

SEAL AND PATIENT INTERFACE HAVING SAME

TECHNICAL FIELD

The disclosure relates to a patient interface for providing respiratory support to a patient. More particularly, though not exclusively, the disclosure relates to individual components of the patient interface, such as a seal and frame of the patient interface.

BACKGROUND

One method of treating respiratory distress and certain respiratory disorders (including Chronic Obstructive Pulmonary Disease or COPD and Obstructive Sleep Apnea or OSA) is the provision of Continuous Positive Airway Pressure (CPAP) therapy or other forms of Positive Airway Pressure (PAP) therapy to support a patient's respiratory system. Non-invasive respiratory pressurisation is commonly administered by delivering pressurised breathing gases to a patient's mouth and/or nose.

PAP therapy is usually provided by a breathing assistance system. Breathing assistance systems generally incorporate a source of pressurised gases (potentially a compressor, pressurised gas cylinder, or hospital pressurised air supply) and an interface configured to deliver the pressurised gases to a patient. Additionally, breathing assistance systems may incorporate a humidifier for heating and humidifying the breathing gases before delivery to the patient.

Other supported breathing systems include ventilators and respirators. These may adjust pressure between inspiratory and expiratory phases of the breathing cycle, and typically include a dual-limb breathing circuit.

Patient interfaces are configured to form a seal with the patient's face to facilitate adequate pressurisation of the patient's respiratory system. These interfaces are configured to seal with a patient's face, mouth, nose, and external nares, respectively.

The seal formed between the interface and patient's respiratory system allows the mask pressure to be regulated by reducing gas leaks and providing a controlled breathing gases exhaust.

Existing nasal pillow type masks usually seal on the inside of a patient's nares. This can cause discomfort due to sensitive tissue inside the nares.

Given naris size and shape can vary a lot between patients, in order to seal within a nare of a patient the seal must closely match the nares in size and shape. This results in needing a large range of seal sizes to cover a majority of the population. This can make it difficult to select the best seal size and requires more parts to be manufactured.

Another disadvantage of traditional nasal pillows is that they generally cannot be used by patients with deviated septums. Patients with deviated septums generally have different sized nares. Because traditional nasal pillows seal inside the nares and have the pillows are the same size, they generally do not adapt well to sealing two different nasal sizes.

SUMMARY

According to a first aspect a seal for a patient interface configured to provide respiratory therapy to a patient is provided. The seal comprises: a hollow body comprising a proximal end and a distal end, the proximal end comprising an inlet opening and the distal end comprising an outlet opening, wherein the hollow body is configured to provide, in use, a flow path for breathing gases from the inlet opening to the outlet opening; and a membrane extending outwardly from the hollow body, wherein the membrane comprises a sealing surface configured to seal against an exterior surface of or adjacent a single external nare of the patient.

The membrane may extend outwardly from the distal end of the hollow body.

At least a portion of the membrane may extend radially outwardly from the hollow body.

At least a portion of the membrane may be curved towards the proximal end of the hollow body.

The sealing surface may comprise a convex geometry.

At least a portion of the membrane may extend substantially perpendicularly from the hollow body.

The sealing surface of the membrane, in a resting configuration, may extend outwardly from a distal end of the hollow body at an angle equal to or more than 90 degrees in relation to a longitudinal axis or centreline defined between the inlet opening of the hollow body and the outlet opening of the hollow body.

The hollow body may comprise a tubular wall having a straight section at the distal end of the hollow body.

The sealing surface of the membrane, in a resting configuration, may extend outwardly from the distal end of the hollow body at an angle equal to or more than 90 degrees in relation to the straight section.

The membrane may be configured to rest against an exterior surface of the patient's external nare, so as to not extend into the patient's nare, in use.

The membrane may be cantilevered from the hollow body, in a cross-section plane comprising a longitudinal axis or centreline of the hollow body.

The membrane may comprise a quarter-rounded curvature, in the cross-section plane.

The membrane may taper in thickness towards an outermost end of the membrane.

The seal may further comprise a zone that has a curvature being larger than a curvature of the sealing surface.

The seal may further comprise a zone that has a curvature towards the proximal end of the hollow body.

The membrane and/or sealing surface may have a curvature gradually increasing towards the outermost end, in a cross-section plane comprising a longitudinal axis or centreline of the hollow body.

The sealing surface may comprise two or more different curvatures along its outward dimension, in a cross-section plane comprising a longitudinal axis or centreline of the hollow body.

The membrane may comprise: a first zone peripheral to the outlet opening, and a second zone peripheral to the first zone, wherein the second zone comprises a curvature greater than a curvature of the first zone in a cross-section plane comprising a longitudinal axis or centreline of the hollow body.

The second zone may comprise, in the cross-section plane, continuously varying curvature.

In the cross-section plane, a minimum curvature of the second zone may be greater than a maximum curvature of the first zone.

At least the first zone may be configured to seal with the single external nare of the patient.

At least part of the first zone may extend substantially perpendicularly to the hollow body.

The first zone may comprise the sealing surface.

The membrane may further comprise an outer zone formed between the second zone and the outermost end of the membrane.

In the cross-section plane, at least part of the outer zone may be substantially parallel with a section of the hollow body.

The outer zone may be configured to control in the deformation of the first zone or second zone when experiencing an external load, in use.

The second zone may comprise a greater curvature than the outer zone.

In the cross-section plane, a minimum curvature of the second zone may be greater than a maximum curvature of the outer zone.

The membrane may comprise at least two-fold rotational symmetry.

The membrane may comprise an elliptical surface in cross section.

One or more of the membrane, hollow body, or seal may comprise rotational symmetry.

One or more of the membrane, hollow body, or seal may comprise at least two-fold rotational symmetry.

The membrane and hollow body may be integrally formed.

The membrane may comprise a lower surface opposite the sealing surface and at least partially facing the proximal end of the hollow body.

The lower surface of the membrane may extend to an outermost end of the membrane.

The lower surface of the membrane may comprise a concave geometry.

The lower surface of the membrane and a wall of the hollow body may together define a cavity between the membrane and the hollow body.

The cavity may have a toroidal geometry.

The membrane may comprise a decoupling zone.

The decoupling zone may comprise an indentation in a surface of the membrane.

The indentation may be formed in a lower surface of the membrane.

The indentation may comprise a circular groove in the membrane.

At least a part of the membrane may surround the flow path for breathing gases.

The membrane may be a non-inflatable membrane.

The seal may further comprise a connecting portion configured to support the hollow body and to couple with a source of breathing gases.

The connecting portion may have a greater inner diameter than an outer diameter of the proximal end of the hollow body.

In a resting configuration, the proximal end of the hollow body may be at least partially recessed into the connecting portion.

The connecting portion and hollow body may be concentric.

The connecting portion may be configured to couple with a frame.

The seal may further comprise a suspension element connected to the proximal end of the hollow body.

The suspension element may comprise one or more folds configured to deform to allow the membrane and/or hollow body to pivot and/or translate with respect to the connecting portion, in use.

The suspension element may be peripheral to the proximal end of the hollow body.

The suspension element may comprise a first bend.

The suspension element may comprise a second bend.

The first bend may be arranged between the proximal end of the hollow body and the second bend.

The second bend may be arranged between the first bend and the connecting portion.

The suspension element may comprise an inflection between the first bend and the second bend.

The first bend may have a first radius, and the second bend may have a second radius, wherein the first radius is different from the second radius.

The first bend and second bend may be concentric.

The suspension element may comprise an S-curve in cross-section.

The suspension element may be connected to the connecting portion.

The connecting portion, hollow body and suspension element may be concentric.

The suspension element may be at least partially recessed into the connecting portion.

The suspension element may space the connecting portion and the hollow body apart from each other.

The suspension element may be configured to deform such that, in use, the hollow body is able to tilt relative to the connecting portion.

The suspension element may be configured to deform such that, in use, the hollow body is able to move longitudinally relative to the connecting portion.

The hollow body and the suspension element may be integrally formed.

The connecting portion and the suspension element may be integrally formed.

The suspension element may extend between the proximal end of the hollow body and a distal end of the connecting portion.

The sealing surface may comprise a convex geometry and further comprising a connecting portion connected to the hollow body at or near the proximal end of the hollow body via a suspension element.

The membrane may be not arranged in the flow path for breathing gases, in use.

The hollow body may form one or more tubular regions between the proximal end and distal end.

Each tubular region may extend longitudinally around a centreline of the hollow body.

At least one of the one or more tubular regions may comprise a tubular wall.

The tubular wall of at least one of the one or more tubular regions may have a wall profile being symmetrical about the centreline of the hollow body.

At least one of the one or more tubular regions may have a shape different from the shape of another of the one or more tubular regions.

Each tubular region may extend between two longitudinal boundaries of the hollow body.

Each longitudinal boundary may be formed in plane perpendicular to the centreline of the hollow body.

One of the one or more tubular regions may extend to a longitudinal boundary from which another of the one or more tubular regions extends.

A first tubular region of the one or more tubular regions may extend between a first longitudinal boundary arranged at the proximal end of the hollow body or at a first longitudinal distance from the proximal end of the hollow body, and a second longitudinal boundary arranged at a second longitudinal distance from the proximal end of the hollow body, wherein the second longitudinal distance is larger than the first longitudinal distance.

A second tubular region of the one or more tubular regions may extend between the second longitudinal boundary and a third longitudinal boundary arranged at the distal end or at a longitudinal distance from the distal end.

At least one of the longitudinal boundaries of each tubular region may be defined at a longitudinal position of the hollow body where there is a longitudinal change in curvature or thickness of the hollow body.

At least one of the one or more tubular regions may be bulbous.

At least one of the one or more tubular regions may be concave with reference to a centreline of the hollow body.

At least one of the one or more tubular regions may be partly oblate spherical.

One of the said at least one tubular region may form the first tubular region.

At least one of the one or more tubular regions may be cylindrical.

The second tubular region may be cylindrical.

Each tubular region, in a frontal plane dividing the hollow body into two symmetrical halves, may have a first wall profile and a second wall profile arranged either side of the centreline.

The first wall profile of at least one tubular region may have a shape symmetrical to that of the second wall profile in relation to the centreline.

The first wall profile may have the same length as that of the second wall profile.

An interior lateral dimension between the first wall profile and the second wall profile at the proximal end may be larger than an interior lateral dimension between the first wall profile and the second wall profile at the distal end.

The at least one tubular region may form a deformation region arranged to deform when subject to an external load.

The deformation region may allow the distal end of the hollow body to be compressed towards the proximal end of the hollow body, in use.

The deformation region may allow the membrane to pivot relative the inlet opening of the hollow body, in use.

An internal lateral dimension between the first wall profile and second wall profile of a tubular region, at a longitudinal position between the two longitudinal boundaries of said tubular region, may be larger than an internal dimension between the first wall profile and second profile of said region, at the distal end or proximal end of the hollow body.

The internal lateral dimension(s) may be defined in a plane perpendicular to a frontal plane dividing the hollow body into two symmetrical halves.

A largest internal lateral dimension between the first wall profile and second wall profile of a tubular region, at a longitudinal position between the two longitudinal boundaries of said tubular region, may be smaller than a largest interior lateral dimension of the connecting portion.

A largest internal lateral dimension between the first wall profile and second wall profile of a tubular region, at a longitudinal position between the two longitudinal boundaries of said tubular region, may be larger than a largest interior lateral dimension of the connecting portion.

A largest internal lateral dimension between the first wall profile and second wall profile of a tubular region, at a longitudinal position between the two longitudinal boundaries of said tubular region, may be smaller than a lateral dimension, such as outer diameter, of the membrane.

A largest internal lateral dimension between the first wall profile and second wall profile of a tubular region, may be formed longitudinally half-way or substantially half-way between the two longitudinal boundaries of said tubular region.

At least one of the first wall profile and second wall profile may comprise at least one of the following:

- a portion having a continuously varying curvature;

a portion concave with reference to a longitudinal axis or centreline of the hollow body;

a rounded or bulbous portion;

a bellows-shaped portion;

a parabolic portion;

a portion shaped like part of a substantially oblate sphere; and

an S-shaped portion.

In a resting configuration, the first wall profile of one of the one or more tubular regions may comprise a portion concave with reference to the longitudinal axis or centreline of the hollow body between the first longitudinal boundary and second longitudinal boundary, and/or the second wall profile of said associated tubular region may comprise a portion concave with reference to the longitudinal axis or centreline of the hollow body between the first longitudinal boundary and second longitudinal boundary.

In the resting configuration, the first wall profile of one of the one or more tubular regions may comprise a straight portion between the second longitudinal boundary and the distal end, and/or the second wall profile of said associated tubular region may comprise a straight portion between the first longitudinal boundary and the second longitudinal boundary.

In one example, a shape of the tubular region continuously gradually changes between the first longitudinal boundary and the second longitudinal boundary.

At least a portion of one of the first wall profile and second wall profile may be symmetrical about a transverse plane orthogonal to the frontal plane and the centreline of the hollow body.

The transverse plane may comprise a halfway point between the first longitudinal boundary and second longitudinal boundary.

At least one of the one or more tubular regions may have a tubular wall profile with a shape asymmetrical in relation to the centreline of the hollow body.

The first wall profile of one of the one or more tubular regions may have a shape asymmetrical to the shape of the second wall profile of said tubular region in relation to the centreline of the hollow body.

The first wall profile of one of the one or more tubular regions may have length that is different, such as longer, than that of the second wall profile of said tubular region.

The first wall profile may be symmetrical about a transverse plane orthogonal to the frontal plane and the centreline, and the second wall profile may be asymmetrical about the transverse plane.

The tubular region may have a shape conforming with the first wall profile spanning a first angular distance either side of the frontal plane around the centreline of the hollow body.

The first angular distance may be defined between a first angular transition point and a second angular transition point along the perimeter of the hollow body.

The first angular distance may be larger than 180° , such as 240° to 270° , such as 260° .

The tubular region may have a uniform shape across the first angular distance around the centreline .

The tubular region may have a shape conforming with the second wall profile in the frontal plane.

The tubular region may have a shape conforming with second wall profile only in the frontal plane.

The tubular region may further comprise a first transition region having a shape geometrically transitioning from the shape of the first wall profile at the first angular transition point to the shape of the second wall profile at the frontal plane, and a second transition region having a shape geometrically transitioning from the shape of the first wall profile at the second angular transition point to the shape of the second wall profile at the frontal plane.

The tubular region may have a shape conforming with the second wall profile spanning a second angular distance either side of the frontal plane around the centreline of the hollow body.

The second angular distance may be defined between a third angular transition point and a fourth angular transition point along the perimeter of the hollow body.

The second angular distance may be less than 110° , such as 100° .

The angular distance between the third angular transition point and the first angular transitions point may be identical to the angular distance between the between the fourth angular transition point and the second angular transition point.

The sum of the angular distance between the third angular transition point and the first angular transition point and the angular distance between the second angular transition point and fourth angular transition point may be 360° less the first angular distance less the second angular distance.

The first angular distance may be 80° to 120° , such as 100° , and the second angular distance may be 80° to 120° , such as 100° .

The first angular transition point and the second angular transition point may be located at a common radial distance from the centreline of the hollow body.

The tubular region may further comprise a third transition region having a shape geometrically transitioning from the shape of the first wall profile at the first angular transition point to the shape of the second wall profile at the third angular transition point, and a fourth transition region having a shape geometrically transitioning from the shape of the first wall profile at the second angular transition point to the shape of the second wall profile at the fourth angular transition point.

The first zone may be planar or substantially planar.

The first zone in the resting configuration may extend perpendicular or substantially perpendicular to the centreline of the at the distal end of the hollow body.

The first zone may extend from a first radial position to a second radial position in relation to the centreline of the hollow body, wherein the second radial position is larger than one or more of:

- an outermost radial position of the hollow body in the resting configuration or in-use configuration; and

- an outermost radial position of the connecting portion in the resting configuration or in-use configuration.

The first zone may extend from a first radial position to a second radial position in relation to the centreline of the hollow body, wherein the membrane has a first thickness at the first radial position, and a second thickness at the second radial position, wherein the first thickness is larger than the second thickness.

The thickness of the membrane may gradually reduce from the first thickness to the second thickness between the first radial position and the second radial position.

The second radial position may be located between 8.5mm to 12mm from the centreline of the hollow body, thereby forming an outer diameter of the first zone between 17mm and 24mm.

At least one tubular region of the hollow body may have a uniform thickness.

A thickness of the first wall profile may be different from a thickness of the second wall profile.

A distal end of the connecting portion is provided to the proximal end of the hollow body and a proximal end of the connecting portion may be configured to couple with a frame.

The connecting portion, in a frontal plane dividing the hollow body into two symmetrical halves, may comprise a first connecting portion wall profile and a second connecting portion wall profile arranged either side of a centreline of the connecting portion.

The connecting portion may be arranged to:

support the hollow body, and

resist self-deformation while enabling deformation of the hollow body, in use.

The first connecting portion wall profile may comprise at least one fold configured to deform to allow the membrane and/or hollow body to pivot and/or translate with respect to the connecting portion, in use.

The second connecting portion wall profile may be fold-less.

In a frontal plane dividing the hollow body into two symmetrical halves, the connecting portion may have a shape conforming with the first connecting portion wall profile spanning a first angular distance either side of the frontal plane around the centreline of the connecting portion.

The connecting portion may have a shape conforming with the second connecting portion profile spanning a second angular distance either side of the frontal plane around the centreline of the connecting portion.

The second angular distance may be defined between a third angular transition point and a fourth angular transition point along the perimeter of the connecting portion.

The connecting portion may further comprise a first transition region having a shape geometrically transitioning from the shape of the first connecting portion wall profile at the first angular transition point to the shape of the second connecting portion wall profile at the third angular transition point, and a second transition region having a shape geometrically transitioning from the shape of the first connecting portion wall profile at the second angular transition point to the shape of the second connection portion wall profile at the fourth angular transition point.

The thickness of the connecting portion may reduce from its proximal end towards its distal end.

In a frontal plane dividing the hollow body into two symmetrical halves, the membrane may be convex in relation to the proximal end of the hollow body.

The membrane may be a sealing membrane and the seal may further comprise a support membrane extending outwardly from the hollow body, wherein the support membrane is positioned between the sealing membrane and the distal end of the hollow body.

In a frontal plane dividing the hollow body into two symmetrical halves, the support membrane may be concave in relation to the proximal end of the hollow body.

The sealing membrane may have an undulating outer edge.

At least one of the one or more tubular regions may have a frustoconical shape in a resting configuration.

The first tubular region may be attached to a connecting portion at a proximal end thereof.

The first tubular region may form a proximal-most tubular region of the hollow body.

The connecting portion may be attached or integrally formed with the first tubular region.

The connecting portion may comprise a lip arranged exterior or interior of the first tubular region at its proximal end, wherein the lip is configured to attach to a corresponding attachment region of a frame of a patient interface.

Two or more of the tubular regions may have, or each of the tubular regions has, a frustoconical shape in the resting configuration.

At least one of the one or more frustoconical shaped tubular regions may be arranged to retain its frustoconical shape when deformed.

The frustoconical shape may be formed by a wall profile of the tubular region angled against a longitudinal axis or centreline of the hollow body.

At least one of or each of the frustoconically shaped tubular regions may have a first internal diameter at a proximal end thereof and a second internal diameter, different from the first internal diameter, at a distal end thereof.

The hollow body may comprise a first tubular region at the proximal end of the hollow body, a second tubular region, and a third tubular region, wherein the second tubular region is arranged between the first tubular region and third tubular region.

At least one of or each of the frustoconically shaped tubular regions has an internal diameter decreasing in a proximal to distal direction.

An internal diameter of the first tubular region, in proximal to distal direction, may range between a first internal diameter and a second internal diameter.

An internal diameter of the second tubular region may range between the second internal diameter and a third internal diameter.

An internal diameter of the third tubular region may range between the third internal diameter and a fourth internal diameter.

The first internal diameter of the first tubular region at the proximal end of the hollow body may be larger than the second internal diameter. The second internal diameter may be larger than the third internal diameter. The third internal diameter may be larger than the fourth internal diameter.

A longitudinal extension of the first tubular region may be larger than longitudinal extension of the second tubular region and a longitudinal extension of the third tubular region.

A longitudinal extension of the third tubular region may be larger than a longitudinal extension of the second tubular region.

A thickness of a wall profile of the second tubular region may be less than that of the first tubular region or the third tubular region.

A thickness of a wall profile of the first tubular region may transition from a first thickness at the first longitudinal boundary to a second thickness at the second longitudinal boundary.

A thickness of a wall profile of the second tubular region may transition from a second thickness at the second longitudinal boundary to a third thickness at the third longitudinal boundary.

A thickness of the wall profile of the respective tubular region may transition to a thickness of an adjacent tubular region at the interfaces thereof.

At least one tubular region may be configured to deform from the frustoconical shape to an inverted frustoconical shape upon deformation.

The third frustoconically shaped tubular region may be configured to be longitudinally displaced at least partly into the first frustoconically shaped tubular region upon deformation.

At least one frustoconically shaped tubular region may have an internal diameter increasing in proximal to distal direction.

The first tubular region, and second tubular region may have respective internal diameters increasing in proximal to distal direction, and the third frustoconically shaped tubular region may have an internal diameter decreasing in proximal to distal direction.

The first internal diameter of the first tubular region at the proximal end of the hollow body may be smaller than the second internal diameter. The second internal diameter may be smaller than the third internal diameter. The third internal diameter may be larger than the fourth internal diameter.

The first tubular region may be configured to recess into the third tubular region, and optionally contact the third tubular region, upon deformation.

A thickness of the second tubular region may be less than that of the first tubular region or third tubular region.

According to a second aspect a patient interface for providing respiratory therapy to a patient is provided. The patient interface comprises: a pair of seals, each seal comprising: a hollow body comprising a proximal end and a distal end, the proximal end comprising an inlet opening and the distal end comprising an outlet opening, wherein the hollow body is configured to provide, in use, a flow path for breathing gases from the inlet opening to the outlet opening; and a membrane extending outwardly from the hollow body, wherein the membrane comprises a sealing surface configured to seal with a single external nare of the patient. The patient interface further comprises a frame configured to receive a flow of breathing gas, the frame comprising a pair of seal attachment regions, wherein each seal attachment region comprises an aperture configured to direct breathing gases to the inlet opening of the seal; and a connecting portion at or near the proximal end of the hollow body configured to couple with the frame.

The connecting portion may be removably attachable to the seal attachment region.

The seal attachment region may comprise a male portion configured to connect to an interior wall of the connecting portion for supporting the seal.

The male portion may surround the aperture.

An inner surface of the connecting portion may be configured to removably attach to an outer surface of the male portion.

The male portion may comprise an exterior recess configured to removably attach to an interior lip of the connecting portion.

The pair of seals may be connected to each other.

The pair of seals may be separate from each other.

The frame may be more rigid than the pair of seals.

The frame may comprise an air inlet for connection with a gases delivery tube, and an interior chamber for receiving breathing gases from the gases delivery tube.

The frame may be configured to maintain its structural integrity with changes in a pressure of breathing gas during respiratory therapy, in use.

The sealing surfaces of each pair of seals may be angled towards each other.

In a resting configuration, the angle between the sealing surfaces of each pair of seals is between 100° and 146°.

The sealing surfaces of each pair of seals may be configured to conform to a sub-nasal angle of a patient, in use.

In a resting configuration, the angle between the sealing surfaces of each pair of seals may be smaller than a sub-nasal angle of a patient.

The angle between the sealing surfaces of each pair of seals in the resting configuration may be larger than the angle between the sealing surfaces of the pair of seals, in use.

In at least a resting configuration, the membranes of each of the pair of seals may be in contact at a central point between the pair of seals.

In at least a resting configuration, the membranes of each of the pair of seals may interfere and/or deform when assembled with the frame.

The sealing surface of each pair of seals may comprise: a first zone peripheral to the distal opening, and a second zone peripheral to the first zone, wherein, the second zone comprises a curvature greater than a curvature of the first zone in a cross-section plane comprising a longitudinal axis or centreline of the hollow body; wherein the membranes of each pair of seals contact each other at their respective second zones.

The patient interface may comprise a seal comprising any one or more of the associated features disclosed herein.

BRIEF DESCRIPTION OF THE DRAWINGS

A number of examples will now be described by way of example with reference to the accompanying drawings, in which:

Figure 1 illustrates a respiratory therapy system for supplying breathing gases to a patient;

Figure 2 illustrates a cross-sectional front view of a seal according to an example;

Figure 3 illustrates a cross-sectional front view of a seal according to one example;

Figure 4 illustrates a top view of a seal of Figure 3;

Figure 5 illustrates a perspective front view of the seal of Figure 3;

Figure 6 illustrates a perspective bottom view of the seal of Figure 3;

Figure 7 illustrates a cross-sectional front view of a seal according to one example;

Figure 8 illustrates a top view of a seal of Figure 7;

Figure 9 illustrates a perspective front view of the seal of Figure 7;

Figure 10 illustrates a front view of a frame according to one example;

Figure 11 illustrates a cross-sectional front view of the frame of Figure 10;

Figure 12 illustrates a top view of the frame of Figure 10;

Figure 13 illustrates a bottom view of the frame of Figure 10;

Figure 14 illustrates a perspective front view of the frame of Figure 10;

Figure 15 illustrates a perspective top view of the frame of Figure 10;

Figure 16 illustrates a perspective bottom view of the frame of Figure 10;

Figure 17 illustrates a perspective view of the frame of Figure 10;

Figure 18 illustrates a perspective front view of the frame of Figure 10 with one seal attached to one of the associated seal attachment regions;

Figure 19 illustrates a front view of a patient interface according to one example;

Figure 20 illustrates a cross-sectional front view of the patient interface of Figure 19;

Figure 21 illustrates a perspective top view of the patient interface of Figure 19;

Figure 22 illustrates a perspective front view of the patient interface of Figure 19;

Figure 23 illustrates a perspective rear view of the patient interface of Figure 19;

Figure 24 illustrates a perspective front view of the patient interface of Figure 19;

Figure 25 illustrates an exploded view of a frame and two seals according to one example;

Figure 26 illustrates a close-up view of the frame and one seal of Figure 25;

Figure 27A illustrates the seal of Figures 25 and 26 being attached to the frame;

Figure 27B illustrates a close-up view of Figure 27A showing a connecting portion of the seal and seal attachment region of the portion of the frame;

Figure 28 illustrates a cross-sectional front view of a seal according to one example, wherein a possible deformation of the membrane is shown in dashed contour lines;

Figure 29A illustrates a cross-sectional front view of a patient interface with two seals attached to a frame, wherein the seals are angled at a first seal face angle according to one example;

Figure 29B illustrates a cross-sectional front view of a patient interface with two seals attached to a frame, wherein the seals are angled at a second seal face angle according to one example;

Figure 29C illustrates a cross-sectional front view of a patient interface with two seals attached to a frame, wherein the seals are angled at a third seal face angle according to one example;

Figure 30 illustrates a bottom view of two seals disclosed herein, super positioned over an example nose of a patient;

Figure 31 illustrates a side view of a seal according to one example, which is sealing against an exterior surface of a patient's external nares;

Figure 32 illustrates a front view of patient's nose with the associated sub-nasal angle identified;

Figures 33A to 33D show various examples of alternative cross-sectional profiles of the membrane disclosed herein;

Figure 34 shows a cross sectional frontal plane view of a seal in the resting configuration according to an example;

Figure 35 shows a perspective front view of the seal of Figure 34;

Figure 36A shows the seal of Figures 34 and 35 in the cross sectional frontal plane in the resting configuration;

Figures 36B to 36F show the seal of Figure 36A when subject to various external loads;

Figure 37 shows the seal of Figures 34 to 36F overlaid with the seal of Figure 2.

Figure 38A shows the seal of Figures 34 and 35 in the cross sectional frontal plane in the resting configuration;

Figures 38B to 38C show the seal of Figure 38A in the cross sectional frontal plane, when subject to various longitudinal external loads;

Figures 39 to 41 show a patient interface comprising two of the seals of Figures 34 and 35 attached to a frame in the resting configuration;

Figure 42 shows a cross sectional frontal plane view of a seal in the resting configuration according to an example;

Figure 43 shows a perspective front view of the seal of Figure 42;

Figure 44 shows a cross sectional frontal plane view of a seal in the resting configuration according to another example;

Figure 45 shows a perspective front view of the seal of Figure 44;

Figure 46 shows a cross sectional frontal plane view of a seal in the resting configuration according to another example;

Figure 47 shows a perspective front view of the seal of Figure 46;

Figure 48A shows a cross sectional frontal plane view of a seal in the resting configuration according to another example;

Figure 48B shows a decoupling portion of the seal of Figure 48A;

Figure 49 shows a perspective front view of the seal of Figure 48A;

Figure 50 shows a cross sectional frontal plane view of the seal in the resting configuration according to an example;

Figure 51 shows a perspective side view of the seal of Figure 50;

Figure 52 shows a cross sectional frontal plane view of a seal in the resting configuration according to an example;

Figure 53 shows a side view of the seal of Figure 52;

Figure 54 shows a bottom perspective view of the seal of Figure 52;

Figure 55 shows a cross sectional top view of the seal of Figure 52;

Figure 56 shows a cross sectional perspective side view of the seal of Figure 52;

Figure 57 shows a front view of a patient interface comprising a pair of seals of Figure 52 attached to a frame in the resting configuration;

Figure 58 shows a cross sectional frontal plane view of the patient interface of Figure 57;

Figure 59 shows a cross sectional frontal plane view of a seal in the resting configuration according to an example;

Figures 60A and 60B show respective side views of the seal of Figure 59;

Figure 61 show a perspective top view of the seal of Figure 59;

Figure 62 shows a top view of the seal of Figure 59;

Figure 63 shows a cross sectional frontal plane view of a seal in the resting configuration according to an example;

Figures 64A and 64B show respective side views of the seal of Figure 63;

Figure 65 show a perspective top view of the seal of Figure 63;

Figure 66 shows a top view of the seal of Figure 63;

Figure 67 shows a cross sectional side view of a seal according to an example;

Figure 68 shows a perspective view of the seal of Figure 67;

Figure 69 shows a cross sectional side view of a seal according to another example;

Figure 70 shows a cross sectional side view of a seal according to yet another example;

Figure 71 shows a cross sectional side view of a seal according to a further example;

Figure 72a shows the tubular regions of the seal of Figure 71 in the resting configuration;

Figure 72b shows the three tubular regions of the seal of Figure 71 in the in-use, e.g. deformed, configuration after the seal is subject to an external load;

Figure 73 shows a cross sectional side view of a seal according to an example; and

Figure 74 shows a perspective view of the seal of Figure 73.

DETAILED DESCRIPTION

For the purpose of facilitate the discussion of any particular element shown in the accompanying drawings, a single reference numeral may refer to the same, a similar, or an equivalent element in two or more examples. For brevity, the detailed description of that element in relation to one of those examples is intended to apply equally in relation to any other examples comprising that element, except as described or otherwise clearly apparent from the context.

Unless the context clearly requires otherwise, throughout the description and claims the words "comprising," "including" and variants are to be construed in an inclusive sense rather than an exclusive sense. That is, such terms are to be construed in the sense of "including, but not limited to" rather than "consisting solely of."

Figure 1 illustrates an example respiratory therapy system 100 suitable for supplying breathing gases to a patient for positive airway pressure (PAP) therapy (e.g., continuous positive airway pressure (CPAP) therapy or non-invasive ventilation (NIV) therapy). The example respiratory therapy system 100 may include a gas source 101, a humidifier 102, a patient interface assembly 103 and a breathing gas circuit 104 that connects the humidifier 102 (or gas source 101) to the patient interface assembly 103. The gas source 101 can provide a supply of breathing gas to the humidifier 102. The gas source 101 may comprise a blower in which breathing gas, e.g., ambient air, is drawn into the gas source 102 through an inlet 104 in the gas source 101 and pressurised by an impeller 105. The rotational speed of the impeller 105 may be modulated to regulate the pressure of the breathing gas delivered to the patient. Breathing gas may include any single gas or multiple gases that are breathable by a patient of the respiratory therapy system 100.

The pressure and/or flow rate of breathing gas exiting the gas source 101 may be regulated by a controller 106. The controller 106 may modulate the rotational speed of the impeller 105 according to one or more predetermined algorithms. And in accordance with one or more user inputs that may be provided via a user input 107.

The gas source 101 represents an actively controlled flow generator. Other gas sources, such as a compressed air cylinder with suitable pressure or flow regulation, may alternatively, or additionally, be used to supply breathing gas.

The outlet of the gas source 101 may be coupled to a separate humidifier 102, as shown. The humidifier 102 may be configured to heat and/or humidify the breathing gas before delivery to the patient. In some examples, the humidifier 102 may be integrated with the gas source 101, e.g., within a single housing. The humidifier 102 may include a base 1021 and a humidifier chamber 1022. The humidifier chamber 1022 may be configured to hold humidification fluid 1023, such as

water. The humidifier chamber 1022, and may be disengaged, e.g., temporarily disengaged, from the humidifier base 1021 to allow it to be filled or replaced. The humidifier 102 receives gases from the gas source 101 through chamber inlet 1024. The humidifier base 1021 can include a heater such as a heater plate 1025. The humidifier chamber 1022 rests on the heater plate 1025 when engaged with the humidifier base 1021. The heater plate 1025 dissipates heat, e.g., heat generated by electrical resistance, to the humidifier chamber 1022. The humidifier chamber 1022 preferably has a heat conductive base to enable the heat generated by the heater plate to pass efficiently to the humidification fluid 1023. The humidifier 102 may include a controller 108. The controller 108 may control the humidifier 102, and in particular the supply of electrical energy to the heater plate 1025, to regulate any function of the humidifier 102, e.g., the temperature and humidity of the breathing gas supplied to the patient, according to one or more predetermined algorithms and/or in accordance with one or more user inputs that may be provided via a user input 1027. Alternatively, or additionally, the humidifier 102 may be controlled by the controller 106 of the gas source 101 and/or in accordance with one or more user inputs that may be provided via the user input 107 of the gas source 101.

The breathing gas can be supplied to the patient via a chamber outlet 1026 and breathing gas circuit 104. The breathing gas circuit 104 may be in the form of a conduit. The conduit may incorporate a heater (not shown), e.g., a heater wire or heated water jacket, to heat or warm the breathing gases during transportation to the patient interface assembly 103. The electrical energy supplied to the heater wire may be controlled by the controller 106 or controller 108. The controller 106 or controller 108 may receive feedback from one or more sensors incorporated in a control network throughout the respiratory therapy system to monitor properties of the breathing gas, such as, but not limited to, any one or more of pressure, flow, temperature, and/or humidity. For example, the respiratory therapy system 100 may include one or more of a gas flow rate sensor 1091 or a temperature sensor 1092 which are connected through a connector 110 and which can communicate with the controller 106 or controller 108. A heater plate temperature sensor 111 can communicate with the controller 106 or controller 108.

The patient interface assembly 103 couples the patient with the respiratory therapy system 100, such that gases, e.g., heated, and humidified gases from the humidifier 102, may be delivered to the patient's respiratory system. Breathing gases can be delivered to the patient at, or near, optimal temperature and humidity (e.g., warmed and fully saturated with water vapor at temperatures of between 27 and 37 °C) as the gases are delivered to the patient's nares and/or mouth. Heating and/or humidifying the breathing gas may help maintain patient comfort and compliance.

Emulating the conditions within healthy adult lungs (37 °C, 44 mg/L humidity) can help maintain healthy mucociliary function in patients with respiratory disorders affecting secretion. Further details of a patient interface suitable for use in the respiratory therapy system 100 are provided below.

In the illustrated respiratory therapy system 100, the breathing gas circuit 104 comprises a single limb circuit, i.e., an inspiratory conduit. Expiratory gases from the patient, and any excess breathing gas not inspired by the patient, may be vented to the ambient atmosphere at, or near, the patient interface assembly 103. And in the case of a nasal interface, the patient may expire through their mouth. In other examples, which may be used for NIV therapy for example, the breathing gas circuit may comprise a dual-limb circuit. A Y-piece may be provided between the inspiratory conduit, the patient interface assembly 103, and an expiratory conduit provided to convey expiratory gases and excess inspiratory gases from the Y-piece to a return inlet of the gas source. The expiratory conduit may include a heater, e.g., a heater wire or heated water jacket. Alternatively, or additionally, the expiratory conduit may be formed from a breathable material.

Examples of a patient interface assembly, and components thereof, will now be described in further detail.

In some examples the patient interface assembly comprises a nasal seal that seals against the outside of the patient's nares. The nasal seal may be designed to seal against an exterior surface associated with an external nare of the patient. The nasal seals disclosed herein may in some examples form part of a nasal pillows interface. The disclosed seal may seal against the exterior surface of or adjacent the patient's nare, via a sealing surface of the seal. This enables the disclosed seal to make a tight connection with the exterior surface of or adjacent the patient's external nare.

In some examples, the patient interface assembly comprises a nasal seal designed to exclusively seal against exterior surfaces associated of the patient's external nare. Such a seal may be designed not to make contact with the interior surfaces, such as the mucous membrane, of the patient's nare.

On the other hand, in other examples the patient interface may comprise a nasal seal arranged to extend into, and/or seal within the patient's naris, optionally in combination with sealing against an exterior surface of or adjacent the patient's external nare.

The seal disclosed herein allows for a highly versatile pillow design that can accommodate a large variety of patients. In some examples, the seal is designed to provide a 'one-size-fits-all' experience that delivers a dependable and repeatable setup process, even for a novice user. However, rather than intruding

into the nasal vestibule, the seal according to some examples may sit below the external naris to create a seal against the exterior surfaces around the external naris, when set up correctly.

The patient interface disclosed herein may comprise one or more seals, and a frame. The patient interface may be said to form a patient interface assembly when the respective components of the patient interface, such as the one or more seals, and frame, are assembled together. The patient interface assembly may optionally further comprise a headgear for connection to the frame. In some situations, the patient interface assembly may also comprise an inlet conduit such as the breathing gas circuit 104 connected to the frame.

According to an example, with reference to Figure 2, a seal 200 for a patient interface configured for use in a respiratory therapy system is shown. Figure 2 illustrates a cross-sectional side view of the seal 200. The seal 200 comprises a hollow body 201 having a proximal end 2010 and a distal end 2011. The proximal end 2010 comprises an inlet opening 2013. The distal end 2011 comprises an outlet opening 2014. The inlet opening 2013 is in fluid communication with the outlet opening 2014. A flow path 20152 is formed between the inlet opening 2013 and the outlet opening 2014. The flow path 20152 is configured to allow breathing gases to flow between the inlet opening 2013 and outlet opening 2014. In use, the inlet opening 2013 may be configured to receive a flow of breathing gas from a gas source, e.g., via one or more of a humidifier, inspiratory conduit, Y-piece, or frame of the patient interface. And the outlet opening 2014 may be configured to supply the flow of breathing gas directly to a naris of the patient.

According to one example, the hollow body 201 may comprise or form a stem. The stem may act as a support structure for the membrane. The hollow body 201 may be tubular or cylindrical.

The seal 200 further comprises a membrane 202. The membrane may extend outwardly, e.g., radially, from the hollow body 201, such as from the distal end 2011 of the hollow body 201. In this way, the membrane 202 may surround the outlet opening 2014 formed by the hollow body 201. A lateral dimension, such as a diameter, of the outlet opening 2014 may be smaller than a corresponding lateral dimension, such as a diameter, of the membrane 202. The membrane 202 may comprise a sealing surface 2021 configured to seal with an exterior surface of or adjacent a single external nare, i.e., naris, of the patient.

As will be further explained below, the hollow body 201 may be attached to a frame 300 of a patient interface via a connecting portion 203.

Depending on the patient specific anatomy, in some examples the sealing surface 2021 may for example seal against the septum and lower surfaces adjacent the external nares.

The membrane 202 comprising the sealing surface 2021 may have a flange or flap configuration. Additionally, or alternatively, the membrane 202 may be dome-shaped. Additionally, or alternatively, the membrane 202 may have a partially rounded shape, such as in three dimensions (3D) or in cross section.

The sealing surface 2021 may face away from the proximal end 2010 of the hollow body 201. The sealing surface 2021 may be provided immediately adjacent to and surrounding the outlet opening 2014 of the hollow body 201. The sealing surface 2021 may be an upper surface of the membrane 202, when the seal 200 is oriented as shown in Figure 2. An opposing lower surface 2025 of the membrane 202 may face towards the proximal end 2010 of the hollow body 201. The lower surface 2025 may extend to the outermost end 2029 of the membrane.

In some examples the membrane 202 is angularly arranged at or near 90 degrees (°) in relation to the hollow body 201, e.g., a wall 2016 or an axis of the hollow body 201.

In one example, the membrane extends near to or perpendicular from the hollow body.

According to one example, the lower surface 2025 of the membrane is arranged to not be exposed to the pressurised breathing gas, in use. In other words, the lower surface 2025 may be exposed to atmospheric pressure, in use. The membrane 202 may be arranged to seal against the exterior surface of the patient's external nare, without the assistance of the pressurized breathing gas forcing the membrane into engagement with said exterior surface.

The exterior surface of the external nare may include at least a portion of the nasal septal cartilage, septum, the lateral crus of the major alar cartilage, the medial crus of the major alar cartilage, and/or the skin tissue covering the alar fibrofatty tissue.

The general geometry of the membrane 202 may be referred herein as the membrane profile. The membrane profile relates to the geometry of the membrane 202 when observed in lateral cross-section. The associated plane of the lateral cross-section may comprise a longitudinal axis or centreline 2015 of the hollow body 201. In some examples, the hollow body 201 is rotationally symmetric around this longitudinal axis or centreline.

In one example, the membrane 202 extends outwardly from the distal end 2011 of the hollow body 201.

In one example, at least a portion of the membrane 202 may extend radially outwardly from the hollow body 201.

According to one example, at least a portion of the membrane 202 is curved or rounded towards the proximal end 2010 of the hollow body 201.

In some examples, the curvature of the membrane 202 gradually increases towards its outermost end 2029.

As shown with reference to Figures 7 to 9, the membrane 202 may include a first zone 2022. The first zone 2022 may immediately surround the outlet opening 2014 or be located in the immediate vicinity of the outlet opening 2014. In some examples, the first zone 2022 has a curvature that is substantially flat. From the first zone 2022, the curvature of the membrane 202 may gradually increase as it extends radially outwardly.

In some examples, the curvature may gradually increase such that an outer zone 2024 of the membrane 202 may extend substantially parallel or parallel with a wall 2016 or a general longitudinal direction of the hollow body 201. The outer zone 2024 may include the outermost end 2029. The outer zone 2024 may form a skirt portion.

In some examples, the sealing surface 2021 comprises a convex geometry. In use, the convex geometry may in some examples be configured to follow a general exterior contour of the exterior surfaces of the patient's face adjacent the naris opening, e.g., the upper lip region.

The convex geometry may facilitate the engagement and locating of the seal and also assists in sealing against a variety of nasal geometries. In some patients with large external nares the sealing surface may cover part of the nostril opening. Depending on the size of the external nare, for some patients at least a portion of the membrane will be located within the external nare opening, in use. However, due to the geometry of the membrane disclosed in some examples herein, the parts of the membrane located within external nare opening, in use, will not engage with the inside of the external nares. Rather, the membrane seals against nasal surfaces exterior of or adjacent the external nares.

In some examples, the sealing surface 2021 is convex in two orthogonal planes. The sealing surface 2021 may be convex in a first plane with a first radius of curvature and convex in a second plane orthogonal to the first plane along a second radius of curvature, whereby the sealing surface 2021 forms a toroidal surface. The first radius of curvature may be identical to the second radius of curvature. Alternatively, the first radius of curvature may be different from the second radius of curvature.

In some examples, the membrane 202 comprises a quarter-rounded curvature, in the cross-section plane.

According to some examples, the outermost end 2029 forms a free end. The free end of the outermost end 2029 is not physically attached or connected to any other component of the seal. This improves the overall deformability of the membrane 202, including the deformability of the outermost end 2029 in use.

In some examples, the membrane 202 is only physically connected to another entity at its innermost end 20222. The innermost end 20222 of the membrane 202 may be connected to the distal end 2011 of the hollow body 201. The innermost end 20222 of the membrane 202 may form part of the first zone 2022 immediately surrounding the outlet opening 2014 of the hollow body 201. In some examples, other than the innermost end 20222 of the membrane 202, no other parts of the membrane 202 are physically attached to any other part of the seal. This may make at least some parts of the membrane 202 more deformable in comparison to the innermost end of the membrane 202.

In one example, in a resting configuration the membrane, in an axial direction of the wall 2016, extends at least to between 40% and 80%, such as 45% to 75%, 50% to 70%, 55% to 65%, 60%, or about 60% of the length of the hollow body 201. The length of the hollow body 201 may be defined as the axial distance between the proximal end 2010 and the distal end 2011. The axial direction of the wall 2016 is indicated by a dashed line in Figure 3. As may be observed in Figure 3 the membrane extends to about 60% of the length of the hollow body. In other words, a height of the membrane equals 60% of the length of the hollow body in Figure 3. The axial distance between the innermost end 2022' of the membrane and the outermost end 2029 of the membrane is thus about 75% of the length of the hollow body 201.

The resting configuration, as referred to throughout the description, may be defined as the configuration where the associated structure, such as the membrane, is free from in-use external loads or forces. For example, the external loads or forces may be caused by physical contact with the patient, in use. As will follow, the resting configuration may be defined in either the disassembled state of the associated structure, or the assembled state of the associated structure. In the assembled state, there may be forces associated with the assembly acting on the structure, such as connection forces acting between the seal and frame when the seal is connected to the frame. In the resting configuration there are no external forces, i.e., forces external to the associated disassembled structure or assembled structure, acting thereupon.

Figures 33A to 33D show various examples of alternative cross-sectional profiles of the membrane 202.

The arrows 500, 502 in Figures 33A to 33D represent theoretical naris dimensions, such as naris width, of a population.

The dashed arrows 500 represent a theoretical smaller naris dimension, and the solid arrows 502 represent a theoretical larger naris dimension of a population. The ends of the arrows 500, 502 indicate approximately where a patient having an associated naris width would contact the various membrane 202 profiles.

Figure 33A shows a membrane 202 having a semi-circular cross-sectional profile. In this profile, the profile of the membrane 202 has a single radius of curvature.

Figure 33B shows a membrane 202 having a semi-elliptical cross-sectional profile. In this profile, the profile of the membrane 202 has a radius of curvature that gradually decreases in a laterally outwards direction.

Figure 33C shows a membrane 202 having a segmental cross-sectional profile. In this profile, the profile of the membrane 202 has a central region/ inner zone having a semi-circular or semi-elliptical profile and an outer zone 2024 that changes direction abruptly to extend in the axial direction.

Figure 33D shows a membrane 202 having a quarter rounded profile. In this profile, the profile of the membrane 202 has a central region/ inner zone having a substantially flat or planar profile that curves towards an outer zone 2024 that changes direction and curves towards the proximal end of the seal 200. This curved region of this membrane 202 profile may have a single radius of curvature.

The spacing between the arrows 500 and 502 indicates a difference in a depth of protrusion of the membrane 200 into a patient's nares, between a smaller naris patient and a larger naris patient.

For patients with larger external nares the semi-circular profile of Figure 33A would protrude further into the larger patient's nares than the other profiles of Figures 33B to 33D as it has a greater curvature. Thus, a flatter profile as per Figures 33B to 33D may be advantageous as it does not extend as far into the nares for patients with larger nares. This may be beneficial for comfort.

A more curved profile, as per the semi-circular profile of Fig. 33A, may help to enable the seal to fit a greater range of nose geometries. In particular, a more curved surface may help to align the seal with a patient's external nares if the patient has a small sub-nasal angle.

The outer zones 2024 provided by the segmental and the quarter rounded profiles may be beneficial in controlling how the membrane 202 deforms. If the membrane 202 is deformed in a lateral direction the hoop forces in the outer zone 2024 of the segmental and/or quarter-round profiles reduce the likelihood of the outermost end 2029 of the membrane 200 deforming into a sharp point. The outer zone 2024 may also help to keep an edge of the outermost end 2029 of the membrane 200 to face away from the patient, in use. In this way, any potentially uncomfortable contact between the edge of the outermost end 2029 and the patient may be reduced.

According to an example, the thickness of the membrane 202 tapers from a location near the outlet opening 2014, such as in the first zone 2022, to the outermost end 2029 of the membrane 202. The gradually decreasing thickness may provide the membrane with gradually increased flexibility along its lateral extension towards its outermost end 2029. As will be further explained below, this gradual decrease in thickness may allow the outer zones 2024 and/or outermost ends 2029 of the membranes 202 of a pair of seals 200, when assembled to a frame 300 of the patient interface, to conform with each other without negatively affecting the respective sealing surface 2021 functionality of the respective membrane 202. It may also enable the outer zone 2024 and/or outermost end 2029 of each membrane 202 to conform with an upper lip region of the patient.

In at least one example, for example with reference to Figures 2, 3, 7, 20, 25, 26, 27A, and 28 the membrane 202 tapers continuously in thickness towards an outermost end 2029 of the membrane 202.

In one example, the membrane 202 tapers continuously in thickness towards an outermost end 2029 of the membrane 202, except for in a decoupling zone 2027 as will be further explained below.

In some examples the thickness of the membrane 202 at its innermost end 20153 adjacent the hollow body is about 1 mm, such as 1.1 mm. The innermost end of the membrane may be located at or adjacent an axis 20151 parallel with the longitudinal axis or centreline of the hollow body, as shown with reference to Figures 2 and 3. The thickness of the membrane at its outermost end 2029 may be about 0.5 mm, such as 0.4 mm. The thickness may reduce gradually from the innermost end 20153 towards to the outermost end 2029 of the membrane.

Each seal 200 disclosed herein is designed to seal against one external nare of the patient. To seal against the exterior surfaces of both external nares of the patient, a patient interface 400, such as that shown with reference to Figures

19 to 24, may be provided with two such seals 200. The two seals 200 may be identical to each other. As each seal 200 comprises one membrane 202, the respective membrane 202 is configured to seal against the exterior surfaces of or adjacent one nare only.

In one example, each seal is sized to fit a majority of the human population. The convex geometry of the membrane, the circular shape, and the free end allow the seal to seal on or adjacent the external surfaces of the patient's external nares. This in turn enables a single seal size to fit more people.

In one example, the outer diameter of the membrane is between 20 mm to 25 mm, such as about 23 mm. Without wishing to be bound by theory, it is thought that this size would enable the seal to work with at least the 90th percentile naris length in the adult patient population. The 90th percentile of naris length in the target patient population could for example be derived from available anthropometric data.

In one example, an outer diameter of the membrane is about 300% of an outer diameter of the hollow body.

In cross-section, such as lateral cross-section, the outlet opening 2014 may have a flat profile. In some examples, the size of the outlet opening 2014 is designed to be larger than an expected average naris width of a patient population, e.g., an average among adult patients. In other examples, the size of the outlet opening 2014 may be designed to be smaller than an expected average naris length of a patient population.

In one example, the outlet opening has a diameter of about 6.5 mm to 7.5 mm, such as 7.2 mm. Without wishing to be bound by theory, it is thought that this size would enable the seal to work with at least the 45th percentile naris width in the adult patient population. This means that for 55% of the population the outlet opening 2014 will be smaller than the width of their nostrils.

In some examples the outlet opening 2014 is circular. The circular outlet opening 2014 may have a diameter larger than an average naris width but smaller than an average naris length of a patient population.

In some examples, the membrane 202 has a lateral dimension large enough for the associated sealing surface 2021 to sit against the exterior surface(s) of or adjacent the patient's naris.

In an example the seal 200, or at least the membrane 202 thereof, may be formed, at least in part, from a soft and deformable material, e.g., an elastomeric material such as liquid silicone rubber (LSR), to allow the membrane to deform to the various shapes or contours of the exterior surfaces of the patient's external nare. The ability to deform to the shape or contour of the

exterior surface of the external nare, for a range of various external naris geometries of patients, allows the membrane to provide a substantially air-tight seal against the external nare geometry of the patient.

In some examples the membrane 202, hollow body 201, and connecting portion 203 (as will be further explained below) are integrally formed and made of the same material, e.g. an elastomeric material such as LSR. For example, the respective seals shown with reference to Figures 2 to 66 may be integrally formed.

In one example, with reference to Figures 2 and 3, at least a first portion 20221 of the membrane 202 may extend substantially perpendicularly from the hollow body 201.

Figures 2 and 3 identify an associated membrane angle MA. The membrane angle MA is formed between an axis 20151 parallel with a longitudinal axis or centreline 2015 of the hollow body 201 and the membrane 202, such as the sealing surface 2021 of the membrane 202. In Figure 3, the axis parallel to a longitudinal axis or centreline 2015 of the hollow body, is shown as a dashed line along the wall 2016 of the hollow body 201. The first portion 20221 may form part of the first zone 2022. The first portion 20221 may form an innermost portion 20221 of the first zone 2022.

In some examples, at least the first portion 20221 of the membrane 202 may extend substantially perpendicularly from a wall 2016 of the hollow body 201. An axial direction of the wall 2016 is shown with dashed lines in Figure 3. The first portion 20221 may form a right angle or substantially right angle with the wall 2016 of the hollow body 201. The axial direction of the exterior wall 2016 may be an axis parallel to the longitudinal axis or centreline 2015 of the hollow body 201.

In some examples, the first portion 20221 forms an inner portion of the membrane. The inner portion 2021 of the membrane 202 is connected to, e.g., integral with, the hollow body 201.

In some examples, the term "substantially perpendicular" in terms of the membrane angle MA may be defined as including angles equal to, slightly below (e.g., up to 10° below) or slightly above (e.g., up to 10° above) 90°. For example, when the membrane extends more than 90° from a wall 2016 of the hollow body 201, this in turn will mean that the membrane 202 will extend towards the proximal end 2010 of the seal 200.

In some examples, the distal-most end of the seal 200 is defined by a distal-most end of the membrane 202.

The hollow body 201 may have a tubular shape. In some examples the tubular shape may be a cylinder having a circular cross-section. Alternatively, the tubular shape may have an elliptical cross-section.

According to one example, the sealing surface 2021 of the membrane 202, in a resting configuration, extends outwardly from the distal end 2011 of the hollow body 201 at an angle equal to or more than 90° in relation to an axis 20151 being parallel to a longitudinal axis or centreline 2015 defined between the inlet opening 2013 of the hollow body and the outlet opening 2014 of the hollow body. Such a longitudinal axis or centreline is illustrated as a dashed line in Figure 3.

The hollow body 201 may comprise a tubular wall having, in lateral cross-section, a straight or substantially straight portion at its distal end, as that shown with reference to Figures 2 to 9, 20, 25 to 31. According to one example, the sealing surface 2021 of the membrane 202, in a resting configuration, extends outwardly from the distal end 2011 of the hollow body 201 at an angle equal to or more than 90° in relation to the straight portion.

In use, the membrane 202 may be configured to engage an exterior surface(s) or face of the patient's external nare, so as to not extend into the patient's nare.

In some examples, the membrane 202 is cantilevered from the hollow body 201, in a cross-section plane comprising a longitudinal axis or centreline 2015 of the hollow body 201.

According to an example the membrane 202 comprises one or more zones, each having a different membrane profile, e.g., thickness and/or curvature. The respective membrane profiles may be designed to enable the various zones to behave in a desired way depending on the intended function or use of the respective zone, in use.

With reference to Figures 7 to 9, the membrane 202 may comprise a first zone 2022 peripheral to the outlet opening 2014. The first zone 2022 may comprise at least a portion of the sealing surface 2021. A second zone 2023 may be arranged outwardly from the first zone 2022. As perhaps best seen in Figure 7, the second zone 2023 may comprise a curvature greater than a curvature of the first zone 2022 in a cross-section plane comprising a longitudinal axis or centreline 2015 of the hollow body 201. The membrane 202 may be thinner in the second zone 2023 than in the first zone 2022.

In some examples, the sealing surface 2021 extends at least partly across the first zone 2022 and second zone 2023.

In one example, the second zone 2023 may comprise, in the cross-section plane, such as in lateral cross-section, a continuously varying curvature.

In some examples, a curvature of the second zone is greater than a curvature in the first zone 2022. As a higher curvature relates to a lower radius, this means that the associated radius of curvature of the second zone is smaller than the radius of curvature of the first zone. For example, the associated radius of curvature of the first zone may range between 10 mm to about 15 mm, whereas the radius of curvature of the second zone may range between 3 mm to 10 mm.

In some examples, a minimum curvature of the second zone 2023 is greater than a maximum curvature in the first zone 2022. This means that the associated maximum radius of curvature of the second zone 2023 is smaller than the minimum radius of curvature of the first zone 2022.

According to an example, at least the first zone 2022 is configured to seal with the single external nare of the patient.

In one example, at least part of the first zone 2022 may extend substantially perpendicularly to the hollow body 201.

In some examples, the second zone 2023 may be formed between the outermost end 2029 and the sealing surface 2021.

The second zone 2023 may comprise a surface having a curvature being larger than a curvature of the sealing surface 2021 and/or the first zone 2022. Here a larger or increased curvature is associated with a sharper bend. A sharper bend in turn may imply that the curve formed by the curvature is approximated by a smaller radius. Hence, a larger or increased curvature may be associated with a smaller radius approximating the curve of the curvature.

The second zone 2023 may curve outwardly and towards the proximal end 2010 of the hollow body 201. In this way the second zone 2023 may form a section of the dome-shaped membrane.

In one example, as perhaps best seen with reference to Figures 7 and 9, the sealing surface 2021 may have a curvature gradually increasing towards the outermost end 2029, in a cross-section plane comprising a longitudinal axis or centreline 2015 of the hollow body 201.

According to one example, the sealing surface 2021 comprises two or more different curvatures in a cross-section plane comprising a longitudinal axis or centreline 2015 of the hollow body 201. As may be observed from Figure 7, the curvature of the sealing surface 2021 is relatively flat adjacent to the outlet opening 2014 and more curved closer to the second zone 2023.

In one example, the curvature of the sealing surface 2021 increases in a laterally (radially) outwards direction away from the outlet opening 2014.

According to one example, the first zone 2022 comprises the sealing surface 2021. Alternatively, or additionally, the sealing surface 2021 may extend over more than one zone of the membrane, such as both the first zone 2022 and the second zone 2023. In some examples, the sealing surface 2021 may extend over the entire upper surface of the membrane 202.

The membrane 202 and the hollow body 201 may be integrally formed, e.g., injection moulded or overmoulded.

Alternatively, the membrane 202 and the hollow body 201 may be formed as separate parts. The membrane 202 may be attached to the distal end 2011 of the hollow body 201 by any suitable means, such as by using an adhesive.

The membrane 202 may further comprise an outer zone 2024 formed between the second zone 2023 and the at the outermost end 2029 of the membrane 202.

In some examples, the sealing surface 2021 extends at least partly across the first zone 2022, second zone 2023, and the outer zone 2024.

As perhaps best seen in Figure 7, in the cross-section plane, at least part of the outer zone 2024 may be substantially parallel with the hollow body 201. This configuration may allow the outer zone 2024 to be deflected inwardly, i.e., laterally towards the longitudinal axis or centreline 2015 of the hollow body. The inward deflection may be observed with reference to Figures 19, and 21 to 24 illustrating a patient interface 400 comprising two seals 200 attached to a frame 300. Here, the outer zones 2024 contact each other at a central location of the frame. The inwards deflection may also be the result of the respective seal contacting the patient, e.g., the patient's upper lip region, in use.

It has been found that a small displacement of the respective outer zones 2024, resulting from at least a portion of the outer zone 2024 of each seal contacting each other as shown in Figures 19 to 24, does not appear to affect sealing or patient comfort due to the high flexibility and softness of the outer zone 2024. By varying a centre-to-centre distance between the two apertures 3011, 3021 or attachment regions 301, 302 of the frame 300, and/or varying the lateral dimension, such as diameter, of the membrane 202, a predetermined overlap in the resting configuration may be enabled.

The overlap of the seals may allow the patient interface to accommodate for a wide range of nasal sizes. By arranging the seals 200 to overlap in the resting configuration, as will be described further below with reference to Figures 19 and 20, and 29A to 29C, this will allow for a greater range of the outlet

opening centre to outlet opening centre distance D. According to some examples, the overlap enables the minimum value of D to be less than if there was no overlap. This allows the patient interface to fit patients with a smaller spacing between the nares. To adequately seal against larger nasal sizes the membrane 202 needs to have a certain minimum size, such as minimum lateral size, or diameter. The overlap is caused by arranging the seals 200 onto the frame 300 such that the outlet opening 2014 centre to outlet opening 2014 centre distance D in the resting configuration is smaller than the minimum size of the membrane 202. When the seals of the patient interface 400 engage with a patient's nose having a relatively small sub-nasal angle the resulting outlet opening centre to outlet opening centre distance D may be reduced from that of the resting configuration, as shown with reference to Figure 29A. Upon engagement with a patient's nose having a relatively large sub-nasal angle the resulting outlet opening centre to outlet opening centre distance D may be increased from that of the resting configuration, as shown with reference to Figure 29C. The contact between the seals 200, present in the resting configuration, may reduce, or even cease to exist as the seals 200 engage the exterior surfaces of or adjacent the patient's external nares, in use. The contact between the seals 200 may be reduced or even ceases to exist as the outlet opening centre to outlet opening centre distance D moves further away from the outlet opening centre to outlet opening centre distance D in the resting configuration. The reduced or removed contact between the seals 200 may allow for reduced pressure on the septum of the patient, in particular for patients with larger nasal sizes.

The outer zone 2024 may be configured to control the deformation of the first zone 2022 or second zone 2023, in use.

In at least one example, the second zone 2023 comprises a greater curvature than that of the outer zone 2024.

In some examples, in the cross-section plane, a minimum curvature of the second zone 2023 is greater than a maximum curvature in the outer zone 2024.

As shown with reference to each of the accompanying drawings, the membrane 202 may comprise at least two-fold rotational symmetry. In this way the membrane may be rotationally symmetric about the longitudinal axis or centreline 2015 of the hollow body 201.

The membrane 202 may comprise an elliptical profile in a cross section orthogonal to the longitudinal axis or centreline 2015 of the hollow body 201. An elliptical profile may conform better with the elliptical shape of the external nare of the patient. The membrane 202 may have a first lateral dimension, such as

length, being larger than a second lateral dimension, such as width, perpendicular to the first lateral dimension.

In one example, the membrane has an elliptical shape when viewed from the top in its resting configuration.

In some examples, the membrane 202 may comprise a rotational symmetry. A rotational symmetry minimises the risk of the membrane 202 not being positioned correctly and may therefore allow for a more user/operator friendly solution.

In one example, as shown Figure 4, or Figure 8, the membrane has a circular shape when viewed from the top in its resting configuration.

In one example, at least due to the engagement between the outer zones 2024 of the pair of seals, the respective membrane and/or seal may deform to an ovoid shape, in use.

In some examples, the membrane 202 and the hollow body 201 both comprise at least two-fold rotational symmetry.

For example, the membrane 202 and hollow body 201 may comprise a rotational symmetry.

In some examples, the seal (in its entirety) may comprise at least two-fold rotational symmetry. The seal may comprise rotational symmetry.

According to one example, the membrane 202 may comprise a lower surface 2025 opposite the sealing surface 2021 and at least partially facing the proximal end 2010 of the hollow body 201.

The lower surface 2025 may comprise a concave geometry, as illustrated in Figure 7.

The lower surface 2025 and a wall 2016 of the hollow body 201 together define a cavity 2026 between the membrane 202 and the hollow body 201.

The cavity 2026 between the membrane 202 and the hollow body 201 may be at least partly toroidal.

According to an example, with reference to Figure 7 the seal 200 may comprise a decoupling zone 2027. The decoupling zone 2027 may allow the membrane 202 to move more freely in relation to the distal end 2011 of the hollow body 201, thereby minimising undesired translation of forces between the hollow body 201 and the membrane 202. The decoupling zone 2027 may act to reduce any pressure points created by the hollow body 201 pressing the membrane 202 against the exterior surfaces of or adjacent the external nare of the patient, in use.

The decoupling zone 2027 may be arranged at an interface between the membrane 202 and the hollow body 201.

The decoupling zone 2027 may allow for an amount of decoupling, optionally in combination with reducing the rigidity of the interface between the membrane 202 and the hollow body 201.

In at least one example, the decoupling zone 2027 may be replaced by a rigidity reducing zone 2027 acting to reduce the rigidity between the membrane 202 and the hollow body 201.

The decoupling zone 2027 may comprise an annular thinning of the membrane 202. The decoupling zone 2027 may be directly adjacent the outer wall of the hollow body 201.

The decoupling zone 2027 may comprise an indentation or recess formed in a surface, such as the lower surface 2025 of the membrane 202.

In some examples, the indentation comprises a circular groove in the membrane 202.

According to one example, the membrane 202 is configured to surround the distal end 2011 of the hollow body 201. The membrane 202 may be arranged to surround the flow path 20152 of the hollow body 201.

The membrane may be arranged such as not to obstruct the flow path 20152. Hence, the membrane may not be arranged in the flow path 20152 of the hollow body.

According to one example, the membrane 202 is a non-inflatable membrane. In one example, the lower surface 2025 of the membrane is not exposed to the breathing gas, in use.

In one example, the sealing surface 2021 is configured to seal with a single naris of the patient without assistance of pressure of the breathing gases.

In some examples, with reference to Figures 3, 5 to 7, and 9, the seal 200 further comprises a connecting portion 203 for connecting the seal to a frame 300 of a patient interface 400. The connecting portion 203 may also be referred to as a mount 203. The mount 203 may be configured to support the hollow body 201. Alternatively, or additionally the mount 203 may also be configured to be fluidly coupled with a source of breathing gases (such as the gas source 101 of Figure 1).

The connecting portion 203 may be arranged to connect or couple to a frame 300 of a patient interface 400, such as that shown with reference to Figures 10 to 17. The connecting portion 203 may further be attached to the proximal end 2010 of the hollow body 201, for example via a suspension element 204 further explained below.

Figure 18 shows the connecting portion 203 of a first seal 200 attached to the frame 300. Figure 19 shows the respective connecting portions 203 of first

and second seals 200 attached to the respective attachment regions 301, 302 of the frame 300.

The connecting portion 203 may have a tubular section.

According to some examples, at least a part of the connecting portion 203 has a greater interior lateral dimension, such as an inner diameter, than an outer lateral dimension, such as an outer diameter, of the proximal end 2010 of the hollow body 201. For example, as may be observed from Figure 7, the inner diameter of the connecting portion 203 at a proximal end 2031 (i.e., the end to be connected to the frame) is larger than the outer diameter of the hollow body 201.

For example, the inner diameter of the connecting portion 203 at the proximal end 2031 may be measured at a distal-most end of the connecting portion 203, and the outer diameter of the hollow body 201 may be measured at a proximal-most end of the hollow body 201.

In one example, the connecting portion 203 and hollow body 201 are concentric.

The seal 200 may further comprise a suspension element 204. The suspension element 204 may be arranged between the hollow body 201 and the connecting portion 203. A first end of the suspension element 204 may be attached to the proximal end 2010 of the hollow body 201. A second end of the suspension element 204 may be attached to the connecting portion 203.

The suspension element 204 may extend between the proximal end 2010 of the hollow body 201 and the connecting portion 203.

The suspension element 204, or at least a part thereof, may be arranged peripheral to the proximal end 2010 of the hollow body 201.

The suspension element 204 may comprise the first suspension element section 2041 attached to and/or extending from the proximal end 2010 of the hollow body 201.

The first suspension element section 2041 may form a first bend of the suspension element 204. The first bend 2041 may form a bend in relation to the axial direction of the hollow body 201. In some examples, the first bend 2041 forms a bend in relation to the axial direction of a wall 2016 of the hollow body 201. The first bend 2041 may form an outwardly extending bend in relation to the hollow body 201 and/or its associated flow path 20152. Such a configuration is shown in Figure 7, depicting the resting configuration of the seal 200. Here, the first bend 2041 of the suspension element 204 bends outwards from the wall 2016 of the hollow body 201. In some examples the first suspension element section 2041 has a thickness of about between 0.4 mm and 0.5 mm.

The suspension element 204 may further comprise a second suspension element section 2042 extending from the first bend 2041 towards the membrane 202, such as towards the lower surface 2025 thereof. In some examples the second suspension element section 2042 has a thickness of about 0.5 mm.

A third suspension element section 2043, forming a second bend 2043, may be formed between an end of the second suspension element section 2042 and a fourth suspension element section 2044. The second bend 2043 may form a bend so as to enable the fourth suspension element section 2044 to extend away from the membrane 202, and/or the lower surface 2025 thereof. In some examples the third suspension element section 2043 has a thickness of about 0.7 mm.

In some examples, the third suspension element section 2043 has a thickness gradually increasing from the second bend 2043 towards the connecting portion 203. The thickness may for example increase from about 0.7 mm at the second bend to about 1.1 mm at the connecting portion 203.

In some examples, the first suspension element section 2041 may provide a transition in thickness between the wall 2016 of the hollow body 201 and the second suspension element section 2042. The thickness of the first suspension element section 2041 may gradually increase from about 0.4 mm adjacent the wall 2016 of the hollow body 201 to about 0.5 mm adjacent the second suspension element section 2042.

In a resting configuration, the proximal end 2010 of the hollow body 201 may be at least partially recessed into or within at least a portion of a suspension element 204, such as the third suspension element section 2043 thereof, as will be further explained below. Such a configuration is shown in Figure 7.

In one example, in a resting configuration, the proximal end 2010 of the hollow body 201 may be at least partially recessed into the structure formed by the suspension element 204 and the connecting portion 203 being attached together or integrally formed. In another example, in a resting configuration, the proximal end 2010 of the hollow body 201 may be positioned between the proximal end 2031 of the connecting portion 203 and the third suspension element section 2043, in the axial direction of the hollow body 201.

The first bend 2041 may thus be said to be located between the proximal end 2010 of the hollow body and the second bend 2043.

The second bend 2043 may also be said to be located between the first bend 2041 and the connecting portion 203.

The first bend 2041 may be radially outwards of the hollow body 201 and the second bend 2043 may be radially outwards of the first bend 2041.

At an end opposite that of the second bend 2043, the fourth suspension element section 2044 may be attached to the connecting portion 203.

In some examples, the fourth suspension element section 2044 may form part of the connecting portion 203.

The first bend 2041 may, at least in the resting configuration, be associated with a bend of more than 90° in relation to the general axial direction of the hollow body at its proximal end 2010 thereof. The second bend 2043 may, at least in the resting configuration, be associated with a bend of more than 90° between the second suspension element 2042 and the fourth suspension element 2044.

In one example, the suspension element 204 comprises an inflection between the first bend 2041 and the second bend 2043. The inflection may be formed in the second suspension element section 2042. The inflection may be designed to control the deformation of the suspension element 204 as the sealing surface 2021 is pressed against the exterior surface of the patient's external nares, in use.

The suspension element 204, optionally taken in combination with the hollow body 201, may form a bellows-like structure.

According to one example, the suspension element 204 may comprise one or more bellows.

In one example, the suspension element comprises one or more folds configured to deform to allow the membrane and/or hollow body to pivot and/or translate with respect to the connecting portion, in use.

The suspension element 204 may act as a decoupler that helps to isolate the force experienced by the membrane 202 of the seal 200 and the frame 300. This minimizes the effect of frame movements on the seal membrane 202 and vice versa.

In at least one example, the suspension element 204 in cross-section, such as lateral cross-section, may comprise an S-curve. For example, the first bend 2041, the second suspension element section 2042, and the second bend 2043 may form an S-curve in cross-section.

In some examples, the S-curve is formed by a section in between the proximal end 2010 of the hollow body 201 and the suspension element 204.

In at least one example, the first bend 2041 may have a first radius and the second bend 2043 may have a second radius. The first radius may be different from the second radius. For example, the first bend 2041 may have a smaller radius than the second bend 2043. The bend with the smaller radius may encourage deformation to occur at the smaller radius bend first. This may assist

the hollow body to pivot or tilt side to side before moving laterally in a translational manner.

Alternatively, the first bend 2041 may have a larger radius than the second bend 2043.

In some examples, the first bend 2041 and the second bend 2043 may have equal radii.

According to one example, the first bend 2041 and second bend 2043 are concentric.

In one example, the connecting portion 203, hollow body 201, and suspension element 204 are concentric. In one example, the connecting portion 203, hollow body 201, suspension element 204, and membrane 202 are concentric.

In one example, the first and second bends are concentric with the hollow body 201 and/or the connecting portion 203.

According to one example, at least a portion of the suspension element 204, such as at least a portion of the first suspension element section 2041, second suspension element section 2042, third suspension element section 2043, and/or fourth suspension element section 2044 may extend into the cavity 2026 formed between the membrane 202 and a wall 2016 of the hollow body 201.

In one example, the second bend 2043 is recessed into the cavity 2026.

Additionally, or alternatively, the suspension element 204 may space the connecting portion 203 and the hollow body 201 apart from each other. For example, as may be observed from Figure 7, the connecting portion 203 is arranged radially outwardly from the hollow body 201.

The suspension element 204 may be configured to deform such that, in use, the hollow body 201 is able to tilt or pivot relative to the connecting portion 203. One way of enabling this is to provide the connecting portion 203 with relatively more material or higher density material, and/or the suspension element 204 with relatively less material, or less dense material. When the suspension element 204 is made of the same material as that of the connecting portion 203, the thickness of the suspension element 204 may be made smaller than that of the connecting portion 203. When the material of suspension element 204 and the connecting portion 203 comprise the same thickness, the suspension element 204 and the connecting portion 203 may be made of different material and/or have different material density. These configurations may reduce deformation of the hollow body 201. Additionally, or alternatively, these configurations allow the hollow body to be displaced or adjusted in the axial direction to suit the patient by means of the suspension element 204.

In one example, the suspension element 204 is configured to deform such that, in use, the hollow body 201 is able to move longitudinally relative to the connecting portion 203. For example, by providing the suspension element 204 with a thickness that is smaller than that of the connecting portion 203, the suspension element 204 will have a tendency to move or deform longitudinally towards and away from the connecting portion 203, which in turn enables the hollow body 201 to move longitudinally towards and away from the connecting portion 203, when an external load is applied to the membrane 202.

In at least one example, the suspension element 204 is formed into a separate component and arranged to attach to the hollow body 201 (for example attach to the proximal end 2010 of the hollow body 201), for example via a connector or any other conventional attachment solution (not shown). Similarly, the suspension element 204 may further be attached to the connecting portion 203 via a connector or other conventional attachment solution (not shown).

In one example, the suspension element 204 is integrally formed with the hollow body 201, e.g., by injection moulding or overmoulding.

In one example, the suspension element 204 is integrally formed with the connecting portion 203, e.g., by injection moulding or overmoulding.

In one example, the suspension element 204 is integrally formed with the hollow body 201 and the connecting portion 203, e.g., by injection moulding or overmoulding.

In one example, the suspension element 204 is integrally formed with the hollow body 201, the membrane 202, and the connecting portion 203, e.g., by injection moulding or overmoulding.

As mentioned previously, the membrane 202, hollow body 201, suspension element 204 and connecting portion 203 may be integrally formed, thus all forming part of the seal 200.

The suspension element 204 may be made from an elastomeric material such as liquid silicon rubber (LSR), which allows it to pivot in a multitude of directions relative to the frame 300.

The seal 200 may in some examples be said to form a nasal pillow.

The seal 200, or a pair of seals 200, may be arranged to be connected to a frame 300. When connected, the pair of seals 200 and frame 300 may form a patient interface 400, or part thereof.

With reference to Figures 10 to 17 an example of the frame 300 is shown. The frame 300 may comprise a pair of seal attachment regions 301, 302, wherein each seal attachment region 301, 302 comprises an aperture 3011, 3021 configured to direct breathing gases to the inlet opening 2013 of the seal 200.

The respective seal attachment regions 301, 302 may be configured to attach to the connecting portion 203 of a respective seal 200. When connected, the connecting portion 203 of the seal 200 and the seal attachment region 301, 302 form a substantially air-tight connection, allowing breathing gases to be directed from the frame 300 via the respective apertures 3011, 3021 to the flow path 20152 and to the outlet opening 2014 of each seal 200.

The respective connecting portion 203 may be removably attachable to the associated seal attachment region 301, 302. The seals 200 may be removably attached for cleaning and replacement, for example.

The respective seal attachment regions 301, 302 may comprise a male portion 3012, 3022 configured to engage with an inner surface of the wall 2032 of the connecting portion 203 and for supporting and/or retaining the seal. The respective male portion 3012, 3022 may protrude from a main body 303 of the frame 300. Each male portion 3012, 3022 may surround the respective aperture 3011, 3021.

According to one example, the inner surface or wall 2032 of the respective connecting portion 203 is configured to removably attach to an outer surface 3013, 3023 of the respective male portions 3012, 3022. For example, in a friction fit or an interference fit.

The outer surface 3013, 3023 of the respective male portions 3012, 3022 may comprise an exterior recess 3014, 3024. The inner surface of the wall 2032 of the respective connecting portion 203 may comprise a lip 2033. The exterior recess 3014, 3024 may have a corresponding shape to that of the interior lip 2033 so that the interior lip 2033 can engage with the exterior recess 3014, 3024.

The exterior recess 3014, 3024 may extend laterally inward from the respective outer surface 3013, 3023 of the male portions 3012, 3022. In some examples, the exterior recess 3014, 3024 extends laterally inwards from the outer surface 3014, 3024 of the male portions 302 with reference to a longitudinal axis or centreline 2015 of the respective aperture 3011, 3021 formed through the respective male portion 301, 302. On the other hand, the interior lip 2033 may protrude laterally away, such as inwardly, from the inner surface of the wall 2032 of the respective connecting portion 203. The interior lip 2033 may protrude towards a longitudinal axis or centreline 2015 of the flow path 20152.

In one example, the exterior recess 3014, 3024 of the respective male portions 3012, 3022 is configured to removably attach to the respective interior lip 2033 of the connecting portion 203.

According to one example, the frame 300 is rigid or semi-rigid. The frame 300 may be formed, e.g., injection moulded, from a polymer material such

as polycarbonate. The frame 300 and/or polymer material of the frame 300 may be relatively rigid compared to the seal 200 and/or elastomeric material of the seal 200.

The frame 300 may be configured to maintain its structural integrity with changes in a pressure of breathing gas during respiratory therapy, in use. The frame 300 may also be configured to maintain its structural integrity under external loads applied by contact with a patient's face and/or tension within the headgear, in use. A rigid or semi-rigid construction of the frame 300 may allow for this.

The frame 300 may further comprise a gas inlet 304 for connection with a gases delivery tube (not shown in Figures 10 to 17), such as breathing gas circuit 104 shown in Figure 1. The breathing gas may be received by an interior chamber 305 defined, at least in part, by the frame 300. The interior chamber 305 is in fluid connection with the respective apertures 3011, 3021. The interior chamber 305 provides a gas flow path between the gas inlet 304 and the respective frame apertures 3011, 3021. In this way, breathing gas entering through the gas inlet 304 may flow into the interior chamber 305 and exit the frame 300 via the respective apertures 3011, 3021. When the frame 300 is connected to a seal 200 as disclosed herein, this allows breathing gas entering through the gas inlet 304 to flow via the interior chamber 305 through the respective frame apertures 3011, 3021, into the inlet opening 2013 of the seal 200, and out through the outlet opening 2014 of the seal 200.

In one example, the gas inlet 304 may be arranged in a bottom portion of the main body 303.

According to one example, the gas inlet 304 is arranged in the bottom portion of the main body 303 symmetrically in relation to the mid plane M. A longitudinal axis or centreline of the gas inlet 304 may be formed in the mid plane M. In other examples, a gas inlet may be provided on one or each side of the frame 300.

The respective apertures 3011, 3021 may be arranged at an upper portion of the main body 303.

The respective apertures may be arranged at a superior end of the main body 303.

In one example, the apertures 3011, 3021 are arranged at a side of the frame, being oppositely arranged to a side in which the gas inlet 304 is formed.

The frame 300 may further comprise one or more vent holes 306. The vent holes extend from an exterior surface of the main body 303 to an interior surface. The vent holes 306 thus form holes that extend from the exterior surface

of the main body to the interior chamber 305. The vent holes 306 may extend through an exterior wall of the main body 303. In some examples, the vent holes 306 may be tapered.

In one example, the vent holes 306 are arranged in one or more rows, e.g., two rows, along the exterior wall of the main body 303. The vent holes 306 in one row may be offset from the vent holes 306 in another row, e.g., an adjacent row. In some examples, two or more rows of vent holes 306 may be provided in a chevron pattern.

The vent holes 306 may be symmetrically arranged with reference to a mid-plane, such as a medial plane M, of the frame 300. The medial plane M is shown as a dashed line in Figure 10, illustrating a front view of the frame 300.

In one example, two rows of vent holes 306 are provided.

The vent holes 306 may be oriented such that breathing gas from the interior chamber 305 may be allowed to exit at an angle perpendicular or substantially perpendicular to a longitudinal axis or centreline LA1, LA2 of the respective frame aperture 3011, 3021.

In some examples the vent holes 306 are provided in an exterior wall of the frame 300 that is designed to face away from the patient, in use. In other words, the vent holes 306 may be arranged at a side of the frame 300, being distal to the patient, in use.

In the in-use configuration, i.e., when the seals 200 attached to the frame 300 are sealing against the exterior surface of the respective external nares of the patient, the vent holes 306 allow breathing gas and/or expiratory gases to exit the interior chamber 305 in an outward direction from the patient.

The frame 300 may further comprise two connectors 307, 308 for attaching the frame 300 to headgear. The respective connectors 307, 308 may be arranged at either side of the frame 300. For example, the respective connector 307, 308 may be arranged at a lateral outmost end of the frame 300. According to one example, the first connector 307 is arranged at a lateral outmost end of the frame at one side of the frame whereas the second connector 308 is arranged at an opposite lateral outermost end of the frame 300, i.e., at the other side of the frame 300. Such a configuration is shown with reference to Figures 10 to 17.

A first connector 307 may be provided at one side of the mid plane, and the second connector 308 may be provided at the other side of the mid plane.

Additionally, or alternatively the respective connector 307, 308 may be arranged at a location of the frame 300 being proximal the patient, in use. The respective connector 307, 308 may thus be arranged at a location of the frame 300 being opposite that in which the vent holes 306 are arranged.

The connectors 307, 308 may form attachment points for straps on the frame 300. The connectors 307, 308 may be configured so as to allow the seal 200 a high degree of freedom for movement. When connected to a headgear the frame and headgear act to stabilise the patient interface, while the seals are allowed a high degree of freedom for movement.

In one example, the frame 300 further comprises an upper lip cushion (not shown). The upper lip cushion may for example be made of silicone. The upper lip cushion may be arranged at the proximal side of the frame 300 where it comes in contact with the upper lip region of the patient, in use. The upper lip cushion may provide for enhanced patient comfort.

In one example, the respective connector 307, 308 is provided flush with the upper lip cushion provided at a proximal side of the frame 300. The headgear strap may be integrated with the upper lip cushion.

While two strap connectors 307, 308 are disclosed herein, it may also be envisaged that more than two strap connectors may be used. By keeping the number of strap connectors to a minimum, the overall bulkiness of the patient interface may be reduced. Further, using only two strap connectors not only simplifies the assembly of the patient interface, but it also makes the connection of the patient interface to the patient easier.

In one example, the frame 300 comprises a single strap connector. The single strap connector may extend across the lateral dimension, such as width, of the frame.

In one example, the single strap connector extends across the full lateral dimension, such as width, of the frame.

In one example, the single strap connector is indirectly connected to the frame by a yoke or other clip arrangement.

In at least one example, such as that shown with reference to Figures 2 to 9, each seal 200 is provided as a separate entity or unit for attachment to the associated seal attachment region 301, 302.

According to one example, each seal 200 is configured to seal against the exterior surface of one external nares of the patient. Given each patient has two external nares, it follows that two seals 200 are required to adequately seal against the external nares of the patient. The two seals 200 form a pair of seals.

In some examples, the pair of seals are provided separate from each other.

In other examples, two seals 200 (one for each external nares) may be connected to each other. The two connected seals 200 may form a seal unit. Connecting two seals, i.e., having a pair of seals, together for subsequent

attachment to the respective seal attachment region 301, 302 may allow for an easier connection between the frame 300 and the seals 200.

According to one example, the respective connecting portions 203 of two seals 200 may be connected together via a connecting portion (not shown). The connecting portion may act to hold the seals 200 together while spacing the respective connecting portions 203 apart at a distance corresponding to that between the respective apertures 3011, 3021 of the frame 300.

In some examples, the pair of seals 200 are moulded together with a silicone base that can be attached onto the frame 300. By providing the two seals 300 in one unit, it is possible to reduce the risk of the individual seals from becoming unintentionally detached from the frame 300, in use.

Figures 19 and 20 illustrate an outlet opening centre to outlet opening centre (OOC-to-OOC) distance D between the two attached seals 200 in the resting configuration. The OOC-to-OOC distance D may be defined between a first location where the longitudinal axis or centreline LA1 of the first aperture 3011 intersects the corresponding seal face axis SFA1, and a second location where the longitudinal axis or centreline LA2 of the second aperture 3021 intersects the corresponding seal face axis SFA2.

The respective seal face axis SFA1, SFA2 may be defined as an axis being perpendicular to the associated longitudinal axis or centreline LA1, LA2 of the respective aperture.

Alternatively, the respective seal face axis may be defined as an axis being perpendicular to the associated longitudinal axis or centreline of the hollow body.

In at least one example, the OOC-to-OOC distance D may be selected between about 15 mm to about 20 mm, such as about 16 mm to about 19 mm, such as about 17 mm to 18 mm, such as 17 mm.

In one example, the frame 300 and seals 200 are designed such that the associated OOC-to-OOC distance D corresponds to the 50th percentile of distance between external nares, in the target population. The associated 50th percentile of distance between external nares may be derived from available anthropometric data.

In one example, as shown with reference to Figures 19 to 24, a patient interface 400 is provided. The patient interface 400 comprises the frame 300 and a pair of seals 200 as previously disclosed herein. Each seal 200 comprises a hollow body 201 comprising a proximal end 2010 and a distal end 2011, the proximal end 2010 comprising an inlet opening 2013 and the distal end 2011 comprising an outlet opening 2014. The hollow body 201 is configured to provide,

in use, a flow path 20152 for breathing gases from the inlet opening 2013 to the outlet opening 2014. Each seal 200 further comprises a membrane 202 extending outwardly from the hollow body 201. The membrane 202 comprises a sealing surface 2021 configured to seal with a single external naris of the patient. Each seal 200 further comprises a connecting portion 203. The connecting portion 203 is arranged at or near the proximal end 2010 of the hollow body 201 and configured to couple with the frame 300. The frame 300 comprises a pair of seal attachment regions 301, 302, wherein each seal attachment region 301, 302 comprises an aperture 3011, 3021 configured to direct breathing gases to the inlet opening 2013 of the seal 200.

As may be observed from Figures 10, 19 and 20, the apertures 3011, 3021 of the frame 300 are oriented at an angle towards each other.

In some examples, the associated aperture face angle θ_F may be selected from a range of 100° to 180° , such as about 106° .

With reference to Figure 10, it may be observed that the longitudinal axis or centreline LA1 of the first aperture 3011 is not parallel to the longitudinal axis or centreline LA2 of the second aperture 3021. With reference to the general outward flow direction of each aperture 3011, 3021, the longitudinal axis or centreline LA1 of the first aperture 3011 may be tilted towards the longitudinal axis or centreline LA2 of the second aperture 3021, and vice versa.

When the frame apertures 3011, 3021 are angled towards each other, this too will affect the angle between the seals 200 when mounted or attached to the frame 300. Hence, in a resting configuration, when seals 200 are attached to the apertures 3011, 3021 that are angled towards each other, the seals 200 will also be angled towards each other. This also impacts the angular relationship between the respective sealing surfaces of the seals 200. Hence, in a resting configuration, when one seal 200 is attached to each of the two apertures 3011, 3021 being angled towards each other, the respective sealing surfaces 2021 of the two seals 200 will also be angled towards each other.

In one example, the sealing surfaces 2021 of each pair of seals 200 are configured to be angled towards each other in the resting configuration.

Each aperture 3011, 3021 has an associated aperture face axis AFA1, AFA2 that is substantially perpendicular or perpendicular to the associated longitudinal axis or centreline LA1, LA2.

The respective aperture face axis AFA1, AFA2 may be parallel to a face of the associated aperture 3011, 3012.

The angle formed between the aperture face axis AFA1 of the first aperture 3011 and the aperture face axis AFA2 of the second aperture 3021, is hereinafter denoted the aperture face angle θ_F .

With reference to Figures 19, and 20 each illustrating the patient interface 400 in a resting configuration, it may be observed that the respective seal face axis SFA1, SFA2 form a seal face angle θ_S . The seal face axis may be defined as an axis being substantially parallel or parallel to the face of the outlet opening 2014 of the respective seal 200.

In one example, the aperture face angle θ_F between the aperture face axes AFA1 and AFA2 is constant, in use, given the inherent rigidity of the frame. However, the corresponding seal face angle θ_S is able to attain a range of angles, as shown with reference to Figures 29A to 29C further explained below.

In the resting configuration, as that shown in Figures 19 and 20, it may be observed that the aperture face angle θ_F is equal to the seal face angle θ_S . This follows from the seal face axis SFA1 being substantially parallel or parallel to the aperture face axis AFA1 and the seal face axis SFA2 being substantially parallel or parallel to the aperture face axis AFA2 in the resting configuration.

Figure 28 illustrates a cross-sectional front view of a seal 200 according to one example. Here, the dashed contour lines of the membrane 202 indicate the membrane's 202 ability to deform. As shown in Figure 28 the deformation may result in the outermost end 2029 of the membrane 202 being moved towards, such as inwardly towards, the hollow body 201. The actual deformation of the membrane 202 is dependent on the magnitude of the external load and/or the location of the membrane 202 being subject to the external load. For example, the dashed contour line deformation shown on the left-hand side or right-hand side of Figure 28 may be the result of the outer zones of the two seals 200 engaging with each other, as shown with reference to Figures 19, and 21 to 24.

Turning now to Figures 29A, 29B, and 29C, these Figures show the patient interface 400 in three different in-use configurations. From these Figures it may be observed that the seal face angle θ_S may differ from the aperture face angle θ_F . In fact, the seal 200 is configured to allow the seal face angle θ_S to differ from the aperture face angle θ_F . This allows the patient interface 400 disclosed herein to act as a one-size-fits-all or one-size-fits-most patient interface. In fact, the patient interface 400 according to some examples has been designed to allow the seal face angle θ_S to attain the value selected from a range of sub-nasal angles found in an example human population.

As an example, without wishing to be bound by theory, it is thought the front/coronal plane sub-nasal angle may generally vary between about 132° and

180°. An average sub-nasal angle is thought to be around 160° to 161°. The design of the seal 200, e.g., both in flexibility of the seals 200, and the configuration of the deforming suspension elements 204, etc, ensures that each membrane 202 may align itself with the external nares regardless of the variation of the assumed sub-nasal angle.

In one example, the expected range of sub-nasal angles of the population is used as an input to determine the seal face angle.

In one example, the seal face angle θ_s and/or aperture face angle θ_F are designed to be smaller than the expected minimum sub-nasal angle of the population.

In one example, the seal face angle θ_s and/or aperture face angle θ_F are designed to be smaller than the expected average sub-nasal angle. This may encourage engagement between the laterally outer parts of the membranes 202 and the patient's nasal alae to occur before the membranes 202 engage with the septum of the patient. The initial engagement with the alae in turn may cause the membranes 202 to pivot outwardly until the laterally inwards part of the membranes 202 contact the septum. This may help to reduce pressure on the septum of the patient.

Turning to Figure 29A, the seals 200 are deformed such that the seal face angle θ_s corresponds to a sub-nasal angle that is less than the seal surface angle θ_s , when the seals 200 are in a neutral position or resting configuration (as shown in Figure 29B). For example, the seals 200 may be deformed to have seal surface angle θ_s of 110° or approximately 110°. This is achieved by extending or stretching one side of the suspension element 204 while retracting or buckling the other side of the suspension element 204. The seal face angle θ_s of Figure 29A may be observed to be smaller than the aperture face angle θ_F .

Turning to Figure 29B, the seal face angle θ_s corresponds to a sub-nasal angle that is substantially equal to the seal face angle θ_s when the seals 200 are in a neutral position or resting configuration. For example, the seals 200 may have a seal face angle θ_s of 145° or approximately 145°, when in a neutral position or resting configuration, and be engaged with a patient's nose that has a sub-nasal angle of 145 degrees or approximately 145 degrees°. It may be observed that there is little or no extension or retraction of the suspension element 204. The seal face angle θ_s of Figure 29B is substantially equal or equal to the aperture face angle θ_F , which means that it is close to or identical to its value in the resting configuration. It may be said that the in-use configuration shown in Figure 29B may relate to a neutral position or resting configuration of the patient interface 400.

In some examples the aperture face angle θ_F may be about 106° .

Turning now to Figure 29C, the seals 200 are deformed such that the seal face angle θ_S corresponds to a sub-nasal angle of approximately 180° or 180° . Hence the seal face angle θ_S is approximately 180° or 180° in this example. This is achieved by extending or stretching one side of the suspension element 204 while retracting or buckling the other side of the suspension element 204. It may be observed that the side of the suspension element 204 that was extending and stretching in Figure 29A is in Figure 29C retracting or buckling, and the side of the suspension element 204 that was retracting or buckling in Figure 29A is in Figure 29C extending and stretching. The seal face angle θ_S of Figure 29C may be observed to be larger than the aperture face angle θ_F .

As may be observed from Figures 29A, 29B, and 29C, the outlet opening centre to outlet opening centre distance D (identified as D1, D2, D3) varies with varying seal face angles θ_S . A smaller seal face angle θ_S will result in a smaller outlet opening centre to outlet opening centre distance D. A larger seal face angle θ_S will result in a larger outlet opening centre to outlet opening centre distance D. With reference to Figures 29A to 29C, it may be observed that the outlet opening centre to outlet opening centre distance D1 of Figure 29A is smaller than the outlet opening centre to outlet opening centre distance D2 of Figure 29B and the outlet opening centre to outlet opening centre distance D3 of Figure 29C. Further, the outlet opening centre to outlet opening centre distance D2 of Figure 29B is smaller than the outlet opening centre to outlet opening centre distance D3 of Figure 29C. In other words, $D1 < D2 < D3$.

According to one example, in a resting configuration, the angle, i.e., seal face angle θ_S , between the sealing surfaces 2021 of each pair of seals 200 is between 100° and 146° , such as 105° and 140° , 110° and 135° , 115° and 130° , 120° and 125° , 127° and 140° , 132° and 135° , such as 106° .

In one example, sealing surfaces 2021 of each pair of seals 200 are configured to conform to a sub-nasal angle of a patient, in use.

In some examples, the suspension element 204 is configured to deform upon experiencing an external load to allow the sealing surfaces 2021 of each pair of seals 200 to conform to a sub-nasal angle of a patient, in use.

In one example, in a resting configuration, the angle, such as seal face angle θ_S , between the sealing surfaces 2021 of each pair of seals 200 is smaller than a sub-nasal angle of a particular or average patient.

In one example, the angle, such as seal face angle θ_S , between the sealing surfaces 2021 of each pair of seals 200 in the resting configuration is larger than

the angle, such as seal face angle θ_s , between the sealing surfaces 2021 of the pair of seals 200, in use.

In one example, the angle, such as seal face angle θ_s , between the sealing surfaces 2021 of each pair of seals 200 in the resting configuration is smaller than the angle, such as seal face angle θ_s , between the sealing surfaces 2021 of the pair of seals 200, in use.

According to one example, in at least a resting configuration, the membranes 202 of each pair of seals 200 are in contact at a central point between the pair of seals 200. Such a configuration is shown with reference to Figures 19 to 24.

According to an example, at least in a resting configuration, each seal 200 contacts the other in the second zone(s) 2023 of the respective membranes 202.

According to one example, with reference to Figures 25 to 27B, a method of assembling the patient interface 400 disclosed herein is provided. The method comprises attaching a first seal 200 to a first seal attachment region 301 of a frame 300, attaching a second seal 200 to a second seal attachment region 302 of the frame 300, wherein attaching the first seal 200 and second seal 200 to the respective seal attachment region includes forcing a lip 2033, such as an interior lip, of a connecting portion 203 of the seal 200 into a corresponding recess 3014, such as an exterior recess, of the seal attachment region 301, 302.

In one example, the connecting portion 203 and the respective seal attachment region 301, 302 are configured to provide a snap-fit type connection that provides and audible or tactile/haptic feedback to the user to allow them to know the seal is properly assembled to the frame.

Once the seal 200 is attached to the frame 300, in a resting configuration, at least the first bend 2041, the second suspension element section 2042, and the second bend 2043 are spaced from the seal attachment region 301, 302. This configuration is shown in Figure 27B, where the double ended arrows indicate the vertical and horizontal spacing between the seal attachment region and the associated sections of the suspension element 204.

Now turning to Figure 30 a bottom view of two seals 200 sealing against the external nares of a patient is shown. From Figure 30 it may be observed that the external nares have mostly an elliptical shape that angle towards each other near the top, i.e., at the tip of the nose of the patient. The indicated external nare angle x formed between the two major axis of the elliptical external nares may for example vary between 29° and 141° . Since the membranes 202 according to some examples may be circular and its diameter selected to be larger than the largest major axis length of the naris for the target population group, the large variations in the external

nare angles do not affect sealing performance as its all encompassed by the (for example circular) membranes 202. Further, due to the softness and the flexibility of the membranes 202, they have the capacity to deform (such as roll) and conform to the shape and orientation of the external nare and its ovality upon contact with the patient's nose and upper lip. After deforming into an elliptical shape, the major and minor axes of the membranes 202 (denoted by 'Y' and 'X', respectively) are observed to be longer than the major and minor axes of the external naris, respectively.

Hence, while the membranes 200 in a resting configuration may have a circular shape or outline, in the in-use configuration, the circular membrane 202 may be deformed into an elliptical shape, as shown with reference to Figure 30. The respective cross-sections of the seal in the in-use configurations are shown at the right-hand side of Figure 30. For example, the bottom right cross-section of Figure 30 illustrates a cross-section taken along the illustrated z-axis, where the outermost end 2029 of the membranes 202 including the outer zone 2024 is deformed inwards. On the other hand, the illustrated cross-section taken along the y-axis shows outermost end 2029 and associated outer zone 2024 of the membranes 202 deform outwards. These varying deformations over each membrane 202 may result in the in-use elliptical shape.

In alternative examples, the membranes 202 may deform asymmetrically dependent on where they contact the patient's nose and the nasal geometry of the patient. Hoop forces within the outer zones 2024 may cause deformation to be transferred, within or across the membranes 202, from a location where a load is applied to another location within the membrane 202.

Turning now to Figure 31, a side view of the seal in the in-use configuration is shown. Here, the seal 200 is sealing against an exterior surface of the patient's external nare. The nasolabial angle indicated by X of Figure 31 represents another measurement in anthropometric data that shows considerable variability. While positioning the frame 300 (not shown) could aid in aligning with this angle, as a component of the patient interface design, the aim is to construct a headgear that secures the frame firmly on the face. Hence, relying solely on frame movement to achieve the necessary flexibility may not be feasible. Instead, the movement of the suspension element 204 disclosed herein facilitates the seal 200 to conform to the nasolabial and/or sub-nasal angle.

Figure 32 identifies the sub-nasal angle SNA of an example patient nose. The sub-nasal angle may be defined in the front/coronal plane as the angle formed between a first line 601 touching the patient's subnasale 602 and the left ala (or wing) 603 of the patient's nose, and a second line 604 touching the patient's subnasale 602 and the right ala (or wing) 605 of the patient's nose. The location at which the first

line 601 touches the left ala may be at the base of the left ala 603 and the location at which the second line 604 touches the right ala 605 may be at the base of the right ala 605. The respective alar base may be defined at the junction between the respective ala 603, 605 and the upper lip area of the patient. The right ala 605 and left ala 603 of the patient's nose may be referred to as the right wing and left wing of the patient's external nares, respectively. The sub-nasal angle may be formed in the front/coronal plane between the first line 601 and second line 604 at the side of the respective lines facing the patient's nose. In some examples, the sub-nasal angle relates to the smallest angle formed between the first line 601 and second line 604 in the front/coronal plane.

While the components, such as seal(s), frame(s), patient interface(s) disclosed herein are designed to be used as components for providing respiratory therapy to a patient, it should also be appreciated that they may be used as components for providing respiratory support to a user that is not undergoing therapy.

The seals 200 disclosed herein may be provided in a nasal patient interface 400 that is sealing only against the external nares of the patient. Such a nasal patient interface is shown with reference to Figure 19 to 24.

However, it should be appreciated that the seals disclosed herein could also be used in a compact full-face mask type patient interface. A compact full face mask patient interface may be a non-invasive interface. A compact full-face mask may be configured to seal with, or about, the patient's nares and mouth, e.g., without engaging an upper part of the patient's nasal region such as one or more of the nasion, rhinion, or supratip.

The compact full face mask patient interface may include a cushion. The cushion may be formed from an elastomeric material such as liquid silicone rubber (LSR). The cushion may be injection moulded. The cushion 1622 may comprise a pair of seals 200 as disclosed herein, that are configured to seal against the exterior surfaces of or adjacent the external nares of the patient. The pair of seals enable the flow of respiratory gases to be supplied to the patient's external nares.

In some examples, the cushion and/or the compact full-face patient interface may be configured to be entirely inferior to the patient's orbital region when properly fitted to the patient, in use.

The cushion may further comprise an oral sealing portion configured to seal around the patient's mouth. The oral sealing portion may be configured to seal against at least the oral region of the patient's head. The oral sealing portion may be further configured to seal with one or more of the buccal region and the mental region, for example.

The oral sealing portion may include a single oral aperture through which the flow of respiratory gases may be supplied to the patient's mouth.

The compact full-face patient interface may include a frame. The frame may be configured to support the cushion. The frame may be relatively rigid compared to the cushion. The frame may be formed from a polymer material, e.g., a thermoplastic polymer material, such as polycarbonate. In other examples, the frame may be formed from an elastomeric material.

The cushion, including the seals, may be permanently attached with, e.g., overmoulded to, the frame. The cushion may mechanically interlock with the frame. The cushion may be chemically bonded with the frame.

The frame may include an inlet configured to receive the flow of respiratory gases from a gases source, e.g., via an inspiratory conduit. The inlet may be integrally formed as part of the frame. In some examples, the inlet may have an axis which is substantially vertical or inclined at an acute angle with respect to the vertical direction. The inlet may be configured to connect with a connector, e.g., a swivel connector, of an inspiratory conduit. In some examples, the compact full-face patient interface may include an inlet tube, e.g., permanently, or removably attached to the inlet. The inlet tube may be configured to connect with the connector of the inspiratory conduit. In some examples, the inlet may include an elbow, e.g., a swivel elbow. The frame and the cushion, in combination, may define a chamber. In use, the flow of respiratory gases may be received by the chamber through the inlet, then supplied to the patient through nasal apertures of the frame connected to the pair of seals and through the oral aperture connected to the oral sealing portion.

In an example, the hollow body 201 forms one or more tubular regions 201a, 201b. Each of the tubular regions 201a, 201b may be formed at least partially between the proximal end 2010 and distal end 2011.

In one example, the proximal end 2010 is the end of the hollow body arranged closest to the source of pressurized air, in use. The distal end 2011 may refer to an end of the hollow body arranged closest to the patient, in use.

One tubular region 201a may be arranged at or adjacent to the proximal end 2010. A further tubular region 201b may be arranged at or adjacent to the distal end 2011.

Figures 34 and 35 show an example of the seal in the resting configuration wherein the hollow body 201 may comprise two tubular regions 201a, 201b.

The one or more tubular regions 201a, 201b may be removably or permanently attached to each other. Alternatively, the one or more tubular regions 201a, 201b may be integrally formed.

Each tubular region may extend longitudinally around a longitudinal axis or centreline 2015 of the hollow body.

In an example, with reference to Figure 34, at least one of the one or more tubular regions 201a, 201b comprises or is formed by a tubular wall 2016. The tubular wall may define the flow path 20152 of the hollow body 201. In some examples, the tubular wall is arranged to prevent the tubular region 201a from buckling inwards. In some examples, the tubular wall has a constant thickness. Alternatively, the tubular wall may have a varying thickness.

As shown with reference to Figures 34, 36A, 37, 38A, 42, 44, 46, and 48A, in the resting configuration, each tubular region 201a, 201b may comprise a wall profile being symmetrical about the longitudinal axis or centreline 2015 of the hollow body 201.

In one example, at least one of the one or more tubular regions 201a, 201b, has a shape different from the shape of another of the one or more tubular regions 201b, 201a. For example, in Figure 34, the second tubular region 201b has a shape with a generally cylindrical inner wall profile about the longitudinal axis or centreline 2015, whereas the first tubular region 201a has a shape with a non-cylindrical inner wall profile about the longitudinal axis or centreline 2015.

In one example, each tubular region extends between two longitudinal boundaries 20111, 20112, 20113 of the hollow body 201. Figure 42 illustrates a seal where the first tubular region 201a extends between a first longitudinal boundary 20111, and a second longitudinal boundary 20112. Further, the second tubular region 201b extends between the second longitudinal boundary 20112, and a third longitudinal boundary 20113. The respective longitudinal boundaries are shown as dashed lines in Figure 42.

In one example, each longitudinal boundary is formed in a plane that is at least substantially perpendicular to the longitudinal axis or centreline 2015 of the hollow body, such as when the hollow body is in its resting configuration. Such a configuration is shown in Figure 42, where the dashed lines indicating the respective longitudinal boundaries are perpendicular to the longitudinal axis or centreline 2015.

In one example, each tubular region 201a, 201b extends between two longitudinal boundaries of the hollow body, wherein one of the one or more tubular regions extends to a longitudinal boundary from which another of the one or more tubular regions extends. Hence, one longitudinal boundary may be shared by two adjacent tubular regions. With reference to Figure 42, a second longitudinal boundary 20112 of Figure 42 acts as a shared longitudinal boundary between the first tubular region 201a, and the second tubular region 201b.

In an example, a first tubular region 201a of the one or more tubular regions extends between a first longitudinal boundary 20111 and a second longitudinal boundary 20112. The first longitudinal boundary 20111 may be arranged at the proximal end of the hollow body. Alternatively, the first longitudinal boundary 20111 is arranged at a first longitudinal distance L1 from the proximal end of the hollow body. The second longitudinal boundary 20112 is arranged at a second longitudinal distance L2 from the proximal end of the hollow body. The second longitudinal distance L2 is larger than the first longitudinal distance L1. When the first longitudinal distance L1 is zero the first longitudinal boundary 20111 is arranged at the proximal end 2010.

With reference to Figure 42, a first longitudinal boundary 20111, from which the first tubular region 201a extends, is at the proximal end 2010 of the hollow body 201. The first longitudinal distance L1 is therefore considered zero in Figure 42. The second longitudinal boundary 20112, to which the first tubular region 201a extends, is located at a longitudinal distance L2 away from the proximal end 2010.

In an example, a second tubular region 201b of the one or more tubular regions extends between the second longitudinal boundary 20112 and a third longitudinal boundary 20113. The third longitudinal boundary 20113 may be arranged at longitudinal distance L3 from the proximal end, as shown in Figure 42. In some examples, the third longitudinal boundary is arranged at the distal end of the hollow body. In other examples, such as that shown in Figure 42, the third longitudinal boundary 20113 may be located at a longitudinal distance L0 from the distal end 2011.

In some examples, the longitudinal distance L0 is defined between the distal end 2011 and a distal-most longitudinal boundary of the seal. For example, in the example shown in Figure 42, wherein the seal comprises two tubular regions 201a, 201b, the third longitudinal boundary 20113 forms the distal-most longitudinal boundary of the seal.

For a seal with two tubular regions, when the longitudinal distance L0 is zero this means that the third longitudinal boundary 20113 is located at the distal end. When the longitudinal distance L0 is greater than zero, for a seal with two tubular regions, the third longitudinal boundary 20113 is provided longitudinally offset the distal end 2011 of the hollow body 201, as shown in Figure 42.

In seal configurations comprising more than two tubular regions (not shown), a further tubular region, may extend between the third longitudinal boundary 20113 and a fourth longitudinal boundary (not shown). Here, the fourth longitudinal boundary may be arranged at a fourth longitudinal distance L4 from

the proximal end. The fourth longitudinal distance L4 may be larger than L3. When the fourth longitudinal distance L4 is larger than L3, the fourth longitudinal boundary is arranged closer to the distal end 2011 than that of the third longitudinal boundary 20113... For a seal with three tubular regions, the fourth longitudinal boundary forms the distal-most longitudinal boundary.

In an example, the membrane 202 may extend from the second tubular region 201b, or a distal-most tubular region of the one or more tubular regions arranged closest to the distal end 2011 of the seal. As shown with reference to Figure 42, at least part of the membrane 202 is attached to or extends from the second tubular region 201b.

In some examples, the membrane 202 is attached to or integrally formed with one of the one or more tubular regions.

In one example, the longitudinal distance between the proximal end 2010 and the distal end 2011 of the hollow body 201, for a seal with two tubular regions 201a, 201b, is equal to the sum of L3 and L0.

In one example, the longitudinal distance between the proximal end 2010 and the distal end 2011 of the hollow body 201, for a seal with one tubular region 201a is equal to the sum of L2 and L0.

In one example, the longitudinal distance between the proximal end 2010 and the distal end 2011 of the hollow body 201, for a seal with three tubular regions 201a, 201b, 201c is equal to the sum of L4 and L0.

The longitudinal extension of a first tubular region 201a may be defined as L2 less L1. The longitudinal extension of a second tubular region 201b may be defined as L3 less L2. The longitudinal extension of a third tubular region 201c may be defined as L4 less L3, and so forth.

The hollow body 201 may have a shape comprising a curvature, such as an interior curvature, an exterior curvature, or both an interior curvature and exterior curvature. The curvature of the hollow body 201 may change between the proximal end and distal end. The curvature may change along the longitudinal extension of the tubular wall of the hollow body 201, thereby forming a longitudinal change.

In an example, at least one of the longitudinal boundaries of each tubular region is defined at a longitudinal position of the hollow body 201 where there is a longitudinal change in curvature or thickness of the hollow body 201. The longitudinal position of the hollow body may be located along the longitudinal extension of the hollow body between the proximal end and the distal end.

With reference to Figure 42, the second longitudinal boundary 20112 is located where the interior curvature changes from a curved to straight section.

In some examples, at least one of the longitudinal boundaries of each tubular region is defined at a longitudinal position of the hollow body where there is a longitudinal change in thickness of the hollow body. The thickness of the hollow body may refer to a wall thickness of the hollow body. For example, the thickness of the hollow body may refer to the thickness of the tubular wall of the hollow body and/or the thickness of a wall profile of the hollow body.

In some examples, thickness of the hollow body may be defined along a plane transverse the longitudinal extension of the hollow body.

In some examples, thickness of the hollow body may be defined along a plane transverse the longitudinal extension of the tubular wall.

In some examples, thickness of the hollow body may be defined along a plane transverse the centreline or longitudinal axis of the hollow body.

For example, the second longitudinal boundary 20112 may be located where there is a change in thickness of the hollow body 201. In this example, the thickness of the first tubular region 201a is relatively larger than a thickness at the proximal-most end of the second tubular region 201b.

In an example, at least one of the one or more tubular regions is bulbous, such as in the resting configuration. For example, the respective first tubular region 20111 of Figures 34, 36A, 38A, 39 to 41, 42, 44, 46, 48A, 59 to 66 may be bulbous.

A bulbous shape may allow for or facilitate deformation, such as longitudinal deformation, of the tubular region when the seal is subject to an external load, e.g., in use.

In some examples, at least one of the one or more tubular regions is concave with reference to a longitudinal axis or centreline of the hollow body, such as in the resting configuration.

A tubular region concave with reference to the longitudinal axis or centreline may allow for or facilitate deformation, such as longitudinal deformation, of the tubular region when the seal is subject to an external load in use.

In an example, at least one of the one or more tubular regions is partly oblate spherical, such as in the resting configuration. For example, the first tubular region 201a of the seal of Figure 46 is partly oblate spherical.

In some examples, the first tubular region, i.e. the tubular region closest to the proximal end of the hollow body, is bulbous, concave in relation to the longitudinal axis or centreline of the hollow body or partly oblate spherical.

In an example, at least one of the one or more tubular regions, such as the first tubular region, is cylindrical. For example, the tubular region formed by

the hollow body 201 of Figures 2, 3, 7, 20, 25, 26, and 27A may be cylindrical or partly cylindrical.

In some examples the second tubular region 201b may be cylindrical or partly cylindrical. For example, the second tubular region 20112 in Figures 34, 36A, 42, 44, 46, 50, 52, 59 to 66 may be at least partly cylindrical.

A tubular region with a cylindrical shape may resist longitudinal deformation. Alternatively, or additionally, a cylindrical tubular region may provide more relative rigidity in comparison to any non-cylindrical tubular regions of the hollow body 201. A cylindrical tube may further promote laminar flow of fluid through the seal.

For the purpose of describing the various shapes of tubular regions disclosed herein, some examples will be described with reference to a frontal plane of the hollow body. The frontal plane of the hollow body may be defined as a plane dividing the hollow body into two symmetrical halves. In some examples, the frontal plane refers to the cross-sectional plane comprising the longitudinal axis or centreline of the hollow body.

The shapes disclosed herein, refer to the shape in the resting configuration of the hollow body unless expressly stated otherwise. In the resting configuration the hollow body may be subject to no external load.

A cylindrical tubular region may be said to have a straight profile in a frontal plane of the hollow body. The frontal plane may be defined as the cross sectional plane comprising the longitudinal axis or centreline of the hollow body. The straight profile is straight in the longitudinal direction. The straight profile may be said to have zero curvature.

The degree of curvature of the tubular region affects the degree of longitudinal deformability. A zero curvature tubular region, such as a cylindrical tubular region, may provide for minimum longitudinal deformability. A tubular region having a circular curvature, i.e. a curvature following a constant radius, in the frontal plane, may be said to have maximum curvature. The maximum curvature may in some examples provide for maximum longitudinal deformability. Other factors affecting the longitudinal deformability may include but are not limited to the material characteristics of the tubular region, and/or the thickness of the tubular region. Decreasing thickness may increase the longitudinal deformability, while increasing thickness may decrease the longitudinal deformability.

In the frontal plane, i.e. the plane dividing the hollow body 201 into two symmetrical halves, each tubular region of the hollow body forms a first wall

profile 2012a and a second wall profile 2012b arranged either side of the longitudinal axis or centreline.

In an example, the first wall profile 2012a of at least one tubular region has a shape symmetrical to that of the second wall profile 2012b in relation to the centreline. The symmetrical first 2012a and second 2012b wall profiles provides the tubular region with a symmetrical shape about the centreline in the frontal plane. For example, the respective seal of Figures 2 to 9, 19 to 29, and 34 to 49 may have tubular regions with symmetrical first 2012a and second 2012b wall profiles.

In some examples, the first wall profile 2012a has the same length as that of the second wall profile 2012b. For example, when the first wall profile 2012a is symmetrical to the second wall profile 2012b, it follows that the first wall profile 2012a may have the same length as that of the second wall profile 2012b. However, in some examples, the first wall profile 2012a may have the same length as that of the second wall profile 2012b, even where the first wall profile 2012a is asymmetrical to the second wall profile 2012b.

In some examples, at least in the resting configuration, an interior lateral dimension between the first wall profile 2012a and the second wall profile 2012b at the proximal end of the hollow body is larger than an interior lateral dimension between the first wall profile 2012a and the second wall profile 2012b at the distal end of the hollow body. The interior lateral dimension may refer to an interior dimension being transverse the centreline or longitudinal axis 2015 of the hollow body 201. The internal lateral dimension may refer to the internal diameter of the hollow body. For example, with reference to the seal of Figure 34, the internal diameter d1 between the first 2012a and second 2012b wall profiles of the hollow body at the proximal end is larger than the internal diameter d2 between the first 2012a and second 2012b wall profiles at the distal end.

A reason for providing a larger internal lateral dimension between the first wall profile 2012a and second wall profile 2012b at the proximal end than the distal end is that the larger internal lateral dimension provides a reduced resistance to the gases flow, such as when the hollow body is deformed in use,. Figure 36A to 36F show the seal of Figures 34 and 35 in various configurations when subject to different external loads in use. Figure 36A shows the seal of Figures 34 and 35 in the resting configuration. As may be observed from Figure 36A the internal diameter of the hollow body is larger at the proximal end than that at the distal end. Figure 36F shows a deformed configuration where the seal is subject to an external load acting to the right of the longitudinal axis. The right wall profile at the proximal end pivots or hinges.

In examples where the centreline in the frontal plane is curved, i.e. not straight, such as the example shown with reference to Figures 52 to 58, the internal lateral dimension may be defined as the interior distance between the first wall profile 2012a and the second wall profile 2012b in a plane perpendicular to the centreline

In an example, each of the one or more tubular regions may form a deformation region arranged to deform when subject to an external load.

As discussed above the shape, thickness, and material characteristics of the respective tubular region affects its deformability. Since each tubular region forms a deformation region, it is possible to design a hollow body with certain tubular regions promoting deformation and others resisting deformation.

In some examples, while not shown, non-cylindrical tubular regions may be provided in combination with a connecting portion 203 provided with a suspension element 204, as shown with reference to Figure 2 to 9, and 28 to 29C.

However, as a non-cylindrical tubular region increases the deformability, in some examples, the provision of such a non-cylindrical tubular region in the hollow body may at least partially compensate for the deformability provided by the suspension element. As a consequence, in some examples, the deformation regions of the hollow body may provide for adequate deformability without the provision of a suspension element 204.

Replacing the suspension element 204 with deformation regions of the hollow body disclosed herein, acts to move a centre of deformation towards the distal end 2011 of the seal 200. For example, the centre of deformation of the seal of Figure 3, and 29A to 29C, may be said to be laterally within the suspension elements 204, centred within the height of the connecting portion 203, and/or relatively close to the proximal end 2031 of the connecting portion 203. In contrast, the centre of deformation of the seal of Figure 36A to 36F, that lacks a suspension element, may be said to be laterally within the first tubular region, relatively closer to the distal end of the seal.

Figure 36A show the seal of Figures 34 and 35 in the cross-sectional frontal plane in the resting configuration, e.g., when subject to no external load.

Figures 36B to 36F show the seal of Figure 36A when subject to various external loads, in use. In one example, the at least part of the external load is applied via contact with the user's nose. The double arrows of Figures 36B to 36F indicate the external load or force vector acting on the seal. The arrows shown within the hollow body in Figures 36B, 36D, 36E and 36F indicate the tensile and compression forces acting on the hollow body in response to the external load.

The dashed circle in Figures 36A to 36F indicate the centre of deformation of the seal 200.

The deformation region may allow the membrane 202 to pivot relative to the inlet opening 2013, in use. The membrane may pivot around the centre of deformation of the hollow body.

By bringing the centre of deformation closer to the distal end, the seal may be subject to less lateral movement at the distal end between its resting configuration and the in use configuration. The minimised lateral movement at the distal end in turn may minimise the potential risk of the outlet opening 2014 being laterally displaced beyond the patient's nostril in use. Hence, by designing the one or more tubular regions of the hollow body to deform, the same seal may be able to fit a wider range of patients, thereby improving the one-size-fits-most aspect of the patient interface.

In an example, the deformation region allows the distal end of the hollow body 201 to be compressed towards the proximal end of the hollow body 201.

The seal 200 may be configured to be compressible in a longitudinal direction (along the centreline). The associated compression may help to reduce force applied to the user's nose. At least one of the connecting portion 203, suspension element 204 or the proximal end of the hollow body 201 may be configured to deform such that the hollow body 201 can move in a distal to proximal direction.

When the seal is provided with a suspension element 204, under a longitudinal compression force the proximal end 2010 of the hollow body 201 may be recessed further into the structure formed by the suspension element 204 and the connecting portion 203 than in the resting configuration.

In one example the seal 200 may have a compression range, of at least 10%, (or about 2mm) of a longitudinal extension of the seal 201. The longitudinal extension of the seal may be measured between the proximal-most end of the connecting portion 203 and the distal-most end of the hollow body 201.

For example, one or more of the tubular regions may be compressed when the seal, e.g., in use, is subjected to an external load having a component along the longitudinal axis of the hollow body 201. Such configuration is shown with reference to Figures 38A to 38C. Figure 38A shows the seal of Figure 34 in the resting configuration. The seal face of the membrane in the resting configuration is shown as a dashed line. Figure 38B shows the seal of Figure 34 in use when subjected to an external load, as indicated by the double arrow. Subject to the external load, the first tubular region of the hollow body may deform by compression, resulting in the membrane 202 of the seal being displaced towards

the proximal end 2010 of the hollow body 201. The deformation may move the seal face of the membrane away from the dashed line, thereby reducing the overall length of the seal as compared to that in the resting configuration. Figure 38C shows the seal of Figure 38A when being subject to an external load larger than that applied in Figure 38B. This may result in the first tubular region deforming even further, leading to the seal face of the membrane, indicated by the dashed dot line, being displaced even further away from the dashed line than that of Figure 38B. The final displacement C is indicated between the dashed and dashed dot line in Figure 38C.

In an example, an internal lateral dimension between the first wall profile 2012a and second wall profile 2012b of a tubular region, at a longitudinal position between the two longitudinal boundaries of said tubular region, is larger than an internal lateral dimension between the first wall profile 2012a and second profile of said region, at the distal end or proximal end of the hollow body. For example, each symmetrical tubular region with first 2012a and second 2012b wall profiles being concave in relation to the centreline (or bulbous etc) may have an internal lateral dimension between the longitudinal boundaries being larger than that at the boundaries, the proximal end 2010, or distal end 2011. For example, from Figure 34, it follows that the internal lateral dimension d3, such as the diameter, between first 2012a and second 2012b wall profiles is larger at a longitudinal position, such as halfway, between the first 20111 and the second boundaries 20112 than the internal diameter at the first boundary 20111 and the second boundaries 20112 between which the first tubular region 201a is defined.

In an example, the internal lateral dimensions are defined on a plane perpendicular to a frontal plane dividing the hollow body into two symmetrical halves.

In an example, the internal lateral dimension between the first 2012a and second 2012b wall profiles at a first longitudinal boundary of a tubular region is at least substantially equal to the internal lateral dimension between the first 2012a and second 2012b wall profiles at a second longitudinal boundary of said tubular region. When the tubular region has a circular shape in transverse cross section at the first longitudinal boundary and at the second longitudinal boundary, this means that the internal lateral dimension at the first longitudinal boundary may be at least substantially the same as that at the second longitudinal boundary.

As discussed above, in seal examples with non-straight centrelines in the frontal plane, the internal lateral dimension may be defined in a plane perpendicular to a tangent of the longitudinal axis or centreline.

In an example, a largest internal lateral dimension between the first wall profile 2012a and second wall profile 2012b of a tubular region, at a longitudinal position between the two longitudinal boundaries of said tubular region, may be smaller than a largest interior lateral dimension of the connecting portion. Such an example is shown with reference to Figures 3 to 29C, 34, 36A, 42 to 45, 48A to 51.

In some examples, a largest internal lateral dimension between the first wall profile 2012a and second wall profile 2012b of a tubular region, at a longitudinal position between the two longitudinal boundaries of said tubular region, may be larger than a largest interior lateral dimension of the connecting portion. Such an example is shown with reference to Figures 46 to 47.

In an example, a largest internal lateral dimension between the first wall profile 2012a and second wall profile 2012b of a tubular region, at a longitudinal position between the two longitudinal boundaries of said tubular region, may be smaller than a lateral dimension, such as outer diameter, of the membrane 202. Such an example is shown with reference to Figure 34 to 66.

In an example, a largest internal lateral dimension between the first wall profile 2012a and second wall profile 2012b of a tubular region, may be formed longitudinally half-way or approximately half-way between the two longitudinal boundaries of said tubular region. Such an example is shown with reference to Figures 34, 36A, 42 to 45, 48A to 51, and 59 to 66.

In some examples, in the resting configuration, at least one of the first wall profile 2012a and second wall profile 2012b comprises at least one of the following:

- a portion having a continuously varying curvature;
- a portion concave with reference to the longitudinal axis or centreline;
- a rounded or bulbous portion;
- a bellows-shaped portion;
- a parabolic portion;
- a portion shaped like part of a substantially oblate sphere; and
- an S-shaped portion.

In one example, an S-shaped portion may resist compression along a direction of the centreline, and/or resist tilting or pivoting of the membrane.

In an example, e.g. in the resting configuration, the first wall profile 2012a of one or more tubular regions comprises a portion concave with reference to the longitudinal axis or centreline between the first longitudinal boundary and second longitudinal boundary. Alternatively, or additionally, the second wall profile 2012b of said associated tubular region may comprise a portion concave

with reference to the longitudinal axis or centreline between the first longitudinal boundary and second longitudinal boundary.

In some examples, e.g., in the resting configuration, the first wall profile 2012a of one of the one or more tubular regions comprises a straight portion between the second longitudinal boundary and the distal end. Such examples are shown with reference to Figures 34 to 36F, 38A to 47, and 50 to 66. Alternatively, or additionally, the second wall profile 2012b of said associated tubular region may comprise a straight portion between the first longitudinal boundary 20111 and the second longitudinal boundary 20112.

In some examples, the shape of the tubular region continuously gradually changes between the first longitudinal boundary and the second longitudinal boundary. For example, the shape of the first 2012a and second 2012b wall profiles may continuously gradually change between the first longitudinal boundary and the second longitudinal boundary. The continuous gradual change of the shape of the tubular regions may improve the laminar flow of the fluid while enabling the desired deformability, and/or allowing for smooth continuous movement.

In an example, at least one of the tubular regions has a circular cross section in a transverse plane orthogonal to the frontal plane and the centreline of the tubular region.

In an example, at least one of the tubular regions has a circular transverse (i.e. transverse to the frontal plane and the centreline of said tubular region) cross section extending between the first and second longitudinal boundaries of said tubular region. The circular transverse cross section extending between the first and second longitudinal boundaries may change in an internal lateral dimension, such as diameter, between the first and second longitudinal boundaries. Hence, at least some of the transverse cylindrical cross sections of a tubular region may have different lateral dimensions. In some examples, the lateral dimension of the transverse circular cross sections of a tubular region may change gradually between the first and second longitudinal boundaries of the tubular region.

In an example, at least a portion of one of the first wall profile 2012a and second wall profile 2012b is at least substantially symmetrical about a transverse plane orthogonal to the frontal plane and the longitudinal axis or centreline of the hollow body. Such an example is shown with reference to Figures 2, 3 and 7.

In an example, the transverse plane comprises a halfway point between the first longitudinal boundary and second longitudinal boundary.

As discussed above, the membrane may have a decoupling zone 2027. The decoupling zone 2027 may comprise an indentation in a surface of the membrane.

In some examples, the decoupling zone 2027 is arranged at an interface between the hollow body 201 and the membrane 202.

In some examples, with reference to Figures 48A and 48B, the decoupling zone 2027 may form an extension of the hollow body 201. Figure 48A shows a seal in a cross sectional frontal view dividing the hollow body in two symmetrical halves in the resting configuration. The decoupling zone may comprise a wall profile forming an extension of the wall profile of the hollow body.

The decoupling zone 2027 may comprise a curved wall profile, e.g., in a cross sectional plane comprising the centreline or longitudinal axis, or e.g., in a cross sectional frontal plane dividing the hollow body in two symmetrical halves. The wall profile of the decoupling zone 2027 may have a gradually changing direction.

The decoupling zone 2027 may form a non-cylindrical wall profile in the cross sectional front view.

The decoupling zone 2027 may have the same thickness as the hollow body 201, such as a distal-most portion of the hollow body 201.

The decoupling zone 2027 may have a thickness that is smaller than the largest thickness of the membrane.

In some examples, the largest thickness of the membrane may be located laterally in line with an exterior-most point of the hollow body, e.g., in the resting configuration. With reference to Figure 48A, the exterior-most point of the hollow body may be indicated by the dashed dot line being parallel to the centreline or longitudinal axis of the hollow body. The dashed dot line intersects the membrane 202 at the lateral location where the membrane may have its largest thickness. With reference to Figure 48A the thickness of the decoupling zone 2027 may generally conform with the thickness of a tubular region 201a of the hollow body 201.

In some examples, the thickness of the decoupling zone 2027 may gradually increase towards a maximum thickness of the membrane 202. In some examples, the innermost portion of the membrane has a thickness conforming with that of the decoupling zone. The decoupling zone may terminate where its wall profile attains a flat or substantially flat sidewall profile. The flat or substantially flat sidewall profile forms the start of the first zone 2022 of membrane. An example of the interface between the decoupling zone 2027 and the membrane 202 is shown with reference to the dashed line in Figure 48A. The

thickness of the membrane may gradually increase from the interface between the decoupling zone and the membrane, as indicated by the dashed line, towards the maximum thickness of the membrane, as indicated by the dashed dot line in Figures 48A and 48B. The thickness of the membrane may be decreasing laterally outward from the location of maximum thickness towards the exterior tip of the membrane.

In an example, at least one of the one or more tubular regions has a tubular wall profile with a shape asymmetrical in relation to the longitudinal axis or centreline of the hollow body.

In an example, at least one of the one or more tubular regions in the frontal plane (i.e. a plane splitting the tubular region in two symmetrical halves) has a first wall profile 2012a and second wall profile 2012b being asymmetrical in relation to the longitudinal axis or centreline of the hollow body. Such an example is shown with reference to the examples of Figures 50 to 58. Figures 50 to 51 shows an example where the first wall profile 2012a (e.g. to the left in Figure 50) of the first tubular region 201a is asymmetrical to the second wall profile 2012b (e.g. to the right in Figure 50) of the first tubular region 201a. In this example, the first wall profile 2012a of the first tubular region is concave with reference to the longitudinal axis or centreline. The second wall profile 2012b of the first tubular region may comprise a bellows-like shape. The bellows-like shape of the second wall profile 2012b may promote deformation. In use, e.g., when the seal is subject to an external load, the second wall profile 2012b may deform and be compressed to a larger extent than the first wall profile 2012a. This may result in the seal tilting towards the second wall profile 2012b. The bellows-like shape of the second wall profile 2012b may therefore be used to control the deformability towards certain directions of the seal.

For example, when attached to a frame, the two seals may be arranged with the respective bellows-like shaped second wall profiles facing each other.

Alternatively, when attached to a frame, the two seals may be arranged with the respective bellows-like shaped second wall profiles facing away from each other, e.g. so that they face opposite directions. The bellows-like shaped second wall profiles of the two seals may be oppositely arranged when attached to the frame.

An S-shaped second wall profile 2012b may also promote deformability. An S-shaped wall profile may provide for decreased longitudinal deformability as compared to a bellows-like shaped wall profile. In terms of longitudinal deformability an S-shaped wall profile may fall between a straight wall profile (associated with a cylindrical tubular region) and the bellows-like shaped wall

profile. An S-shaped second wall profile 2012b may promote deformability in the first wall profile 2012a.

As discussed above, with reference to Figures 29A to 29C, and as shown with reference to Figures 39 to 41, the seal face axes SFA1, SFA2 of the seals when attached to the frame may be arranged at an angle towards each other so that the seals face each other in the resting configuration when attached to the frame. This arrangement is advantageous to provide a satisfactory seal for a wide range of sub-nasal angles SNA.

In one example, a patient interface 400 is provided comprising two of the seals 200 of Figures 50 and 51 attached to the frame 300 so that the respective bellows-like second wall profiles face each other. In this example, the second wall profiles are centrally located or located near the medial plane of the patient interface. When subject to an external load, the bellows-like second wall profiles will deform to a greater extent than the first wall profiles, whereby the seal face angle will be further decreased. This configuration is suitable for patients with a relatively sharper sub-nasal angle. Further, this configuration allows the patient interface to alleviate pressure at the columella, a particularly sensitive area of the nose, thereby enhancing user comfort.

Alternatively, by arranging the bellows-like second wall profiles of the seals of Figures 50 and 51 away from each other, with the first wall profiles arranged centrally or near the medial plane of the patient interface, the patient interface can be adapted to a patient with a flat or generally flat sub-nasal angle. In this configuration, when the seals are subject to a generally flat bottom nose profile, the associated external load may act to deform the respective seal to a larger extent where the bellows-like shaped second wall profiles 2012b are located, thereby increasing the angle between the seal face axes SFA1, SFA2 to adapt to the generally flat bottom nose profile.

In an example, the first wall profile 2012a of one of the one or more tubular regions has a length different from that of the second wall profile 2012b of said tubular region. The length of the wall profile may refer to the length along a surface, or a centreline, of the wall profile. The length of the first wall profile 2012a of a tubular region may thus be longer or shorter than that of the second wall profile 2012b of the tubular region. The length of the first wall profile 2012a may differ from that of the second wall profile 2012b as a result of the first wall profile 2012a being asymmetric to the second wall profile 2012b in the frontal plane. For example, with reference to Figure 50, the bellows-like shaped wall profile 2012a (to the right in Figure 50) of the first tubular region 201a may be

longer, i.e. greater in length, than the concave wall profile 2012b (to the left in Figure 50) of the first tubular region 201a.

In an example, a portion of the first wall profile 2012a may be symmetrical about a transverse plane orthogonal to the frontal plane and the centreline of the hollow body, while the second wall profile 2012b is asymmetrical about the transverse plane.

In an example, the tubular region has a shape conforming with the first wall profile 2012a spanning a first angular distance AD1 either side of the frontal plane around the longitudinal axis or centreline of the hollow body. The first angular distance AD1 represents the angle for which a tubular region maintains the first wall profile 2012a around the centreline or longitudinal axis.

The first angular distance AD1 may be defined between a first angular transition point and a second angular transition point along the perimeter of the hollow body. The wall profile of the tubular region thus remains the same, i.e. maintains the first wall profile 2012a shape, around the longitudinal axis or centreline between the first angular transition point and second angular transition point.

The first angular transition point may be comprised in a first transition plane intersecting the frontal plane along the centreline or the longitudinal axis of the hollow body.

The second angular transition point may be comprised in a second transition plane intersecting the frontal plane along the centreline or the longitudinal axis of the hollow body.

The first angular distance AD1 may be defined as the angle between the first angular transition point and the second angular transition point. Alternatively, the first angular distance AD1 may be defined as the angle between the first transition plane and the second transition plane.

The first angular transition point may be at least substantially symmetrically arranged relative to the second angular transition point in relation to the frontal plane. This is because the frontal plane divides the hollow body into two symmetrical halves.

In some examples, the first angular distance AD1 is larger than 180°, such as 240° to 270°, e.g., 260°. Figure 50 shows an example seal in the frontal plane cross section where the first angular transition point TP1 is represented as a curved line. Each point along this curved line may represent a first angular transition point. The curved angular transition point line is shown on the right side of the longitudinal axis or centreline. The first wall profile 2012a (e.g., concave in relation to the longitudinal axis or centreline) defined at the left side in

the frontal plane of the first tubular region 201a may extend more than 90 degrees to the first angular transition point, e.g., because the first angular transition point is located at the right of the centreline. In fact, the angle from the frontal plane to the first angular transition point in this example may be 130 degrees or around 130 degrees. In examples where the frontal plane divides the hollow body into two symmetrical halves, the first angular distance AD1 may be twice the angle, for which the first wall profile 2012a is maintained, between the frontal plane to the first angular transition point. Hence, the first angular distance AD1 in this example may be two times 130 degrees, i.e. 260 degrees or around 260 degrees.

In an example, the tubular region has a uniform shape in relation to the longitudinal axis or centreline over the first angular distance AD1. The shape of the tubular region may be uniform, e.g., by the first wall profile 2012a being maintained across the first angular distance AD1 around the longitudinal axis or centreline.

The first and second angular transition points may represent locations along the perimeter of the tubular region at which the associated wall profiles will start transitioning from one wall profile, such as the first wall profile 2012a, towards another wall profile, such as a second wall profile 2012b.

In an example, the tubular region has a shape conforming with the second wall profile 2012b in the frontal plane. The tubular region may also conform with the first wall profile 2012a in the frontal plane. This is because the frontal plane may divide the hollow body, including the one or more tubular regions, into two symmetrical halves.

In some examples, the tubular region has a shape conforming with the second wall profile 2012b only in the frontal plane. Here, the second wall profile 2012b which is arranged opposite the first wall profile 2012a in the frontal plane, may act as a reference wall profile towards which the wall profile of the associated tubular region transitions beyond the respective first angular transition point TP1 and second angular transition point TP2. The seal of Figure 51 shows such an example in which the shape of the first tubular region 201a may start to transition from the first wall profile 2012a beyond the second angular transition point towards the second wall profile 2012b defined at the frontal plane FP.

In some examples, the tubular region further comprises a first transition region TR1 (see Figure 50) having a shape geometrically transitioning from the shape of the first wall profile 2012a at the first angular transition point TP1 to the shape of the second wall profile 2012b at the frontal plane. Similarly, the tubular region may comprise a second transition region TR2 having a shape geometrically

transitioning from the shape of the first wall profile 2012a at the second angular transition point TP2 to the shape of the second wall profile 2012b at the frontal plane. While the first transition line TP1 is not shown in Figure 51, at least part of the first transition region TR1 is shown in Figures 50 and 51 and the second transition region TR2 is shown in Figure 51.

In an example, with reference to Figures 52 to 58, the tubular region may have a shape conforming with the second wall profile 2012b spanning a second angular distance AD2 either side of the frontal plane around the longitudinal axis or centreline of the hollow body. The second angular distance AD2 may be defined between a third angular transition point TP3 and a fourth angular transition point TP4 along the perimeter of the hollow body. As shown in Figure 54 for example, the third and fourth angular transition points TP3 and TP4 are shown with reference to the curved lines. In this example, the first tubular region may maintain a uniform shape (conforming with the first wall profile 2012a) between the first and second angular transition points TP1 and TP2 at the left side of Figure 54. Similarly, the first tubular region 201a may maintain a uniform shape (conforming with the second wall profile 2012b) between the third and fourth transitions points TP3 and TP4 at the right side of Figure 54. Figure 55 shows a cross sectional top view of the seal 200 of Figures 53 and 54. Figure 55 identifies the respective angular transition points TP1, TP2, TP3, TP4.

In some examples, the first angular distance AD1 is measured between the first angular transition point TP1 and second angular transition point TP2 across the section of the frontal plane at which the first wall profile 2012a is located.

In some examples, the second angular distance AD2 is measured between the third angular transition point TP3 and fourth angular transition point TP4 across the section of the frontal plane at which the second wall profile 2012b is located.

In the example of Figures 52 to 58, the first angular distance AD1 may represent the smallest angular distance between the first angular transition point TP1 and second angular transition point TP2, and the second angular distance AD2 may represent the smallest angular distance between the third angular transition point TP3 and fourth transitions point TP4.

In some examples, the second angular distance AD2 is less than 110°, such as 100°.

In some examples, the first angular distance AD1 is at least substantially equal to the second angular distance AD2.

In some examples, the first angular distance AD1 is different from the second angular distance AD2.

The angular distance between the third angular transition point TP3 and the first angular transition point TP1 is at least substantially identical to the angular distance between the fourth angular transition point TP4 and the second angular transition point TP2. This is because the frontal plane in relation to which the transition points are defined, may divide the hollow body, including the tubular regions, in two halves that are at least substantially symmetrical.

In an example, the sum of the angular distance TP1-TP3 between the third angular transition point TP3 and the first angular transition point TP1 and the angular distance TP2-TP4 between the second angular transition point TP2 and fourth angular transition point TP4 is 360° less the first angular distance AD1 less the second angular distance AD2.

In an example, the first angular distance AD1 is 80° to 120°, such as 100°, and the second angular distance AD2 is 80° to 120°, such as 100°.

In some examples, the first angular transition point TP1 and the second angular transition point TP2 may be located at a common radial distance from the longitudinal axis or centreline of the hollow body.

The tubular region may further comprise a third transition region TR3 (see Figure 54) having a shape geometrically transitioning from the shape of the first wall profile 2012a at the first angular transition point TP1 to the shape of the second wall profile 2012b at the third angular transition point TP3. The tubular region may further comprise a fourth transition region TR4 having a shape geometrically transitioning from the shape of the first wall profile 2012a at the second angular transition point TP2 to the shape of the second wall profile 2012b at the fourth angular transition point TP4. In some examples, the third transition region TR3 is a mirror image of the fourth transition region TR4 about the frontal plane FP.

With reference to Figures 52 to 58, the example shown may provide increased deformability towards the first wall profile 2012a of the first tubular region that is concave in relation to the interior of the tubular region. With reference to Figure 52, e.g., subject to an external load (such as having a component in a direction from the distal end 2011 towards the proximal end 2010), concave first wall profile 2012a may be compressed causing the seal to tilt towards the left.

Turning to the membrane, and as discussed above, the first zone 2022 may be planar or substantially planar. Figures 42 to 48B illustrates examples of

seals comprising a planar or substantially planar first zone 2022 of the membrane 202.

In some examples, the first zone 2022 in the resting configuration may extend perpendicular or substantially perpendicular to the longitudinal axis or centreline 2015 at the distal end 2011 of the hollow body 201.

The first zone may extend from a first radial position RP1 to a second radial position RP2 in relation to the longitudinal axis or centreline 2015 of the hollow body 201. The first radial position RP1 and second radial position RP2 are shown in Figure 42 as dashed lines either side of the longitudinal axis or centreline 2015.

The second radial position may be larger than one or more of:
an outermost radial position of the hollow body in the resting configuration or in-use configuration; and

an outermost radial position of the connecting portion in the resting configuration or in-use configuration.

In some examples, the first zone extends 2022 from a first radial position to a second radial position in relation to the centreline 2015 of the hollow body, wherein the membrane 202 has a first thickness at the first radial position, and a second thickness at the second radial position, wherein the first thickness is larger than the second thickness. For example, Figures 42 and 44 show examples of the membrane thickness varying with radial position within the first zone 2022.

The thickness of the membrane 202 may gradually reduce from the first thickness to the second thickness between the first radial position and the second radial position.

In some examples, the second radial position RP2 is located between 8.5mm to 12mm from the longitudinal axis or centreline of the hollow body, thereby forming an outer diameter of the first zone 2022 between 17mm and 24mm.

In an example, at least one of the tubular regions of the hollow body has a thickness that is at least substantially uniform. For example, the first hollow region 201a of Figure 34, 36a, 42, 44, 46, 48A, 50 to 58, and 59 to 66, may have a uniform thickness. Similarly, the hollow body 201 of Figures 2 to 28 may have a uniform thickness.

The thickness may be measured transverse the tubular wall of the tubular region.

In some examples, the thickness of the tubular region can be measured between a first point at a first side of the tubular wall and a second point at an opposite second side of the tubular wall. The first point may form part of a first

tangent touching the first side of the tubular wall at the first point. The second point may form part of a second tangent touching the second side of the tubular wall at the second point. The first tangent and second tangent may be parallel to each other.

In an example, a thickness of the first wall profile 2012a is different from a thickness of the second wall profile 2012b.

According to an example, a distal end of the connecting portion 203 is provided to the proximal end 2010 of the hollow body 201 and a proximal end 2031 of the connecting portion 203 is configured to couple with a frame 300. In some examples, the frame 300 may be attached to a housing/body portion of a seal (e.g. a silicone body)

The distal end 2034 of the connecting portion 203 may be attached or integrally formed with the hollow body 201 at or proximate to the first longitudinal boundary 20111. For reference, an example of the proximal end 2031 and distal ends of the connecting portion is shown in Figure 34.

The connecting portion 203 may, in a frontal plane dividing the hollow body into two halves that are at least substantially symmetrical, comprise a first connecting portion wall profile and a second connecting portion wall profile arranged either side of a longitudinal axis or centreline of the connecting portion 203.

In an example, the connecting portion 203 is arranged to support the hollow body 201. The connecting portion 203 may be arranged to resist self-deformation while enabling deformation of the hollow body 201, e.g., in use.

In an example with reference to Figures 52 to 58, the first connecting portion wall profile comprises at least one fold 521 configured to deform to allow the membrane and/or hollow body 201 to pivot and/or translate with respect to the connecting portion 203, in use. The fold 521 is shown with reference to the left wall profile in Figure 52.

The second connecting portion wall profile may be fold-less, i.e. the second connecting portion may contain no folds. The right wall profile in Figure 52 has no folds. In some examples, each tangent of a fold-less wall profile is angled at most 90 degrees in relation to any other tangent of the associated wall profile.

Like the tubular regions discussed above, the connecting portion 203 may have an at least substantially uniform wall profile formed by the first wall profile 2012a spanning over a first angular distance AD1.

That is, in the frontal plane dividing the hollow body 201 into two at least substantially symmetrical halves, the connecting portion 203 may have a shape conforming with the first connecting portion wall profile spanning a first angular

distance AD1 either side of the frontal plane around the longitudinal axis or centreline of the connecting portion 203.

The connecting portion 203 may have shape conforming with the second connecting portion profile spanning a second angular distance AD2 either side of the frontal plane around the longitudinal axis or centreline of the connecting portion 203.

In some examples, the second angular distance AD2 is defined between a third angular transition point and a fourth angular transition point along the perimeter of the connecting portion 203.

The connecting portion 203 may comprise a first transition region having a shape geometrically transitioning from the shape of the first connecting portion wall profile at the first angular transition point to the shape of the second connecting portion wall profile at the third angular transition point.

The connecting portion may comprise a second transition region having a shape geometrically transitioning from the shape of the first connecting portion wall profile at the second angular transition point to the shape of the second connection portion wall profile at the fourth angular transition point.

In some examples, the thickness of the connecting portion may reduce from its proximal 2031 end towards its distal end 2034. For example, each seal shown with reference to Figures 3 to 28, 34, 36A, 42, 44, 46, 48A, 50, 52, 59, and 63 may have a connecting portion reducing from its proximal end 2031 towards its distal end.

In one example, a thickened bead or proximal end of the connecting portion is provided for engagement with a corresponding notch in a frame. The bead or proximal end 2031 may provide for the actual connection to the frame.

According to an example, with reference to Figures 59 to 62 and Figures 63 to 66, in the frontal plane, the membrane 202 is convex in relation to the proximal end 2010 of the hollow body 201.

The membrane 202 may be a sealing membrane. The sealing membrane may be configured to seal at least partly around the lower portion of the user's nose in use. The convex shape may allow the sealing membrane to seal against the exterior surface of or adjacent a single external nare of the patient. Additionally, or alternatively, the convex shape may allow the sealing membrane to seal at least partly against the lower alar side portions. The convex shape may allow the membrane to follow the curvature of the user's alar on one side of the membrane; whilst being flexible and deformable to conform to other nasal geometry on other sides. In some cases, the membrane may partially invert in use.

With reference to Figures 59 to 62, the seal 200 may further comprise a support membrane 202a extending outwardly from the hollow body 201, wherein the support membrane 202a is positioned between the sealing membrane 202 and the distal end 2011 of the hollow body 201.

In the frontal plane, the support membrane 202a may be concave in relation to the proximal end 2010 of the hollow body 201, e.g. similar to the membrane 202 of each of the examples shown with reference to Figures 2 to 58. The sealing membrane 202 may have an undulating outer edge. The undulating outer edge may be designed to improve sealing with the lower alar side portions. In some examples, the undulating edge forms four peaks and/or troughs (low points). This relieves hoop forces to enable deformation of the membrane in a downwards direction. Peaks may improve seal by extending further up the alars of the user.

As discussed above, the connecting portion 203 may be attached to the proximal end 2010 of the hollow body 201.

In some examples, the first, e.g. proximal-most, tubular region 201a of the hollow body 201 is attached to the connecting portion 203. In some examples the proximal-most tubular region 201a is integrally formed with the connecting portion 203.

In some examples the proximal-most tubular region 201a forms the connecting portion 203.

As discussed herein, the connecting portion 203 may including a lip 2033 to connect to the frame 300. Depending on the configuration the lip 2033 may extend outwardly, such as radially outwardly, from the proximal-most end of the first tubular region 201a, or inwardly from the proximal-most end of the first tubular region 201a. A corresponding recess 3014 of the frame 300 may be arranged to attach, such as sealingly attach, to the lip 2033.

In one example, at least one of the tubular regions 201a, 201b, 201c has a frustoconical shape, in the resting configuration.

In some examples two or more of the tubular regions 201a, 201b, 201c, has a frustoconical shape in the resting configuration.

In some examples, each of the tubular regions 201a, 201b, 201c has a frustoconical shape in the resting configuration.

Providing the seal with frustoconically shaped tubular regions 201a, 201b, 201c may provide the seal with a greater compression range.

As will be further explained below at least one of the one or more frustoconical shaped tubular regions may retain its frustoconical shape when deformed.

The frustoconical shape may be formed by a wall profile angled against the longitudinal axis or centreline 2015 of the hollow body 201.

The angle between the wall profile and the longitudinal axis or centreline 2015, as discussed herein, may be measured between flat or essentially flat inner surface or tangent of the wall profile and the longitudinal axis or centreline 2015.

The frustoconical shape implies that the associated tubular region has a first internal diameter at a proximal end thereof and a second internal diameter, different from the first internal diameter, at a distal end thereof.

In some examples, the different first and second internal diameters and a longitudinal extension of the respective frustoconically shaped tubular region defines the angle between the associated wall profile and the longitudinal axis or centreline 2015 of the hollow body 201.

In one example, with reference to Figure 67 the seal 200 comprises a hollow body 201 having three frustoconical tubular regions 201a, 201b, 201c. Figure 67 shows a cross section of a seal 200 in a plane, such as the frontal plane, comprising the longitudinal axis 2015 of the hollow body. The internal diameter of the first, e.g. proximal-most, tubular region 201a ranges between a first internal diameter and a second internal diameter. The internal diameter of the second tubular region ranges between the second internal diameter and a third internal diameter. The internal diameter of the third tubular region ranges between the third internal diameter and a fourth internal diameter. The first internal diameter is larger than the second internal diameter. The second internal diameter is larger than the third internal diameter. The third internal diameter is larger than the fourth internal diameter.

As discussed herein, each tubular region may be defined between two longitudinal boundaries. For example, the first tubular region 201a may be defined between a first longitudinal boundary 20111 and a second longitudinal boundary 20112. The second tubular region 201b may be defined between the second longitudinal boundary 20112 and a third longitudinal boundary 20113. The third tubular region 201c may be defined between the third longitudinal boundary 20113 and a fourth longitudinal boundary 20114.

The first internal diameter may be defined at the first longitudinal boundary 20111. The second internal diameter may be defined at the second longitudinal boundary 20112. The third internal diameter may be defined at the third longitudinal boundary 20112. The fourth internal diameter may be defined at the fourth longitudinal boundary 20112.

In some examples, the respective frustoconically shaped tubular region has internal diameters decreasing in a proximal to distal direction.

In an example, the first internal diameter may be about 17 mm. The second internal diameter may be about 14 mm. The third internal diameter may be about 7.5 mm. In an example, the fourth internal diameter may be about 6.5 mm.

In one example, a longitudinal extension of the first tubular region 201a is measured between the first boundary 20111 and the second boundary 20112, a longitudinal extension of the second tubular region 201b is measured between the second boundary 20112 and the third boundary 20113, and a longitudinal extension of the third tubular region 201c is measured between the third boundary 20113 and the fourth boundary 20114. The longitudinal extension of the first tubular region 201a is larger than the longitudinal extension of the second tubular region 201b, and the longitudinal extension of the third tubular region 201c. Additionally or alternatively, the longitudinal extension of the third tubular region 201c may be larger than the longitudinal extension of the second tubular region 201b.

In one example, a longitudinal extension of the first tubular region 201a may be about 9 mm, the longitudinal extension of the second tubular region 201b may be about 4 mm, and the longitudinal extension of the third tubular region 201c may be about 3 mm.

In one example, the angle between the wall profile of the first tubular region 201a and the longitudinal axis or centreline 2015 may be about 9 degrees. The angle between the wall profile of the second tubular region 201b and the longitudinal axis or centreline 2015 may be about 54 degrees. The angle between the wall profile of the third tubular region 201c and the longitudinal axis or centreline 2015 may be about 4 degrees. As shown in Figure 67 the membrane 202 is similar or identical to that shown with reference to Figures 48A and 48B. However, it should be appreciated that the seal 200 with one or more frustoconical tubular regions 201a, 201b, 201c may comprise any one of the membranes 202 disclosed herein.

Figure 68 shows a perspective view of the seal of Figure 67.

In reference to the seal 200 of Figure 67, flexibility and deformability of a tubular region 201a, 201b, 201c may be determined by adapting the thickness of the respective tubular region. In some examples, the flexibility and deformability of the seal 200 may be determined by the flexibility and deformability of one or more of the tubular regions 201a, 201b, 201c. For example, the flexibility and deformability of the seal 200 may be increased by decreasing the thickness of the wall profile of at least one of the first tubular region 201a and second tubular region 201b.

In some examples, a thickness of a wall profile of the second tubular region may be less than that of the first tubular region or the third tubular region.

With reference to Figure 67, the thickness of the wall profile of the first tubular region 201a is about 1 mm, the thickness of the wall profile of the second tubular region 201b is about 0.6 mm, and the thickness of the wall profile of the third tubular region 201c is about 1 mm.

Figure 69 shows a seal 200 having three frustoconically shaped tubular regions 201a, 201b, 201c. In this example, the thickness of the wall profile of the first tubular region 201a may be about 1 mm, the thickness of the wall profile of the second tubular region 201b may be about 0.4 mm, and the thickness of the wall profile of the third tubular region 201c may be about 1 mm. Transitions in wall profile thickness may occur within at least one of the tubular regions, such as the second tubular region 201b. In this example the first tubular region 201a has a constant wall profile thickness between the first boundary 20111 and second boundary 20112. The third tubular region 201c has a constant wall profile thickness between the third boundary 20113 and the fourth boundary 20114. The second tubular region has a varying wall profile thickness between the second boundary 20112 and third boundary 20113.

Figure 70 shows a seal 200 having three frustoconically shaped tubular regions 201a, 201b, 201c. In this example, the thickness of the wall profile of the first tubular region 201a may be about 1 mm at the first longitudinal boundary 20111 and 0.6 mm at the second longitudinal boundary 20112. The thickness of the first tubular region 201a may transition, such as gradually transition, from its thickness at the first longitudinal boundary 20111 to its thickness at the distal end at the second longitudinal boundary 20112. The thickness of the wall profile of the second tubular region 201b may be about 0.6 mm. The thickness of the wall profile of the third tubular region 201c may be about 1 mm.

In the example of Figure 70 the first tubular region 201a has a varying wall profile thickness between first boundary 20111 and second boundary 20112. The second tubular region has constant wall profile thickness between the second boundary 20112 and third boundary 20113. The third tubular region 201c has a varying wall profile thickness between the third boundary 20113 and the fourth boundary 20114.

In some examples, a thickness of a wall profile of the second tubular region is less than that of the first tubular region and identical to that of the third tubular region.

Figure 71 shows a seal 200 having three frustoconically shaped tubular regions 201a, 201b, 201c. In this example, the thickness of the wall profile of the first tubular region 201a may be about 1 mm at the first longitudinal boundary 20111 and 0.4 mm at the second longitudinal boundary 20112. The thickness of the first tubular region 201a may transition from its thickness at the first longitudinal boundary 20111 to its thickness at the second longitudinal boundary 20112. The thickness of the wall profile of the second tubular region 201b may be about 0.4 mm. The thickness of the wall profile of the third tubular region 201c may be about 1 mm.

It should be appreciated that any one of the tubular regions 201a, 201b, 201c may have a respective first wall profile thickness at its proximal end, and a respective second wall profile thickness at its distal end, wherein the thickness of the said tubular region(s) transitions from the first wall profile thickness to the second wall profile thickness.

In the example of Figure 71, the first tubular region 201a has a varying wall profile thickness between first boundary 20111 and second boundary 20112. The second tubular region has a varying wall profile thickness between the second boundary 20112 and third boundary 20113. The third tubular region 201c has a constant wall profile thickness between the third boundary 20113 and the fourth boundary 20114.

The examples shown with reference to Figures 70 and 71 may allow for greater range of compression than for the examples shown in Figures 67 to 69.

In each of the examples of Figures 67 to 71, the thickness of the wall profiles of the respective tubular region may transition, such as gradually transition, to the thickness of the adjacent tubular region at the interfaces thereof, or adjacent the interface between the tubular regions.

In some examples, at least one tubular region, such as the second tubular region, is configured to deform from the frustoconical shape to an inverted frustoconical shape upon deformation.

Figure 72a shows the three tubular regions of the seal of Figure 71 in the resting configuration. Figure 72b shows the three tubular regions of the seal of Figure 71 in an in-use, e.g. deformed, configuration when an external load having a component along the longitudinal axis 2015 is applied to the seal 200. As may be observed from Figure 72b, the third frustoconically shaped tubular region 201c is able to be longitudinally displaced at least partly into the first frustoconically shaped tubular region 201a. At the same time, the second tubular region 201b undergoes deformation that changes its shape from the frustoconical shape in the resting configuration shown in Figure 72a to an inverted frustoconical shape shown in Figure 72b. The second tubular region may fold relative the third tubular region 201c such that the third tubular region 201c may be recessed into the first tubular region 201a. The folding motion is indicated by the arrows in Figures 71a and 72b. This folding motion provides the seal of Figures 67 to 71 with an initial compression range of about 25% of the longitudinal extension of the hollow body 201 in the resting configuration, or about 4.5 mm. It should be appreciated that the initial compression range does not refer to the maximum compression range of the seal. The initial compression range may be reached when the seal is subject to a predetermined force. In some examples the predetermined force is the force required for the second tubular region 201b to

undergo the transition from its frustoconical shape to its inverted frustoconical shape. When the second tubular region 201b has attained its inverted frustoconical shape, the seal may be said to have reached an initial deformed configuration.

If an applied force is greater than the predetermined force (associated with the initial deformed configuration) the first tubular region 100a may deform by 'rolling' inwards (towards the centreline and proximal end as indicated by the arrows in Figure 72B), in regions where its wall profile thickness is reduced. This additional force may increase the compression range further. This additional deformation further increases the compression range, by at least 10%, or about 2mm. The compression range may thus be 35% (25% + 10%) of the longitudinal extension of the hollow body 201 in the resting configuration, or about 6.5 mm. This additional compression range (beyond the initial compression range) may be identical or of the same magnitude as that associated with the seal 200 of Figures 3 to 9 and 19 to 29C.

Compression of the seal 200 from the resting configuration towards a deformed configuration may cause the second internal diameter of the first tubular region 201a to change (such as initially increasing) compared to the resting configuration, thereby facilitating the second tubular region to undergo the deformation to the inverted frustoconical shape.

Once in the initial deformed, in-use, configuration shown in Figure 72B, the second tubular region 201b may allow the third tubular region 201c to translate laterally or pivot relative to the first tubular region 201a, as indicated by the arrows in Figure 72b. This movement may be identical or of the same magnitude as that associated with the seal of Figures 29A to 29C. This movement may allow the seal face angle θ_s and position of the membrane 202 to conform to a user's sub-nasal geometry, in a similar manner to the seal of figures 3 to 9 and 19 to 29C. In this example, this angular adjustment is achieved by stretching one side of the second tubular region 201b while retracting or buckling the other side of the second tubular region 201b.

While the examples of Figure 68 to 71 show seals in the resting configuration having frustoconically shaped tubular regions having internal diameters decreasing in a proximal to distal direction, other frustoconical configurations are also possible.

In some examples, in the resting configuration, at least one frustoconically shaped tubular region has internal diameters decreasing in a proximal to distal direction, and at least one frustoconically shaped tubular region has internal diameters increasing in proximal to distal direction.

In one example, with reference to Figure 73 a seal 200 is provided. The seal 200 has a hollow body 201 with three frustoconically shaped tubular regions 201a, 201b, 201c. Here, the first tubular region 201a, and second tubular region 201b have

respective internal diameters increasing in proximal to distal direction. The third frustoconically shaped tubular region has internal diameters decreasing in proximal to distal direction. The first tubular region 201a, and second tubular region 201b have reverse or inverted frustoconical shapes in relation to the examples of Figures 68 to 71. An advantage of providing at least the first, proximal-most, frustoconically shaped tubular region 201a with internal diameters increasing in proximal to distal direction is that it allows the proximal opening 2013 of the first tubular region to have a relatively small footprint, e.g. a relatively small internal diameter. A smaller footprint allows for minimising the space required to connect the seal to a frame or other interface component. For example, while the internal diameter of the proximal opening 2013 of the examples of Figures 68 to 71 may be about 17 mm, the internal diameter of the proximal opening 2013 of the seal of Figure 73 may be about 8 mm, resulting in about 45% less footprint.

In some examples, the internal diameter of the second tubular region 201b increases from the second longitudinal boundary 20112 to a point between the second longitudinal boundary 20112 and third longitudinal boundary 20113, and then decreases towards the third longitudinal boundary 20113.

In the example of Figure 73, the first internal diameter of the first tubular region at the first longitudinal boundary 20111 at the proximal end of the hollow body is smaller than the second internal diameter at the second longitudinal boundary 20112. The second internal diameter is smaller than the third internal diameter at the third longitudinal boundary 20113. The third internal diameter is larger than the fourth internal diameter at the fourth longitudinal boundary 20114.

With reference to Figures 73 and 74, the first internal diameter of the first tubular region 201a, being smaller than the second internal diameter of the first tubular region 201a, allows the seal to act as a male connecting portion that may be inserted into an attachment region 301, such as an opening, of the frame, housing or other interface component (not shown). The lips 2033 on the exterior of the proximal end 2010 of the first tubular region 201a may prevent the seals from detaching once assembled onto the frame or housing. The lips may be configured to engage with opposing geometry or an internal surface of the housing or frame in order to prevent or resist accidental detachment.

Alternatively, the lips 2033 may be arranged on the interior of the proximal end of the first tubular region 201a, similar to the examples shown with reference to Figures 3 to 9, 18 to 29C, and 34, 36A to 36F to 38C, to 42, 44, 46, 48A, 50, 52, 58, 59, and 63. In this example, the lips 2033 form part of a female connecting portion 203 to connect to a male connecting portion or attachment regions 301 on the frame.

In use, when subject to an external load having a component along the longitudinal axis 2015 towards the proximal end, the seal of Figure 73 may deform such that the second tubular region 201b folds towards the proximal end towards the outside of the first tubular region 201a, to attain an inverted frustoconical shape as compared to its frustoconical shape in the resting configuration. As a result, the first tubular region 201a recesses into the third tubular region 201c. The deformation in the proximal direction may be limited by contact between the distal end of the first tubular region 201a and a mid-region of the third tubular region 201c, as a result of the third tubular region 201c having a frustoconical shape inverted in relation to that of the first tubular region 201a.

In the Figure 73 example the thickness of the wall profile of the first tubular region 201a may be about 0.8 mm. The thickness of the wall profile of the second tubular region 201b may transition from the thickness of the first tubular region 201a to about 0.4 mm at the third longitudinal boundary 20113. The thickness of the wall profile of the third tubular region 201c may transition from the thickness of the second tubular region 201b at the third longitudinal boundary 20113 to about 0.8 mm at the fourth longitudinal boundary 20114. The reduced thickness of the second tubular region 201b may promote deformation in said region.

With reference to the seal of Figure 73, the angle between the wall profile of the first tubular region 201a and the longitudinal axis or centreline 2015 may be about 4 degrees. The angle between the wall profile of the second tubular region 201b and the longitudinal axis or centreline 2015 may be about 54 degrees. The angle between the wall profile of the third tubular region 201c and the longitudinal axis or centreline 2015 may be about 25 degrees.

With reference to the seal of Figure 73, the longitudinal extension, i.e. a shortest distance between the first longitudinal boundary 20111 and the second longitudinal boundary 20112, of the first tubular region is larger than longitudinal extension of the second tubular region 201b, and the longitudinal extension of the third tubular region 201c. Here, the longitudinal extension of the respective tubular regions is defined as a shortest distance between the respective longitudinal boundaries between which the tubular region is defined. In this example the longitudinal extension of the second tubular region is smaller than that of the first tubular region 201a, and the third tubular region 201c. For example, the longitudinal extension of the first tubular region 201a may be about 9 mm, the longitudinal extension of the second tubular region 201b may be about 5 mm, and the longitudinal extension of the third tubular region 201c may be 6.5 mm.

While the seal(s) disclosed herein have been described for connection to a frame 300 via the connecting portion, it should be appreciated that corresponding

connection features may be provided to a housing, plenum chamber or other mask components, thereby allowing the seal(s) disclosed herein also being arranged to connect to such components. Alternatively, the seal may be integrally formed with said frame 300, housing, plenum chamber or other mask components.

CLAIMS

1. A seal for a patient interface configured to provide respiratory therapy to a patient, the seal comprising:

a hollow body comprising a proximal end and a distal end, the proximal end comprising an inlet opening and the distal end comprising an outlet opening, wherein the hollow body is configured to provide, in use, a flow path for breathing gases from the inlet opening to the outlet opening; and

a membrane extending outwardly from the hollow body, wherein the membrane comprises a sealing surface configured to seal against an exterior surface of or adjacent a single external nare of the patient.

2. The seal of claim 1, wherein the membrane extends outwardly from the distal end of the hollow body.

3. The seal of claim 1 or 2, wherein at least a portion of the membrane extends radially outwardly from the hollow body.

4. The seal of any one of claims 1 to 3, wherein at least a portion of the membrane is curved towards the proximal end of the hollow body.

5. The seal of any one of claims 1 to 4, wherein the sealing surface comprises a convex geometry.

6. The seal of any one of claims 1 to 5, wherein at least a portion of the membrane extends substantially perpendicularly from the hollow body.

7. The seal of any one of claims 1 to 6, wherein the sealing surface of the membrane, in a resting configuration, extends outwardly from a distal end of the hollow body at an angle equal to or more than 90° in relation to a longitudinal axis or centreline defined between the inlet opening of the hollow body and the outlet opening of the hollow body.

8. The seal of any one of claims 1 to 7, wherein the hollow body comprises a tubular wall having a straight section at the distal end of the hollow body.

9. The seal of claim 8, wherein the sealing surface of the membrane, in a resting configuration, extends outwardly from the distal end of the hollow body at an angle equal to or more than 90° in relation to the straight section.

10. The seal of any one of claims 1 to 9, wherein the membrane is configured to rest against an exterior surface of the patient's external nare, so as to not extend into the patient's nare, in use.

11. The seal of any one of claims 1 to 10, wherein the membrane is cantilevered from the hollow body, in a cross-section plane comprising a longitudinal axis or centreline of the hollow body.

12. The seal of claim 11, wherein the membrane comprises a quarter-rounded curvature, in the cross-section plane.

13. The seal of any one of claims 1 to 12, wherein the membrane tapers in thickness towards an outermost end of the membrane.

14. The seal of any one of claims 1 to 13, further comprising a zone that has a curvature being larger than a curvature of the sealing surface.

15. The seal of claim any one of claims 1 to 14, further comprising a zone that that has a curvature towards the proximal end of the hollow body.

16. The seal of claim any one of claims 1 to 15, wherein the membrane and/or sealing surface has a curvature gradually increasing towards the outermost end, in a cross-section plane comprising a longitudinal axis or centreline of the hollow body.

17. The seal of any one of claims 1 to 16, wherein the sealing surface comprises two or more different curvatures along its outward dimension, in a cross-section plane comprising a longitudinal axis or centreline of the hollow body.

18. The seal of any one of claims 1 to 17, the membrane comprising:
a first zone peripheral to the outlet opening, and
a second zone peripheral to the first zone,
wherein the second zone comprises a curvature greater than a curvature of the first zone in a cross-section plane comprising a longitudinal axis or centreline of the hollow body.

19. The seal of claim 18, the second zone comprising, in the cross-section plane, continuously varying curvature.

20. The seal of claim 18 or 19, wherein, in the cross-section plane, a minimum curvature of the second zone is greater than a maximum curvature of the first zone.

21. The seal of any one of claims 18 to 20, wherein at least the first zone is configured to seal with the single external nare of the patient.

22. The seal of any one of claims 18 to 21, wherein at least part of the first zone extends substantially perpendicularly to the hollow body.

23. The seal of any one of claims 18 to 22, wherein the first zone comprises the sealing surface.

24. The seal of any one of claims 18 to 23 in combination with claim 13, wherein the membrane further comprises an outer zone formed between the second zone and the outermost end of the membrane.

25. The seal of claim 24, wherein, in the cross-section plane, at least part of the outer zone is substantially parallel with a section of the hollow body.

26. The seal of claim 24 or 25, wherein the outer zone is configured to control in the deformation of the first zone or second zone when experiencing an external load, in use.

27. The seal of any one of claims 24 to 26, wherein the second zone comprises a greater curvature than the outer zone.

28. The seal of any one of claims 24 to 27, wherein, in the cross-section plane, a minimum curvature of the second zone is greater than a maximum curvature of the outer zone.

29. The seal of any one of claims 1 to 28, the membrane comprising at least two-fold rotational symmetry.

30. The seal of any one of claims 1 to 29, the membrane comprising an elliptical surface in cross section.

31. The seal of any one of claims 1 to 30, wherein one or more of the membrane, hollow body, or seal comprising rotational symmetry.

32. The seal of any one of claims 1 to 31, wherein one or more of the membrane, hollow body, or seal comprising at least two-fold rotational symmetry.

33. The seal of any one of claims 1 to 32, wherein the membrane and hollow body are integrally formed.

34. The seal of any one of claims 1 to 33, wherein the membrane comprises a lower surface opposite the sealing surface and at least partially facing the proximal end of the hollow body.

35. The seal of claim 34, wherein the lower surface extends to an outermost end of the membrane.

36. The seal of claim 34 or 35, wherein the lower surface comprises a concave geometry.

37. The seal of any one of claims 34 to 36, wherein the lower surface and a wall of the hollow body together define a cavity between the membrane and the hollow body.

38. The seal of claim 37, wherein the cavity has toroidal geometry.

39. The seal of any one of claims 1 to 38, wherein the membrane comprises a decoupling zone.

40. The seal of claim 39, wherein the decoupling zone comprises an indentation in a surface of the membrane.

41. The seal of claim 40, wherein the indentation is formed in a lower surface of the membrane.

42. The seal of claim 30 or 41, wherein the indentation comprises a circular groove in the membrane.

43. The seal of any one of claims 1 to 42, wherein at least a part of the membrane surrounds the flow path for breathing gases.

44. The seal of any one of claims 1 to 43, wherein the membrane is a non-inflatable membrane.

45. The seal of any one of claims 1 to 44, comprising a connecting portion configured to support the hollow body and to couple with a source of breathing gases.

46. The seal of claim 45, wherein the connecting portion has a greater inner diameter than an outer diameter of the proximal end of the hollow body.

47. The seal of claim 45 or 46, wherein, in a resting configuration, the proximal end of the hollow body is at least partially recessed into the connecting portion

48. The seal of any one of claims 45 to 47, wherein the connecting portion and hollow body are concentric.

49. The seal of any one of claims 45 to 48, wherein the connecting portion is configured to couple with a frame.

50. The seal of any one of claims 45 to 49, comprising a suspension element connected to the proximal end of the hollow body.

51. The seal of claim 50, wherein the suspension element comprises one or more folds configured to deform to allow the membrane and/or hollow body to pivot and/or translate with respect to the connecting portion, in use.

52. The seal of claim 50 or 51, wherein the suspension element is peripheral to the proximal end of the hollow body.

53. The seal of any one of claims 50 to 52, wherein the suspension element comprises a first bend.

54. The seal of any one of claims 50 to 53, the suspension element comprises a second bend.

55. The seal of claim 54, wherein the first bend is arranged between the proximal end of the hollow body and the second bend.

56. The seal of claim 54 or 55, wherein the second bend is arranged between the first bend and the connecting portion.

57. The seal of any one of claims 54 to 56, wherein the suspension element comprises an inflection between the first bend and the second bend.

58. The seal of any one of claims 54 to 57, wherein the first bend has a first radius, and the second bend has a second radius, wherein the first radius is different from the second radius.

59. The seal of any one of claims 54 to 58, wherein the first bend and second bend are concentric.

60. The seal of any one of claims 50 to 59, wherein the suspension element comprises an S-curve in cross-section.

61. The seal of any one of claims 50 to 60, wherein the suspension element is connected to the connecting portion.

62. The seal of any one of claims 50 to 61, wherein the connecting portion, hollow body and suspension element are concentric.

63. The seal of any one of claims 50 to 62, wherein the suspension element is at least partially recessed into the connecting portion.

64. The seal of any one of claims 50 to 63, wherein the suspension element spaces the connecting portion and the hollow body apart from each other.

65. The seal of any one of claims 50 to 64, wherein the suspension element is configured to deform such that, in use, the hollow body is able to tilt relative to the connecting portion.

66. The seal of any one of claims 50 to 65, wherein the suspension element is configured to deform such that, in use, the hollow body is able to move longitudinally relative to the connecting portion.

67. The seal of any one of claims 50 to 66, wherein the hollow body and the suspension element are integrally formed.

68. The seal of any one of claims 50 to 67, wherein the connecting portion and the suspension element are integrally formed.

69. The seal of any one of claims 50 to 68, wherein the suspension element extends between the proximal end of the hollow body and a distal end of the connecting portion.

70. The seal of claim 1, wherein the sealing surface comprises a convex geometry; and further comprising
a connecting portion connected to the hollow body at or near the proximal end of the hollow body via a suspension element.

71. The seal of any one of claims 1 to 70, wherein the membrane is not in the flow path for breathing gases, in use.

72. The seal of any one of claims 1 to 71, wherein the hollow body forms one or more tubular regions between the proximal end and distal end.

73. The seal of claim 72, wherein each tubular region extends longitudinally around a centreline of the hollow body.

74. The seal of claim 72 or 73, wherein at least one of the one or more tubular regions comprises a tubular wall.

75. The seal of claim 74, wherein the tubular wall of at least one of the one or more tubular regions has a wall profile being symmetrical about the centreline of the hollow body.

76. The seal of any one of claims 72 to 75, wherein at least one of the one or more tubular regions has a shape different from the shape of another of the one or more tubular regions.

77. The seal of any one of the claims 72 to 75, wherein each tubular region extends between two longitudinal boundaries of the hollow body.

78. The seal of claim 77, wherein each longitudinal boundary is formed in plane perpendicular to the centreline of the hollow body.

79. The seal of claim 77 or 78, wherein one of the one or more tubular regions extends to a longitudinal boundary from which another of the one or more tubular regions extends.

80. The seal of any one of claims 72 to 79, wherein a first tubular region of the one or more tubular regions extends between
a first longitudinal boundary arranged at the proximal end of the hollow body or at a first longitudinal distance from the proximal end of the hollow body, and
a second longitudinal boundary arranged at a second longitudinal distance from the proximal end of the hollow body, wherein the second longitudinal distance is larger than the first longitudinal distance.

81. The seal of claim 80, wherein a second tubular region of the one or more tubular regions extends between the second longitudinal boundary and a third longitudinal boundary arranged at the distal end or at a longitudinal distance from the distal end.

82. The seal of any one of claims 77 to 81, wherein at least one of the longitudinal boundaries of each tubular region is defined at a longitudinal position of the hollow body where there is a longitudinal change in curvature or thickness of the hollow body.

83. The seal of any one of claims 72 to 82, wherein at least one of the one or more tubular regions is bulbous.

84. The seal of any one of claims 72 to 82, wherein at least one of the one or more tubular regions is concave with reference to a centreline of the hollow body.

85. The seal of any one of claims 72 to 82, wherein at least one of the one or more tubular regions is partly oblate spherical.

86. The seal of claim 83, 84, or 85 when dependent on claim 80, wherein one of said at least one tubular region forms the first tubular region.

87. The seal of any one of claim 72 to 86, wherein at least one of the one or more tubular regions is cylindrical.

88. The seal of claim 81, wherein the second tubular region is cylindrical.

89. The seal of any one of claims 72 to 88, wherein each tubular region, in a frontal plane dividing the hollow body into two symmetrical halves, has a first wall profile and a second wall profile arranged either side of the centreline.

90. The seal of claim 89, wherein the first wall profile of at least one tubular region has a shape symmetrical to that of the second wall profile in relation to the centreline.

91. The seal of claim 89 or 90, wherein the first wall profile has the same length as that of the second wall profile.

92. The seal of any one of claims 89 to 91, wherein
an interior lateral dimension between the first wall profile and the second wall profile at the proximal end is larger than
an interior lateral dimension between the first wall profile and the second wall profile at the distal end.

93. The seal of any one of claims 83 to 86 or any claim dependent thereon, wherein said at least one tubular region forms a deformation region arranged to deform when subject to an external load.

94. The seal of claim 93, wherein the deformation region allows the distal end of the hollow body to be compressed towards the proximal end of the hollow body, in use.

95. The seal of claim 93 or 94, wherein the deformation region allows the membrane to pivot relative the inlet opening of the hollow body, in use.

96. The seal of claim 89 or any claim dependent thereon, wherein an internal lateral dimension between the first wall profile and second wall profile of a tubular region, at a longitudinal position between the two longitudinal boundaries of said tubular region, is larger than an internal dimension between the first wall profile and second profile of said region, at the distal end or proximal end of the hollow body.

97. The seal of claim 96, wherein said internal lateral dimensions are defined in a plane perpendicular to a frontal plane dividing the hollow body into two symmetrical halves.

98. The seal of claim 89 in combination with claim 45 or any claim dependent thereon, wherein a largest internal lateral dimension between the first wall profile and second wall profile of a tubular region, at a longitudinal position between the two longitudinal boundaries of said tubular region, is smaller than a largest interior lateral dimension of the connecting portion.

99. The seal of claim 89 in combination with claim 45 or any claim dependent thereon, wherein a largest internal lateral dimension between the first wall profile and second wall profile of a tubular region, at a longitudinal position between the two longitudinal boundaries of said tubular region, is larger than a largest interior lateral dimension of the connecting portion.

100. The seal of claim 89 in combination with claim 45 or any claim dependent thereon, wherein a largest internal lateral dimension between the first wall profile and second wall profile of a tubular region, at a longitudinal position between the two longitudinal boundaries of said tubular region, is smaller than a lateral dimension, such as outer diameter, of the membrane.

101. The seal of claim 89 in combination with claim 45 or any claim dependent thereon, a largest internal lateral dimension between the first wall

profile and second wall profile of a tubular region, is formed longitudinally half-way or substantially half-way between the two longitudinal boundaries of said tubular region.

102. The seal of claim 89 or any claim dependent thereon, wherein in the resting configuration, at least one of the first wall profile and second wall profile comprises at least one of the following:

- a portion having a continuously varying curvature;
- a portion concave with reference to a longitudinal axis or centreline of the hollow body;
- a rounded or bulbous portion;
- a bellows-shaped portion;
- a parabolic portion;
- a portion shaped like part of a substantially oblate sphere; and
- an S-shaped portion.

103. The seal of claim 89 in combination with claim 77, wherein in a resting configuration,

the first wall profile of one of the one or more tubular regions comprises a portion concave with reference to the longitudinal axis or centreline of the hollow body between the first longitudinal boundary and second longitudinal boundary, and/or

the second wall profile of said associated tubular region comprises a portion concave with reference to the longitudinal axis or centreline of the hollow body between the first longitudinal boundary and second longitudinal boundary.

104. The seal of claim 89 in combination with claim 77, wherein in the resting configuration, wherein

the first wall profile of one of the one or more tubular regions comprises a straight portion between the second longitudinal boundary and the distal end, and/or

the second wall profile of said associated tubular region comprises a straight portion between the first longitudinal boundary and the second longitudinal boundary.

105. The seal of claim 89 in combination with claim 77, wherein a shape of the tubular region continuously gradually changes between the first longitudinal boundary and the second longitudinal boundary.

106. The seal of claim 89 in combination with claim 77, wherein at least a portion of one of the first wall profile and second wall profile is symmetrical about a transverse plane orthogonal to the frontal plane and the centreline of the hollow body.

107. The seal of claim 106, wherein the transverse plane comprises a halfway point between the first longitudinal boundary and second longitudinal boundary.

108. The seal of any one of claims 72 to 107, wherein at least one of the one or more tubular regions has a tubular wall profile with a shape asymmetrical in relation to the centreline of the hollow body.

109. The seal of any one of claims 89 or any claim dependent thereon, wherein the first wall profile of one of the one or more tubular regions has a shape asymmetrical to the shape of the second wall profile of said tubular region in relation to the centreline of the hollow body.

110. The seal of any one of claim 89 or any claim dependent thereon, wherein the first wall profile of one of the one or more tubular regions has a length that is different, such as longer, than that of the second wall profile of said tubular region.

111. The seal of claim 89 or any claim dependent thereon, wherein the first wall profile is symmetrical about a transverse plane orthogonal to the frontal plane and the centreline, and the second wall profile is asymmetrical about the transverse plane.

112. The seal of claim 89 or any claim dependent thereon, wherein the tubular region has a shape conforming with the first wall profile spanning a first angular distance either side of the frontal plane around the centreline of the hollow body.

113. The seal of claim 112, wherein the first angular distance is defined between a first angular transition point and a second angular transition point along the perimeter of the hollow body.

114. The seal of claim 112 or 113, wherein the first angular distance is larger than 180°, such as 240° to 270°, such as 260°.

115. The seal of any one of claims 112 to 114, wherein the tubular region has a uniform shape across the first angular distance around the centreline .

116. The seal of any one of claims 112 to 115, wherein the tubular region has a shape conforming with the second wall profile in the frontal plane.

117. The seal of any one of claims 112 to 116, wherein the tubular region has a shape conforming with second wall profile only in the frontal plane.

118. The seal of claim 113 or any claim dependent thereon, wherein the tubular region further comprises

a first transition region having a shape geometrically transitioning from the shape of the first wall profile at the first angular transition point to the shape of the second wall profile at the frontal plane, and

a second transition region having a shape geometrically transitioning from the shape of the first wall profile at the second angular transition point to the shape of the second wall profile at the frontal plane.

119. The seal of claim 89 or any claim dependent thereon, wherein the tubular region has a shape conforming with the second wall profile spanning a second angular distance either side of the frontal plane around the centreline of the hollow body.

120. The seal of claim 119, wherein the second angular distance is defined between a third angular transition point and a fourth angular transition point along the perimeter of the hollow body.

121. The seal of claim 119 and 120, wherein the second angular distance is less than 110°, such as 100°.

122. The seal of any one of claims 119 to 121, wherein
the angular distance between the third angular transition point and the first angular transitions point is identical to the angular distance between the between the fourth angular transition point and the second angular transition point.

123. The seal of claim 122, wherein the sum of the angular distance between the third angular transition point and the first angular transition point and the angular distance between the second angular transition point and fourth angular transition point is 360° less the first angular distance less the second angular distance.

124. The seal of claim 113, wherein the first angular distance is 80° to 120° , such as 100° , and the second angular distance is 80° to 120° , such as 100° .

125. The seal of claim 113 or any claim dependent thereon, wherein the first angular transition point and the second angular transition point are located at a common radial distance from the centreline of the hollow body.

126. The seal of claim 125, wherein the tubular region further comprises
a third transition region having a shape geometrically transitioning from the shape of the first wall profile at the first angular transition point to the shape of the second wall profile at the third angular transition point, and

a fourth transition region having a shape geometrically transitioning from the shape of the first wall profile at the second angular transition point to the shape of the second wall profile at the fourth angular transition point.

127. The seal of claim 18 or any claim dependent thereon, wherein the first zone is planar or substantially planar.

128. The seal of claim 127, wherein the first zone in the resting configuration extends perpendicular or substantially perpendicular to the centreline of the at the distal end of the hollow body.

129. The seal of claim 127, wherein the first zone extends from a first radial position to a second radial position in relation to the centreline of the hollow body, wherein the second radial position is larger than one or more of:

an outermost radial position of the hollow body in the resting configuration or in-use configuration; and

an outermost radial position of the connecting portion in the resting configuration or in-use configuration.

130. The seal of claim 18 or any claim dependent thereon, wherein the first zone extends from a first radial position to a second radial position in relation to the centreline of the hollow body, wherein the membrane has a first thickness at the first radial position, and a second thickness at the second radial position, wherein the first thickness is larger than the second thickness.

131. The seal of claim 130, wherein the thickness of the membrane gradually reduces from the first thickness to the second thickness between the first radial position and the second radial position.

132. The seal of any one of claims 127 to 131, wherein the second radial position is located between 8.5mm to 12mm from the centreline of the hollow body, thereby forming an outer diameter of the first zone between 17mm and 24mm.

133. The seal of claim 72 or any claim dependent thereon, wherein at least one tubular region of the hollow body has a uniform thickness.

134. The seal of claim 89 or any claims dependent thereon, wherein a thickness of the first wall profile is different from a thickness of the second wall profile.

135. The seal of any one of claims 72 to 134, when dependent on claim 45, wherein a distal end of the connecting portion is provided to the proximal end of the hollow body and a proximal end of the connecting portion is configured to couple with a frame.

136. The seal of claim 135, wherein the connecting portion, in a frontal plane dividing the hollow body into two symmetrical halves, comprises a first connecting portion wall profile and a second connecting portion wall profile arranged either side of a centreline of the connecting portion.

137. The seal of claims 135 or 136, wherein the connecting portion is arranged to:
support the hollow body, and
resist self-deformation while enabling deformation of the hollow body, in use.

138. The seal of claim 136 or any claim dependent thereon, wherein the first connecting portion wall profile comprises at least one fold configured to deform to allow the membrane and/or hollow body to pivot and/or translate with respect to the connecting portion, in use.

139. The seal of claim 136 or any claim dependent thereon, wherein the second connecting portion wall profile is fold-less.

140. The seal of any one of claims 135 to 139, wherein, in a frontal plane dividing the hollow body into two symmetrical halves, the connecting portion has a shape conforming with the first connecting portion wall profile spanning a first angular distance either side of the frontal plane around the centreline of the connecting portion.

141. The seal of claim 140, wherein the connecting portion has a shape conforming with the second connecting portion profile spanning a second angular distance either side of the frontal plane around the centreline of the connecting portion.

142. The seal of claim 141, wherein the second angular distance is defined between a third angular transition point and a fourth angular transition point along the perimeter of the connecting portion.

143. The seal of claim 142, wherein the connecting portion further comprises

a first transition region having a shape geometrically transitioning from the shape of the first connecting portion wall profile at the first angular transition point to the shape of the second connecting portion wall profile at the third angular transition point, and

a second transition region having a shape geometrically transitioning from the shape of the first connecting portion wall profile at the second angular transition point to the shape of the second connection portion wall profile at the fourth angular transition point.

144. The seal of any one of claims 135 to 143, wherein the thickness of the connecting portion reduces from its proximal end towards its distal end.

145. The seal of any one of claims 72 to 144, wherein, in a frontal plane dividing the hollow body into two symmetrical halves, the membrane is convex in relation to the proximal end of the hollow body.

146. The seal of claim 145, wherein the membrane is a sealing membrane and the seal further comprises a support membrane extending outwardly from the hollow body, wherein the support membrane is positioned between the sealing membrane and the distal end of the hollow body.

147. The seal of claim 146, wherein, in a frontal plane dividing the hollow body into two symmetrical halves, the support membrane is concave in relation to the proximal end of the hollow body.

148. The seal of claim 146 or 147 wherein the sealing membrane has an undulating outer edge.

149. The seal of any one of claims 72 to 82, wherein the at least one of the one or more tubular regions have a frustoconical shape in a resting configuration.

150. The seal of claim 149, comprising a first tubular region attached to a connecting portion at a proximal end thereof.

151. The seal of claim 150, wherein the first tubular region forms a proximal-most tubular region of the hollow body.

152. The seal of claim 150 or 151, wherein the connecting portion is attached or integrally formed with the first tubular region.

153. The seal of any one of claims 150 to 152, wherein the connecting portion comprises a lip 2033 arranged exterior or interior of the first tubular region at its proximal end, wherein the lip is configured to attach to a corresponding attachment region of a frame of a patient interface.

154. The seal of any one of claims 149 to 153, wherein two or more of the tubular regions have, or each of the tubular regions has, a frustoconical shape in the resting configuration.

155. The seal of any one of claims 149 to 154, wherein at least one of the one or more frustoconical shaped tubular regions is arranged to retain its frustoconical shape when deformed.

156. The seal of any one of claims 149 to 155, wherein the frustoconical shape is formed by a wall profile of the tubular region angled against a longitudinal axis or centreline of the hollow body.

157. The seal of any one of the claims 149 to 156, wherein at least one of or each of the frustoconically shaped tubular regions has a first internal diameter at a proximal end thereof and a second internal diameter, different from the first internal diameter, at a distal end thereof.

158. The seal of any one of claims 149 to 157, wherein the hollow body comprises a first tubular region at the proximal end of the hollow body, a second tubular region, and a third tubular region, wherein the second tubular region is arranged between the first tubular region and third tubular region.

159. The seal of claim 158, wherein at least one or each of the frustoconically shaped tubular regions has an internal diameter decreasing in a proximal to distal direction.

160. The seal of claim 158, wherein an internal diameter of the first tubular region, in proximal to distal direction, ranges between a first internal diameter and a second internal diameter, an internal diameter of the second tubular region ranges between the second internal diameter and a third internal diameter, and an internal diameter of the third tubular region ranges between the third internal diameter and a fourth internal diameter.

161. The seal of claim 160, wherein the first internal diameter of the first tubular region at the proximal end of the hollow body is larger than the second internal diameter, the second internal diameter is larger than the third internal diameter, and the third internal diameter is larger than the fourth internal diameter.

162. The seal of any one of claims 158 to 161, wherein a longitudinal extension of the first tubular region is larger than longitudinal extension of the second tubular region and a longitudinal extension of the third tubular region.

163. The seal of claim 162, wherein a longitudinal extension of the third tubular region is larger than a longitudinal extension of the second tubular region.

164. The seal of any one of claims 158 to 163, wherein a thickness of a wall profile of the second tubular region is less than that of the first tubular region or the third tubular region.

165. The seal of any one of claims 158 to 164, wherein a thickness of a wall profile of the first tubular region transitions from a first thickness at the first longitudinal boundary to a second thickness at the second longitudinal boundary.

166. The seal of any one of claims 158 to 165, wherein a thickness of a wall profile of the second tubular region transitions from a second thickness at the second longitudinal boundary to a third thickness at the third longitudinal boundary.

167. The seal of any one of claims 158 to 166, wherein a thickness of the wall profile of the respective tubular region transitions to a thickness of an adjacent tubular region at the interfaces thereof.

168. The seal of any one of claims 158 to 167, wherein at least one tubular region is configured to deform from the frustoconical shape to an inverted frustoconical shape upon deformation.

169. The seal of any one of claims 158 to 168, wherein the third frustoconically shaped tubular region is configured to be longitudinally displaced at least partly into the first frustoconically shaped tubular region upon deformation.

170. The seal of claim 160, wherein at least one frustoconically shaped tubular region has an internal diameter increasing in proximal to distal direction.

171. The seal of 170, wherein the first tubular region, and second tubular region has respective internal diameters increasing in proximal to distal direction, and the third frustoconically shaped tubular region has an internal diameter decreasing in proximal to distal direction.

172. The seal of claim 171, wherein the first internal diameter of the first tubular region at the proximal end of the hollow body is smaller than the second

internal diameter, the second internal diameter is smaller than the third internal diameter, and the third internal diameter is larger than the fourth internal diameter.

173. The seal of claim 172, wherein the first tubular region is configured to recess into the third tubular region, and optionally contact the third tubular region, upon deformation.

174. The seal of claim 173, wherein a thickness of the second tubular region is less than that of the first tubular region or third tubular region.

175. A patient interface for providing respiratory therapy to a patient comprising:

a pair of seals, each seal comprising:

a hollow body comprising a proximal end and a distal end, the proximal end comprising an inlet opening and the distal end comprising an outlet opening, wherein the hollow body is configured to provide, in use, a flow path for breathing gases from the inlet opening to the outlet opening; and

a membrane extending outwardly from the hollow body, wherein the membrane comprises a sealing surface configured to seal with a single external nare of the patient;

a frame configured to receive a flow of breathing gas, the frame comprising a pair of seal attachment regions, wherein each seal attachment region comprises an aperture configured to direct breathing gases to the inlet opening of the seal; and

a connecting portion at or near the proximal end of the hollow body configured to couple with the frame.

176. The patient interface of claim 175, wherein the connecting portion is removably attachable to the seal attachment region.

177. The patient interface of claim 175 or 176, the seal attachment region comprising a male portion configured to connect to an interior wall of the connecting portion for supporting the seal.

178. The patient interface of claim 177, wherein the male portion surrounds the aperture.

179. The patient interface of claim 177 or 178, wherein an inner surface of the connecting portion is configured to removably attach to an outer surface of the male portion.

180. The patient interface of claim 178 or 179, wherein the male portion comprises an exterior recess configured to removably attach to an interior lip of the connecting portion.

181. The patient interface of any one of claims 175 to 180, wherein the pair of seals are connected to each other.

182. The patient interface of any one of claims 175 to 180, wherein the pair of seals are separate from each other.

183. The patient interface of any one of claims 175 to 182, wherein the frame is more rigid than the pair of seals.

184. The patient interface of any one of claims 175 to 183, wherein the frame comprises an air inlet for connection with a gases delivery tube, and an interior chamber for receiving breathing gases from the gases delivery tube.

185. The patient interface of claim 184, wherein the frame is configured to maintain its structural integrity with changes in a pressure of breathing gas during respiratory therapy, in use.

186. The patient interface of any one of claims 175 to 185, wherein the sealing surfaces of each pair of seals are angled towards each other.

187. The patient interface of any one of claims 175 to 186, wherein, in a resting configuration, the angle between the sealing surfaces of each pair of seals is between 100° and 146°.

188. The patient interface of any one of claims 175 to 187, wherein the sealing surfaces of each pair of seals are configured to conform to a sub-nasal angle of a patient, in use.

189. The patient interface of any one of claims 175 to 188, wherein, in a resting configuration, the angle between the sealing surfaces of each pair of seals is smaller than a sub-nasal angle of a patient.

190. The patient interface of any one of claims 175 to 187, wherein the angle between the sealing surfaces of each pair of seals in the resting configuration is larger than the angle between the sealing surfaces of the pair of seals, in use.

191. The patient interface of any one of claims 175 to 190, wherein, in at least a resting configuration, the membranes of each of the pair of seals are in contact at a central point between the pair of seals.

192. The patient interface of any one of claims 175 to 191, wherein, in at least a resting configuration, the membranes of each of the pair of seals interfere and/or deform when assembled with the frame.

193. The patient interface of any one of claims 175 to 192, wherein the sealing surface of each pair of seals comprises:
a first zone peripheral to the distal opening, and
a second zone peripheral to the first zone,
wherein, the second zone comprises a curvature greater than a curvature of the first zone in a cross-section plane comprising a longitudinal axis or centreline of the hollow body;
wherein the membranes of each pair of seals contact each other at their respective second zones.

194. The patient interface of any one of claims 175 to 192, wherein each seal of the pair of seals further comprises the subject matter of any one of claims 72 to 174.