first prong 3531 may comprise a distinct first prong exhaust cavity 3536 and a distinct first prong flushing cavity 3538 and the second prong 3540 may comprise a distinct second prong exhaust cavity 3546 and a distinct second prong flushing cavity 3548, without any of the cavities being defined by the boundaries of each other. Said another way, the first prong 3531 may comprise a body comprising the first prong exhaust cavity 3536 and the first prong flushing cavity 3538, with each of the cavities formed separately of one another, and the second prong 3540 may comprise a body comprising the second prong exhaust

cavity 3546 and the second prong flushing cavity 3548, with each of the cavities formed separately of one another.

[0368] In a further alternative embodiment, the first prong 3531 may comprise a first body comprising the first prong exhaust cavity 3536 and a second body comprising
5 the first prong flushing cavity 3538, and the second prong 3540 may comprise a third body comprising the second prong exhaust cavity 3546, and a fourth body comprising the second prong flushing cavity 3548.

[0369] In the illustrated embodiment, the first prong 3531 and the second prong 3540 are sealing nasal prongs. Sealing nasal prongs are configured to form a seal
10 with a respective nare of the patient's nares, in use. Each of the first prong 3531 and the second prong 3540 comprises an outer surface which is configured to form a seal with an inner surface or rim of a respective nare of the patient's nares.
Alternatively, or additionally, the outer surfaces of each of the first prong 3530 and the second prong 3540 may form a seal with an outer surface of a respective nare of
15 the patient's nares.

[0370] In an alternative embodiment, the first prong 3531 and second prong 3540 may be non-sealing nasal prongs. Non-sealing nasal prongs are not configured to form a seal with a respective nare or nostril of the patient's nares or nostrils, in use. Said another way, the cross-sectional area of the first prong 3531 and second prong
20 3540 at their respective free ends 3532, 3542 are designed to be less than the cross-sectional area of the entrance of a respective nare or nostril of the intended patient's nares or nostrils.

[0371] In an alternative embodiment, nasal interface 3600 may comprise only a single prong 3530 and therefore only a single exhaust conduit inlet 3515 and a single
25 flushing conduit outlet 3615. In this configuration the first prong 3531 extends from manifold 3550 to a first free end 3532, the first free end 3532 comprising the first exhaust conduit inlet 3515 and the first flushing conduit outlet 3615. The first prong 3531 being bifurcated by a first prong dividing wall 3536 and comprising a first prong exhaust cavity 3536 and first prong flushing cavity 3538. The first prong exhaust
30 cavity 3536 being in fluid communication with the first exhaust conduit inlet 3515 and the first prong flushing cavity 3538 being in fluid communication with the first flushing conduit outlet 3615. The first prong 3531 comprises an outer surface which is

configured to form a seal with an inner surface of a respective nare of the patient's nares and/or with an outer surface of a respective nare of the patient's nares. It will be appreciated that the above description is not intended to be limiting and any features and functions described in the specification relating to the first prong 3530
5 can be incorporated into the configuration of the nasal interface 3600 comprising only a single prong.

[0372] It is to be appreciated that while the illustrated embodiment comprises a nasal interface 3600 comprising an exhaust conduit 3500 and a flushing conduit 3610 as a combined assembly, in an alternative embodiment, the patient interface
10 3000 could comprise a separate exhaust conduit 3500 and flushing conduit 3610. In this embodiment, each of the exhaust conduit 3500 and flushing conduit 3610 could comprise separate prongs such that two prongs are positioned within, near, or adjacent to each nare of the one or both of the patient's nares. In such a configuration all features and functions of the first prong 3531 and/or second prong
15 3540 relating to the exhaust conduit 3500 could be incorporated into a first and/or second exhaust conduit prong. All features and functions of the first prong 3531 and/or second prong 3540 relating to the flushing conduit 3610 could be incorporated into a first and/or second flushing conduit prong.

[0373] As mentioned previously, nasal interface 3600 may be permanently
20 connected to housing 3200, or may be removably connected to housing 3200, for example by removable connection between the body 3560 and housing 3200 as described above. Alternatively, portions of the nasal interface 3600 may be integrally formed with housing 3200 and then the remainder of the nasal interface 3600 removably or permanently connected to the integrally formed portion of the nasal
25 interface 3600.

[0374] In embodiments where the nasal interface 3600 is integral with the housing 3200, portions of the nasal interface 3600 may be overmoulded to, co-moulded with, or integrally formed with, the housing 3200. Specifically, body 3560 may be integrally formed with housing 3200 and the remainder of the nasal interface 3600 may be
30 permanently or removably connected to the body 3560.

[0375] Alternatively, a majority of the nasal interface 3600 may be integrally formed with housing 3200 while the first prong 3531 and/or second prong 3540 for example

may be constructed of a different material to the housing 3200 and connected to the remainder of the nasal interface 3600 in a secondary process. For example, body 3560 and manifold 3550 may be integrally formed with the housing 3200 via moulding an integral component and the first prong 3531 and/or second prong 3540
5 may be formed of an elastomeric material in a separate moulding process and then connected to the remainder of the nasal interface 3600.

[0376] Alternatively, the body 3560 and manifold 3550 of the nasal interface 3600 may be integrally formed with the housing 3200. Such integral forming may involve injection moulding with a plastics material. The first prong 3531 and/or second prong
10 3540 may then be overmoulded to the integrally formed housing 3200, body 3560, and manifold 3550 component with an elastomeric material. In one example the plastics material is polycarbonate, and the elastomeric material is silicone.

[0377] The nasal interface 3600 may be sold separately from the remainder of the patient interface 3000. This enables the nasal interface 3600 to be retrofitted to
15 existing patient interfaces. In such circumstances, the nasal interface 3600 is located within the cavity of the existing patient interface and the exhaust conduit outlet 3505 is in fluid communication with the outlet or bias vent of the existing patient interface. In this way existing patient interfaces may be fitted with nasal interface 3600 to improve the performance of these existing patient interfaces.

[0378] The exhaust conduit inlet 3510 has a cross-sectional area comprising the first exhaust conduit inlet 3515 and where applicable the second exhaust conduit inlet 3520. This cross-sectional area of the exhaust conduit inlet 3510 is configured to be less than the cross-sectional area of the inlet 3220 of housing 3200. In the illustrated embodiment, all gas entering the cushion module 3010 enters through the inlet 3220,
20 and excluding unintentional leaks, substantially all gas exiting the cushion module 3010 exits through the outlet 3210. The exhaust conduit 3500 is in sealed fluid communication with the outlet 3210 of the housing 3200. The reduced cross-sectional area of the exhaust conduit inlet 3510 compared with the inlet 3220 of housing 3200 creates a flow restriction which accelerates gas flow into exhaust
25 conduit 3500 when pressurised gas flows into the cushion module 3010 via the inlet 3220 and the into the exhaust conduit 3500 in order to exit the cushion module 3010. The reduced cross-section in the flow path creates a pressure drop which
30

accelerates gas flow entering exhaust conduit 3500. The significance of this acceleration of gas is explained in the following paragraphs.

[0379] In the illustrated embodiment, the flow restriction mentioned in the above paragraph is created by the exhaust conduit inlet 3510 having a cross-sectional area
5 that is less than the cross-sectional area of the inlet 3220 of the housing 3200. However, this flow restriction may be placed elsewhere in the exhaust conduit 3500, or more specifically, elsewhere in the one or more prongs 3530, manifold 3550 or body 3560. For example, a flow restrictor may be located within the exhaust flow passage 3501 near or adjacent to the exhaust conduit inlet 3510 to create
10 acceleration of gas as it flows into the exhaust conduit 3500.

[0380] In the illustrated embodiment of patient interface 3000 the ratio of the cross-sectional area of the first exhaust conduit inlet 3515 to the second exhaust conduit inlet 3520 is 1:1, meaning the cross-sectional area of both exhaust conduit inlets is equal. However, in alternative embodiments, the cross-sectional area of the first
15 exhaust conduit inlet 3515 may be unequal to the cross-sectional area of the second exhaust conduit inlet 3520. The ratio of the cross-sectional area of the first exhaust conduit inlet 3515 to the cross-sectional area of the second exhaust conduit inlet 3520 can range from 1:1.1 to 1:4. In one configuration the ratio of the cross-sectional area of the first exhaust conduit inlet 3515 to the cross-sectional area of the second
20 exhaust conduit inlet 3520 is 1:3.

[0381] In addition to, or instead of, the differing exhaust conduit inlet cross-sectional areas, the first prong 3531 and the second prong 3540 may differ in shape and/or size in at least one aspect such as the prong diameter, length, or shape. Such an embodiment where the first prong 3531 and second prong 3540 have differing
25 shapes and/or sizes may be described as having asymmetrical first and second prongs 3531, 3540.

[0382] The flushing conduit outlet 3613 has a cross-sectional area comprising the first flushing conduit outlet 3614 and where applicable the second flushing conduit outlet 3615. In the illustrated embodiment, the total cross-sectional area of the
30 flushing conduit outlet 3613 is configured to be less than the cross-sectional area of the flushing conduit inlet 3612.

[0383] The reduced cross-sectional area of the flushing conduit outlet 3613, compared with the cross-sectional area of the flushing conduit inlet 3612, creates a flow restriction at the flushing conduit outlet 3613. This flow restriction accelerates gas flow exiting the flushing conduit outlet 3613 when pressurised gas flows through the flushing flow passage 3611. In use, gas flow therefore exits the flushing conduit outlet 3613 at a higher velocity than gas flow enters the flushing conduit inlet 3612 from within the cavity 3012 of cushion module 3010. The significance of this acceleration of gas is explained in the following paragraphs.

[0384] In alternative embodiments it will be appreciated that the necessary flow restriction may be created at or near the flushing conduit outlet 3613 by means other than the cross-sectional area of the flushing conduit outlet 3613. For example, a flow restrictor may be located within the flushing flow passage 3611 near to, or adjacent to, the flushing conduit outlet 3613 to accelerate gas flow through the flushing conduit 3610.

[0385] Additionally, or alternatively, the flushing flow passage 3611 of the flushing conduit 3610 may taper or reduce in cross-sectional area from the flushing conduit inlet 3612 towards the flushing conduit outlet 3613. This tapering of the flushing flow passage 3611 in combination with, or alternative to, the reduced cross-sectional area of the flushing conduit outlet 3613 compared with the flushing conduit inlet 3612, accelerates gas flow through the flushing conduit 3610.

[0386] In the illustrated embodiment of patient interface 3000 the ratio of the cross-sectional area of the first flushing conduit outlet 3614 to the second flushing conduit outlet 3615 is 1:1, meaning the cross-sectional area of both flushing conduit outlets is equal. However, in alternative embodiments, the cross-sectional area of the first flushing conduit outlet 3614 may be unequal to the cross-sectional area of the second flushing conduit outlet 3615. The ratio of the cross-sectional area of the first flushing conduit outlet 3614 to the cross-sectional area of the second flushing conduit outlet 3615 may range from 1:1.1 to 1:4. In one configuration the ratio of the cross-sectional area of the first flushing conduit outlet 3614 to the cross-sectional area of the second flushing conduit outlet 3615 is 1:3.

[0387] In the illustrated embodiment, the nasal interface 3600 is connected permanently or removably to housing 3200. That is, the nasal interface 3600 is not in

direct contact with the seal 1100. Said another way, nasal interface 3600 is a separate structure from seal 1100. Furthermore, nasal interface 3600 is surrounded by the cavity 3012 of cushion module 3010. It is believed this may be beneficial to improving patient comfort by reducing interference or interaction with the supply seal 1100, which is configured to contact the patient's face. However, it is to be appreciated that in alternative embodiments, the nasal interface 3600 may contact or be connected to the seal 1100 in one or more locations without significantly impacting patient comfort. For example, the nasal interface 3600 may connect to a portion of the seal 1100 away from the patient contacting surface 1120.

10 [0388] Referring to Figures 41 and 42 for illustrative purposes, the patient interface 3000 is shown in cross-section along line E-E' fitted to an anatomical model of a patient (also shown in cross-section). In Figure 41 the patient interface 3000 is illustrated fitted to a patient with their mouth open. In Figure 42 the patient interface 3000 is illustrated fitted to a patient with their mouth closed. Arrows indicate the
15 direction of gas flow into the cushion module 3010 via inlet 3220, and out of the cushion module 3010 via outlet 3210, while fitted to a patient without respiration occurring. The relative size of the arrows should not be interpreted as an indication of gas flow rate or velocity. It will be appreciated that during respiration there will be additional gas flow paths formed beyond which are described. However, for the
20 purpose of explanation it is believed the general operation of patient interface 3000 can be adequately described while ignoring respiration because the effect of the patient interface 3000 is believed to be most prominent at the end of the exhalation cycle, which can be realistically likened to a situation in which no respiration is occurring.

25 [0389] When the patient interface 3000 is fitted to a patient, the nasal interface 3600 is positioned such that the exhaust conduit inlet 3510 and flushing conduit outlet 3613 are positioned within one or a respective one of a patient's nares, or positioned at a position that is below the one or the respective one of the patient's nares and adjacent a lip superior of the patient, or positioned at a position that is immediately
30 adjacent to the one or the respective one of the patient's nares. Said another way, the exhaust conduit inlet 3510 and flushing conduit outlet 3613 are located within, adjacent to, or proximal to, the one or the respective one of a patient's nares.

[0390] More specifically, in embodiments comprising a first exhaust conduit inlet 3515, a second exhaust conduit inlet 3520, a first flushing conduit outlet 3614, and a second flushing conduit outlet 3615, the first exhaust conduit inlet 3515 and the first flushing conduit outlet 3614 are configured to be positioned within a first one of a patient's nares, or to be positioned at a position that is below the first one of a patient's nares and adjacent a lip superior of the patient, or to be positioned at a position that is immediately adjacent the first one of the patient's nares. While the second exhaust conduit inlet 3520 and the second flushing conduit outlet 3615 are configured to be positioned within a second one of a patient's nares, or to be positioned at a position that is below the second one of a patient's nares and adjacent a lip superior of the patient, or to be positioned at a position that is immediately adjacent the second one of the patient's nares.

[0391] In embodiments comprising a single exhaust conduit inlet 3515 and a single flushing conduit outlet 3614, the first exhaust conduit inlet 3515 and first flushing conduit outlet 3614 are configured to be positioned within a first one of a patient's nares, or to be positioned at a position that is below the first one of a patient's nares and adjacent a lip superior of the patient, or to be positioned at a position that is immediately adjacent the first one of the patient's nares..

[0392] Referring to Figure 41, where the patient interface 3000 is fitted to a patient with the patient's mouth open, without respiration occurring, and where pressurised gas is being delivered to the patient interface 3000 via conduit connector 1300. The flow of pressurised gas enters cushion module 3010 via inlet 3220. Excess pressurised gas from within cushion module 3010 and/or from within the patient's airways then flows into exhaust conduit 3500 via exhaust conduit inlet 3510, the gas then travels along exhaust flow passage 3501 and through outlet 3210 of cushion module 3010 to exit the cushion module 3010. Due to the intended positioning of the exhaust conduit inlet 3510 relative to a patient's nare(s) (including the positioning of either or both the first exhaust conduit inlet 3515 and second exhaust conduit inlet 3520) described above, a first significant flow path and a second significant flow path are formed for gas to enter the exhaust conduit 3500 via the exhaust conduit inlet 3510.

[0393] The first significant flow path extends from within the cushion module 3010 into the patient's oral cavity via their mouth, through the patient's throat, into the patient's nasal cavity and: (1) into the exhaust conduit inlet 3510 when the exhaust conduit inlet 3510 is positioned within a nare or nares of the patient, or (2) out of the one or more nares of the patient and into the exhaust conduit inlet 3510 when the exhaust conduit inlet 3510 is positioned at a position adjacent the one or more nares of the patient, or positioned at a position that is below the one or more nares of the patient and adjacent a lip superior of the patient, or positioned at a position that is immediately adjacent the one or more nares of the patient. In all instances this flow of gas entering the patient's oral cavity and exiting through the nasal cavity is believed to cause anatomical dead space flushing of at least some of the patient's oral cavity, throat, and nasal cavity.

[0394] The second significant flow path extends from within the cushion module 3010 through the flushing conduit inlet 3612, along the flushing flow passage 3611, and out of the flushing conduit outlet 3613 where the gas flow is accelerated and flows: (1) into the nasal cavity of the patient where the gas flow decelerates and/or the direction of the gas flow changes so that the gas flow can enter the exhaust conduit inlet 3510 when the exhaust conduit inlet 3510 is positioned within the one or more nares of the patient, or (2) through the one or more nares of the patient and into the nasal cavity of the patient where the gas flow decelerates and/or the direction of the gas flow changes so that the gas flow exits the one or more nares of the patient and can enter the exhaust conduit inlet 3510 when the exhaust conduit inlet 3510 is positioned at a position adjacent the one or more nares of the patient, or positioned at a position that is below the one or more nares of the patient and adjacent a lip superior of the patient, or positioned at a position that is immediately adjacent the one or more nares of the patient.

[0395] In the first instance it is believed that the acceleration of gas flow out of the flushing conduit 3610 and into the nasal cavity of the patient before entering the exhaust conduit inlet 3510 will cause anatomical deadspace flushing of at least some of the patient's nasal cavity. In the second instance, it is believed that the acceleration of the gas flow out of the flushing conduit 3610 will cause at least some gas flow to enter the patient's nasal cavity via the one or more nares before decelerating and/or changing direction and exiting the nasal cavity via the one or

more nares and entering the exhaust conduit inlet 3510. It is believed that this portion of accelerated gas flow entering the nasal cavity will cause some anatomical deadspace flushing of the patient's nasal cavity. Said another way, it is believed that in both instances, the second significant flow path formed at least partially through the flushing conduit 3610, and the resultant acceleration of gas entering the patient's nasal cavity, will cause anatomical deadspace flushing of at least some of the patient's nasal cavity and/or throat.

[0396] Referring to Figure 42, where the patient interface 3000 is fitted to a patient with the patient's mouth closed, without respiration occurring, and where pressurised gas is being delivered to the patient interface 3000 via conduit connector 1300. The flow of pressurised gasses enters cushion module 3010 via inlet 3220. Excess pressurised gas from within cushion module 3010 and/or from within the patient's airways then flows into exhaust conduit 3500 via exhaust conduit inlet 3510, the gas then travels along exhaust flow passage 3501 and through outlet 3210 of cushion module 3010 to exit the cushion module 3010. However, due to the patient's mouth being closed only the second significant flow path is formed. The second flow path is discussed in detail in the paragraph immediately preceding this.

[0397] In the illustrated embodiment of patient interface 3000, because gas flow through the first significant flow path and the second significant flow path are both thought to cause anatomical deadspace flushing to some extent, it is believed that the patient interface 3000 provides a significant benefit beyond traditional non-invasive ventilation masks. The ability to provide pressure support and simultaneous deadspace flushing with the patients mouth open or closed is advantageous in NIV therapy. Additionally, in embodiments where the nasal interface 3600 is removable it is envisioned that the patient interface 3000 with the nasal interface 3600 removed could be used to provide standard NIV therapy should such an outcome be desired. For example, it is envisioned that a patient may only require anatomical dead space flushing during discrete periods of time of the day. This enables the patient interface 3000 to be utilized for alternating periods of time with the nasal interface 3600 in place, and with the nasal interface 3600 removed.

[0398] In the preceding paragraphs, dead space flushing of the anatomical dead space of a patient has been discussed as an intended benefit of patient interface

3000. The anatomical dead space of a patient consists of the total volume of the respiratory tract segments of a patient that are responsible for conducting air to the alveoli and respiratory bronchioles but do not take part in the process of gas exchange itself. The anatomical dead space is therefore the total volume of the conducting airways from the nose or mouth to the terminal bronchioles of a patient including the oral cavity, nasal cavity, and pharynx (also referred to as the throat).

[0399] During respiration by a patient, lower CO₂ content air is inhaled into the lungs and higher CO₂ content air is exhaled from the lungs. At the end of an exhalation cycle a portion of the exhaled higher CO₂ content air remains in the anatomical deadspace of the patient. This higher CO₂ content air is then inhaled, or rebreathed, during the next respiration cycle. This rebreathing of high CO₂ content air leads to a reduced efficiency in the gas exchange occurring within a patient's lungs.

[0400] The process of dead space flushing replaces at least a portion of the exhaled higher CO₂ content air present in the anatomical dead space of a patient with fresh lower CO₂ content air so that during the following inhalation cycle a reduced amount of exhaled higher CO₂ content air is inhaled, or rebreathed. This reduction in rebreathing of higher CO₂ content air improves the efficiency of gas exchange occurring within a patient's lungs.

[0401] As mentioned in preceding paragraphs, the exhaust conduit inlet 3510 has a cross-sectional area that is configured to be less than the cross-sectional area of the inlet 3220 of housing 3200. The smaller cross-sectional area of the exhaust conduit inlet 3510 compared with the inlet 3220 of housing 3200 forms a flow restriction which creates a pressure drop and therefore an acceleration of gas flow into the exhaust conduit 3500, when pressurised gas is supplied to the cushion module 3010 of patient interface 3000 in use. It is believed that this acceleration of gas flow into exhaust conduit 3500 may also cause entrainment of surrounding gas into the exhaust conduit 3500.

[0402] The entrainment of gasses at a position surrounding exhaust conduit inlet 3510 into exhaust conduit 3500 may be beneficial to the anatomical deadspace flushing of a patient when the exhaust conduit inlet 3510 is positioned within one or a respective one of the patient's nares or is positioned at a position immediately adjacent the patient's nares or is positioned at a position that is below the patient's

nares and adjacent a lip superior of the patient. As gas flow is accelerated into the exhaust conduit inlet 3510 higher CO₂ content gas present in the patient's anatomical deadspace may be entrained into exhaust conduit inlet 3510 due to a combination of the acceleration of gas flow and/or the localized pressure drop. It is believed that this entrainment of higher CO₂ content gas may provide anatomical deadspace flushing instead of or in addition to the anatomical deadspace flushing described above in relation the significant flow paths formed during use.

[0403] Having regard to Figures 43 to 54, a patient interface 4000 of a fourth embodiment is shown. The patient interface 4000 is a variation of the patient interface 1000 of the general form and incorporates all components and functions with the patient interface 1000 unless stated otherwise. More specifically the patient interface 4000 incorporates at least the frame 1400, headgear 1900, and conduit connector 1300 of the patient interface 1000. The housing 4200 and seal 4100, and as a result the cushion module 4010, of patient interface 4000 differs from the housing 1200, seal 1100, and cushion module 1010 of patient interface 1000 due to inclusion of a dividing wall 4700. The differences in housing 4200, seal 4100, and cushion module 4010, will be described below, otherwise it should be appreciated that housing 4200, seal 4100, and cushion module 4010, includes all features and functions of housing 1200, seal 1100, and cushion module 1010, respectively.

Features of the housing 4200, seal 4100, and cushion module 4010 which are the same as the features of the housing 1200, seal 1100, and cushion module 1010 are denoted with the same reference numeral, but the leading number is "4" instead of "1".

[0404] In the illustrated embodiment, the patient interface 4000 is in the form of an over the nose full-face mask where the cushion module 4010 comprises a seal 4100 and a housing 4200. Seal 4100 is connected to housing 4200 and collectively the seal 4100 and housing 4200 form a cushion module 4010 having an outer wall 4011 which defines an interior volume 4012. The interior volume 4012 of cushion module 4010 is configured to be pressurised via an inlet 4220 through which respiratory gas can be communicated from the conduit connector 1300 into the interior volume 4012.

[0405] Patient interface 4000 further comprises a dividing wall 4700 that separates the interior volume 4012 of cushion module 4010 into a first chamber 4014 and a

second chamber 4016. The dividing wall 4700 joins to both housing 4200 and seal 4100 to separate the first chamber 4014 from the second chamber 4016.

[0406] Seal 4100 is formed of a soft, resilient material, such as a silicone or other suitable elastomer, and includes a seal opening 4110. When fitted to a patient, the seal opening 4110 is configured to circumscribe the patient's mouth and nose. A patient contacting surface 4120 of the seal 4100 forms a seal about the mouth and nose of the patient. The seal formed by the patient contacting surface 4120 is sufficient to contain, at least substantially, pressurized gas within the cavity 4012. Some leakage of pressurized gas may occur, but such leakage is relatively small so that the supply of pressurized gas to the patient is maintained at levels sufficient to deliver NIV therapy. Accordingly, respiratory gas at elevated pressure can be delivered from the cushion module 4010 to the patient's mouth and/or nares via the seal opening 4110.

[0407] As mentioned, the dividing wall 4700 is a physical barrier that extends across and separates the interior volume 4012 into a separate first chamber 4014 and second chamber 4016. To enable this separation, the dividing wall 4700 joins with both housing 4200 and seal 4100 along a portion of the perimeter of the dividing wall 4700. In the illustrated embodiment, another portion of the perimeter of the dividing wall 4700 bifurcates the seal opening 4110 such that an oral opening 4114 and a nasal opening 4116 is formed.

[0408] The oral opening 4114 is configured in use to circumscribe the patient's mouth. A portion of the patient contacting surface 4120 of the seal 4100 and a portion of the perimeter of the dividing wall 4700 together form a seal about the mouth of the patient.

[0409] The nasal opening 4116 is configured in use to circumscribe the patient's nose. A portion of the patient contacting surface 4120 of the seal 4100 and a portion of the perimeter of the dividing wall 4700 together form a seal about the nose of the patient.

[0410] Accordingly, respiratory gas at elevated pressures can be delivered from the cushion module 4010 to the patient's mouth via the oral opening 4114. Furthermore, respiratory gas at elevated pressures can be delivered from the cushion module 4010 to the patient's nose via the nasal opening 4116.

[0411] The housing 4200 comprises an inlet 4220 through which pressurized respiratory gas can be communicated from the conduit connector 1300 to the interior volume 4012 of the cushion module 4010. It will be appreciated that in alternative embodiments the conduit connector 1300 may be omitted. Instead, pressurized
5 respiratory gas can be communicated from a flow source directly to the inlet 4220 of the housing 4200. It is also contemplated that the inlet 4220 may instead be located on the seal 4100. In this embodiment, pressurised respiratory gas may be communicated to the interior volume 4012 of the cushion module 4010 through an inlet 4220 in the seal 4100.

10 [0412] The housing 4200 comprises an outlet 4210 through which exhaled and excess respiratory gasses can be exhausted from the cushion module 4010 and/or the patient's airways. In the illustrated embodiment, the outlet 4210 is a bias vent 4215 comprising a plurality of apertures extending through the housing 4200.

[0413] In alternative embodiments, the outlet 4210 and bias vent 4215 may be
15 distinct structures located at positions spaced apart from each other. In further embodiments, the patient interface may also include a supplementary bias vent 1416.

[0414] In a further alternative embodiment, the outlet 4210 of cushion module 4010 may be in the form of an opening configured to connect to, or be in fluid
20 communication with, an exhalation conduit of a respiratory circuit. In this configuration exhaled and excess respiratory gasses can be exhausted from the cushion module 4010 and/or from the patient's airways and transported from the patient interface 4000 where they may either be vented to atmosphere or received by the ventilator, flow generator, or other gas source.

25 [0415] In the illustrated embodiment, the perimeter of the dividing wall 4700 joins with the housing 4200 at a position between the inlet 4220 and outlet 4210. In this embodiment, the inlet 4220 is located in the first chamber 4014, and the outlet 4210 is located in the second chamber 4016.

[0416] As a result of the perimeter of the dividing wall 4700 joining with the housing
30 4200 and the seal 4100, and bifurcating the seal opening 4410, at the positions described above, the inlet 4220 and the oral opening 4114 are located in the first

chamber 4014, and the outlet 4210 and the nasal opening 4116 are located in the second chamber 4016.

[0417] In the illustrated embodiment the housing 4200 and the seal 4100 are described as separate components that are permanently connected to form the cushion module 4010. However, it will be appreciated that the housing 4200 and the seal 4100 could instead be a single component which incorporates the features and functions of housing 4200 and seal 4100. It is to be appreciated that disclosure relating to the cushion module 4010 comprising a distinct housing 4200 and seal 4100 is equally applicable to a configuration comprising a combination of the housing 4200 and the seal 4100, or a configuration comprising a singular component incorporating the features and functions of the housing 4200 and the seal 4100.

[0418] The dividing wall 4700 further comprises one or more flow directors 4730 located on the dividing wall 4700. In the illustrated embodiment, the one or more flow directors 4730 extend from the dividing wall 4700 into the second chamber 4016. A flow path extends through each of the one or more flow directors 4730 and the dividing wall 4700. This flow path allows gas to flow from the first chamber 4014 through the one or more flow directors 4730, and into the second chamber 4016. In the illustrated embodiment, the flow path extending through the one or more flow directors 4730 and dividing wall 4700 is the only flow path through the dividing wall 4700.

[0419] In the illustrated embodiment, the one or more flow directors 4730 comprises a first flow director 4732 and a second flow director 4736. The first flow director 4732 comprising a first flow director inlet 4733 through dividing wall 4700, and extending from the dividing wall 4700 to a free end of first flow director 4734 located within the second chamber 4016. The free end of first flow director 4734 comprising a first flow director outlet 4735. The second flow director 4736 comprising a second flow director inlet 4737 through the dividing wall 4700, and extending from the dividing wall 4700 to a free end of second flow director 4738 located within the second chamber 4016. The free end of second flow director 4738 comprising a second flow director outlet 4739.

[0420] In alternative embodiment, the one or more flow directors 4730 may only comprise first flow directors 4732 comprising a first flow director inlet 4733 through

dividing wall 4700, and extending from the dividing wall 4700 to a free end of first flow director 4734 located within the second chamber 4016. The free end of first flow director 4734 comprising a first flow director outlet 4735.

[0421] In the illustrated embodiment, the dividing wall 4700 comprises a spacing
5 element 4731 extending between first flow director 4732 and second flow director 4736 and configured to maintain a spacing between the flow directors in use. In the illustrated embodiment the spacing element 4731 is in the form of a rib extending between, and connected to, the first flow director 4732 and the second flow director 4736. It will be appreciated that the dividing wall 4700 may provide sufficient rigidity
10 around the location of the first flow director 4732 and second flow director 4736 such that the spacing element 4731 could be omitted.

[0422] In alternative embodiments, the first flow director 4732 and/or second flow director 4736 may not extend from the dividing wall 4700 and may instead be formed within the dividing wall 4700. It is envisioned that in such a configuration the first flow
15 director inlet 4733 and/or second flow director inlet 4337 could be located on a surface of the dividing wall 4700 within the first chamber 4014, and the first flow director outlet 4735 and/or second flow director outlet 4739 could be located on a surface of the dividing wall 4700 within the second chamber 4016. In this embodiment, the first flow director 4732 and/or second flow director 4736 each
20 comprising a flow path through the dividing wall 4700.

[0423] In the illustrated embodiment, dividing wall 4700 comprises a deformation region 4720 located at a position on the dividing wall 4700 between the one or more flow directors 4730 and the portion of the perimeter of the dividing wall 4700 that joins housing 4200. The deformation region 4700 is a localized region of reduced
25 thickness of the dividing wall 4700 that is configured to preferentially deform in response to forces applied to the dividing wall 4700 while the patient interface 4000 is in use. This preferential deformation is configured to absorb some, or all, of the unintended forces applied to the dividing wall 4700 in use to minimize deformation or collapse of the one or more flow directors 4730.

30 [0424] The deformation region 4720 comprises a first thickened region 4724 and a second thickened region 4726 joined by a thin region 4721. The thin region 4721 having a thickness that is less than both the first thickened region 4724 and the

second thickened region 4726. The deformation region 4720 is configured to deform by the first thickened region 4724 moving towards the second thickened region 4726 and preferentially deforming the thin region 4721 in the process.

[0425] In the illustrated embodiment, the thin region 4721 comprises a first thin wall 4722 and a second thin wall 4723. The first thin wall 4722 extends from the first thickened region 4724, the second thin wall 4723 extends from the second thickened region 4726, and the first thin wall 4722 and second thin wall 4723 join one another to form an angle less than 180 degrees between them. During deformation of the deformation region 4720, when the first thickened region 4724 moves towards the second thickened region 4726, the angle formed between the first thin wall 4722 and second thin wall 4723 is reduced.

[0426] It will be appreciated that the purpose of the deformation region 4720 is to allow preferential deformation to occur at a predetermined location on the dividing wall 4700 in order to absorb undesired forces applied to the dividing wall 4700 and minimize deformation or collapse of the one or more flow directors 4730.

Accordingly, any suitable structure which enables preferential deformation to occur at a predetermined location on the dividing wall 4700 may be incorporated into patient interface 4000 such as bellows, folds, pleats, corrugations, concertinas, or contractable joints located in the dividing wall 4700, preferably at a position on the dividing wall 4700 between the one or more flow directors 4730 and the portion of the perimeter of the dividing wall 4700 that joins housing 4200.

[0427] The dividing wall 4700 may comprise a single material such as an elastomer or a plastic, or multiple materials such as an elastomer and a plastic. In the illustrated embodiment the dividing wall comprises a rigid portion 4710 comprising a plastic material and an elastomeric portion 4712 comprising an elastomeric material. The rigid portion 4710 comprises the portion of the dividing wall 4700 which joins with the housing 4200, and the elastomeric portion 4712 comprises the portion of the dividing wall 4700 which joins the seal 4100. Additionally, or alternatively, the elastomeric portion 4712 comprises the deformation region 4720 and one or more flow directors 4730. Said another way, the deformation region 4720 and one or more flow directors 4730 comprise an elastomeric material.

[0428] In the illustrated embodiment the rigid portion 4710 comprises a polycarbonate material, and the elastomeric portion 4712 comprises a silicone material. It is envisioned that in alternative embodiments any other suitable plastic and/or elastomeric materials may be used, however. Furthermore, in the illustrated embodiment the rigid portion 4710 and elastomeric portion 4712 are permanently connected, however, in alternative embodiments these could be removably connected by any suitable connection means.

[0429] The flow director outlet 4740 has a cross-sectional area comprising the first flow director outlet 4735 and where applicable the second flow director outlet 4739. This cross-sectional area of the flow director outlet 4740 is configured to be less than the cross-sectional area of the inlet 4220 of housing 4200. In the illustrated embodiment, all gas entering the cushion module 4010 enters through the inlet 4220, and excluding unintentional leaks, substantially all gas exiting the cushion module 4010 exits through the outlet 4210. The inlet 4220 is located in the first chamber 4014, the outlet 4210 is located in the second chamber 4016, and the only flow path through the dividing wall 4700 separating the chambers is through the one or more flow directors 4730. As such, the reduced cross-sectional area of the flow director outlet 4740 compared with the inlet 4220 of housing 4200 creates a flow restriction which accelerates gas flow through the one or more flow directors 4730 when pressurised gas flows into the first chamber 4014 of the cushion module 4010 via the inlet 4220, through the one or more flow directors 4730, and the into second chamber 4016 to exit the cushion module 4010 through outlet 4210. The reduced cross-section in the flow path creates a pressure drop which accelerates gas flow entering second chamber 4016. The significance of this acceleration of gas flow is explained in the following paragraphs.

[0430] In the illustrated embodiment the flow restriction mentioned in the above paragraph is created by the flow director outlet 4740 having a cross-sectional area that is less than the cross-sectional area of the inlet 4220 of the housing 4200. However, it is contemplated by the inventors that this flow restriction could be placed elsewhere in the one or more flow directors 4730.

[0431] In the illustrated embodiment of patient interface 4000 the ratio of the cross-sectional area of the first flow director outlet 4735 to the second flow director outlet

4739 is 1:1, meaning the cross-sectional area of both flow director outlets is equal. However, in alternative embodiments the cross-sectional area of the first flow director outlet 4735 may be unequal to the cross-sectional area of the second flow director outlet 4739. The ratio of the cross-sectional area of the first flow director outlet 4735 to the cross-sectional area of the second flow director outlet 4739 can range from 1:1.1 to 1:4. In one configuration the ratio of the cross-sectional area of the first flow director outlet 4735 to the cross-sectional area of the second flow director outlet 4739 is 1:3.

[0432] Additionally, in the illustrated embodiment, the first flow director 4732 and/or the second flow director 4736, comprises a tapering cross-sectional area from the first flow director inlet 4733 to the first flow director outlet 4735, and from the second flow director inlet 4737 to the second flow director outlet 4739, respectively. This tapering cross-sectional area may improve acceleration of gas flow through the first flow director 4732 and/or second flow director 4736.

[0433] In addition to, or instead of, the differing flow director outlet cross-sectional areas, the first flow director 4732 and the second flow director 4736 may differ in shape and/or size in at least one aspect such as the flow director diameter, length, or shape. Such a configuration where the first flow director 4732 and second flow director 4736 have differing shapes and/or sizes may be described as having asymmetrical first and second flow directors 4732, 4736.

[0434] Referring to Figures 53 and 54 for illustrative purposes, the patient interface 4000 is shown in cross-section along line H-H' fitted to an anatomical model of a patient (also shown in cross-section). In Figure 53 the patient interface 4000 is illustrated fitted to a patient with their mouth open. In Figure 54 the patient interface 4000 is illustrated fitted to a patient with their mouth closed. Arrows indicate the direction of gas flow into the cushion module 4010 via inlet 4220, and out of the cushion module 4010 via outlet 4210, while fitted to a patient without respiration occurring. The relative size of the arrows should not be interpreted as an indication of gas flow rate or velocity. It will be appreciated that during respiration there will be additional gas flow paths formed beyond which are described. However, for the purpose of explanation it is believed the general operation of patient interface 4000 can be adequately described while ignoring respiration because the effect of the

patient interface 4000 is believed to be most prominent at the end of the exhalation cycle, which can be realistically likened to a situation in which no respiration is occurring.

5 [0435] When the patient interface 4000 is fitted to a patient, the one or more flow directors 4730 are positioned with the flow director outlet 4740 below the one or the respective one of the patient's nares and adjacent a lip superior of the patient, or immediately adjacent to the one or the respective one of the patient's nares. Said another way, flow director outlet 4740 is located adjacent to, below, or proximal to, the one or the respective one of a patient's nares.

10 [0436] More specifically, in embodiments comprising a first flow director outlet 4735 and a second flow director outlet 4739, the first flow director outlet 4735 is configured to be positioned at a position that is below the first one of a patient's nares and adjacent a lip superior of the patient, or to be positioned at a position that is immediately adjacent the first one of the patients nares, while the second flow
15 director outlet 4739 is configured to be positioned at a position that is below the second one of a patient's nares and adjacent a lip superior of the patient, or to be positioned at a position that is immediately adjacent the second one of the patients nares.

[0437] Referring to Figure 53, where the patient interface 4000 is fitted to a patient
20 with the patients mouth open, without respiration occurring, and where pressurised gas is being delivered to the patient interface 4000 via conduit connector 1300. The flow of pressurised gas enters the first chamber 4014 of cushion module 4010 via inlet 4220. Pressurised gas within the first chamber 4014 then flows: (1) through the one or more flow directors 4730 and into the second chamber 4016, or (2) into the
25 patient's oral cavity via their mouth, through the patient's throat, into the patient's nasal cavity, out of the patient's nares and into the second chamber 4016. Excess pressurised gas and/or gas from within the patient's airways then flows out of second chamber 4016 through outlet 4210 of cushion module 4010 to exit the cushion module 4010. The dividing wall 4700, first chamber 4014, second chamber 4016,
30 and one or more flow directors 4730 which allow flow between the first chamber 4014 and second chamber 4016, therefore create the first and second significant

flow paths from inlet 4220 of cushion module 4010 to outlet 4210 of cushion module 4010 mentioned above.

[0438] The first significant flow path extends from inlet 4220 of cushion module, through the first chamber 4014 of cushion module 4010 into the patient's oral cavity via their mouth, through the patient's throat, into the patient's nasal cavity, out of the one or more nares of the patient into the second chamber 4016, and through outlet 4210 to exit the cushion module 4010. It is believed that this unidirectional flow of gas entering the patient's oral cavity and exiting through the nasal cavity will cause anatomical deadspace flushing of at least some of the patient's oral cavity, throat, and nasal cavity.

[0439] The second significant flow path extends from inlet 4220 of cushion module, into the first chamber 4014, through the one or more flow directors 4730 where it is believed acceleration of the gas will likely cause at least some gas flow to enter the patient's nasal cavity via the one or more nares before decelerating and/or changing direction and exiting the nasal cavity via the one or more nares into the second chamber 4016, and through outlet 4210 to exit the cushion module 4010. It is also anticipated that some gas will flow through the one or more flow directors 4730 and into second chamber 4016 without entering the patient's nasal cavity. It is believed the gas flow being directed through the one or more flow directors 4730, which are configured to create acceleration of the gas flow, and are configured to be positioned at a position that is below the patient's nares and adjacent a lip superior of the patient, or to be positioned at a position that is immediately adjacent the patients nares, is important to causing at least some gas flow to enter the patient's nasal cavity via the one or more nares before decelerating and/or changing direction and exiting the nasal cavity. It is believed that this portion of gas flow entering the nasal cavity will create some anatomical dead space flushing of the patient's nasal cavity.

[0440] Referring to Figure 54, where the patient interface 4000 is fitted to a patient with the patient's mouth closed, without respiration occurring, and where pressurised gas is being delivered to the patient interface 4000 via conduit connector 1300. The flow of pressurised gas enters the first chamber 4014 of cushion module 4010 via inlet 4220, pressurised gas from within the first chamber 4014 then flows through the one or more flow directors 4730 and into the second chamber 4016, excess

pressurised gas and/or gas from within the patient's airways then flows out of second chamber 4016 through outlet 4210 of cushion module 4010 to exit the cushion module 4010. Due to the patient's mouth being closed only the second significant flow path is formed. The second significant flow path is discussed in detail in the paragraph immediately preceding this.

[0441] Because gas flow through the first significant flow path and the second significant flow path are both thought to cause anatomical dead space flushing to some extent, it is believed that the patient interface 4000 provides a significant benefit beyond traditional non-invasive ventilation masks. The ability to provide pressure support and simultaneous dead space flushing with the patients mouth open or closed is advantageous in NIV therapy.

[0442] In the preceding paragraphs dead space flushing of the anatomical dead space of a patient has been discussed as an intended benefit of patient interface 4000. The anatomical dead space of a patient consists of the total volume of the respiratory tract segments of a patient that are responsible for conducting air to the alveoli and respiratory bronchioles but do not take part in the process of gas exchange itself. The anatomical dead space is therefore the total volume of the conducting airways from the nose or mouth to the terminal bronchioles of a patient including the oral cavity, nasal cavity, and pharynx (also referred to as the throat).

[0443] During respiration by a patient, lower CO₂ content air is inhaled into the lungs and higher CO₂ content air is exhaled from the lungs. At the end of an exhalation cycle a portion of the exhaled higher CO₂ content air remains in the anatomical dead space of the patient. This higher CO₂ content air is then inhaled, or rebreathed, during the next respiration cycle. This rebreathing of high CO₂ content air leads to a reduced efficiency in the gas exchange occurring within a patient's lungs.

[0444] The process of dead space flushing replaces at least a portion of the exhaled higher CO₂ content air present in the anatomical dead space of a patient with fresh lower CO₂ content air so that during the following inhalation cycle a reduced amount of exhaled higher CO₂ content air is inhaled, or rebreathed. This reduction in rebreathing of higher CO₂ content air improves the efficiency of gas exchange occurring within a patient's lungs.

[0445] As discussed in the preceding paragraphs the flow director outlet 4740 has a cross-sectional area that is configured to be less than the cross-sectional area of the inlet 4220 of housing 4200. The smaller cross-sectional area of the flow director outlet 4740 compared with the inlet 4220 of housing 4200 forms a flow restriction which creates an acceleration of gas flow. However, it is to be appreciated that in alternative embodiments the flow restriction may be located anywhere within the one or more flow directors 4730 to create this desired acceleration of gas through the one or more flow directors 4730.

[0446] In an alternative embodiment, the outlet 4210 of cushion module 4010 is configured to have a resistance to flow that is lower than the resistance to flow through the one or more flow directors 4730. This difference in resistance to flow is configured to create a pressure differential between the first chamber 4014 and the second chamber 4016, with the second chamber 4016 being configured to be at a lower pressure than the first chamber 4014 in use.

[0447] It is believed that in during use, with the patients mouth open, and with pressurised gas being supplied to the first chamber 4014 of cushion module 4010, that flow along the first significant path, namely, flow from the first chamber 4014 through the patient's oral cavity, through the throat, into the nasal cavity, out of the nasal cavity via the nares and into the second chamber 4016, may be encouraged by this configured pressure differential.

[0448] It will be appreciated that although the pressure differential described in the above configuration is achieved by configuring the resistance to flow through outlet 4210, that it is envisioned that any suitable method to create a lower pressure within the second chamber 4016 than within the first chamber 4014 may be incorporated into a further alternative configuration.

[0449] Having regard to Figures 55 to 68, a patient interface 5000 of a fifth embodiment is shown. The patient interface 5000 is a variation of the patient interface 4000 and incorporates all components and functions of the patient interface 4000 unless stated otherwise. Features of the patient interface 5000 that are the same as the features of the patient interface 4000 are denoted by the same reference numeral, but with a leading "5" instead of "4".

[0450] Patient interface 5000 differs from patient interface 4000 in that all features and functions of the dividing wall 4700 of patient interface 4000 are incorporated in a dividing wall insert 570 of patient interface 5000. The dividing wall insert 570 is a component manufactured separately from a seal 5100 and a housing 5200 and
5 which is configured to be inserted, either permanently or removably, into cushion module 5010 post manufacture. Said another way, the dividing wall insert 570 is not integrally formed with either of the seal 5100, the housing 5200, or a cushion module 5010 which is formed by the two.

[0451] However, the dividing wall insert 570 and the housing 5200 could be formed
10 separately and then dividing wall insert 570 could be connected to housing 5200 before the seal 5100 is overmoulded to the housing 5200 and/or dividing wall insert 570.

[0452] The dividing wall insert 570 comprises a dividing wall 5700. The dividing wall 5700, like the dividing wall 4700 of patient interface 4000, extends across and
15 separates the cavity 5012 of the cushion module 5010 into a first chamber 5014 and a second chamber 5016 when the dividing wall insert 570 is inserted within cushion module 5010. The dividing wall 5700 intersects and separates the seal opening 5110 to from an oral opening 5114 and a nasal opening 5116. The oral opening 5114 being into the first chamber 5014 and the nasal opening 5116 being into the second
20 chamber 5016.

[0453] The dividing wall 5700 of the dividing wall insert 570 comprises an outer periphery 5705 which is shaped to substantially match the internal geometry of the cushion module 5010. In

[0454] In the illustrated embodiment, the outer periphery 5705 contacts both the
25 housing 5200 and the seal 5100 to sufficiently seal the first chamber 5014 from the second chamber 5016. This limits and/or stops gas flowing between the first chamber 5014 and the second chamber 5016 between the outer periphery 5705 of the dividing wall 5700 and the housing 5200 and/or the seal 5100.

[0455] It is to be understood that there will be differing levels of acceptable gas flow
30 from the first chamber 5014 to the second chamber 5016 between the outer periphery 5705 of the dividing wall 5700 and the housing 5200 and/or the seal 5100. Where a moderate to low amount of gas flow is acceptable the outer periphery 5705

of the dividing wall 5700 may be configured to abut the housing 5200 and/or the seal 5100 within the cushion module 5010 to limit gas flow between the first chamber 5014 and the second chamber 5016. Alternatively, the outer periphery 5705 may even be spaced away from the housing 5200 and/or the seal 5100 to allow for a limited amount of flow between them. Where a minimal amount of gas flow between the dividing wall 5700 and the housing 5200 and/or the seal 5100 is acceptable the outer periphery 5705 may comprise a flange, lip, gasket, or other sealing structure to abut the housing 5200 and/or the seal 5100 and create a substantially airtight seal. Where substantially no gas flow between the dividing wall 5700 and the housing 5200 and/or the seal 5100 is acceptable the outer periphery 5705 may be adhered, chemically bonded, or mechanically connected (such as by a lip and groove arrangement) to the housing 5200 and/or the seal 5100 to create an airtight seal around the periphery 5705 of the dividing wall 5700.

[0456] The illustrated dividing wall insert 570 is configured to be inserted within the cushion module 5010 and connected either removably or permanently to the housing 5200 via connector 5750. However, it will be appreciated that as described above, there may be additional connections between the dividing wall insert 570 and the cushion module 5010. For, for example, there may be a connection between the outer periphery 5705 and the housing 5200 and/or the seal 5100.

[0457] The dividing wall insert 570 comprises a connector 5750 configured for removable or permanent connection with a complimentary connection structure of the housing 5200. In the illustrated embodiment, the connector 5750 is in the form of a sleeve 5755 which is configured to be removably connected to an external surface of the sleeve 5230 of the housing 5200. The connection with the housing 5200 may be with a removable interference or taper fit. This external surface is located within the cushion module 5010, and specifically within the first chamber 5014. This connection can be seen in Figure 63 for example. In this way, the dividing wall insert 570 can be removably connected to patient interface 5000, thereby converting it between a single chamber patient interface and a dual chamber patient interface.

[0458] Alternatively, the sleeve 5755 of connector 5750 may have a permanent connection with the sleeve 5230 of the housing 5200. This may be a one-time connection in which the patient interface 5000 can be converted from a single

chamber patient interface to a dual chamber patient interface, but where the dividing wall insert 570 cannot be removed following this. This may be required for patient safety for example.

[0459] It will be appreciated that once the dividing wall insert 570 is inserted within the cushion module 5010 and connected to the housing 5200 and/or the seal 5100 that the patient interface 5000 will function substantially the same as patient interface 4000. As such, the description of how patient interface 5000 is expected to function in use is not repeated here but can instead be taken from the above paragraphs regarding the expected function of patient interface 4000 in use, unless explicitly stated otherwise.

[0460] The dividing wall insert 570 being a separate, and in some instances removable, component from the seal 5100 and housing 5200 provides at least two benefits. The first being a reduction in complexity of moulding the seal 5100 and/or housing 5200 as moulding a single chamber cushion module is believed to be significantly less challenging than a dual chamber cushion module. Secondly, the dividing wall insert 570 may be retroactively fitted to existing single chamber patient interfaces to convert a single chamber patient interface 1000 into a dual chamber patient interface 5000. Regarding the latter point, it is anticipated that a dividing wall insert 570 could be sold on its own to allow for existing single chamber patient interfaces to be converted to dual chamber patient interfaces.

[0461] Now the specific structural features of the illustrated embodiment of the dividing wall insert 570 will be described with relation to Figures 64 to 68.

[0462] Figure 64 shows a perspective view of the dividing wall insert 570. The illustrated dividing wall insert 570 comprises a dividing wall 5700, connector 5750 attached to the dividing wall 5700, and one or more flow directors 5730 extending from the dividing wall 5700 and defining one or more gas flow paths through the dividing wall 5700.

[0463] The one or more flow directors 5730 comprising at least a first flow director inlet 5733 in fluid communication with the first chamber 5014 and a first flow director outlet 5735 in fluid communication with the second chamber 5016 to allow gas flow through the dividing wall 5700. In the illustrated embodiment, the one or more flow directors 5730 comprise the only gas flow path(s) through the dividing wall 5700.

[0464] In the illustrated embodiment, the dividing wall 5700 comprises a first flow director 5732 and a second flow director 5736. The first flow director 5732 comprising a first flow director inlet 5733 in fluid communication with the first chamber 5014 and a first flow director outlet 5735 in fluid communication with the
5 second chamber 5016. The second flow director 5736 comprising a second flow director inlet 5737 in fluid communication with the first chamber 5014 and a second flow director outlet 5739 in fluid communication with the second chamber 5016.

[0465] Furthermore, as with patient interface 4000, the first flow director outlet 5735 and/or the second flow director outlet 5739 are configured to be positioned near and
10 directed towards a user's nares while the patient interface 5000 is worn by a user to direct gas flow through the one or more flow directors 5730 towards the user's nares.

[0466] In the illustrated embodiment, the dividing wall 5700 comprises a rigid portion 5710 and an elastomeric portion 5711. The connector 5750 of dividing wall insert 570 being attached to the rigid portion 5710 and the one or more flow directors 5730
15 extending from the elastomeric portion 5711 of the dividing wall 5700. In the illustrated embodiment the elastomeric portion 5711 is connected to the rigid portion 5710 via a bead on the elastomeric portion 5711 that is received within a channel on the rigid portion 5710. This allows for a removably mechanical connection. However, any suitable connection could be used, such as overmoulding, adhesives, chemical
20 bonding, or alternative mechanical connections.

[0467] _It is also envisioned that the dividing wall 5700 and its sub-components could be formed entirely from a rigid material, entirely from an elastomeric material, or from an alternative combination of the two, as desired.

[0468] _As described above, the illustrated dividing wall 5700 comprises an outer
25 periphery 5705 which, once inserted into cushion module 5010, contacts the seal 5100 and the housing 5200 to form a seal. In the illustrated embodiment, this outer periphery 5705 comprises a thickened flange which provides an increased surface area of contact to provide an improved seal with the cushion module 5010. This flange may provide a secondary benefit of reducing the contact pressure and helping
30 to spread forces over a larger area. Additionally, a portion of the outer periphery 5705 which bisects the seal opening 5110 is expected to contact the patient's upper

lip in use and as such this flange may provide improved sealing on the patient's upper lip and reduce any discomfort by reducing the contact pressure.

[0469] Optionally, but not illustrated, the elastomeric portion 5711 of dividing wall 5700 may comprises a deformation region 5720 comprising a thin region 5721

5 located between a first thickened region 5724 and a second thickened region 5726 to allow for controlled deformation of the dividing wall 5700 within this thin region 5721 in response to forces applied to the dividing wall 5700 during use. References to "thin" and "thickened" are references to the wall thickness of the elastomeric portion 5711. The deformation region 5720 incorporates all features and functions of
10 dividing wall 4720 as described above in relation to patient interface 4000.

[0470] In the illustrated embodiment, the dividing wall insert 570 comprises a first flow director 5732 and a second flow director 5736 being of equal size and shape. The first flow director 5732 and second flow director 5736 incorporate all features and functions of first flow director 4732 and second flow director 4736 respectively
15 as described above.

[0471] In alternative embodiments the first flow director 5732 and the second flow director 5736 may be asymmetrical, that is they may be shaped differently in at least one way to one another and may differ in at least one of the height, width, thickness, inlet opening size, outlet opening size, or cross-sectional shape for example.

20 [0472] The dividing wall insert 570, in some embodiments, may comprise one or more apertures through the dividing wall 5700 which provide the intended restriction and pressure differential between the first chamber 5014 and second chamber 5016. In these embodiments, the apertures take the place of the one or more flow directors 5730. Such apertures may be aligned with the nares of the user or may be located
25 elsewhere on the dividing wall 5700. However, the apertures do not substantially direct gas flow towards the nares of the patient.

[0473] A benefit of the dividing wall insert 570 being a separate component from the cushion module 5010 is that a range of dividing wall inserts 570 could be provided with each comprising a differing flow director configuration. The configurations could
30 differ in the number of flow directors, flow director sizes, flow director shapes, flow director positions, and/or flow director materials for example. These differing configurations could be suitable for different purposes such as differing therapies,

different nare sizes of the patients, and/or patients with differing nasal cavity restrictions, for example.

[0474] In one embodiment, a selection of dividing wall inserts 570 would be provided with flow directors of differing flow restriction. A first dividing wall insert 570 may
5 have one or more flow directors 5730 with a relatively low flow restriction. A second dividing wall insert 570 may have one or more flow directors 5730 with a relatively moderate flow restriction. A third dividing wall insert 570 may have one or more flow directors 5730 with a relatively high flow restriction., for example but not limiting. These could be provided separately, or as a set. Depending on patient anatomy and
10 ventilation requirements, a suitable dividing wall insert 570 could be selected to tailor the amount of restriction through the dividing wall 5700 and therefore in turn the amount of flushing flow directed through the patient's mouth, around the back of the throat, and out of the nares to flush the patient's anatomical dead space during at least the end of the expiration phase. This flushing mechanism is described above in
15 relation to patient interface 4000 and is incorporated here in its entirety in relation to patient interface 5000.

[0475] In another embodiment, a selection of dividing wall inserts 570 would be provided with asymmetric flow director configurations. In such embodiments the cross-sectional area of the first flow director outlet 5735 may be unequal to the
20 cross-sectional area of the second flow director outlet 5739. One dividing wall insert 570 may be provided with a flow director outlet which is configured to align with the left nare of a user being larger than the flow director outlet which is configured to align with the right nare of the user. A second dividing wall insert 570 may be provided with this arrangement reversed. Further, a third dividing wall insert 570 may
25 be provided with only a single flow director 5732 configured to align with a left nare of a user, and a fourth dividing wall insert 570 may be provided with a single flow director 5732 configured to align with a right nare of a user.

[0476] For the unequal, or asymmetric, flow directors the ratio of the cross-sectional area of the first flow director outlet 5735 to the cross-sectional area of the second
30 flow director outlet 5739 could range from 1:1.1 to 1:4. In one configuration the ratio of the cross-sectional area of the first flow director outlet 5735 to the cross-sectional area of the second flow director outlet 5739 is 1:3. The first flow director inlet 5733

and the second flow director inlet 5737 may be of equal cross-sectional area or could have differing cross-sectional areas of a range from 1:1.1 to 1:4.

[0477] Having regard to Figures 69 to 78, a patient interface 6000 of a sixth embodiment is shown. The patient interface 6000 is a variation of the patient interface 6000 and incorporates all components and functions of the patient interface 5000 unless stated otherwise. Features of the patient interface 6000 that are the same as the features of the patient interface 5000 are denoted with the same reference numeral, but with the leading number being "6" instead of "5".

[0478] Patient interface 6000 differs from patient interface 5000 in that the seal 6100 is a full face undernose seal, and that the dividing wall insert 670 does not comprise a connector 6750. Instead, the dividing wall insert 670 is configured to be adhered, chemically bonded, or mechanically attached to the housing 6200 and/or the seal 6100.

[0479] The seal 6100 is formed of a soft, resilient material, such as a silicone or other suitable elastomer. The seal 6100 includes an oral opening 6114 and a nasal opening 6116. When fitted to a patient, the oral opening 6114 is configured to circumscribe the patient's mouth. A patient contacting surface 6120 surrounding the oral opening 6114 forms a seal about the mouth of the patient. The nasal opening 6116 is configured to circumscribe the patient's nares. The patient contacting surface 6120 surrounding the nasal opening 6116 forms a seal about the nares of the patient. Accordingly, respiratory gas at elevated pressure can be delivered from the cushion module 6010 to the patient's mouth and nares via the oral opening 6114 and nasal opening 6116, respectively.

[0480] As the seal 6100 is an undernose seal comprising a nasal opening 6116 which circumscribes the users' nares but which does not receive the nose of the user, the one or more flow directors 6730 are positioned such that gasses flowing through the one or more flow directors 6730 are directed towards the nasal opening 6116 and in certain situations, with the patients mouth closed at the end of exhalation for example, flow through the nasal opening 6116 and into the patients nares.

[0481] Seal 6100 is configured not to contact the nasal bridge of a user in use and as such has a different shape profile to the over-nose seals shown in previous

embodiments. Owing to the different shape of the undernose seal 6100 compared to seal 1100, the housing 6200 and frame 6400 comprise profiles differing from housing and frames shown in previous embodiments. However, it will be appreciated that the functions and features of housing 6200 and frame 6400 are otherwise substantially identical to the functions and features of housing 1200 and frame 1400 of patient interface 1000 of the general form.

[0482] Furthermore, because seal 6100 comprises a portion of the patient contacting surface 6120 which extends between the oral opening 6114 and the nasal opening 6116 and which is configured to contact the patient's upper lip in use, the outer periphery 6705 of the dividing wall 6700 contacts the seal 6100 and/or housing 6200 around an entirety of its periphery. Said another way, the outer periphery 6705 of dividing wall 6700 is not configured to intersect an opening of seal 6100.

[0483] As mentioned above, the second difference between patient interface 6000 and patient interface 5000 is that the dividing wall insert 670 does not comprise a connector 6750 and instead is configured to be adhered or, chemically bonded, or mechanically attached to housing 6200 and/or seal 6100. As with dividing wall insert 570, dividing wall insert 670 comprises an outer periphery 6705 having a flange of increased thickness. This flange creates an enlarged surface area where adhesives or other bonding agents could be applied. for example.

[0484] In the illustrated embodiment it is anticipated that an adhesive or other chemical agent would be applied to the outer periphery 6705 of the dividing wall 6700 and then the dividing wall insert 670 inserted within cushion module 6010. The outer periphery 6705 would contact the housing 6200 and seal 6100 at respective locations creating a permanent and airtight connection between the dividing wall insert 670 and cushion module 6010.

[0485] In an alternative embodiment, the outer periphery 6705 could be received within a channel or groove on the housing 6200 and/or seal 6100 to mechanically attach the dividing wall insert 670 to cushion module 6010.

[0486] As with patient interface 5000, once the dividing wall insert 670 is inserted within cushion module 6010 and adhered, bonded, or mechanically attached in place the patient interface 6000 will function substantially identically to patient interface 4000 with the only difference being that the seal 6100 seals on an underside of the

patient's nose and does not contact the nasal bridge. As with patient interface 5000 above, the explanation of the anticipated function is therefore not repeated and can be understood by reference to the disclosure of patient interface 4000.

[0487] It is also envisioned that a range of dividing wall inserts 670 could be
5 provided with each comprising differing flow director configurations as discussed above in relation to patient interface 5000. These could be provided in a pack with a single chamber patient interface 6000 and once the desired dividing wall insert 670 had been identified it could be adhered, bonded, or mechanically attached within the cushion module 6010 to form a dual chamber patient interface 6000 having the
10 desired flow director configuration.

[0488] Finally, the dividing wall insert 670, which is configured to be adhered or, bonded, or mechanically attached in place and does not comprise a connector, may be utilized in the over-the-nose patient interface 5000. Additionally, the dividing wall insert 570 which comprises connector 5750 may be utilized with the undernose
15 patient interface 6000.

[0489] Having regard to Figures 79 to 87, a patient interface of a seventh embodiment is shown. The patient interface 7000 is a variation of the patient interface 4000 and incorporates all components and functions of the patient interface 4000 unless stated otherwise. Features of the patient interface 7000 that are the
20 same as the features of the patient interface 4000 are denoted with the same reference numeral, but with the leading number being "7" instead of "4".

[0490] Patient interface 7000 differs from patient interface 4000 in that all features and functions of the one or more flow directors 7730 are incorporated in a flow director insert 773, and that the seal 7100 is an undernose seal. The function and
25 structure of full face undernose seals, and its impact on the shape of the frame 1400 and housing 7200 have been described above in relation to seal 6100 and patient interface 6000 and are incorporated into the seal 7100 and the patient interface 7000 unless explicitly stated otherwise.

[0491] Like the cushion module 4010, the cushion module 7010 comprises a
30 dividing wall 7700 that separates the cavity 7012 of the cushion module 7010 into a first chamber 7014 and a second chamber 7016. The dividing wall 7700 joins to the housing 7200 and/or the seal 7100 respectively around its outer periphery 7705 to

separate the first chamber 7014 from the second chamber 7016. The dividing wall 7700 joins with the seal 7100 between the oral opening 7114 and the nasal opening 7116 such that the oral opening 7114 opens into the first chamber 7014 and the nasal opening 7116 opens into the second chamber 7016.

- 5 [0492] With the exception of the nasal opening 4116 of patient interface 4000 circumscribing the patients nose and contacting the nasal bridge, and the nasal opening 7116 of patient interface 7000 circumscribing the patients' nares and not contacting the nasal bridge, that the two patient interfaces 4000 and 7000 are expected to function substantially the same way in use. Accordingly, it will be
10 understood that the description outlined above regarding operation of the patient interface 4000 applies equally here to the patient interface 7000.

- [0493] As mentioned above, the primary difference of patient interface 7000 is that all features and functions of the one or more flow directors 4730 from patient interface 4000 are incorporated into a removable flow director insert 773. The flow
15 director insert 773 is a separate component from either of the seal 7100, the housing 7200 and the dividing wall 7700. Dividing wall 7700 comprises a flow director aperture 7707 which is configured to removably, or permanently, receive the flow director insert 773.

- [0494] In the illustrated embodiment the flow director insert 773 comprises a channel
20 around a periphery of the insert body 7731 which is configured to receive the rim of the flow director aperture 7707 to removably attach the flow director insert 773 to the dividing wall 7700. This connection can be seen in Figure 84 for example. In alternative embodiments, the flow director insert 773 could be removably or permanently attached to the dividing wall by any suitable mechanical connection,
25 adhesive or chemical bond. For example, the flow director insert 773 may comprise an external geometry configured to be received in the flow director aperture 7707 with a taper or interference fit.

- [0495] The flow director insert 773 comprises one or more flow directors 7730 extending from the insert body 7731. The one or more flow directors 7730
30 incorporate all features and functions of the one or more flow directors 4730. Accordingly, the description above relating to those features of the patient interface 4000 are equally applicable here to the one or more flow directors 7730.

[0496] In the illustrated embodiment the flow director insert body 7731 and the one or more flow directors 7730 comprise an elastomeric material and are formed integrally as a single component. The flow director insert body 7731 is configured to be thicker than the surrounding portions of the dividing wall 7700 to provide stability to the one or more flow directors 7730.

[0497] It is to be appreciated that the flow director insert body 7731 could alternatively be constructed of a rigid material such as a plastic. In such a situation the one or more flow directors 7730 may be constructed from the same rigid material or may be constructed from an elastomeric material that is attached to the rigid flow director insert body 7731.

[0498] Similar to patient interface 5000, it is envisioned that a benefit of the flow director insert 773 being a separate component from the dividing wall 7700 is that a range of flow director inserts could be provided with each comprising differing flow director configurations. The configurations could differ in number of flow directors, flow director sizes, flow director shapes, flow director positions, and/or flow director materials for example. These differing configurations could be suitable for different therapies, different nare sizes of the patients, and/or patients with differing nasal cavity restrictions, for example.

[0499] A number of possible flow director configurations were described above in relation to the range of dividing wall inserts 570 of patient interface 5000, these flow director configurations are incorporated here in their entirety as options for combining with the patient interface 7000 as a range of flow director inserts 773. Furthermore, three exemplary configurations have been illustrated with regard to Figures 88 to 93.

[0500] Figure 88 shows a first flow director insert 773 comprising a first flow director 7732 and a second flow director 7736. The first flow director 7732 comprising a first flow director inlet 7733 in fluid communication with the first chamber 7014 and a first flow director outlet 7735 in fluid communication with the second chamber 7016 when the flow director insert 773 is attached to the dividing wall 7700. The second flow director 7736 comprising a second flow director inlet 7737 in fluid communication with the first chamber 7014 and a second flow director outlet 7739 in fluid

communication with the second chamber 7016 when the flow director insert 773 is attached to the dividing wall 7700.

[0501] The first flow director 7732 and second flow director 7736 are equal in size and symmetrical. Each comprises a flow director outlet being smaller than the
5 corresponding flow director inlet and generally tapering in cross-sectional area from the flow director inlet to the flow director outlet. This is believed to direct and/or accelerate gas flow through the first flow director 7732 and second flow director 7736 towards the nasal opening 7116.

[0502] Figure 90 shows a second alternative flow director insert 873 which
10 comprises a single flow director 8732 comprising a first flow director inlet 8733 in fluid communication with the first chamber 7014 and a first flow director outlet 8735 in fluid communication with the second chamber 7016 when the flow director insert 873 is attached to the dividing wall 7700. The flow director insert 873 further comprises one or more flow director apertures 8745 extending through the flow
15 director insert body 8731. It is believed that this additional flow path through the dividing wall 7700 via the flow director insert 873 may be required to enable the desired pressure differential between the first chamber 7014 and second chamber 7016 given the removal of the second flow director.

[0503] Figure 92 shows a third alternative flow director insert 973 which comprises a
20 first flow director 9732 and a second flow director 9734. The first flow director 9732 comprising a first flow director inlet 9733 in fluid communication with the first chamber 7014 and a first flow director outlet 9735 in fluid communication with the second chamber 7016 when the flow director insert 973 is attached to the dividing wall 7700. The second flow director 9736 comprising a second flow director inlet
25 9735 in fluid communication with the first chamber 7014 and a second flow director outlet 9739 in fluid communication with the second chamber 7016 when the flow director insert 973 is attached to the dividing wall 7700.

[0504] The one or more flow directors 9730 are asymmetric with the ratio of the cross-sectional area of the first flow director outlet 9735 to the cross-sectional area
30 of the second flow director outlet 9739 being in a range from 1:1.1 to 1:4. In the illustrated configuration the ratio of the cross-sectional area of the first flow director outlet 9735 to the cross-sectional area of the second flow director outlet 9739 is 1:3.

The first flow director inlet 9733 and the second flow director inlet 9737 may be of equal cross-sectional area or could have differing cross-sectional areas of a range from 1:1.1 to 1:4.

- [0505] The flow director insert 973 further comprises one or more flow director apertures 9745 extending through the flow director insert body 9731. It is believed that this additional flow path through the dividing wall 9700 may be required to enable the desired pressure differential between the first chamber 7014 and second chamber 7016 given the decrease in cross-sectional area of the second flow director outlet 9737.
- [0506] It is to be understood that the one or more flow director apertures 8745, 9745 may be implemented in any of patient interfaces 4000, 5000, and 6000 in any suitable portion of the dividing wall 4700, 5700 or 6700 respectively to enable a desired pressure differential across the dividing wall 4700, 5700, 6700 from the first chamber 4014, 5014, 6014 to the second chamber 4016, 5016, 6016 respectively.
- As described particularly in the description relating to patient interface 4000, it is believed that this pressure differential is in part responsible for the anatomical dead space flushing believed to occur through the oral cavity and out of the nasal cavity at least during mouth open respiration.

- [0507] In the claims which follow, and in the preceding description, except for where the context requires otherwise due to express language or necessary implication, the term “prong” or “prongs” is to be used interchangeably with “pillow” or “pillows”. It is intended by the applicant that a “sealing prong” as described or claimed is to be considered as being used interchangeably with a “nasal pillow”, “pillow seal” or “pillow”.

- [0508] Those skilled in the art of the present invention will appreciate that many variations and modifications may be made to the preferred embodiment without departing from the spirit and scope of the present invention.

- [0509] In the claims which follow, and in the preceding description, except where the context requires otherwise due to express language or necessary implication, the word “comprise” and variations such as “comprises” or “comprising” are used in an inclusive sense, i.e., to specify the presence of the stated features but not to

preclude the presence or addition of further features in various embodiments of the apparatus and method as disclosed herein.

[0510] In the foregoing description of preferred embodiments, specific terminology has been resorted to for the sake of clarity. However, the invention is not intended to
5 be limited to the specific terms so selected, and it is to be understood that each specific term includes all technical equivalents which operate in a similar manner to accomplish a similar technical purpose. Terms such as "front" and "rear", "inner" and "outer", "above", "below", "top", "bottom", "upper" and "lower", "underside" and "topside", "vertical" and "horizontal" and the like are used as words of convenience to
10 provide reference points and are not to be construed as limiting terms. These terms when used in reference to the patient interface throughout the specification, including the claims, refer to orientations relative to the normal operating orientation, i.e., when the interface is fitted to a patient and the patient's head is upright.

[0511] Throughout the description and claims, terms such as "join", "link" and
15 "connection" should not be construed as requiring two separate components being linked together. Those terms should be interpreted in context, including the option of meaning an intersection of integrally formed features. For example, the dividing wall in the fourth embodiment joins with the outer wall, but they are integrally formed in that embodiment.

[0512] Furthermore, invention has been described in connection with what are
20 presently considered to be the most practical and preferred embodiments, it is to be understood that the invention is not to be limited to the disclosed embodiments, but on the contrary, is intended to cover various modifications and equivalent arrangements included within the spirit and scope of the invention. Also, the various
25 embodiments described above may be implemented in conjunction with other embodiments, for example, aspects of one embodiment may be combined with aspects of another embodiment to realize yet other embodiments. Further, each independent feature or component of any given assembly may constitute an additional embodiment.

CLAIMS

1. A cushion module for a patient interface for delivering positive pressure respiratory therapy to a user, the cushion module comprising:

- a seal for forming a seal around the user's mouth and nares;
- 5 a housing connected to the seal, the housing and seal forming a cavity configured to receive a flow of pressurized gas;
- at least one opening in the seal to communicate the pressurized gas with the user;
- an inlet through which the pressurized gas is received into the cavity;
- 10 an outlet through which gas is exhausted from the cushion module; and
- an exhaust conduit configured to draw gas from the user's nares through at least one exhaust conduit inlet and conduct it to the outlet of the cushion module.

2. A cushion module for a patient interface for delivering positive pressure respiratory therapy to a user, the cushion module comprising:

- a seal for forming a seal around the user's mouth and nares;
- a housing connected to the seal, the housing and seal forming a cavity configured to receive a flow of pressurized gas;
- at least one opening in the seal to communicate the pressurized gas with the user;
- 20 an inlet for receiving pressurized gas into the cavity;
- an outlet for exhausting gas from the cushion module; and
- an exhaust conduit located within the cavity, the exhaust conduit having at least one exhaust conduit inlet through which gas is received into the exhaust conduit, the exhaust conduit extending from the at least one exhaust conduit inlet to the outlet of the cushion module.
- 25

3. The cushion module of claim 1 or 2, wherein each exhaust conduit inlet is configured to be positioned within one or a respective one of the user's nares or to

be positioned at a position that is below the one or the respective one of the users nares and adjacent a lip superior of the user.

4. The cushion module of any one of claims 1 to 3, wherein the cross-sectional area of the at least one exhaust conduit inlet is less than the cross-sectional area of the inlet to cause gas entering the exhaust conduit to accelerate as it flows from the cavity into the exhaust conduit.
5. The cushion module of any one of claims 1 to 4, wherein the exhaust conduit and the at least one exhaust conduit inlet are configured to accelerate gas as it flows from the cavity into the exhaust conduit and to entrain surrounding gas into the exhaust conduit.
6. The cushion module of any one of claims 1 to 5, wherein the entrainment of surrounding gas into the exhaust conduit entrains respiratory gas from within the one or the respective one of the user's nares when the at least one exhaust conduit inlet is positioned within the one or respective one of the user's nares or positioned at the position that is below the one or the respective one of the users nares and adjacent the lip superior of the user.
7. The cushion module of any one of claims 1 to 6, wherein the at least one opening of the seal comprises a first opening encompassing the mouth of the user and a second opening encompassing the nares of the user.
8. The cushion module of any one of claims 1 to 7, wherein the exhaust conduit is further configured to conduct exhaled gas from the mouth and/or nares of the user or to conduct excess gas from the cavity or both to the outlet and is configured to exhaust the exhaled gas from the mouth and/or nares of the user or the excess gas from the cavity or both from the cushion module.
9. The cushion module of any one of claims 1 to 8, wherein the exhaust conduit is adjustably mounted to the housing such that the orientation and/or position with respect to the seal can be adjusted.
10. The cushion module of any one of claims 1 to 9, wherein the exhaust conduit is an enclosed passageway extending from the at least one exhaust conduit inlet to the outlet.

11. The cushion module of any one of claims 1 to 10, wherein the exhaust conduit is configured to prevent ingress of gas from the cavity, other than via the at least one exhaust conduit inlet, and to prevent egress of gas into the cavity
12. The cushion module of any one of claims 1 to 11, herein the exhaust conduit is
5 surrounded by the cavity.
13. The cushion module of any one of claims 1 to 11, wherein the exhaust conduit is a separate structure from the seal.
14. The cushion module of any one of claims 1 to 12, wherein the exhaust conduit comprises at least one prong, and wherein the at least one exhaust conduit inlet is
10 located at a free end of the at least one prong.
15. The cushion module of claim 14, wherein the at least one prong is configured to extend into the one or respective one of the user's nares.
16. The cushion module of claim 14 or 15, wherein the at least one prong is a sealing prong configured to form a seal with the one or respective one of the user's
15 nares.
17. The cushion module of any one of claims 14 to 16, wherein the at least one prong is formed of an elastomeric material.
18. The cushion module of claim 17, wherein the elastomeric material is silicone.
19. The cushion module of claim 14, wherein the at least one exhaust conduit inlet
20 comprises a first exhaust conduit inlet configured to be positioned within a first nare of the user's nares or to be positioned at a position that is below the first nare of the users nares and adjacent a lip superior of the user and a second exhaust conduit inlet configured to be positioned within a second nare of the user's nares or to be positioned at a position that is below the second nare of the users nares and
25 adjacent a lip superior of the user.
20. The cushion module of claim 19, wherein the at least one prong comprises a first prong and a second prong, the first exhaust conduit inlet located at a free end of the first prong, and the second exhaust conduit inlet located at a free end of the second prong.

21. The cushion module of claim 20, wherein the first prong is configured to extend into the first nare of the user and the second prong is configured to extend into the second nare of the user.
22. The cushion module of claim 20, wherein the exhaust conduit further comprises
5 a manifold, the first and second prongs extending from the manifold.
23. The cushion module of claim 20, wherein at least a portion of the exhaust conduit is pliable to allow the position of the first and second prongs to be adjusted.
24. The cushion module of any one of claims 19 to 24, wherein the first exhaust conduit inlet and the second exhaust conduit inlet have different cross-sectional
10 areas.
25. The cushion module of claim 24, wherein the ratio of the cross-sectional area of the first exhaust conduit inlet to the cross-sectional area of the second exhaust conduit inlet is between 1:1.1 and 1:4.
26. The cushion module of claim 25, wherein the ratio of the cross-sectional area of
15 the first exhaust conduit inlet to the cross-sectional area of the second exhaust conduit inlet is 1:3.
27. The cushion module of claim 19 or claim 20, wherein at least part of the exhaust conduit is incorporated into a nasal interface which includes a flushing conduit having at least one flushing conduit inlet within the cavity and at least one flushing
20 conduit outlet at or adjacent to at least one of the first or second exhaust conduit inlets.
28. The cushion module of claim 27 when dependent on claim 19, wherein each of the first and second prongs is a sealing prong configured to form a seal with a respective one of the user's nares.
- 25 29. The cushion module of claim 27 or 28, wherein the flushing conduit has a first flushing conduit outlet at or adjacent to the first exhaust conduit inlet and a second flushing conduit outlet at or adjacent to the second exhaust conduit inlet.
30. The cushion module of any one of claims 27 to 29, wherein the flushing conduit is configured to conduct gas from within the cavity to the one or respective one of the
30 user's nares.

31. The cushion module of any one of claims 27 to 30, wherein the flushing conduit is configured to accelerate gas from the at least one flushing conduit inlet towards the first flushing conduit outlet and second flushing conduit outlet and direct the accelerated gas into the respective nares of the user's nares.
- 5 32. The cushion module of any one of claims 27 to 31, wherein the first and second prongs are formed of an elastomeric material.
33. The cushion module of claim 32, wherein the elastomeric material is silicone.
34. The cushion module of any prior claim, wherein the cushion module outlet is in fluid communication with a filter such that gas exiting the cushion module through the
10 outlet will pass through the filter.
35. The cushion module of claim 34, wherein the filter is located externally of the cushion module.
36. The cushion module of claim 34 or 35, wherein the filter is attached to the cushion module.
- 15 37. The cushion module of any prior claim, wherein the cushion module outlet comprises a bias flow vent.
38. The cushion module of any prior claim, wherein the cushion module outlet is configured to connect to, or be in fluid communication with, an exhalation conduit.
39. The cushion module of claim 37 or 38, wherein the bias flow vent comprises a
20 plurality of apertures.
39. The cushion module of any prior claim, wherein the cushion module is configured to only receive the flow of pressurized gas through the inlet and to only exhaust gas through the outlet.
40. The cushion module of any one of claims 1 to 39, wherein the cushion module
25 further comprises a supplementary bias flow vent, the supplementary bias flow vent in fluid communication with the cavity.
41. The cushion module of claim 40, wherein the supplementary bias flow vent is configured to have a flow rate, in use, that is less than the flow rate through the cushion module outlet.

42. The cushion module of claim 40 or 41, wherein the supplementary bias flow vent is configured to have a resistance to flow, in use, that is higher than the resistance to flow through the cushion module outlet.

5 43. The cushion module of any one of claims 40 to 42, wherein the supplementary bias flow vent comprises at least one aperture, the at least one aperture having a cross-sectional area and the cross-sectional area of the at least one aperture being less than a cross-sectional area of the cushion module outlet.

44. The cushion module of any prior claim, wherein the housing comprises a plastics material and wherein the seal comprises an elastomeric material.

10 45. The cushion module of claim 44, wherein the plastics material is polycarbonate, and the elastomeric material is silicone.

46. The cushion module of any prior claim, wherein the seal and housing are connected by a mechanical connection.

15 47. The cushion module of any prior claim, wherein the housing comprises the cushion module inlet.

48. The cushion module of any prior claim, wherein the housing comprises the cushion module outlet.

49. The cushion module of any one of claims 1 to 47, Wherein the seal comprises the cushion module outlet.

20 50. The cushion module of any one of claims 1 to 46, Wherein the seal comprises the cushion module inlet.

52. The cushion module of any prior claim, wherein the seal is a full-face over-nose seal configured to form a seal on a bridge of the user in use.

25 53. The cushion module of any one of claims 1 to 51, wherein the seal is a full-face undernose seal configured not to form a seal on a bridge of the user in use.

54. The cushion module of any one of claims 1 to 51, wherein the seal is a total-face seal configured to form a seal circumscribing a mouth, nose, and eyes of the user in use.

55. The cushion module of any one of claims 1 to 51, wherein the seal is a helmet style seal configured to form a seal on a neck of the user in use.

56. A patient interface comprising the cushion module of any prior claim, wherein the patient interface further comprises a frame configured to be attached to the cushion
5 module, the frame comprising a plurality of headgear connectors configured to be connected to a headgear for retaining the patient interface on the users face in use.

57. The patient interface of claim 56, wherein the patient interface further comprises a conduit connector configured to be connected to the inlet of the cushion module, the conduit connector comprising an anti-asphyxiation valve and a pressure port and
10 further being configured to be removably attached to a respiratory therapy conduit.

58. The patient interface of claim 57, wherein the conduit connector is configured to be connected to a single-limb respiratory circuit.

59. The patient interface of claim 57, wherein the conduit connector is configured to be connected to a dual-limb respiratory circuit.

15 60. The patient interface of claim 59, wherein the conduit connector is configured to be connected to a dual-limb respiratory circuit via a wye-piece.

61. A patient interface for delivering positive pressure respiratory therapy to a user, the patient interface comprising:

20 (a) a cushion module defining a first cavity configured to be pressurized, the cushion module comprising an inlet configured to receive a flow of pressurized gas into the cavity, an opening configured to encompass a mouth and nares of the user to communicate the pressurized gas with the user, and an outlet configured to exhaust gas to externally of the cushion module,

25 (b) an exhaust conduit located within the first cavity, the exhaust conduit extending from the outlet of the cushion module to at least one exhaust conduit inlet, the at least one exhaust conduit inlet configured to be positioned within a first nare of a one or respective one of the user's nares,

wherein the exhaust conduit comprises at least one prong configured to form a seal with the first nare of the one or respective one of the user's nares, the

at least one exhaust conduit inlet being located at a free end of the at least one prong.

62. A patient interface for delivering positive pressure respiratory therapy to a user, the patient interface comprising:

- 5 (a) a cushion module defining a first cavity configured to be pressurized, the cushion module comprising an inlet configured to receive a flow of pressurized gas into the cavity, an opening configured to encompass a mouth and nares of the user to communicate pressurized gas with the user, and an outlet configured to exhaust gas to externally of the cushion module,
- 10 (b) an exhaust conduit located within the first cavity, the exhaust conduit extending from the outlet of the cushion module to a first exhaust conduit inlet and a second exhaust conduit inlet, the first exhaust conduit inlet configured to be positioned within a first nare of the user's nares and the second exhaust conduit inlet configured to be positioned within a second nare of the user's
- 15 nares.

63. A cushion module for a patient interface for delivering positive pressure respiratory therapy to a user, the cushion module comprising:

- (a) a cavity to communicate respiratory gas to a mouth and nares of the user, and
 - 20 (b) an exhaust conduit to communicate exhaled gas from the mouth and/or nares of the user or to communicate excess respiratory gas from within the cavity or both to externally of the cushion module,
- wherein the exhaust conduit is configured to accelerate respiratory gas as it flows from cavity into the exhaust conduit.

25 64. A non-invasive patient interface which is configured to seal about the mouth and nares of a patient, the patient interface comprising:

- (a) an outer wall defining an interior volume which comprises a first chamber having an oral opening to communicate gas with the mouth and a second chamber having a nasal opening to communicate gas with the nares; and

(b) a dividing wall that separates the first chamber from the second chamber;
and

5 (c) one or more flow directors which enable gas to flow into the second chamber from the first chamber and which flow directors are configured to direct the gas flow into the nares; and

wherein the outer wall is configured to extend over the nasal bridge of the patient.

65. A non-invasive patient interface which is configured to seal about the mouth and nares of a patient, the patient interface comprising:

10 (a) an outer wall defining an interior volume of the patient interface, the outer wall having a patient contacting surface comprising an oral opening which communicates gas with the mouth and a nasal opening which communicates gas with the nares; and

15 (b) a dividing wall that separates the interior volume into a first chamber having the oral opening and a second chamber having the nasal opening; and

(c) one or more flow directors extending from the dividing wall which enable gas to flow into the second chamber from the first chamber and which flow directors are configured to direct the gas flow into the nares; and

20 wherein the flow directors are spaced apart by a spacing element which maintains a spacing between the flow directors; and

wherein the patient contacting surface engages the dorsum nasi of the patient.

66. A non-invasive patient interface which is configured to seal about the mouth and nares of a patient, the patient interface comprising:

25 (a) an outer wall defining an interior volume of the patient interface, the outer wall having an oral opening which communicates gas with the mouth and a nasal opening which communicates gas with the nares;

(b) a dividing wall that separates the interior volume into a first chamber having the oral opening and a second chamber having the nasal opening; and

wherein the dividing wall includes one or more spaced apart flow directors which enable gas to flow into the second chamber from the first chamber and which flow directors are configured to direct the gas flow into the nares; and

wherein the outer wall engages the nasal bridge of the patient.

- 5 67. A patient interface for delivering positive pressure respiratory therapy to a user, the patient interface comprising:

a cushion module comprising a seal and a housing which together define a cavity configured to receive a flow of pressurized gas,

10 the seal configured to form a seal with a user's mouth and nares and comprising at least one opening to communicate the pressurized gas with the user's mouth and nares,

a cushion module inlet through which the pressurized gas is received into the cavity,

a cushion module outlet through which gas is exhausted from the cavity, and

15 a dividing wall insert configured to be inserted within the cavity of the cushion module and comprising a dividing wall and one or more flow directors,

wherein when the dividing wall insert is inserted within the cavity of the cushion module:

20 the dividing wall extends across the cavity and intersects the at least one seal opening to separate the cavity into a first chamber comprising an oral opening to communicate the pressurized gas with the user's mouth and a second chamber comprising a nasal opening to communicate the pressurized gas with the user's nares; and

25 the one or more flow directors enable gas to flow into the second chamber from the first chamber through the dividing wall.

68. The patient interface of claim 67, where the cushion module inlet delivers the pressurized gas into the first chamber.

69. The patient interface of claim 67 or 68, wherein the cushion module outlet exhausts gas from the second chamber.

70. The patient interface of any one of claims 67 to 69, wherein the dividing wall comprises an outer periphery which contacts the housing and/or the seal to sufficiently seal the first chamber from the second chamber around the outer periphery.

- 5 71. The patient interface of any one of claims 67 to 69, wherein the dividing wall comprises an outer periphery which is shaped to substantially match the internal geometry of the housing and/or seal to limit gas flowing between the first chamber and the second chamber around the outer periphery.

72. The patient interface of claim 71, wherein the outer periphery of the dividing wall
10 is configured to be spaced from the housing and/or seal to allow a predetermined amount of gas flow between the outer periphery and the housing and/or seal.

73. The patient interface of claim 70, wherein the outer periphery of the dividing wall is bonded, adhered, or mechanically attached to the housing and/or seal.

74. The patient interface of any one of claims 67 to 72, wherein the dividing wall
15 insert comprises a connector configured for removable connection to the housing to secure the dividing wall insert within the cavity of cushion module.

75. The patient interface of claim 74, wherein the connector of the dividing wall insert comprises a sleeve configured for connection with a sleeve of the housing.

76. The patient interface of any one of claims 67 to 75, wherein the one or more flow
20 directors comprise a first flow director comprising a first flow director inlet in fluid communication with the first chamber and a first flow director outlet in fluid communication with the second chamber.

77. The patient interface of claim 76, wherein the first flow director outlet is
configured to be positioned near to and/or directed towards a user's nare when the
25 patient interface is worn by a user.

78. The patient interface of claim 76, wherein the one or more flow directors further comprise a second flow director comprising a second flow director inlet in fluid communication with the first chamber and a second flow director outlet in fluid communication with the second chamber.

79. The patient interface of claim 78, wherein the first flow director outlet and the second flow director outlet are each configured to be positioned near to and/or directed towards a respective one of the user's nares when the patient interface is worn by a user.
- 5 80. The patient interface of claim 78 or 79, wherein the first flow director and the second flow director are shaped differently to one another in at least one way.
81. The patient interface of any one of claims 78 to 80, wherein the first flow director outlet and the second flow director outlet comprise cross-sectional areas that are unequal.
- 10 82. The patient interface of any one of claims 67 to 81, wherein the dividing wall comprises a rigid portion and an elastomeric portion.
83. The patient interface of claim 82 when dependent on claim 74, wherein the connector is attached to the rigid portion and the one or more flow directors extend from the elastomeric portion.
- 15 84. The patient interface of claim 82 or 83, wherein the elastomeric portion comprises a deformation region, the deformation region comprising a thin region located between a first thickened region and a second thickened region
85. The patient interface of claim 84, wherein the deformation region allows for controlled deformation of the dividing wall within the thin region in response to forces
- 20 applied to the dividing wall in use.
86. The patient interface of any one of claims 67 to 85, wherein the seal is a full-face over-nose seal configured to contact the nasal bridge of the user.
87. The patient interface of any one of claims 67 to 85, wherein the seal is a full face undernose seal configured not to contact the nasal bridge of the user.
- 25 88. A patient interface for delivering positive pressure respiratory therapy to a user, the patient interface comprising:
- a cushion module comprising a seal and a housing which together define a cavity configured to receive a flow of pressurized gas,

- the seal configured to form a seal with a user's mouth and nares and comprising a nasal opening to communicate the pressurized gas with the user's nares and an oral opening to communicate the pressurized gas with the users mouth,
- 5 a cushion module inlet through which the pressurized gas is received into the cavity,
- a cushion module outlet through which gas is exhausted from the cavity, and
- a dividing wall insert configured to be inserted within the cavity of the cushion module and comprising a dividing wall and one or more flow directors,
- 10 wherein when the dividing wall insert is inserted within the cavity of the cushion module:
- the dividing wall extends across the cavity and separates the cavity into a first chamber comprising the oral opening and a second chamber comprising the nasal opening; and
- 15 the one or more flow directors enable gas to flow into the second chamber from the first chamber through the dividing wall.
89. The patient interface of claim 88, where the cushion module inlet delivers the pressurized gas into the first chamber.
90. The patient interface of claim 88 or 89, wherein the cushion module outlet
- 20 exhausts gas from the second chamber.
91. The patient interface of any one of claims 88 to 90, wherein the dividing wall comprises an outer periphery which contacts the housing and/or the seal to sufficiently seal the first chamber from the second chamber around the outer periphery.
- 25 92. The patient interface of any one of claims 88 to 90, wherein the dividing wall comprises an outer periphery which is shaped to substantially match the internal geometry of the housing and/or seal to limit gas flowing between the first chamber and the second chamber around the outer periphery.

93. The patient interface of claim 92, wherein the outer periphery of the dividing wall is configured to be spaced from the housing and/or seal to allow a predetermined amount of gas flow between the outer periphery and the housing and/or seal.

5 94. The patient interface of claim 91, wherein the outer periphery of the dividing wall is bonded, adhered, or mechanically attached to the housing and/or seal.

95. The patient interface of any one of claims 88 to 93, wherein the dividing wall insert comprises a connector configured for removable connection to the housing to secure the dividing wall insert within the cavity of cushion module.

10 96. The patient interface of claim 95, wherein the connector of the dividing wall insert comprises a sleeve configured for connection with a sleeve of the housing.

97. The patient interface of any one of claims 88 to 96, wherein the one or more flow directors comprise a first flow director comprising a first flow director inlet in fluid communication with the first chamber and a first flow director outlet in fluid communication with the second chamber.

15 98. The patient interface of claim 97, wherein the first flow director outlet is configured to be positioned near to and/or directed towards a user's nare when the patient interface is worn by a user.

20 99. The patient interface of claim 97, wherein the one or more flow directors further comprise a second flow director comprising a second flow director inlet in fluid communication with the first chamber and a second flow director outlet in fluid communication with the second chamber.

25 100. The patient interface of claim 99, wherein the first flow director outlet and the second flow director outlet are each configured to be positioned near to and/or directed towards a respective one of the user's nares when the patient interface is worn by a user.

101. The patient interface of claim 99 or 100, wherein the first flow director and the second flow director are shaped differently to one another in at least one way.

30 102. The patient interface of any one of claims 99 to 101, wherein the first flow director outlet and the second flow director outlet comprise cross-sectional areas that are unequal.

103. The patient interface of any one of claims 88 to 102, wherein the dividing wall comprises a rigid portion and an elastomeric portion.

104. The patient interface of claim 103 when dependent on claim 95, wherein the connector is attached to the rigid portion and the one or more flow directors extend
5 from the elastomeric portion.

105. The patient interface of claim 103 or 104, wherein the elastomeric portion comprises a deformation region, the deformation region comprising a thin region located between a first thickened region and a second thickened region

106. The patient interface of claim 105, wherein the deformation region allows for
10 controlled deformation of the dividing wall within the thin region in response to forces applied to the dividing wall in use.

107. The patient interface of any one of claims 88 to 106, wherein the seal is a full-face over-nose seal configured to contact the nasal bridge of the user.

108. The patient interface of any one of claims 88 to 106, wherein the seal is a full
15 face undernose seal configured not to contact the nasal bridge of the user.

109. A patient interface for delivering positive pressure respiratory therapy to a user, the patient interface comprising:

- a cushion module comprising a seal and a housing which together define a cavity configured to receive a flow of pressurized gas,
- 20 the seal configured to form a seal with a user's mouth and nares and comprising a nasal opening to communicate the pressurized gas with the user's nares and an oral opening to communicate the pressurized gas with the users mouth,
- a cushion module inlet through which the pressurized gas is received into the
25 cavity,
- a cushion module outlet through which gas is exhausted from the cavity, and
- a dividing wall that separates the cavity into a first chamber having the oral opening and a second chamber having the nasal opening,

wherein the dividing wall includes a flow director aperture configured to receive a flow director insert, and

wherein the flow director insert comprises one or more flow directors which enable gas to flow into the second chamber from the first chamber when the flow director insert is received within the flow director aperture.

110. The patient interface of claim 109, where the cushion module inlet delivers the pressurized gas into the first chamber.

111. The patient interface of claim 109 or 110, wherein the cushion module outlet exhausts gas from the second chamber.

112. The patient interface of any one of claims 108 to 111, wherein the flow director aperture is configured to removably receive the flow director insert.

113. The patient interface of claim 112, wherein the flow director insert comprises a channel around a periphery of the flow director insert which is configured to receive a rim of the flow director aperture to removably attach the flow director insert to the dividing wall.

114. The patient interface of any one of claims 109 to 113, wherein the flow director insert comprises an elastomeric material.

115. The patient interface of any one of claims 109 to 114, wherein the one or more flow directors comprise a first flow director comprising a first flow director inlet in fluid communication with the first chamber and a first flow director outlet in fluid communication with the second chamber.

116. The patient interface of claim 115, wherein the first flow director outlet is configured to be positioned near to and/or directed towards a user's nare when the patient interface is worn by a user.

117. The patient interface of claim 115, wherein the one or more flow directors further comprise a second flow director comprising a second flow director inlet in fluid communication with the first chamber and a second flow director outlet in fluid communication with the second chamber.

118. The patient interface of claim 117, wherein the first flow director outlet and the second flow director outlet are each configured to be positioned near to and/or

directed towards a respective one of the user's nares when the patient interface is worn by a user.

119. The patient interface of claim 117 or 118, wherein the first flow director and the second flow director are shaped differently to one another in at least one way.

- 5 120. The patient interface of any one of claims 117 to 119, wherein the first flow director outlet and the second flow director outlet comprise cross-sectional areas that are unequal.

121. The patient interface of claim 120, wherein the ratio of the cross-sectional area of the first flow director outlet to the cross-sectional area of the second flow director outlet is in a range from 1:1.1 to 1:4
- 10

122. The patient interface of any one of claims 109 to 121, wherein the flow director insert comprises one or more flow director apertures extending through the flow director insert.

123. The patient interface of any one of claims 109 to 122, wherein the dividing wall comprises an elastomeric portion.
- 15

124. The patient interface of claim 123, wherein the elastomeric portion comprises a deformation region, the deformation region comprising a thin region located between a first thickened region and a second thickened region

125. The patient interface of claim 124, wherein the deformation region allows for controlled deformation of the dividing wall within the thin region in response to forces applied to the dividing wall in use.
- 20

126. The patient interface of any one of claims 109 to 125, wherein the seal is a full-face over-nose seal configured to contact the nasal bridge of the user.

127. The patient interface of any one of claims 109 to 125, wherein the seal is a full face undernose seal configured not to contact the nasal bridge of the user.
- 25