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Patient interface systems

Abstract

A patient interface structure for delivery of respiratory therapy to a patient includes a cushion assembly having a mouth seal configured to seal around the patient's mouth and a nasal seal configured to seal against at least an underside of the patient's nose. A cushion clip is attached to the cushion assembly and adds rigidity to the cushion assembly, while a frame with a plurality of headgear attachment points is configured to snap onto the cushion clip. In addition, an air inlet passage along a posterior surface of the frame includes a first end that is configured to attach to an air delivery tube and a second end that is configured to sealingly attach to an opening in the chamber that is at least partially formed by the cushion assembly and the cushion clip. The patient interface structure also includes headgear attachable to the headgear attachment points on the frame.

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Background/Summary

CROSS REFERENCE TO RELATED APPLICATIONS (1) This application is a continuation of U.S. application Ser. No. 16/032,722, filed Jul. 11, 2018, now allowed, which is a continuation of U.S. application Ser. No. 14/645,457, filed Mar. 12, 2015, now U.S. Pat. No. 10,052,448, which is a continuation of U.S. application Ser. No. 13/876,624, now U.S. Pat. No. 9,010,330, filed Mar. 28, 2013, which is the U.S. national phase of International Application No. PCT/AU2011/001258 filed 30 Sep. 2011 which designated the U.S. and claims the benefit of U.S. Provisional Applications 61/388,357, 61/443,623, 61/457,981, and 61/528,524, filed Sep. 30, 2010, Feb. 16, 2011, Jul. 27, 2011, and Aug. 29, 2011, respectively, the entire contents of each being incorporated herein by reference in its entirety.

FIELD OF THE INVENTION
(1) The present technology relates to a patient interface, or mask, system for treatment of sleep disordered breathing (SDB).
BACKGROUND
(2) Treatment of sleep disordered breathing (SDB), such as obstructive sleep apnea (OSA), by continuous positive airway pressure (CPAP) flow generator systems involves the continuous delivery of air (or other breathable gas) pressurized above atmospheric pressure to the airways of a human via a conduit and a mask. Typically, the mask fits over or in the mouth and/or nose of the patient. Pressurized air flows to the mask and to the airways of the patient via the nose and/or mouth. Pressurized air is delivered to the mask by a conduit connected to the CPAP device and the mask.
(3) The mask should be comfortable and unobtrusive so that a patient may tolerate therapy and maintain usage. Some patients may prefer a pillows or prongs type mask (as known in the art), or a nasal mask or a full face mask. Some patient's may prefer to use one or a combination of these masks interchangeably. However, this would require the purchase of a number of different mask systems, which may be expensive and/or may not be covered by insurance.
(4) In addition, masks including oro-nasal masks typically include a rigid frame. Patients may not find this comfortable. The frame may also dislodge the sealing portion of the mask away from the face of the patient if it is contacted or forced by bed clothing, pillows, etc.
BRIEF SUMMARY
(5) One aspect of the present technology relates to patent interface, or mask, systems that provide integrated nose and mouth seals that are less obtrusive than currently available systems.
(6) Another aspect of the present technology relates to patient interface systems that have reduced part counts compared to currently available systems.
(7) A further aspect of the present technology relates to patient interface systems, for example oro-nasal masks, that provide a visible mouth region of the patient.
(8) Still another aspect of the present technology relates to patient interface systems, for example oro-nasal masks, that do not obstruct the patient's line of sight.
(9) Further aspects of the present technology relate to patient interface systems, for example oro-nasal masks, that are easier and/or more intuitive to assemble, fit, and use by patients, dealers, and clinicians, and provide improved fitting and sealing.
(10) Yet another aspect of the present technology relates to patient interface systems, for example oro-nasal masks, that provide size selection from remote locations, and without assistance and/or instruction.
(11) Another aspect of the present technology relates to patient interface systems, for example oro-

nasal masks, that are considered physiologically non-threatening and will increase patient selection of the system and adherence to therapy.
(12) Further aspects of the present technology relate to patient interface systems, for example oro-nasal masks, that seal the mouth and nasal airways but have no nasal bridge touch points and/or fewer total points of contacts with the patient's face than current systems.
(13) Another aspect of the present technology relates to patient interface systems, for example oro-nasal masks, that comprises a substantially planar fascia that may provide a visible mouth region of the patient.
(14) Another aspect of the present technology relates to patient interface systems, for example oro-nasal masks, that comprises a substantially curved and/or smooth fascia that may provide a visible mouth region of the patient.
(15) Another aspect of the present technology relates to patient interface systems, for example oro-nasal masks, that comprises a substantially curved and/or smooth fascia that may have no ridges, connector portions or other obstructions in the region of the patient's mouth, so that the fascia may provide a visible mouth region of the patient.
(16) Another aspect of the present technology relates to patient interface systems, for example oro-nasal masks, that comprises a substantially smooth fascia that may have no complex shapes, connector portions or other obstructions in the region of the patient's mouth, so that the fascia may provide a visible mouth region of the patient.
(17) Another aspect of the present technology relates to patient interface systems, for example oro-nasal masks, that comprises an air delivery tube connection, the air delivery tube connection positioned on the cushion.
(18) Another aspect of the present technology relates to patient interface systems, for example oro-nasal masks, that comprises an air delivery tube connection, the air delivery tube connection positioned on the fascia and offset from the centre of the fascia, that may provide a visible mouth region of the patient.
(19) Another aspect of the present technology relates to patient interface systems, for example oro-nasal masks, that are substantially comprised of flexible components.
(20) Another aspect of the present technology relates to patient interface systems, for example oro-nasal masks, that are stabilised at the nose sealing portion separately to the mouth sealing portion.
(21) A patient interface structure for delivery of respiratory therapy to a patient according to an example embodiment of the present technology comprises a front plate configured to conform to the shape of the patient's face; a mouth cushion defining a breathing chamber and provided to the front plate and configured to seal around the patient's mouth; and a nasal cushion configured to seal the patient's nasal airways, wherein the nasal cushion is supported by the mouth cushion, does not contact a bridge of the patient's nose in use, and extend at least partially into the breathing chamber.
(22) A patient interface structure for delivery of respiratory therapy to a patient according to an example embodiment of the present technology comprises a front plate configured to conform to the shape of the patient's face; a mouth cushion defining a breathing chamber and provided to the front plate and configured to seal around the patient's mouth; and a nasal cushion configured to seal the patient's nasal airways, wherein the nasal cushion is supported by the mouth cushion, does not contact a bridge of the patient's nose in use, and is raised above the breathing chamber.
(23) A patient interface system according to an example embodiment of the present technology comprises a patient interface structure according to the present technology and a patient interface structure positioning system configured to position, stabilize and secure the patient interface structure in sealing engagement with the patient's face.
(24) A patient interface system according to an example embodiment of the present technology comprises a cushion adapted to sealingly engage with a patient's airways, the cushion comprising a slot adapted to receive a headgear connecting portion of a fascia.
(25) Other aspects, features, and advantages of this technology will become apparent from the

following detailed description when taken in conjunction with the accompanying drawings, which are a part of this disclosure and which illustrate, by way of example, principles of this technology.

Description

BRIEF DESCRIPTION OF THE DRAWINGS

(1) The accompanying drawings facilitate an understanding of the various embodiments of this technology. In such drawings, in which like reference symbols indicate like features:

(2) FIGS. **1-6** are front isometric, front, rear, left, right, and bottom views, respectively, of an example embodiment of a patient interface system according to the present technology;

(3) FIGS. **7-13** are front isometric, front, rear, top, bottom, right and left side views, respectively, of a fascia, or front plate, of the patient interface system of FIGS. **1-6**;

(4) FIGS. **14-19** are front isometric, front, left side, right side, rear and bottom views, respectively, of a patient interface system according to another example embodiment of the present technology;

(5) FIGS. **20-25** are front, rear, rear isometric, top, bottom, and left side views, respectively, of a fascia, frame or front plate, of the patient interface system of FIGS. **14-19**;

(6) FIG. **26** is a front isometric view of a patient interface according to another example embodiment of the present technology and FIGS. **27-33** are front isometric, front, rear, right side, left side, top, and bottom views, respectively, of a fascia, frame or front plate, of the patient interface system of FIG. **26**;

(7) FIGS. **34-40** are front isometric, front, rear, left side, right side, top, and bottom views, respectively, of a patient interface system according to another example embodiment of the present technology;

(8) FIGS. **41-47** are front isometric, front, rear, left side, right side, top, and bottom views, respectively, of the fascia, frame or front plate, including an elbow and the patient interface positioning system of the patient interface system of FIGS. **34-40**;

(9) FIG. **48** is a front isometric view of the fascia, or front plate, including the elbow, and the seal (e.g. cushion) of the patient interface system of FIGS. **34-30**;

(10) FIGS. **49-55** are front isometric, front, rear, right side, left side, top, and bottom views, respectively, of the fascia, frame or front plate, including the elbow, of the patient interface system of FIGS. **34-40**;

(11) FIGS. **56-62** are front isometric, front, rear, rear isometric, right side, top, and bottom views, respectively, of a patient interface positioning system according to an example embodiment of the present technology;

(12) FIGS. **63-69** are front isometric, front, rear, top, bottom, right side, and left side views, respectively, of a mouth seal, or cushion, according to an example embodiment of the present technology;

(13) FIGS. **70-76** are front/bottom isometric, front, rear, top, bottom, side, and front/top isometric views, respectively, of a nasal seal, or cushion, according to an example embodiment of the present technology;

(14) FIGS. **77-83** are front isometric, front, rear isometric, rear, right side, top, and bottom views, respectively, of a seal, or cushion, including the mouth and nasal seals, or cushions, of FIGS. **63-69** and **70-76**, respectively, according to an example embodiment of the present technology;

(15) FIG. **84** is a front view of a patient interface system according to another example embodiment of the present technology;

(16) FIG. **85** is a front view of a patient interface system according to another example embodiment of the present technology;

(17) FIG. **86** is a front isometric view of a patient interface system according to another example embodiment of the present technology;

(18) FIG. **87** is a rear view of a patient interface system according to another example embodiment of the present technology;
(19) FIGS. **88-94** are views of a patient interface system according to another example embodiment of the present technology;
(20) FIG. **95** is a front isometric view of a patient interface system according to another example embodiment of the present technology;
(21) FIG. **96** is a front view of a patient interface system according to another example embodiment of the present technology;
(22) FIG. **97** is a front view of a patient interface system according to another example embodiment of the present technology;
(23) FIG. **98** is a front view of a patient interface system according to another example embodiment of the present technology;
(24) FIG. **99** is a front view of a patient interface system according to another example embodiment of the present technology;
(25) FIG. **100** is a front view of a patient interface system according to another example embodiment of the present technology;
(26) FIG. **101** is a front isometric view of a patient interface system according to another example embodiment of the present technology;
(27) FIG. **102** is an exploded assembly view of a patient interface system according to another example embodiment of the present technology;
(28) FIG. **103** is a front isometric view of a patient interface system according to another example embodiment of the present technology;
(29) FIG. **104** is a rear view of a mouth seal, or cushion, according to an example embodiment of the present technology;
(30) FIG. **105** is a left side view of the mouth seal, or cushion, of FIG. **104**;
(31) FIG. **106** is a schematic illustration of a fascia, or front plate, and a seal, or cushion, including an anti-asphyxia valve according to an example embodiment of the present technology;
(32) FIG. **107** is a schematic illustration of a fascia, or front plate, and a seal, or cushion, including an anti-asphyxia valve according to another example embodiment of the present technology;
(33) FIG. **108** is a schematic illustration of a fascia, or front plate, and a seal, or cushion, including a gusseted side wall according to an example embodiment of the present technology;
(34) FIG. **109** is a schematic illustration of a strap, for example a rear strap, of a patient interface positioning system (e.g. headgear) according to an example embodiment of the present technology;
(35) FIG. **110** is schematic illustration of the strap of FIG. **109** connected to a delivery tube or conduit or hose;
(36) FIG. **111** is a schematic illustration of a strap, for example a rear strap, of a patient interface positioning system (e.g. headgear) according to another example embodiment of the present technology;
(37) FIG. **112** is a schematic illustration of a strap, for example a rear strap, of a patient interface positioning system (e.g. headgear) according to another example embodiment of the present technology;
(38) FIG. **113** is a schematic illustration of a fascia, or front plate, including a venting arrangement according to an example embodiment of the present technology;
(39) FIG. **114** is a schematic illustration of a patient interface system rotatably connectable to a patient interface positioning system according to an example embodiment of the present technology;
(40) FIG. **115** is a rear view of a cushion assembly, including a mouth seal or cushion and a nasal seal or cushion;
(41) FIG. **116** is a front view of the cushion assembly of FIG. **115** including a cushion clip;
(42) FIG. **117** is a cross section view of the cushion assembly and cushion clip along line **117-117**

in FIG. **116**;
(43) FIG. **118** is a detailed view of the connection of the cushion assembly and the cushion clip at a lower portion of the cushion assembly;
(44) FIG. **119** is a detailed view of FIG. **118**;
(45) FIG. **120** is a detailed view of the connection of the cushion assembly and the cushion clip at an upper portion of the cushion assembly;
(46) FIG. **121** is a detailed view of FIG. **120**;
(47) FIG. **122** is a top view of the cushion assembly and cushion clip;
(48) FIG. **123** is a rear view of the cushion clip;
(49) FIG. **124** is a front view of the cushion clip;
(50) FIG. **125** is a cross section view of the cushion clip along line **125-125** in FIG. **124**;
(51) FIG. **126** is a left side view of the cushion clip;
(52) FIG. **127** is a detailed view of FIG. **125**;
(53) FIG. **128** is a top view of the cushion clip;
(54) FIG. **129** is a rear isometric view of a cushion assembly according to an embodiment of the present technology;
(55) FIG. **130** is a rear view of the cushion assembly of FIG. **129**;
(56) FIG. **131** is a cross section view of the cushion assembly along line **131-131** in FIG. **130**;
(57) FIG. **132** is a rear isometric view of a cushion according to an embodiment of the present technology;
(58) FIG. **133** is a rear view of the cushion assembly of FIG. **132**;
(59) FIG. **134** is a cross section view of the cushion assembly along line **134-134** in FIG. **133**;
(60) FIG. **135** is a front isometric view of the cushion assembly and cushion clip of FIG. **125**; and
(61) FIG. **136** is a left side view of the cushion assembly and cushion clip of FIG. **135**.

DETAILED DESCRIPTION OF ILLUSTRATED EMBODIMENTS

(62) The following description is provided in relation to several embodiments which may share common characteristics and features. It is to be understood that one or more features of any one embodiment may be combinable with one or more features of the other embodiments. In addition, any single feature or combination of features in any of the embodiments may constitute additional embodiments.
(63) In this specification, the word “comprising” is to be understood in its “open” sense, that is, in the sense of “including”, and thus not limited to its “closed” sense, that is the sense of “consisting only of”. A corresponding meaning is to be attributed to the corresponding words “comprise”, “comprised” and “comprises” where they appear.
(64) The term “air” will be taken to include breathable gases, for example air with supplemental oxygen. It is also acknowledged that the blowers described herein may be designed to pump fluids other than air.
(65) Patient Interface Systems
(66) Referring to FIGS. **1-13** and **56-62**, a patient interface system or mask **10** system **10** in accordance with an example embodiment of the present technology comprises a patient interface structure or mask structure **20** that is positioned, stabilized and secured on a patient's head in sealing engagement with the patient's mouth and nasal airways by a patient interface positioning system **30**, e.g. a headgear. The patient interface structure **20** comprises a fascia or lens or front plate or front panel or frame **21** having a mouth seal, or cushion **23** that is connected to the front plate **21**. The front plate **21** includes patient interface positioning system connectors **22** (e.g. headgear connectors) to connect the patient interface positioning system (e.g. headgear) **30** to the patient interface structure (e.g. mask) **20**. The patient interface structure further comprises a nasal seal, or cushion **24** connected to the mouth seal, or cushion **23** to seal the patient's nasal airways. A vent (or vent holes) **25** may be provided in the front plate **21** to vent exhaled gases in a breathing chamber defined by the front plate **21**, the mouth cushion **23** and the nasal cushion **24**. The vents

may be provided in the front plate **21** proximate the nares and/or mouth of the patient to improve CO.sub.2 washout. The array of vent holes **25** may be laser cut, molded or otherwise formed in an upper region of front plate **21**.

(67) Patient Interface Positioning System

(68) The patient interface positioning system **30** comprises a crown strap **31** adapted to cup or encircle the crown of the patient's head. Top side (or upper side straps) **32** extend from the crown strap **31** and connect to the front plate **21** through slots **27**. The ends **33** of the top side straps **32** may be looped through the slots **27** and connect to the top side straps **32** by, for example, hook and loop material. It should also be appreciated that other connections, for example buckles, may be used to secure the ends **33** of the top side straps **32**. The top side straps **32** may be thickened or widened at the region where they connect to the crown strap **31** to allow ends **33** a larger space to connect to and also a range of angles to position ends **33** relative to slots **27**, thereby improving the fit range of the headgear **30**. Such an arrangement may also improve comfort and/or to assist in stabilizing and positioning the top side straps **32** on the patient's cheek bone regions.

(69) The crown strap **31** may further comprise a loop **40** through which a right bottom, or lower side strap **35** may pass and connect to a left bottom, or lower side strap **34**. It should also be appreciated that the loop may be formed in the lower side strap(s) **34** and/or **35**, for example as shown in U.S. Applications 61/443,623 and 61/457,981, each of which is incorporated by reference herein in its entirety. It should further be appreciated that other headgear may be used with the patient interface system, for example as disclosed in U.S. Patent Application Publication 2008/0110466 A1, the entire contents of which are incorporated herein by reference. The bottom right side strap **35** may comprise a first end **38** in the form of a loop or slot and a first end **36** of the bottom left side strap **34** may connect to the first end **38** by passing through the loop or slot and connecting through hook and loop material or buckles or other connectors. The second end **37** of the bottom left side strap **34** and the second end **39** of the bottom right side strap **35** may be connected to the front plate **21** through slots **26** in the connectors **22**.

(70) Headgear **30** may be formed from a composite e.g. fabric and foam, which may be flame laminated and may be ultrasonically die cut or welded along its edge to create a rounded, more comfortable edge.

(71) Front Plate/Fascia/Lens

(72) The front plate **21** is configured to conform to or accommodate the shape of the patient's face. The front plate **21** may be flexible to allow the front plate to follow the shape of the patient's face. The front plate **21** may be formed of, for example, a flexible polymer that is able to bend and conform around the patient's mouth once the front plate **21** is connected to the patient interface positioning system **30** and fitted to the patient. The front plate **21** may also be malleable to allow the front plate to conform to the shape of the patient's face. A rib(s) **28** may be provided to the front plate **21**. The ribs **28** may be provided along the top and bottom of the front plate **21** and aid in alignment and engagement with the cushion **23**, as well as providing strength to the fascia.

(73) Front plate **21** may be substantially planar, curved and/or smooth. Masks known in the art tend to include complex shapes and/or structures on the frame, and these complex shapes and/or structures make it difficult to see the patient's mouth clearly and to clean the frame. For example, these complex shapes and/or structures may include elbows, elbow connectors, ports, ridges, contours, headgear connectors, etc. Front plate **21** is adapted to be substantially smooth and without complex shapes or structures i.e. having a substantially planar surface in the region of the patient's mouth, to act as a window to permit clear visibility to the patient's mouth.

(74) As shown on FIGS. **14** and **15**, the patient interface structure **20** may be generally rectangularly or trapezoidally shaped and comprise the front panel **21** that wraps across the face of the patient **1**, and the cushion **23**, **24** attached to the front plate **21**. The cushion **23** may comprise the integrated mouth seal or cushion **23** and the nasal seal or cushion **24**. The front plate **21** may be generally convex when viewed from the non-patient contacting side, curved or rounded shaped and

adapted to follow the contour of the patient's face. The bottom side strap connector slots **26** and the top side strap connector slots **27** of the connectors **22** on either side of the front plate **21** may receive the headgear straps **32**, **34**, **35** and the tension or force from the headgear straps **32**, **34**, **35** may bend or flex the front plate **21** to conform to the shape of the patient's face. The top side strap connector slots **27** are directed generally upwards and are adapted to aid sealing of the nasal cushion **24** and direct the headgear away from the patient's eyes **4**, and the bottom side strap connector slots **26** are adapted to aid sealing of the mouth cushion **23** and direct the headgear straps **34**, **35** under the ears **2** of the patient **1**.

(75) The fascia or lens or front plate **21** is positioned in front of the patient's mouth, and is adapted to provide support to the other components of the patient interface system **10** and aid in positioning these other components, for example the front plate has headgear connectors **22** and a cushion connection portion adapted to receive the patient interface positioning system **30** and a cushion **23** and position these components relative to one another. The front plate **21** also provides some structure to the patient interface system **10** due to the comparatively greater rigidity of the front plate **21** when compared to the cushion **23**.

(76) The front plate **21** may take the form of a lens made from a clear material such as nylon, polycarbonate or nearly clear material such as polypropylene. The lens may be shaded, selectively shaded (e.g. gradient, patterned, random assortment of shapes), printed on or otherwise coloured. The lens may also have colour changing properties e.g. it may be clear when the light is on, and may be opaque when the light it off. The lens may also be customizable. The lens may be provided with a skin or adhesive layer that may customize or otherwise alter the lens. The lens may be surface treated e.g. frosted. The lens may be die cut, drape formed, vacuum formed, molded, cast, ultrasonically cut or formed in any other method to create the desired shape. The lens may also be formed with vent holes. The vent holes may be molded in, laser cut or otherwise formed with the lens. The lens may be flexible or capable of being shaped to fit the patient's face.

(77) Cushion/Seal

(78) Referring to FIGS. **63-83**, the cushion or seal of the patient interface system may comprise two components the mouth cushion or seal **23** and the nasal cushion or seal **24**. The cushions **23**, **24** may be molded together or otherwise permanently attached (e.g. glue, weld). The mouth cushion **23** provides the mouth sealing portion and also the support for the nasal cushion **24**. The mouth cushion **23** also connects to the front plate **21**. The nasal cushion **24** is a nares sealing portion that may be molded from the same or alternative material to mouth cushion **23**. Separating the cushion into two components allows use of a lower durometer (i.e. lower hardness) material for the nasal seal or cushion **24**, and the tooling required to mold the nasal seal or cushion **24** with the mouth seal or cushion **24** is difficult, so molding them in two steps rather than one facilitates manufacturing.

(79) The cushions **23**, **24** may be made from a single material such as silicone, TPE, TPU. However, combinations of materials and/or hardnesses of materials may be used. For example, the mouth seal or cushion **23** may have a TPE or silicone body, with a seal portion or flap adapted to interface with the patient. The nasal seal **24** may comprise a seal portion formed of an alternative material, for example a lower hardness silicone, TPU, fabric, etc.

(80) Referring to FIGS. **63-69**, the mouth cushion **23** comprises a groove or channel **231** around a front portion **238** that is adapted to receive the front plate **21**. The channel **231** may have a flap (or sealing wall) **232** around the inner side of the channel that is adapted to seal against the face of the patient around the patient's mouth. The flap **232** may comprise a single wall seal, although it should be appreciated that the flap **232** may comprise more than one wall, for example two or three walls. The mouth cushion **23** may be constructed from a deformable material such as TPE, TPU, silicone, foam (skinned or unskinned), or gel.

(81) It should be appreciated that the mouth cushion **23** may be insert, over, or co-moulded to the front plate **21**. It should be further appreciated that a cushion clip may be provided to the cushion to

clip to the front plate **21**. The clip may be insert, over, or co-moulded into the cushion **23** as one part. The cushion clip may add stiffness and rigidity to the cushion **23** where required, provide patient interaction points, and allow for a locating and attaching method of the cushion **23** to the front plate **21**, e.g. the cushion clip may snap onto the front plate **21**. The cushion clip may simplify the process of attaching the cushion **23** to the front plate **21** by reducing stretching and warping of the cushion **23** during assembly.

(82) Slots **234** are provided in side walls **233** of the cushion **23** and are adapted to receive the connectors **22** of the front plate **21**. Slots **234** may be generally rectangular, however any other shape may be possible, such that slots **234** may be complimentary to the shape of connectors **22**. Connectors **22** may sealingly engage with side walls **233**, for example side walls **233** may comprise a lip seal or other arrangement adapted to seal against connectors **22**.

(83) The upper portion **237** of the mouth seal or cushion **23** has a greater depth when compared with the lower portion **239** of the mouth seal or cushion **23**, i.e. the distance of the seal portion to the clip portion of the upper portion may be longer than the distance from the seal portion to the clip portion of the lower portion, to tilt the cushion **23** when in use to reduce the profile of the mask **20** when in use. The upper portion **237** of the mouth seal or cushion **23** may also have a greater depth than the lower portion **239** to accommodate nasal seal or cushion **24** and patients with long noses.

(84) Flaps **252** are provided on nares support portions **235** to assist in positioning and stabilizing the nasal seal or cushion **24** to engage with the sides of the patient's nose or the patient's top lip. Raised portions **253** on the nares support portion **235** aid in positioning the nasal seal **24** against the flares of the patient's nostrils. A connecting structure **254** in the form of indents or apertures is formed in the nasal support portions **235** and are adapted to receive lugs **241** on nasal seal or cushion **24** to aid in alignment.

(85) A channel **251** may be provided around the nares support portions **235** to form a flexible region (e.g. could be localized thinning of material) adapted to permit movement of the nasal seal or cushion **24** to accommodate varying anthropometrics.

(86) The side walls **233** of the mouth seal or cushion **23** may have a “question mark” cross section, i.e. the mouth seal portion does not have a straight wall section but rather has a gusseted side wall that acts as a built-in spring so that the mouth seal portion can flex to fit varying patient anthropometrics. Such a side wall cross section is disclosed in, for example, U.S. Patent Application Publication 2008/0110464 A1, the entire contents of which are incorporated herein by reference.

(87) The front portion **238**, the side walls **233** and the flap **232** of the mouth cushion **23** may have different hardnesses. For example, the front portion **238** may have a Shore A durometer of about 30-50, for example about 40. The side walls **233** and/or the flap **232** may have a Shore A durometer of 5-10, for example about 7.

(88) Referring to FIGS. **104** and **105**, the cushion or seal may be formed of a foam, gel, or low durometer material to seal with the patient. Two gusset or spring portions **288**, **289** may be formed behind the seal portion to aid in adjustment of the positioned of the seal portion. The corner **287** of the nose region may be raised to ensure the seal abuts the patient's face and seals in this region.

(89) Referring to FIG. **108**, a gusset type arrangement may be provided to permit flexibility of the cushion and aid sealing under air pressure, with the flap **232** turning outwards. This arrangement may increase the fit range.

(90) Referring to FIGS. **70-76**, the nasal seal or cushion **24** may comprise lugs **241** adapted to be received in indents **254** of the nare support portions **235** of the mouth seal or cushion **23**. The nasal seal or cushion **24** may have a geometry the same as or similar to that disclosed in, for example, WO 2010/139014 A1, the entire contents of which are incorporated herein by reference. The nare support portions **235** and the cradle wall **236** form a trampoline type join with the nasal seal or cushion **24**. The nasal seal or cushion **24** may have a Shore A durometer of about 30-50, for

example about 40. The nasal seal or cushion **24** may have a Shore A durometer of about 5-10, for example about 7.

(91) Referring to FIGS. **77-83**, in the assembled condition, the flaps **252** of the nares support portions **235** of the mouth seal or cushion **23** attach to the respective sides of the nasal seal or cushion **24**. A central portion **242** of the nasal seal or cushion **24** is left unsupported by the nares support portions **235** to allow the flexibility of the central portion **242** accommodate varying shaped lip regions of patients. As shown in FIG. **78**, the upper portion **237** of the mouth seal or cushion **23** is generally in line with or vertically aligned to the nasal seal or cushion **24** so the patient's nose is likely to rest inside the cushion. The nasal seal or cushion **24** is positioned to reside within the mouth cushion **23** which reduces visual bulk and streamlines the outer edge of the mask. As shown in FIG. **79**, the slots **234** for the connectors **22** of the front plate **21** are positioned below the nasal seal **24** so as to direct the headgear straps **34**, **35** along or below the patient's cheeks. It should be appreciated that the patient interface system may comprise a number of nasal seals or cushions **24**. For example, a single mouth cushion **23** may be provided to fit a large percentage of the patient population and two or more nasal seals or cushions **24** may be provided to provide a more custom fit for individual patients nose sizes.

(92) Referring to FIG. **96**, it should be appreciated that a nasal seal or cushion comprising nasal pillows may be provided to the mouth cushion. It should be appreciated that a plurality of nasal seals or cushions having different size nasal pillows may be provided to the patient interface system.

(93) Referring to FIG. **97**, the tube connector may comprise an elbow **269** that is rotatably connected to the front plate **21**. Elbow **269** may be lockable in the two positions as show, i.e. left and right horizontal orientations.

(94) Referring to FIG. **98**, the patient interface structure **20** may include an anti-asphyxia valve **360** provided in the front plate **21**.

(95) Referring to FIG. **99**, the front plate **21** may include a receptacle **270** configured to receive a clip **271** provided on a strap **35** of the patient interface positioning system. As shown in FIG. **100**, the front plate **21** may include receptacles **270** on opposing sides, each configured to receive a clip **271** attached to a strap **34**, **35**. The clips and receptacles may also be magnetic.

(96) Cushion/Seal—Cushion Clip

(97) Referring to FIGS. **115-128**, **135** and **136**, a seal or cushion assembly includes a mouth seal or cushion **23** and a nasal seal or cushion **24**. The cushion assembly may be similar to that disclosed with respect to FIGS. **63-83** except as otherwise described herein. The cushion assembly may comprise a cushion clip **400** attached to the cushion assembly and configured to attach the cushion assembly to a fascia or front plate or lens as described herein. The cushion clip **400** may comprise detents **402** on opposite sides to retain the cushion assembly on the fascia. As shown in, for example, FIG. **128**, the cushion clip **400** may have a curved portion **401** that curves away from the cushion assembly to allow the nasal seal **24** to have a greater depth than a top surface of the mouth cushion **23**. This may allow the nasal seal **24** to accommodate long noses. As shown in FIG. **116**, the central portion **242** of the mouth cushion **23** may dip or curve downwards towards the patient's lip to avoid contacting the patient's septum. As shown on FIG. **115**, nasal seal **24** may comprise raised upper corner regions, these raised upper corner regions adapted to engage a patient's nostrils or nasal flares, thereby reducing the force on the patient's nose tip.

(98) Referring to FIG. **115**, the height of the aperture in the mouth cushion may be about 25-35 mm. Preferably, the height of the aperture on the mouth cushion may be about 25-30 mm. The height is measured from the lowest portion of the opening at the chin region to the dip or curve of the opening at the top lip region. The height of the aperture may increase towards the cheek or left and ride side regions.

(99) Referring to FIG. **122**, the height of the aperture in the nose cushion may be about 5-15 mm. Preferably, the height of the aperture in the nose cushion may be about 7-12 mm. The height of the

aperture in the nose cushion may be less in the central region of the aperture compared to the height of the aperture at the side regions. That is, the nose cushion aperture may have a dip or curved portion at the central region. Such an arrangement may aid in alignment of the cushion, avoid placing excess pressure on the patient's septum and/or ensure that the lower portion of the nasal cushion is not under tension and therefore may not exert pressure on the patient's top lip.

(100) Referring to FIG. **115**, the width of the aperture in the mouth cushion may be about 60-70 mm. Preferably the width of the aperture in the mouth cushion may be about 63-68 mm. Such a width may accommodate varying mouth widths of patient's.

(101) Referring to FIG. **122**, the total width of the nose and mouth cushion may be about 90-105 mm. Preferably, the total width of the nose and mouth cushion may be about 95-100 mm. Such a width may accommodate varying patient anthropometrics.

(102) Referring to FIG. **115**, the total height of the nose and mouth cushion may be about 60-75 mm. Preferably, the total height of the nose and mouth cushion may be about 65-75 mm. Such a height may accommodate varying patient anthropometrics.

(103) The patient contacting portion of the nose and/or mouth cushions may be about 0.3-1.5 mm thick. Preferably, patient contacting portion of the nose and/or mouth cushions may be about 0.3-0.7 mm thick. Such a thickness may ensure conformability of the cushion and comfort for the patient.

(104) Referring to FIG. **116**, the height of the clip may be about 40-55 mm. Preferably, the height of the clip may be about 45-55 mm. The height of the clip may be greater than the height of the mouth cushion aperture. Such an arrangement may be simpler to engage the clip with a fascia (for example) and may increase the structural integrity of the cushion.

(105) Referring to FIG. **116**, the width of the clip may be about 70-85 mm. Preferably, the width of the clip may be about 75-80 mm. The width of the clip may be greater than the width of the mouth cushion aperture. Such an arrangement may be simpler to engage the clip with a fascia (for example) and may increase the structural integrity of the cushion.

(106) As shown in, for example, FIG. **124**, the cushion clip may be generally trapezoidal, with the top portion being wider than the lower portion. Such an arrangement may mean that the overall shape of the mask is shaped to match the general shape of a humans face i.e. taper from a greater width at the top lip region to a lower width at the chin region. The top portion may be, for example, about 75-85 mm wide. The lower portion may be, for example, about 65-75 mm wide.

(107) As shown in, for example, FIGS. **117-121**, the cushion may be integrally formed in one piece. The mouth cushion **23** may have a single sealing wall **232** and the nasal cushion **24** may have a dual wall construction comprising a sealing wall **243** and a supporting wall **244**. It should be appreciated that the mouth cushion **23** and the nasal cushion **24** may each include a single wall, or each may include multiple walls. The sealing walls **232** and **243** of the mouth cushion **23** and the nasal cushion **24** may curve inwards toward a breathing chamber or cavity formed by the cushions. As shown in FIG. **117**, only a portion of the supporting wall **244** of the nasal cushion **24** may be present, for example, at the tip of the nose region and not at the top of the lip region. Referring to FIG. **122**, a parting line **245** of the mould used to form the cushion assembly may be provided so as to be above the patient contacting areas of the cushion assembly.

(108) Referring to FIG. **136**, the cushion assembly and the cushion clip **400** may be formed integrally in one piece. The cushion assembly may be insert, over, or co-moulded into the cushion **23** as one part. Alternatively, the cushion assembly and the cushion clip **400** may be chemically or mechanically bonded together. The cushion assembly and cushion clip **400** may also be repeatably attachable and detachable from one another. For example, the cushion clip **400** may include a flange configured to be received in a channel in the cushion assembly.

(109) As shown in FIGS. **117-121**, **126** and **127**, the cushion clip **400** may include a flange or rib **403** to increase the surface area of the cushion clip **400** to enhance the bond between the cushion clip **400** and the cushion assembly. The cushion assembly, for example the mouth cushion **23**, may

include a thickened region **310** to provide support for the sealing wall **232** and to improve the bond to the cushion clip **400**. Rib **403** may have a varying height around the perimeter of the cushion clip **400**. This varying height may support the cushion more in some regions (i.e. the regions with a greater rib height such as sensitive regions of the face such as the top lip) compared to support in other regions (i.e. regions with a lower rib height such as less sensitive regions of the face such as the cheeks).

(110) Cushion Assembly—Continuous Sealing Surface

(111) Referring to FIGS. **129-131**, a cushion assembly including a mouth cushion **23** and a nasal cushion **24** may comprise a continuous sealing surface **246**. As show in FIG. **131**, the sealing surface **246** is continuous with the mouth cushion sealing wall **232** and the nasal cushion sealing wall **243**. The curvature of the sealing surface **246** may be constant or approximately constant. Such an arrangement may be comfortable for the patient as there are no ridges or undulations that may mark or otherwise irritate the patient's skin. In this arrangement, the definition between the nose and mouth seal portions is not distinct, such that the seal is continuous.

(112) Cushion Assembly—Separate Sealing Surfaces

(113) Referring to FIGS. **132-134**, a cushion assembly including a mouth cushion **23** and a nasal cushion **24** includes separate sealing surfaces **247**, **248**. A channel **249** is provided to separate the nasal sealing surface **247** from the mouth sealing surface **248**. Such an arrangement may be preferable as the nose and mouth seal portions are visually distinct which may assist the patient with aligning the device.

(114) Patient Interface Systems—Tube Connection—Behind Connector

(115) Referring to FIGS. **14-25**, a patient interface system **10** according to an example embodiment of the present technology includes a delivery hose, or tube, or conduit **11** that is connected to the front panel **21** by a connector **12**, e.g. a swivel connector. The tube **11** may be as disclosed in, for example, U.S. Patent Application Publication 2009/0078259 A1, the entire contents of which are incorporated herein by reference. The front panel includes an air inlet or elbow **29** that may be integrally formed with the front plate **21**. It should be appreciated that the elbow **29** may be formed separately from the front plate **21** and attached or connected to the front plate **21** or the cushion **23**, for example by adhesive or mechanical fasteners. The elbow **29** is positioned behind or adjacent to the connector **22** of the front plate **21** on the left side, although it should be appreciated that the elbow **29** may be provided on the right side of the front plate **21**. The shape of the elbow **29** is curved to avoid obscuring the headgear connector **22**. However other configurations would be possible if the headgear connector **22** was located in an alternative position.

(116) The tube connection portion of the elbow **29** is adapted to receive the tube **11** in a longitudinal (e.g. vertical) direction, however other orientations are possible. The elbow **29** is not visible from the front as it is hidden behind the headgear connector **22** of the front plate **21**. This arrangement is advantageous as it is reduces the part count (i.e. no separate elbow is required) and the design may be more visually appealing. The tube **11** is connected at the side of the patient interface or mask system **10** so as to permit clear view to the patient's mouth. Because the tube connection is positioned behind the headgear connector **22** at the front plate **21**, the tube **11** is less obtrusive. The eyes **4** of the patient **1** are unobstructed and in the case of the front plate **21** being in the form of a lens, for example a clear polymer (e.g. polycarbonate), the patient's mouth would also be visible.

(117) The elbow **29** may comprise a lip or protruding edge **41**, in the form of for example a chamfer, adapted to receive a slot or aperture of the cushion. The cushion **23** may comprise a slot that may be positioned to abut or align with the chamfer to aid alignment, and also ensure an air tight seal between the cushion **23** and the front plate **21** is achieved.

(118) The patient interface structure **20** sits under the patient's nose **3** and the nasal cushion **24** seals around or in the nares. The mouth cushion **23** sits in the crease of the patient's chin **5**. The crown strap **31** of the headgear **30** is positioned over the top of the patient's crown and generally in line

with the patient's ears **2**, although it should be appreciated that the positioning of the crown strap **31** may vary between patients.
(119) Although the front plate **21** shown in FIGS. **20-25** includes only the bottom side strap connector slots **26**, it should be appreciated that the embodiment shown in FIGS. **20-25** may also comprise top sides strap connector slots **27**. It should also be appreciated that the front plate **21** may be provided with a vent, or alternatively another component, such as the tube **11**, the connector **12**, or the elbow **29** may have a vent.
(120) Referring to FIG. **101**, a tube connector **272** may be positioned either on the front plate **21** or molded with the cushion **23**. The tube connector **272** may receive an intermediate portion or portion **274** of a tube **273** that may interface with the tube connector **272** by an interference fit. The interference fit may be achieved by pinching or otherwise misshaping the intermediate portion or portion **274** of the tube **273** and placing it within the tube connector **272**. When the pinch or other force is released, the intermediate portion or portion **274** of the tube **273** may resiliently flex back to its original shape and interface with an inner surface of the tube connector **272**. In an alternative arrangement, tube **273** that may interface with the tube connector **272** by an interference fit such as an isometric taper or a quarter turn lock.
(121) Patient Interface Systems—Tube Connection—Front Surface
(122) Referring to FIGS. **26-33**, a patient interface system **10** according to another example embodiment of the present technology comprises a patient interface structure **20** comprising a front plate **21**, a mouth cushion **23** provided to the front plate **21**, and a nasal cushion **24** provided to the mouth cushion **23**. The front plate **21** comprises a tube connector **42** on a front surface that is configured to receive a tube in a horizontal direction.
(123) A tube may connect directly to the tube connector **42** or may have an intermediate structure such as an elbow or swivel between the tube and the tube connector **42**, possibly shaped to avoid the tube obscuring the headgear connector **22**. The tube connector **42** may have vent holes **25** molded or otherwise formed in it. The tube connector **42** may also have a lip or protruding edge **43**, which may aid in sealing the tube connector **42** to the tube or intermediate structure. The tube connector **42** may have an anti-asphyxia valve (AAV) in form of a flap built in (described in more detail below) that may occlude or block some of the vent holes **25** when air is delivered from the tube and through the tube connector **42**. When air pressure is not supplied, the AAV may flip away from the vent holes to permit the patient to breath in sufficient atmospheric air.
(124) The rear face of the front plate **21** may have an aperture **44** adapted to permit the flow of air from the tube connector into the mask. The vents **25** may have a thicker cross section than the rest of the tube connector **42** (e.g. they are on a raised rectangular portion) to improve manufacturability. This may also be to increase the length of the vent holes **25** as longer vent holes are typically quieter than comparatively shorter vent holes. The tube connector **42** may follow the same general curvature of the front plate to reduce the visual bulk (i.e. more streamlined look) of the mask and aid in tube management.
(125) Patient Interface Systems—Tube Connection—Elbow
(126) Referring to FIGS. **34-55**, a patient interface system **10** according to another example embodiment of the present technology may comprise an elbow **45** connected substantially perpendicular to the front plate **21**. The elbow **45** may be a swivel elbow or may be a ball joint elbow. The elbow **45** may be removably attachable or molded with the front plate **21**.
(127) Patient Interface Systems—Vents
(128) Referring to FIG. **84**, a patient interface system **10** may comprise a front plate **21** having a vent **25** comprising a plurality of vent holes provided around a perimeter of the front plate **21**. The perimeter arrangement aids diffusivity of the exhaust gases and reduces the visibility of the vent **25**.
(129) Referring to FIG. **85**, a patient interface system **10** may comprise a front plate **21** having a vent **25** that comprises micro-perforated holes over the front surface of the front plate **21**.
(130) Referring to FIG. **113**, a tortuous vent path through front plate **21** may be provided for

reducing noise. The tortuous path will slow down the exhaled gases **296** as it moves through the tortuous path, thereby having a lower sound power. The mouth seal may have an interface seal **293** and a flap or castellation **294** that obstructs the vent holes **25**, with the exhaled gases **296** moving through the vented pathway **295** of a raised portion **292** of the front plate **21** rather than directly out of the vent holes **25** to increase the length of the path for exhaled gases to get out of the mask.

(131) Patient Interface Systems—Tube Cuff

(132) Referring to FIG. **86**, a patient interface system **10** may include a mouth cushion **23** having a tube cuff **255** attached to, for example, the side wall **233** of the cushion **23**. The tube cuff **255** may be moulded onto the side wall **233** and may have a hardness greater than that of the side wall **233**.

(133) Referring to FIG. **95**, a tube cuff **268** may be moulded onto the cushion **23** that is configured to be connected to a connector **12**, e.g. a swivel connector, that is configured to be connected to a tube **11**, for example a tube as disclosed in U.S. Patent Application Publication 2009/0078259 A1, the entire contents of which are incorporated herein by reference. It should be appreciated that the tube cuff **268** may be connected to the cushion by, for example, adhesive or mechanical connectors.

(134) Referring to FIG. **103**, a gap **286** between a tube connector **283** and a cuff **284** (having less width when compared to the tube connector for example) may be adapted to receive a headgear strap that extends in a substantially vertical direction. The cuff **284** may include a link or slot **285** to receive a headgear strap that extends in a substantially horizontal direction. The cuff **284** may be soft or relatively flexible. The cuff **284** may be glued on or otherwise attached to the tube connector **283**. The cuff **284** may be formed with the tube connector **283**.

(135) Patient Interface Systems—Anti-Asphyxia Valves (AAV)

(136) Referring to FIG. **87**, a patient interface system **10** may comprise a front plate or lens **21** having a hole **256**. An anti-asphyxia valve in the form of a flap **257** formed in the mouth seal or cushion **23** is forced against the front plate **21** and covers the hole **256** when a flow of pressurized gas is delivered through a tube or hose or conduit **258**. In the absence of the flow, the flap **257** is released from contact with the front plate **21** and uncovers the hole **256**, allowing the patient to breathe ambient air through the hole **256** in the front plate **21**.

(137) Referring to FIGS. **88-95**, a patient interface system **10** may comprise a front plate **21** having a tube connector **42** configured for connection with a tube or hose or conduit **259**. The tube connector **42** comprises an aperture or window **264** that may be closed by an anti-asphyxia valve **260**. The anti-asphyxia valve **260** comprises a flap **261** that is configured to open and close the aperture **264**. The flap **261** may comprise a vent **25** for venting exhalation gases when the flap **261** closes the aperture **264**. The anti-asphyxia valve further includes a tab **262** that secures the anti-asphyxia valve **260** in the tube connector **42** through a slot **265** in the tube connector **42**. The flap **261** is pivotably connected to the tab **262** by a hinge **263**, e.g. a living hinge. As shown in FIG. **94**, in the absence of a flow of gas in the tube connector **42**, the flap **261** extends across the tube connector, and the patient may breathe through the aperture **264**. When gas flow **266** is delivered to the tube connector **42**, the pressure of the gas flow **266** pivots the flap **261** in the direction shown by arrow **267** to close the aperture **264**. Exhalation gases may be vented through the vent **25**. Referring to FIG. **92**, the flap **261** may include elongated vent holes **25** to reduce venting noise and increase diffusivity of the vent flow.

(138) Referring to FIGS. **106** and **107**, the cushion may have a flap or thin portion **290** around its perimeter that interfaces or otherwise abuts the front plate **21**. The flap **290** may be pressure activated i.e. when air is delivered under pressure into the mask, the flap **290** may be forced to abut the front plate **21** causing an air tight seal. If air is no longer delivered to the mask, the flap **290** may relax and permit air from atmosphere into the mask via a gap **291** created between the flap **290** and the front plate **21**.

(139) Patient Interface Systems—Materials

(140) Referring to FIG. **102**, a patient interface system **10** may comprise a polyester front plate or window **279** having a TPE “macro” seal **280** and a low durometer nasal seal **281** comprising

pillows, or a seal as disclosed in WO 2010/139014 A1, the entire contents of which are incorporated herein by reference. A foam “micro” seal **275** may be attached to the seal **280**. A TPE or TPU headgear **276** may be provided to position the patient interface system on the patient's head. Elastic webbing or ultrasonic die cut spacer fabric **277** may be provided. A tube connect **278** may be connected to a textile sock **282**.

(141) Patient Interface Systems—Headgear Strap and Tube Attachment

(142) Referring to FIGS. **109**-**112**, a headgear strap, e.g. a lower headgear strap that is positioned under the patient's ears and loops through a slot in the crown strap, may be connected to an air delivery tube. The air delivery tube **298** may connect to an end of the headgear strap **297**, with gases being delivered through the headgear clip **299**. The clips **299**, **300** may interface with the front plate. As shown in FIGS. **111** and **112**, the headgear strap **301** may be configured to deliver gases through an air delivery tube **302** and the clips **303**, **304** may be formed in such a way that the strap **301** can be oriented either left (FIG. **111**) to right or right to left (FIG. **112**).

(143) Patient Interface Structure—Patient Interface Positioning System Connection

(144) Referring to FIG. **114**, the front plate **21** may include a plurality of attachment locations **305** for the patient interface positioning system, e.g. headgear, and/or a rotatable attachment location **306** that provides adjustment of the angle between the patient interface structure, e.g. mask, and the patient interface positioning system, e.g. headgear. The attachment locations may be in the form of rings **307**.

(145) Patient Interface Structure—Fascia

(146) The fascia, frame or lens portion may comprise a fixed elbow connection, the elbow connection directed horizontally. Such an arrangement can be seen in, for example, FIG. **99**. The fascia be structured and arranged to be flipped or rotated, such that the direction of the elbow may be changed from pointing to the left, for example, to pointing to the right. This means that the fascia may be symmetrical.

(147) While the technology has been described in connection with what are presently considered to be the most practical and preferred embodiments, it is to be understood that the invention is not to be limited to the disclosed embodiments, but on the contrary, is intended to cover various modifications and equivalent arrangements included within the spirit and scope of the invention. Also, the various embodiments described above may be implemented in conjunction with other embodiments, e.g., aspects of one embodiment may be combined with aspects of another embodiment to realize yet other embodiments. Further, each independent feature or component of any given assembly may constitute an additional embodiment. Furthermore, each individual component of any given assembly, one or more portions of an individual component of any given assembly, and various combinations of components from one or more embodiments may include one or more ornamental design features. In addition, while the invention has particular application to patients who suffer from OSA, it is to be appreciated that patients who suffer from other illnesses (e.g., congestive heart failure, diabetes, morbid obesity, stroke, bariatric surgery, etc.) can derive benefit from the above teachings. Moreover, the above teachings have applicability with patients and non-patients alike in non-medical applications.

Claims

1. A patient interface structure for delivery of respiratory therapy to a patient, the patient interface structure comprising: a cushion assembly comprising a mouth seal configured to seal around the patient's mouth, a nasal seal configured to seal against at least an underside of the patient's nose, and a pair of nares support portions supporting respective lateral sides of the nasal seal; a frame attachment structure that is attached to the cushion assembly and adds rigidity to the cushion assembly, the cushion assembly and the frame attachment structure combining to form at least part of a chamber; and a frame with a plurality of headgear attachment and a posterior side configured

to snap onto the frame attachment structure, the frame comprising: a first opening on lower side of the frame that is oriented to receive an air delivery tube from a substantially downward direction and direct air in a substantially upward direction; a second opening on a posterior side of the frame that is oriented to face a second direction to direct air in the second direction; and an air inlet passage connecting the first opening to the second opening and comprising a first end at the first opening and a second end at the second opening and is configured to sealingly attach to an opening in the chamber, wherein the air inlet passage is configured to change the direction of air flowing through the air inlet passage from the substantially upward direction at the first end to the second direction at the second end.

2. The patient interface structure of claim 1, wherein the frame is malleable to conform to the shape of the patient's face.

3. The patient interface structure of claim 1, wherein an anterior surface of the frame is substantially planar.

4. The patient interface structure of claim 1, wherein an anterior surface of the frame is generally convex.

5. The patient interface structure of claim 1, wherein the frame is more rigid than the cushion assembly.

6. The patient interface structure of claim 1, wherein the air inlet passage is integrally formed with a main body of the frame.

7. The patient interface structure of claim 1, wherein the air inlet passage is in the form of an elbow.

8. The patient interface structure of claim 1, wherein the air inlet passage is configured to receive the pressurized respiratory gas from below the frame.

9. The patient interface structure of claim 1, wherein the air inlet passage is fixed relative to a main body of the frame.

10. The patient interface structure of claim 1, wherein the second end of the air inlet passage projects from a posterior side of a main body of the frame.

11. The patient interface structure of claim 1, further comprising headgear attachable to the headgear attachment points on the frame, wherein the headgear is configured to support the cushion assembly on the patient's face, and wherein the headgear comprises a crown strap configured to cup the crown of the patient's head in use.

12. The patient interface structure of claim 1, wherein the headgear attachment points on the frame include a pair of upper connector slots positioned on opposite lateral sides of the frame.

13. The patient interface structure of claim 12, further comprising headgear attachable to the headgear attachment points on the frame, wherein the headgear is configured to support the cushion assembly on the patient's face, wherein the frame comprises a pair of laterally extending arms, and wherein the upper connector slots are located at respective ends of the laterally extending arms.

14. The patient interface structure of claim 13, wherein the headgear comprises a pair of upper side straps configured to extend over the patient's ears in use, and wherein the upper connector slots are configured to secure the upper side straps to the frame.

15. The patient interface structure of claim 14, wherein the headgear comprises a pair of lower side straps configured to extend below the patient's ears in use, wherein the headgear attachment points on the frame include a pair of lower connector slots positioned on opposite lateral sides of the frame, and wherein the lower connector slots are configured to secure the lower side straps to the frame.

16. The patient interface structure of claim 15, wherein the headgear comprises a rear panel configured to be positioned at a rear of the patient's head in use, and wherein the upper and lower side straps are connected to the rear panel.

17. The patient interface structure of claim 1, wherein the frame comprises a guide for aligning the frame with the cushion assembly.

18. The patient interface structure of claim 1, wherein the air inlet passage comprises an anti-asphyxia valve.
19. The patient interface structure of claim 18, wherein the anti-asphyxia valve comprises a flap configured to cover an aperture in the air inlet passage in use when the pressurized respiratory gas is delivered to the patient interface structure.
20. The patient interface structure of claim 1, wherein the nasal seal comprises raised portions configured to position the nasal seal in use against the flares of the patient's nostrils.
21. The patient interface structure of claim 1, further comprising headgear attachable to the headgear attachment points on the frame, wherein the headgear is configured to support the cushion assembly on the patient's face, wherein the frame is malleable to conform to the shape of the patient's face, wherein an anterior surface of the frame is substantially planar, wherein the anterior surface of the frame is generally convex, wherein the frame is more rigid than the cushion assembly, wherein the air inlet passage is integrally formed with a main body of the frame, wherein the air inlet passage is in the form of an elbow, wherein the air inlet passage is configured to receive the pressurized respiratory gas from below the frame, wherein the air inlet passage is fixed relative to a main body of the frame, wherein the air inlet passage projects in the posterior direction from a main body of the frame, wherein the headgear comprises a crown strap configured to cup the crown of the patient's head in use, wherein the headgear attachment points on the frame include a pair of upper connector slots positioned on opposite lateral sides of the frame and a pair of lower connector slots positioned on opposite lateral sides of the frame, wherein the frame comprises a pair of laterally extending arms, and wherein the upper connector slots are locate at respective ends of the laterally extending arms, wherein the headgear comprises a pair of upper side straps configured to extend over the patient's ears in use, and wherein the upper connector slots are configured to secure the upper side straps to the frame, wherein the headgear comprises a pair of lower side straps configured to extend below the patient's ears in use, and wherein the lower connector slots are configured to secure the lower side straps to the frame, wherein the headgear comprises a rear panel configured to be positioned at a rear of the patient's head in use, and wherein the upper and lower side straps are connected to the rear panel, wherein the frame comprises a guide for aligning the frame with the cushion assembly, wherein the air inlet passage comprises an anti-asphyxia valve, wherein the anti-asphyxia valve comprises a flap configured to cover an aperture in the air inlet passage in use when the pressurized respiratory gas is delivered to the patient interface structure, and wherein the nasal seal comprises raised portions configured to position the nasal seal in use against the flares of the patient's nostrils.
22. The patient interface structure of claim 1, wherein the pair of nares support portions are configured to support the nasal seal against the sides of the patient's nares.
23. The patient interface structure of claim 1, wherein the frame, the cushion assembly, and the frame attachment structure are all configured to be positioned below the patient's eyes, in use.