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Inventor(s)	Galgali; Amit et al.

Nasal seal, mask and respiratory interface assembly

Abstract

A nasal seal, mask or an interface assembly have a seal body defining a breathing chamber. A nasal port is provided in the seal body. The nasal port has a central portion straddled by a pair of lateral portions. The nasal port further has an upper edge and a lower edge. The upper edge defines an inwardly projecting portion within the central portion. The lower edge defines an inwardly protection portion within the central portion. Thus, the nasal port can be generally bean-shaped or bowtie-shaped. The mask can include a frame having a central portion that supports the seal and a pair of arm portions that extend rearwardly of the seal and are configured to connect to headgear. The central portion can be more rigid than the arm portions. The mask can be configured to reduce noise transmitted through a bias flow vent.

Inventors: Galgali; Amit (Auckland, NZ), Sintive; Bruno (Auckland, NZ), Gordon; Callum Ross (Auckland, NZ), Thompson; Mark Andrew (Auckland, NZ), Graham; Ryan Anthony (Auckland, NZ), McLaren; Mark Arvind (Auckland, NZ)

Applicant: Fisher & Paykel Healthcare Limited (Auckland, NZ)

Family ID: 58239160

Assignee: Fisher & Paykel Healthcare Limited (Auckland, NZ)

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Primary Examiner: Dixon; Annette

Attorney, Agent or Firm: VIA LLP

Background/Summary

INCORPORATION BY REFERENCE TO PRIORITY APPLICATIONS (1) This application is a continuation application of U.S. patent application Ser. No. 15/757,148, filed Mar. 2, 2018, which is a national stage application under 35 U.S.C. § 371 (c) of PCT Application No. PCT/IB2016/055369, filed Sep. 9, 2016, which is related to and claims priority to U.S. Provisional Application Nos. 62/381,496, filed Aug. 30, 2016, 62/310,549, filed Mar. 18, 2016, 62/300,578, filed Feb. 26, 2016, and, 62/217,656, filed Sep. 11, 2015, the entireties of which are hereby incorporated by reference herein and made a part of the present disclosure.

BACKGROUND

Field

(1) The disclosure generally relates to a nasal seal for a respiratory interface, and to an interface including the nasal seal, comprising either a mask or a mask and headgear.

Description of Related Art

(2) Respiratory interfaces are used to provide respiratory gas or gases, such as air in continuous positive airway pressure (CPAP) therapy, to a user under positive pressure. A nasal interface

delivers gas to the nose.

(3) The seal of an indirect nasal interface contacts the upper lip, the face on either side of the nose, and the bridge of the nose, and substantially encloses the nose. An indirect nasal interface may be relatively large on the face, may put pressure on the bridge of the nose, and the frame of the interface may include a T-piece connecting to headgear at the wearer's forehead which typically obstructs also wearing spectacles for example.

(4) A direct nasal interface is typically smaller on the face, and does not comprise a T-piece, and is thus less obstructive. However a direct nasal interface typically comprises nasal pillows or similar which enter into the nares of the wearer to ensure an effective seal.

(5) CPAP is a therapy for sleep apnea (e.g., obstructive sleep apnea). Patients being treated with CPAP for sleep apnea wear a face or nasal mask during sleep. It is desirable that respiratory interfaces be comfortable to wear while maintaining a good seal between the respiratory interface and the user.

SUMMARY

(6) The systems, methods and devices described herein have innovative aspects, no single one of which is indispensable or solely responsible for their desirable attributes. Without limiting the scope of the claims, some of the advantageous features will now be summarized.

(7) In some configurations, a nasal seal includes a seal body defining a breathing chamber. A nasal port is provided in the seal body. The nasal port comprises a central portion straddled by a pair of lateral portions. The nasal port further comprises an upper edge and a lower edge. The upper edge defines an inwardly projecting portion within the central portion. The lower edge defines an inwardly protection portion within the central portion.

(8) In some configurations, the inwardly projection portions of one or both of the upper edge and the lower edge is curved.

(9) In some configurations, the nasal port is generally bean-shaped or bowtie-shaped.

(10) In some configurations, the nasal seal further comprises a thickened rim portion extending around a portion or an entirety of a periphery of the nasal port, the thickened rim portion having a larger wall thickness than a portion of the seal immediately adjacent the thickened rim portion.

(11) In some configurations, the seal body comprises a central portion straddled by a pair of lateral portions, wherein in use the seal body is configured such that the lateral portions move inwardly when pressure is applied to the central portion by a user.

(12) In some configurations, a user-facing surface of the nasal seal comprises a thinned wall portion. In some configurations, the thinned wall portion of the user-facing surface has or is equal to the smallest wall thickness of the seal body.

(13) In some configurations, the nasal seal further comprises a pair of thickened wall portions that, in use, contact the user's cheeks. In some configurations, the thickened wall portions have or are equal to the largest wall thickness of the seal body.

(14) In some configurations, the thickened wall portions each comprise a groove within the thickened wall portion that allows decoupled movement of portions of the thickened wall portion on either side of the groove.

(15) In some configurations, the nasal seal further comprises a connector configured to allow the nasal seal to be coupled to a frame, wherein the connector comprises a first portion within the seal body and a second portion outside of the seal body, wherein the first portion and the second portion are coupled to one another.

(16) In some configurations, the first portion comprises a flange and a hub, wherein the hub extends through an aperture of the seal body and wherein the second portion is coupled to the hub of the first portion.

(17) In some configurations, the seal body comprises a rim extending partially or entirely around the aperture, wherein the rim is captured between the first portion and the second portion.

(18) In some configurations, the rim comprises a generally T-shaped cross-section having a base, a

first lobe extending in a first direction from the base and a second lobe extending in a second direction from the base opposite the first direction.

(19) In some configurations, each of the first portion and the second portion of the connector comprises a recess configured to receive a respective one of the first lobe and the second lobe.

(20) In some configurations, the seal and the connector comprise interfering portions that inhibit or prevent relative rotation between the seal and the connector.

(21) In some configurations, the seal body has a first texture on a user-contacting side and a second texture on the opposite side, wherein the second texture is different from the first texture.

(22) In some configurations, a nasal mask comprises the nasal seal of any of the preceding paragraphs and a frame, wherein the frame comprises a central portion and a pair of arm portions that extend rearwardly from the central portion, wherein the arm portions are configured for connection to a headgear.

(23) In some configurations, the central portion of the frame is shaped to correspond to a side of the seal body that faces the central portion.

(24) In some configurations, the central portion is more rigid than the arm portions.

(25) In some configurations, the pair of arm portions are overmolded onto the central portion.

(26) In some configurations, each of the pair of arm portions comprises a hinge portion that permits rearward ends of the arm portions to flex relative to the central portion of the frame.

(27) In some configurations, the central portion comprises a seal connector portion configured to removably receive the seal.

(28) In some configurations, the central portion comprises a conduit connector portion that supports a conduit connector.

(29) In some configurations, the conduit connector comprises an elbow.

(30) In some configurations, a bias flow vent is located on the conduit connector portion.

(31) In some configurations, the nasal mask further comprises an expansion within a flow passage defined between an upstream end of the conduit connector portion and the breathing chamber of the seal body, wherein the bias flow vent is located upstream of the expansion.

(32) In some configurations, a mask tube is coupled to the conduit connector, an upstream end of the mask tube comprising a connector configured to be connected to a gases supply conduit of an associated respiratory therapy system, wherein an interior of the connector is the same size and shape as an interior of the mask tube.

(33) In some configurations, an end of the connector abuts against the upstream end of the mask tube and the connector and mask tube are coupled by a coupling sleeve. In some configurations, the coupling sleeve is overmolded onto the mask tube and the connector.

(34) In some configurations, a pad is positioned on an inward-facing surface of each of the pair of arm portions.

(35) In some configurations, the pad and the arm portion are joined by an overmolding process.

(36) In some configurations, the pad comprises a textured surface finish.

(37) In some configurations, the pad comprises a fabric outer layer.

(38) In some configurations, an interface assembly comprises the nasal mask as described in any one of the preceding paragraphs and a headgear comprising an upper strap, a rear strap and forward strap extensions that connect to the arm portions of the frame.

(39) In some configurations, at least the upper strap and the forward strap extensions are inextensible. In some configurations, the rear strap is extensible.

(40) In some configurations, the forward strap extensions and the arm portions are adjustably connected to one another.

(41) In some configurations, the forward strap extensions and the arm portions have a plurality of discrete adjustment positions.

(42) In some configurations, one of the forward strap extension and the arm portion includes a plurality of posts and the other of the forward strap extension and the arm portion includes a

plurality of recesses, each configured to receive one of the posts.

(43) In some configurations, an interface assembly includes a nasal mask, a frame attached to the nasal mask, a headgear, and side arms connecting the frame and the headgear. The side arms are rigid in a vertical plane and movable in a horizontal plane with respect to a user's face.

(44) In some configurations, the side arms include a hinge.

(45) In some configurations, the side arms are formed from modular segments.

(46) In some configurations, the side arms include an accordion spring.

(47) In some configurations, the side arms have kerfing on surfaces of the side arms.

(48) In some configurations, ends of the side arms have a hook connector that engages a toothed post disposed on the frame.

(49) In some configurations, the side arms include leaf springs configured to bias the frame between the side arms.

(50) In some configurations, a central portion is connected to ends of the side arms, and a channel is disposed on the frame. The central portion is positioned within the channel such that the frame is movably supported by the central portion.

(51) In some configurations, the side arms are extensible.

(52) In some configurations, the nasal seal further includes a seal body defining a breathing chamber, and a nasal port positioned on the seal body. The nasal port includes a central portion straddled by a pair of lateral portions, the nasal port further includes an upper edge and a lower edge. The nasal seal also includes a flange extending towards the breathing chamber from the upper edge, wherein the flange is configured to contact the user's nose when the user's nose is inserted into the nasal port.

(53) In some configurations, the nasal seal further includes through-holes positioned in the flange.

(54) In some configurations, a nasal seal includes a seal body defining a breathing chamber, a nasal port positioned on the seal body, the nasal port further comprising an upper edge and a lower edge, and a nose obstructing member configured to contact a user's nose that is inserted into the nasal port.

(55) In some configurations, the nose obstructing member is disposed on the nasal port and includes a woven mesh attached to and spanning across the nasal port.

(56) In some configurations, the nose obstructing member is disposed on the nasal port and includes through-holes extending through the nose obstructing member.

(57) In some configurations, the nose obstructing member is disposed on the nasal port and includes tethers attached to a bottom surface of the breathing chamber.

(58) In some configurations, the nose obstructing member extends from a bottom surface of the breathing chamber towards the nasal port.

(59) In some configurations, a distance between the upper and lower edges is narrowest at a midpoint along a width of the nasal port.

(60) In some configurations, wherein the nasal port includes a thickened bead positioned along the upper edge of the nasal port.

(61) In some configurations, a nasal seal includes a seal body defining a breathing chamber, and a nasal port positioned on the seal body. The nasal port further includes outer lateral portions and a central portion positioned between the outer lateral portions. The central portion of the nasal port is narrower than the outer lateral portions of the nasal port. The central portion is configured to contact a user's nose that is inserted into the nasal port.

(62) In some configurations, a distance between an upper edge of the nasal port and a lower edge of the nasal port is narrowest at a lateral midpoint of the nasal port.

(63) In some configurations, the outer lateral portions further comprises ovular ports and the central portion further comprises a throat portion, wherein the throat portion connects the ovular ports.

(64) In some configurations, the ovular ports are angled toward each other.

(65) In some configurations, the throat portion is closer to lower-most edges of the ovular ports

than upper-most edges of the ovular ports.

(66) In some configurations, the throat portion is closer to upper-most edges of the ovular ports than lower-most edges of the ovular ports.

(67) In some configurations, the nasal port is crescent-shaped.

(68) In some configurations, the nasal port is kidney-shaped.

(69) In some configurations, the outer lateral portions comprise ovular ports that are separated by the central portion.

(70) In some configurations, an upper portion of the nasal port and a lower portion of the nasal port overlap.

(71) In some configurations, the upper portion has a recess and the lower portion has a protrusion, wherein the protrusion is positioned within the recess.

(72) In some configurations, a nasal seal includes a seal body defining a breathing chamber, a nasal port positioned on the seal body, and a marking positioned on the seal body configured to indicate a position of the user's nose over the nasal port.

(73) In some configurations, the marking are printed onto the seal body.

(74) In some configurations, the marking are scented.

(75) In some configurations, the marking is formed from frosted silicone.

(76) In some configurations, the marking is deformable.

(77) In some configurations, an interface assembly including a nasal mask, a frame attached to the nasal mask, a headgear, an upper connecting member rotatably connected to an upper portion of the frame and the headgear, and a lower connecting member connecting a lower portion of the frame and the headgear. Relative movement between the upper and lower connecting members cause rotation of the frame.

(78) In some configurations, the upper and lower connecting are connected to the headgear by pulleys.

(79) In some configurations, a nasal seal includes a seal body defining a breathing chamber, and a downwardly-deflectable upper portion. The downwardly-deflectable upper portion rolls in a downward direction relative to a lower portion of the seal.

(80) In some configurations, the nasal seal further includes an upwardly-deflectable lower portion. The upwardly-deflectable lower portion rolls in an upward direction relative to a lower portion of the seal.

(81) In some configurations, a nasal seal includes a seal body defining a breathing chamber, a nasal port positioned on the seal body, and a deformable nose interfacing portion formed around the nasal port. The deformable nose interfacing portion deforms in an inward direction into the breathing chamber and expands in an outward direction from the breathing chamber.

(82) In some configurations, a stiffened region surrounds the nasal port. The stiffened region has a thickness that is greater than the deformable nose interfacing portion.

(83) In some configurations, a nasal seal includes a front wall having a rim that circumferentially surrounds a gas inlet opening. The front wall extends proximally from the rim and joins a rear wall, forming a breathing chamber disposed between the front and rear walls. A central portion of the rear wall extends distal to first and second lateral portions of the rear wall, forming a recess. A nasal aperture in the recess communicates with the breathing chamber.

(84) In some aspects, the front wall has a first region having a first thickness and a second region having a second thickness, the first thickness being at least three times greater than the second thickness. In some configurations, the front wall extends to the second wall without passing through an inflection point. In some aspects, the nasal seal further comprises a connector that is secured to the rim of the front wall. In some configurations, the connector comprises arms that extend proximally along the front wall.

(85) In some configurations, at least a portion of the nasal aperture is disposed closer to a distal-most point of the front wall than to a proximal-most point of the front wall. In some embodiments,

the entire nasal aperture is closer to the distal-most point of the front wall than to the proximal-most point of the front wall.

(86) In some aspects, the nasal seal comprises a bottom wall that extends from the gas inlet opening to the recess. The bottom wall has a front portion that is distal to a back portion. The back portion has a thickness that is greater than the thickness of the front portion. In some embodiments, the bottom wall further comprises a central portion disposed between the front and back portions. The central portion has a thickness that is less than the thickness of the front portion.

(87) In some embodiments, the rear wall comprises a thickened portion that surrounds the nasal aperture. In certain configurations, the thickened portion extends away from the nasal aperture by a maximum width that is less than three times a maximum thickness of the thickened portion. In some embodiments, the thickened portion extends away from the nasal aperture by a maximum width that is more than three times the maximum thickness of the thickened portion.

(88) In some embodiments, the gas inlet opening comprises a truncated region and a non-truncated region, a distance between the central point of the opening and the truncated region being less than a distance between the central point of the opening and the non-truncated region.

(89) Further aspects of the presently disclosed subject matter, which should be considered in all its novel aspects, will become apparent to those skilled in the art upon reading of the following description which provides at least one example of a practical application of the invention.

Description

BRIEF DESCRIPTION OF THE DRAWINGS

(1) Throughout the drawings, reference numbers can be reused to indicate general correspondence between reference elements. The drawings are provided to illustrate example embodiments described herein and are not intended to limit the scope of the disclosure.

(2) FIG. 1 is a view of a respiratory system comprising a flow generator, a humidifier and a user interface.

(3) FIG. 2 is a perspective view of a user interface, comprising a mask and a headgear, which is suitable for use with the respiratory system of FIG. 1.

(4) FIG. 3 is another perspective view of the user interface of FIG. 2.

(5) FIG. 4 is a perspective view of the mask of the user interface of FIG. 2, which comprises a frame and a seal.

(6) FIG. 5 is a sectional view of the mask of FIG. 4 taken along a central, vertical plane of the mask.

(7) FIG. 6 is a perspective view of a portion of the frame of the mask.

(8) FIG. 7 is a top view of the portion of the frame of FIG. 6.

(9) FIG. 8 is a perspective view of the mask with the portion shown in FIGS. 6 and 7 removed.

(10) FIG. 9 is a sectional view of the portion of the mask shown in FIG. 8 taken along a horizontal plane.

(11) FIG. 10 is a front perspective view of a portion of the frame of the mask.

(12) FIG. 11 is a rear perspective view of the portion of the frame of FIG. 10.

(13) FIG. 12 is another perspective view of the mask illustrating internal structures of the seal in dashed lines.

(14) FIG. 13 is a perspective view of the seal separate from the frame.

(15) FIG. 14 is a sectional view of the seal taken along the line 14-14 in

(16) FIG. 13.

(17) FIG. 15 is a sectional view of the seal taken along the line 15-15 in

(18) FIG. 13.

(19) FIG. 16 is an outline of an aperture of the seal.

(20) FIG. 17 is a perspective view of the seal illustrated features of a connector configured to connect to the frame.

(21) FIG. 18 is a perspective view of the seal with a portion of the connector removed.

(22) FIG. 19 is a rear perspective view of a portion of the connector.

(23) FIG. 20 is a front perspective view of another portion of the connector configured to be connected to the portion of the connector of FIG. 19.

(24) FIG. 21 is a perspective view of the seal with the connector removed.

(25) FIG. 22 is a view of the seal with the connector removed showing an upper portion of an aperture of the seal.

(26) FIG. 23 is a perspective view of the headgear separate from the mask.

(27) FIG. 24 is a sectional view of a conventional CPAP hose to mask connection.

(28) FIG. 25 is a sectional view of a CPAP hose to mask connection of the present disclosure.

(29) FIGS. 26A and 26B are velocity diagrams of an expansion within a flow passage with a bias flow vent positioned before and after the expansion, respectively.

(30) FIGS. 27A and 27B are vector diagrams of the expansion within a flow passage with the bias flow vent positioned before and after the expansion, respectively.

(31) FIGS. 28A, 28B and 28C are sectional views of three different designs of a portion of an interface comprising a bias flow vent.

(32) FIG. 29 is a plot of noise level over time for the three designs of FIGS. 28A, 28B and 28C.

(33) FIG. 30 is a side view of an alternative connection between the mask frame and the headgear in a connected configuration.

(34) FIG. 31 is a side view of the connection of FIG. 30 in a disconnected configuration.

(35) FIG. 32 is a side view of another alternative connection between the mask frame and the headgear in a disconnected configuration.

(36) FIG. 33 is a side view of the connection of FIG. 32 in a connected configuration.

(37) FIG. 34 is a perspective view of the entire headgear of FIGS. 32 and 33.

(38) FIG. 35 is an illustration indicating horizontal and vertical planes across a user's face.

(39) FIG. 36A is a side perspective view of an interface with a side arm arrangement having hinges wrapped in concertina covers.

(40) FIG. 36B is a close-up side perspective view of a hinge of the interface of FIG. 36A.

(41) FIG. 36C is a top view of a concertina cover of the interface of FIG. 36A shown in bent and unbent positions.

(42) FIG. 36D is perspective view of the concertina cover of the interface of FIG. 36A.

(43) FIG. 37A is perspective view of an interface having a side arm arrangement having modular segments.

(44) FIG. 37B is a close-up side perspective view of the modular segments of the interface of FIG. 37A.

(45) FIG. 37C is a top view of the interface of FIG. 37A illustrating the articulation of the side arm.

(46) FIG. 38A is perspective view of an interface having a spring-loaded side arm arrangement.

(47) FIG. 38B is a close-up top view of a spring portion of the interface of FIG. 38A.

(48) FIG. 38C is a top view of the interface of FIG. 38A illustrating the side arms in an undeformed shape.

(49) FIG. 38D is a top view of the interface of FIG. 38A illustrating the articulation of the side arms.

(50) FIG. 39A is a close-up side perspective view of an alternative spring-loaded side arm arrangement having elastic and rigid segments.

(51) FIG. 39B is a top view of the elastic and rigid segments in FIG. 39A.

(52) FIG. 40A is perspective view of an interface having a side arm arrangement with kerfing.

(53) FIG. 40B is a top view of the interface of FIG. 40A illustrating the side arms in an unbent and undeformed orientation.

(54) FIG. 40C is a top view of the interface of FIG. 40A illustrating the maximum articulation of the side arms.

(55) FIG. 40D is a close-up top view of the side arm kerfing on the interface of FIG. 40A.

(56) FIG. 40E is a close-up top view of the interface of FIG. 40A illustrating the articulation of the kerfing portions.

(57) FIG. 41A is perspective view of an interface having a hook and post connector arrangement.

(58) FIG. 41B is a close-up top view of a hook and a post connector in FIG. 41A.

(59) FIG. 41C is a close-up perspective view of the hook connector in FIG. 41A.

(60) FIG. 42A is top view of an interface having a biased side arm arrangement.

(61) FIG. 42B is top view of the interface of FIG. 42A illustrating the orientation of the side arms when the interface is positioned on a user lying against a pillow.

(62) FIG. 42C is top view of the interface of FIG. 42A illustrating the orientation of the side arms when the interface is positioned on a user having a crooked nose.

(63) FIG. 42D is top view of the interface of FIG. 42A illustrating the range of the side arm positions.

(64) FIG. 43A is perspective view of an interface having a sliding seal arrangement.

(65) FIG. 43B is top view of the interface of FIG. 43A illustrating the orientation of the seal positioned in an undisturbed position on the user.

(66) FIG. 43C is top view of the interface of FIG. 43A illustrating the orientation of the seal when the interface is positioned on a user lying against a pillow.

(67) FIG. 44A is perspective cross-sectional view of a seal having a flange to indicate to the user that the seal is incorrectly fitted.

(68) FIG. 44B is side cross-sectional view of the seal in FIG. 44A positioned correctly on a user.

(69) FIG. 44C is side cross-sectional view of the seal in FIG. 44A positioned incorrectly on a user.

(70) FIG. 44D is perspective cross-sectional view of a seal having a flange with blow holes to indicate to the user that the seal is incorrectly fitted.

(71) FIG. 44E is side cross-sectional view of the seal in FIG. 44D positioned correctly on a user.

(72) FIG. 44F is side cross-sectional view of the seal in FIG. 44D positioned incorrectly on a user.

(73) FIG. 44G is side cross-sectional view of an alternative flange arrangement having a rounded flange.

(74) FIG. 44H is side cross-sectional view of an alternative flange arrangement having a rounded edge.

(75) FIG. 44I is perspective cross-sectional view of a seal having a flange with recesses to indicate to the user that the seal is incorrectly fitted.

(76) FIG. 45A is perspective cross-sectional view of a seal arrangement having a woven mesh over an aperture to physically prevent or inhibit the user from incorrectly wearing the seal.

(77) FIG. 45B is perspective cross-sectional view of an alternative seal arrangement having a woven mesh offset from an aperture to prevent direct skin contact with the woven mesh.

(78) FIG. 45C is side cross-sectional view of the seal of FIG. 45B.

(79) FIG. 45D is perspective cross-sectional view of an alternative seal arrangement having an aperture cover to physically prevent or inhibit the user from incorrectly wearing the seal.

(80) FIG. 45E illustrates aperture covers having a variety of hole arrangements.

(81) FIG. 46A is perspective cross-sectional view of a seal arrangement having tethers to physically prevent or inhibit the user from incorrectly wearing the seal.

(82) FIG. 46B is side cross-sectional view of the seal arrangement in FIG. 46A.

(83) FIG. 46C is side cross-sectional view of the seal of FIG. 46A illustrating the seal in an undeformed shape.

(84) FIG. 46D is side cross-sectional view of the seal of FIG. 46A illustrating the seal correctly fitted to a user.

(85) FIG. 46E is perspective cross-sectional view of a seal arrangement having a bumper to

physically prevent or inhibit the user from incorrectly wearing the seal.

(86) FIG. 46F is side cross-sectional view of the seal of FIG. 46E illustrating the seal correctly fitted to a user.

(87) FIG. 46G is side cross-sectional view of the seal of FIG. 46B illustrating the seal incorrectly fitted to a user.

(88) FIG. 46H illustrates alternative bumper arrangements.

(89) FIG. 47A illustrates an alternative configuration of an aperture for a seal that prevents or inhibits the user's nose from being inserted into the aperture.

(90) FIG. 47B illustrates an alternative configuration of an aperture for a seal that prevents or inhibits the user's nose from being inserted into the aperture.

(91) FIG. 47C illustrates an alternative configuration of an aperture for a seal that prevents or inhibits the user's nose from being inserted into the aperture.

(92) FIG. 47D illustrates an alternative configuration of an aperture for a seal that prevents or inhibits the user's nose from being inserted into the aperture.

(93) FIG. 47E illustrates an alternative configuration of an aperture for a seal that prevents or inhibits the user's nose from being inserted into the aperture.

(94) FIG. 47F illustrates an alternative configuration of an aperture for a seal that prevents or inhibits the user's nose from being inserted into the aperture.

(95) FIG. 47G is side cross-sectional view of the aperture arrangement in FIG. 47F.

(96) FIG. 48A is a rear view of a nasal seal arrangement having visual markings to indicate correct nose position.

(97) FIG. 48B depicts alternative marking arrangements.

(98) FIG. 48C depicts an alternative combination marking indicating correct nose alignment and position.

(99) FIG. 48D depicts an alternative marking indicating correct nose alignment and position.

(100) FIG. 48E is a rear view of an alternative marking arrangement.

(101) FIG. 48F is a rear view of an alternative scented marking arrangement.

(102) FIG. 48G is a rear view of a nasal seal arrangement having frosted markings to visually indicate correct nose alignment and position.

(103) FIG. 48H is a rear view of a nasal seal arrangement having frosted markings to visually indicate correct nares position.

(104) FIG. 48I depicts alternative frosted marking arrangements.

(105) FIG. 49A is a rear view of a nasal seal arrangement having a depressible dimple to indicate correct nose position.

(106) FIG. 49B is a perspective cross-sectional view of the nasal seal arrangement of FIG. 49A.

(107) FIG. 49C is a side cross-sectional view of the positions of the depressible dimple of the nasal seal arrangement of FIG. 49A.

(108) FIG. 50A is a perspective view of an interface arrangement having a rotatable nasal seal.

(109) FIG. 50B is a side view of the interface arrangement of FIG. 50A illustrating the range of rotation of the rotatable nasal seal.

(110) FIGS. 50C and 50D are schematic side views illustrating the extended and retracted positions of the frame rails causing rotation of a front plane projection line of the rotatable nasal seal of the interface arrangement of FIG. 50A.

(111) FIG. 50E is a side cross-sectional view of the rotatable nasal seal of FIG. 50A fitted to a user having an positive nose angle.

(112) FIG. 50F is a side cross-sectional view of the rotatable nasal seal of FIG. 50A fitted to a user having a negative nose angle.

(113) FIG. 51A is a perspective view of an alternative interface arrangement having pulleys to allow rotation of a nasal seal.

(114) FIG. 51B is a side view of the alternative interface arrangement of FIG. 51A illustrating the

rotation of the nasal seal.

(115) FIGS. **51C** and **51D** are side views of the alternative interface arrangement of FIG. **51A** illustrating various rotation positions of the nasal seal.

(116) FIG. **51E** is a side perspective view of a geared pulley for retaining the rotation position of the nasal seal.

(117) FIG. **51F** is a side perspective view of a geared pulley having a knurled outer surface.

(118) FIG. **51G** is a side perspective view of a geared pulley having a lever.

(119) FIG. **52A** is a perspective view of a rolling nasal seal.

(120) FIG. **52B** is a side perspective cross-sectional view of the rolling nasal seal in FIG. **52A** illustrating an undeformed orientation.

(121) FIG. **52C** is a side perspective cross-sectional view of the rolling nasal seal in FIG. **52A** illustrating a rolled orientation.

(122) FIG. **53A** is a perspective view of a rolling nasal seal having upper and lower rolling sections.

(123) FIG. **53B** is a schematic side view illustrating user nose angles and upper lip angles.

(124) FIG. **53C** is a side view of the rolling nasal seal of FIG. **53A** illustrating an undeformed orientation.

(125) FIG. **53D** is a side view of the rolling nasal seal of FIG. **53A** illustrating a rolled orientation.

(126) FIG. **53E** is a perspective view of an alternative rolling nasal seal having a spring steel section.

(127) FIG. **54A** is a perspective view of a nasal seal having a bellowing region.

(128) FIG. **54B** is a side perspective cross-sectional view of the nasal seal in FIG. **54A**.

(129) FIG. **54C** is a schematic side view illustrating the nasal seal in FIG. **54A** fitted to users with a longer and shorter nose.

(130) FIG. **54D** is a schematic side view illustrating the nasal seal in FIG. **54A** fitted to a user having a level plane longer nose.

(131) FIG. **54E** is a schematic side view illustrating the nasal seal in FIG. **54A** fitted to a user having a downwardly angled longer nose.

(132) FIG. **54F** is a schematic side view illustrating the nasal seal in FIG. **54A** fitted to a user having an upwardly angled shorter nose.

(133) FIG. **54G** is a schematic side view illustrating the nasal seal in FIG. **54A** fitted to a user having a downwardly angled shorter nose.

(134) FIG. **55** is a perspective view of a user interface, comprising a patient interface and a beargear, which is suitable for use with the respiratory system of FIG. **1**.

(135) FIG. **56** is a perspective view of a seal and a frame of the patient interface.

(136) FIG. **57** is a rear perspective view of the frame of FIG. **56**.

(137) FIG. **58A** is a perspective view of an embodiment of a nasal seal.

(138) FIG. **58B** is a perspective view of an embodiment of a nasal seal.

(139) FIG. **58C** is a perspective view of an embodiment of a nasal seal.

(140) FIG. **59A** is a front view of the nasal seal of FIG. **58A**.

(141) FIG. **59B** is a front view of the nasal seal of FIG. **58B**.

(142) FIG. **59C** is a front view of the nasal seal of FIG. **58C**.

(143) FIG. **60A** is a left side view of the nasal seal of FIG. **58A**.

(144) FIG. **60B** is a left side view of the nasal seal of FIG. **58B**.

(145) FIG. **60C** is a left side view of the nasal seal of FIG. **58C**.

(146) FIG. **61A** is a rear view of the nasal seal of FIG. **58A**.

(147) FIG. **61B** is a rear view of the nasal seal of FIG. **58B**.

(148) FIG. **61C** is a rear view of the nasal seal of FIG. **58C**.

(149) FIG. **62A** is a top view of the nasal seal of FIG. **58A**.

(150) FIG. **62B** is a top view of the nasal seal of FIG. **58B**.

(151) FIG. **62C** is a top view of the nasal seal of FIG. **58C**.
(152) FIG. **63A** is a left side view of the nasal seal of FIG. **58A** in use.
(153) FIG. **63B** is a left side view of the nasal seal of FIG. **58B** in use.
(154) FIG. **63C** is a left side view of the nasal seal of FIG. **58C** in use.
(155) FIG. **64** is a perspective view of an embodiment of a nasal seal.
(156) FIG. **65A** is a partial cross-sectional view of the nasal seal of FIG. **58C**.
(157) FIG. **65B** is a partial cross-sectional view of the nasal seal of FIG. **58C**.
(158) FIG. **66A** is a partial rear view of the nasal seal of FIG. **58C**.
(159) FIG. **66B** is a partial sagittal cross-sectional view of the nasal seal of FIG. **58C**.
(160) FIG. **66C** is a sagittal cross-sectional view of the nasal seal of FIG. **58C**.
(161) FIG. **67A** is a partial sagittal cross-sectional view of the nasal seal of FIG. **58A**.
(162) FIG. **67B** is a partial sagittal cross-sectional view of the nasal seal of FIG. **58B**.
(163) FIG. **67C** is a partial sagittal cross-sectional view of the nasal seal of FIG. **58C**.
(164) FIG. **68** is a rear view of an embodiment of a nasal seal.
(165) FIG. **69** is a partial rear view of the nasal seal of FIG. **58B**.
(166) FIG. **70** is a partial rear view of the nasal seal of FIG. **58C**.
(167) FIG. **71A** is a rear view of the nasal seal of FIG. **58A**.
(168) FIG. **71B** is a rear view of the nasal seal of FIG. **58B**.
(169) FIG. **71C** is a rear view of the nasal seal of FIG. **58C**.
(170) FIG. **72** is a perspective view of an embodiment of a connector.
(171) FIG. **73** is a perspective view of the connector of FIG. **72** on a nasal seal.
(172) FIG. **74** is a front perspective view of an embodiment of a connector attached to a nasal seal.
(173) FIG. **75** is a front perspective view of an embodiment of a connector attached to a nasal seal.
(174) FIG. **76A** is a front view of an embodiment of a nasal seal.
(175) FIG. **76B** is a left side view of the nasal seal of FIG. **76A**.
(176) FIG. **76C** is a rear view of the nasal seal of FIG. **76A**.
(177) FIG. **76D** is a top view of the nasal seal of FIG. **76A**.
(178) FIG. **76E** is a bottom view of the nasal seal of FIG. **76A**.
(179) FIG. **77** is a perspective view of an embodiment of a medium-sized nasal seal.
(180) FIG. **78** is a perspective view of an embodiment of a wide-sized nasal seal.
(181) FIG. **79A** is a left side view of the nasal seal of FIG. **76A**.
(182) FIG. **79B** is a left side view of the nasal seal of FIG. **76A**.
(183) FIG. **80** is a side view of the nasal seal of FIG. **76A** positioned on the nose of a user.
(184) FIG. **81** is a front view of the nasal seal of FIG. **76A**.
(185) FIG. **82A** is a front perspective view of an embodiment of a nasal seal.
(186) FIG. **82B** is a front perspective view of the nasal seal of FIG. **82A** illustrating the position on the seal of different regions of wall thickness.
(187) FIG. **83** is a partial cross-section of an embodiment of the nasal seal.
(188) FIG. **84** is a sagittal cross-section of an embodiment of the nasal seal.
(189) FIG. **85** is a front view of the inner surface of the rear wall of an embodiment of the nasal seal illustrating the thickened portion that surrounds the nasal aperture.
(190) FIG. **86** is a bottom view of an embodiment of a nasal seal having a sub-nasal window.
(191) FIG. **87** is a cross-sectional top view of an embodiment of a nasal seal having a sub-nasal window.
(192) FIG. **88** is a bottom view of an embodiment of a nasal seal having a sub-nasal window that extends across the bottom wall of the seal.
(193) FIG. **89** is a cross-sectional top view of an embodiment of a nasal seal having a sub-nasal window that extends across the bottom wall of the seal.
(194) FIG. **90** is a rear perspective view of an embodiment of a nasal seal having a sub-nasal window that extends across the bottom wall of the seal.

- (195) FIG. **91** is a cross-sectional top view of an embodiment of a nasal seal having a partitioned sub-nasal window.
- (196) FIG. **92A** is a front perspective view of an embodiment of a front flange of a connector.
- (197) FIG. **92B** is a rear perspective view of the front flange of FIG. **92A**.
- (198) FIG. **92C** is a front view of the front flange of FIG. **92A**.
- (199) FIG. **92D** is a left side view of the front flange of FIG. **92A**.
- (200) FIG. **92E** is a rear view of the front flange of FIG. **92A**.
- (201) FIG. **92F** is a top view of the front flange of FIG. **92A**.
- (202) FIG. **92G** is a bottom view of the front flange of FIG. **92A**.
- (203) FIG. **93A** is a front perspective view of an embodiment of a rear flange of a connector.
- (204) FIG. **93B** is a rear perspective view of the rear flange of FIG. **93A**.
- (205) FIG. **93C** is a front view of the rear flange of FIG. **93A**.
- (206) FIG. **93D** is a left side view of the rear flange of FIG. **93A**.
- (207) FIG. **93E** is a rear view of the rear flange of FIG. **93A**.
- (208) FIG. **93F** is a top view of the rear flange of FIG. **93A**.
- (209) FIG. **93G** is a bottom view of the rear flange of FIG. **93A**.
- (210) FIG. **94** is a rear perspective view of an assembly of the front flange of FIG. **92A** connected to the rear flange of FIG. **93A**.
- (211) FIG. **95** is a sagittal cross-sectional view of an embodiment of a connector attached to a nasal seal.
- (212) FIG. **96** is a sagittal cross-sectional view of a portion of an embodiment of a connector attached to a nasal seal.
- (213) FIG. **97** is a sagittal cross-sectional view of a portion of another embodiment of a connector attached to a nasal seal.
- (214) FIG. **98** is a sagittal cross-sectional view of a portion of yet another embodiment of a connector attached to a nasal seal.
- (215) FIG. **99** is a sagittal cross-sectional view of a portion of still another embodiment of a connector attached to a nasal seal.

DETAILED DESCRIPTION

- (216) Embodiments of systems, components and methods of assembly and manufacture will now be described with reference to the accompanying figures, wherein like numerals refer to like or similar elements throughout. Although several embodiments, examples and illustrations are disclosed below, it will be understood by those of ordinary skill in the art that the inventions described herein extends beyond the specifically disclosed embodiments, examples and illustrations, and can include other uses of the inventions and obvious modifications and equivalents thereof. The terminology used in the description presented herein is not intended to be interpreted in any limited or restrictive manner simply because it is being used in conjunction with a detailed description of certain specific embodiments of the inventions. In addition, embodiments of the inventions can comprise several novel features and no single feature is solely responsible for its desirable attributes or essential to practicing the inventions herein described.
- (217) Certain terminology may be used in the following description for the purpose of reference only, and thus are not intended to be limiting. For example, terms such as “above” and “below” refer to directions in the drawings to which reference is made. Terms such as “front,” “back,” “left,” “right,” “rear,” and “side” describe the orientation and/or location of portions of the components or elements within a consistent but arbitrary frame of reference which is made clear by reference to the text and the associated drawings describing the components or elements under discussion. Moreover, terms such as “first,” “second,” “third,” and so on may be used to describe separate components. Such terminology may include the words specifically mentioned above, derivatives thereof, and words of similar import.
- (218) FIG. **1** is a schematic diagram of a positive pressure respiratory therapy system in the form of

a continuous positive airway pressure (CPAP) system **10** for providing a heated and humidified air stream to a user **U** through an interface **110** worn by the user, and which is connected to CPAP system **10** by a conduit or tube **12**. A humidification chamber **14** has a heat conductive base in contact with a heater plate **16** of a humidifier **17** to humidify the air stream. The conduit **12** is connected to an outlet **13** of the humidification chamber **14** to convey humidified air to the user interface **110**. The humidifier **17** comprises a controller **18**, such as a microprocessor-based controller that executes computer software commands stored in an associated memory, for example but without limitation. The controller **18** receives input commands from multiple sources, including a user input interface **19** such as a dial or touch screen, which enables the setting of a predetermined value of humidity, temperature, or other characteristic of the humidified air supplied to the user **U**. The controller **18** also may receive input from one or more other sources, such as for example temperature and/or flow velocity sensors **20** and **21**, which are connected through a connector **22** to communicate with the controller **18**, and/or a heater plate temperature sensor **23**. In response to the selected humidity or temperature value, the controller **18** determines when and/or to what level the heater plate **16** should be energized to suitably heat the water contained in the humidification chamber **14**.

(219) As the volume of water in the chamber is heated, water vapour begins to fill the volume of the chamber above a surface of the water. The water vapour passes out of the outlet **13** of the humidification chamber with a flow of air that is provided from a supply **25**, such as a blower **27**, and which enters the humidification chamber **30** through an inlet **26**. The blower **27** can be a variable speed fan, or can include a variable pressure regulator. The blower **27** draws air through an inlet **28**. The blower can be controlled by a controller **29** or by the controller **18**, for example. The controller **18** or **29** may control blower speed, regulated pressure, or the like according to any suitable criteria. For example, the controller **29** may respond to inputs from controller **18** and a user set value (e.g., a preset value) of pressure and/or fan speed, which can be set with a user interface **30** (e.g., a dial).

(220) The conduit **12** may comprise a heater such as a heater wire for example, to heat the walls of the conduit to reduce condensation of humidified gases within the conduit.

(221) The seal and interfaces of the disclosure can be used in such a CPAP system as described whether humidified or not, or alternatively in other forms of respiratory systems, such as for example VPAP (Variable Positive Airway Pressure) systems, BiPAP (Bi level Positive Airway Pressure) systems, or with a ventilator, and are described herein generally with reference to CPAP therapy by way of example only.

(222) FIGS. **2** and **3** are perspective views of an example of the interface assembly or interface **110** of the system **10** of FIG. **1**. The interface **110** comprises a mask **112**, which in some configurations includes a seal **114** and a frame assembly or frame **116**. The interface **110** also includes headgear **118** for securing the mask **112** to the user. In preferred embodiments, the interface **110** does not comprise a T-piece from the frame **116** extending upwardly (when worn) to connect to the headgear **118** at the user's forehead. However, if desired, aspects, features or components of the disclosed interface **110** can be utilized in a design that incorporates a T-piece.

(223) In some configurations, the interface **110** also comprises a short flexible supply conduit or tube **120** extending from the mask **112**, such as from a central connection at the front of the mask **112**, which connects to the supply conduit **12** of the CPAP system **10** or other respiratory system. The conduit **120** is connected to the mask **112** either directly or via a suitable connector, such as a hollow elbow **122**. In some configurations, the elbow **122** can swivel about one or more swivel axes relative to the mask **112** so that the path of the conduit **120** relative to the positioning of the mask **112** on the face of the user can adapt to the sleeping position of the user. However, in other arrangements, the elbow **122** can be integral or unitary with the mask **112**. The end of the conduit **120** opposite the elbow **122** can comprise a suitable connector **124** for connecting the conduit **120** to the supply conduit **12**. In some configurations, the connector **124** can be or comprise a swivel

connector that allows relative rotation between the conduit **120** and the supply conduit **12**.

(224) The interface **110** preferably includes a limited flow outlet or bias flow vent **126** for providing gas washout from the interface **110**. In some configurations, the bias flow vent **126** is in the form of a collection of small apertures. The bias flow vent **126** may be provided in the frame **116**, as shown, in the elbow **122** or elsewhere on the interface **110**.

(225) As described above, the mask **112** can comprise a seal **114** and a frame **116**. In some configurations, the frame **116** (and, if desired, the elbow **122**) can be stiffer than at least a portion of the seal **114**, such as the portion that defines a user-contacting surface. In some configurations, the seal **114** is removably coupled to the frame **116** around a passage through the frame **116** from the interior of elbow **122**. Thus, the seal **114** and the frame **116** together form an enclosure having a gas flow inlet from the CPAP system **10** and an aperture **128** through the seal **114** to the user.

(226) In some configurations, the frame **116** comprises side arms **130** that extend outwardly (away from each other), rearwardly and upwardly at a shallow angle, past left and right extremities of the seal **114** and along the left and right cheeks and in particular cheekbones of a user to connect to the headgear **118** for holding the seal **114** on the face of a user. Such side arms **130** may be longer than they are deep or thick and may be resiliently flexibly connected to the frame and/or resiliently flexible along their length (widthwise but not heightwise). In some configurations, the side arms **130** extend toward or to a location between the ears and eyes of the user and/or to or near the temple of the user, where the side arms **130** connect to the headgear **118**. In some configurations, a length of the side arms **130** is between about 100 mm and about 150 mm. The shape of the side arms **130** and/or angle between them is such that the side arms **130** rest on the left and right cheeks and in particular cheekbones of the user to assist in stabilizing the interface **110** against rotation about a horizontal axis when worn.

(227) The side arms may be resiliently flexible towards and away from the face of the user in an approximately horizontal plane (when worn), to accommodate different face sizes, but are relatively inflexible in an approximately vertical plane. The illustrated side arms **130** are solid, but other versions of the side arms could include one or more apertures or cut-outs extending lengthwise of the side arms to increase the resilient flexibility of the side arms towards and away from the face of the user, but to retain relative inflexibility in an approximately vertical plane (when worn).

(228) In some configurations, the side arms **130** can comprise a softer material on a portion or an entirety of at least the user-facing surfaces of the side arms **130**, or fully around the side arms **130**, for softening contact of the side arms **130** with the face of the user. If desired, an interior surface of the side arms **130** can include pads **132** that face and/or contact the face of the user, as illustrated in FIG. 3. The pads **132** can be removable for cleaning or replacement. The pads **132** and the side arms **130** can be connected by an overmolding or welding process. The pads **132** can have a textured and/or fabric outer surface. The textured surface can increase friction to keep the side arms **130** in place on the user's face and the fabric material can promote comfort.

(229) At their outer or free ends the side arms **130** comprise connector portions **134** for detachably connecting the side arms **130** to the headgear **118**. In some configurations, each of the connector portions **134** comprises a recess or receptacle **136** configured to receive a complementary connector **138** of the headgear **118**. The connector **138** of the headgear **118** can be retained within the receptacle **136** of the side arms **130** by any suitable mechanism, such as a snap-fit arrangement, for example. In some configurations, the connector **138** has orientation features. In some configurations, the receptacle **136** has orientation features. The orientation feature may allow the left-side of the headgear **118** to only connect to the left-side side arm **130** and the right-side of the headgear **118** to only connect to the right-side side arm **130**. In some configurations, the orientation features may allow the left-side of the headgear **118** to connect to the right-side side arm **130** and the right-side of the headgear **118** to connect to the left-side side arm **130**, only in the manner that the headgear **118** is turned inside-out. In the illustrated arrangement, each connector portion **134**

includes at least one protrusion or latch member **140**, such as a pair of latch members **140** each of which is positioned on opposing sides of the receptacle **136**. The latch members **140** can retain the connector **138** within the receptacle **136** in at least one direction, such as in a direction moving outwardly away from the connector portion **134** and in a direction of rotation. The latch members **140** can guide the connector **140** into connected position, for example, when the connector **138** is inserted from the end. In some configurations, the connector portion **134** comprises one or more additional retention elements, such as a protrusion or boss **142**. In the illustrated arrangement, the boss **142** extends outwardly from an outer surface of the receptacle **136** and engages a complementary opening of the connector **138** of the headgear **118** to retain the connector **138** within the receptacle **136** in response to forces tending to move the connector **138** rearwardly or in a longitudinal direction of the side arm **130**. In some configurations, the boss **142** has a chamfer on one side (not shown in the drawings), facilitating the connector **138** clipping into position.

(230) In some configurations, the side arms **130** may be unitarily-formed with another portion or a remainder of the frame **116** by injection moulding from a plastics material, for example. However, in the illustrated arrangement, the frame **116** comprises a central or base portion (referred to herein as a “base”) **144** that supports the seal **114** and a connector portion or connector **146**, which includes the side arms **130**. The base **144** and the connector **146** can be permanently or removably coupled to one another. In some configurations, each of the side arms **130** could include its own connector **146** that could be separately attached to the base **144**.

(231) The illustrated connector **146** is a generally U-shaped member from a top view comprising the side arms **130** and a central portion **148** that connects the two side arms **130** to one another. In the illustrated arrangement, the central portion **148** passes below the elbow **122** and extends upwardly on each side to a respective one of the side arms **130**. The central portion **148** can also be configured to connect to the base **144**, such as via a snap-fit connection, for example. In the illustrated arrangement, the central portion **148** comprises a pair of spaced-apart protrusions **150** that engage a respective one of a pair of complementary slots **152** of the base **144**. In other configurations, this arrangement could be reversed or other suitable connection arrangements could be utilized. The central portion **148** can be removable from the base **144**. That is, the protrusions **150** can be removable from the slots **152**. In other configurations, the central portion **148** and/or side arms **130** can be integrated with the base **144**, such as by a two-shot or over-molding process, for example.

(232) The central portion **148** comprises an inner surface **154** that faces or rests against the base **144**. In some configurations, the central portion **148** includes a shelf or shoulder **156** upon which the base **144** or another portion of the frame assembly **116** or seal **114** rests. In the illustrated arrangement, a lower edge of the base **144** rests upon the shoulder **156** such that a portion of the connector **146** below the shoulder **156** is positioned below the base **144**. The illustrated shoulder **156** is curved in shape with outer ends being lower than a central portion relative to an orientation of the mask **112** in use. In other arrangements, the shoulder **156** could have other shapes, such as curved in an opposite direction (i.e., concave) or flat, for example. In addition, a forward surface of the base **144** defines a recess **157** that accommodates the central portion **148** of the connector **146**. The recess **157** can extend partially or entirely between the slots **152** of the base **144**.

(233) The laterally-outward or rearward portions of the central portion **148** of the connector **138** connect to the side arms **130**. In the illustrated arrangement, the side arms **130** are unitarily-formed with the central portion **148**. However, in other arrangements, the side arms **130** could be formed separately, with the same or different materials, and coupled to the central portion **148**, such as via mechanical fasteners, adhesives, welding process or by a two-shot molding process (e.g., over-moulding), for example.

(234) In some configurations, the laterally-outward or rearward portions of the central portion **148** can be configured to support the side arms **130** in a spaced relationship to the base **144** and/or seal **114**. In the illustrated arrangement, the laterally-outward or rearward portions of the central portion

148 have a greater wall thickness in a direction perpendicular to the inner surface **154** than a center of the central portion **148**. The wall thickness increases progressively in a forward-rearward direction of the laterally-outward or rearward portions of the central portion **148**. As a result, the forward ends of the side arms **130** are spaced outwardly from the inner surface **154**, base **144** and/or seal **114** by a distance **158**. The distance **158** can be, for example, between 3-15 mm, 5-10 mm or about 5 mm. The attachment points of the central portion **148** defined by, for example, the protrusions **150** with the base **144** can define hinges or hinge points of the frame assembly that promotes flexibility of the side arms **130** relative to the central portion **148** and/or the base **144**. The reduced thickness of the forward ends of the side arms **130** relative to the greater wall thickness of the rearward portions of the central portion **148** can facilitate the flexibility of the side arms **130** relative to the central portion **148** and/or the base **144**.

(235) In some configurations, the protrusions **150** are located at or near and end of the laterally-outward or rearward portions of the central portion **148**. With such an arrangement, the central portion **148** of the connector **146** is coupled to the base **144** while the side arms **130** are not directly coupled to the base **144** and are free to move or flex relative to the base **144**. In some configurations, the connector **146** is overmolded onto the base **144** or the connector **146** and base are otherwise joined by an overmolding process. In other arrangements, the connector **146** can be otherwise coupled to the base **144**, preferably on at the central portion **148** such that the side arms **130** are free to flex or move relative to the base **144**. In some configurations, the base **144** is constructed from a material that is more rigid than the material of the connector **146** or at least more rigid than the side arms **130** of the connector **146**. In addition or in the alternative, the side arms **130** can be otherwise configured to be less rigid than the base **144**, such as by reduced material thickness, hinges, cut-outs or other suitable arrangements. In some configurations, the central portion **148** terminates prior to a rearward edge of one or both of the base **144** and seal **114** on each side of the mask **112**. Accordingly, portions of the side arms **130** forward of the rearward edge of one or both of the base **144** and seal **114** can move or flex relative to the base **144** and/or seal **114**.

(236) In some configurations, termination points of the central portion **148** are spaced from a rearward edge of the base **144** by a distance **160** and from a rearward edge of the seal **114** by a distance **162** on each side of the mask **112** as measured along a central axis **164** of the mask **112** that extends in a forward-rearward direction and bisects the mask **112**. The distance **160** can be between one-quarter and one-half of a total length **166** of the mask **112** as measured along the central axis **164**. In some configurations, the distance **160** is between one-third and three-eighths of the total length **166** of the mask **112**. The distance **162** can be between one-third and five-eighths of the total length **166**, between two-fifths and nine-sixteenths of the total length **166**. In some configurations, a length **168** of the side arms **130** can be at least as long as, at least 1.5 times or at least twice the total length **166** of the mask **112** as measured along the central axis **164** depending on where the forward ends of the side arms **130** are located relative to the mask **112**. Such an arrangement provides a desirable level of support to the base **144** and seal **114**, while also permitting a desirable level of movement of the side arms **130** to accommodate a variety of facial geometries.

(237) In an alternative arrangement, instead of the side arms **130** as shown (or with shorter side arms), the ends of headgear **118** may attach to the mask frame **116** (or shorter side arms) on either (left and right) sides via stiffer strap ends, which terminate at the mask **112** by an attachment mechanism which allows movement in an approximately horizontal plane but not in an approximately vertical plane, such as a hook which engages into a vertical upright slot (e.g., slot **152**) on the mask frame **116** (e.g., base **144**).

(238) As described above, in some configurations, the seal **114** is removably coupled to the frame **116**. The seal **114** can be configured to surround a passage through the frame **116** from the interior of elbow **122**. Thus, the seal **114** and/or the frame **116** can form a chamber having a gas flow inlet

from the CPAP system **10** and an aperture **128** through the seal **114** to the user. In the illustrated arrangement, the base **144** of the frame **116** defines a generally U-shape when viewed from above. A central portion of the base **144** defines an aperture **170** through which gases can flow. A first annular wall surrounds the aperture **170** and projects in a rearward direction to define a support or connector **172** for the seal **114**. A second annular wall surrounds the aperture and projects in a forward direction to define a support or connector **174** for the elbow **122**.

(239) The seal **114** defines an aperture **175** configured to receive the connector **172** of the base **144**. The seal **114** and the base **144** can be removably coupled by any suitable arrangement, such as a friction-fit or snap-fit, for example. In the illustrated arrangement, the connector **172** includes one or more recesses **176** configured to receive a corresponding protrusion **178** of the seal **114** to create a snap-fit engagement between the seal **114** and the base **144**. However, this arrangement could also be reversed. Moreover, the entire arrangement could be reversed between the seal **114** and the base **144** in that the seal **114** could include a male connector portion and the base **144** could include a corresponding female connector portion.

(240) Preferably, the seal **114** and the base **144** include an alignment or key arrangement such that the seal **114** and the base **144** can only be assembled in the correct orientation relative to one another. Any suitable arrangement can be used. In the illustrated arrangement, the seal connector **172** includes a recess **180** configured to receive a key or protrusion **182** of the seal **114** (FIG. 17). The illustrated recess **180** and protrusion **182** are located on an upper, central portion of the aperture **170**; however, other locations along the circumference of the aperture **170** could also be used. This arrangement could also be reversed. Moreover, other suitable arrangements could also be used, such as a non-circular shape of the connector **172** and aperture **176**, for example.

(241) The elbow **122** can connect to the elbow connector **174** in any suitable manner. In the illustrated arrangement, the elbow **122** is removably connected to the elbow connector **174** such that the elbow **122** can be removed, such as for cleaning. In the illustrated arrangement, the elbow **122** and the elbow connector **174** are coupled by a snap-fit connection; however, other suitable connections (e.g., friction-fit) can also be used. In some configurations, the elbow connector **174** comprises a recess **184** configured to receive a protrusion **186** of the elbow **122**. In the illustrated arrangement, the recess **184** is an annular recess that extends around the entire circumference of the elbow connector **174** so that the elbow **122** is rotatable relative to the frame **116** on the elbow connector **174**. The protrusion **186** of the elbow **122** can be annular or interrupted around the circumference of the elbow **122**. This arrangement could also be reversed. In alternative arrangements, the connection of the elbow **122** to the frame **116** can provides for both rotation and pivoting of the elbow **122** relative to the frame **116**. For example, the connection may comprise a ball joint connection to the frame **116** so that the elbow **122** can pivot about axes parallel to and perpendicular to its connection with the frame **116**. The elbow **122** may include a ball end that snap fits into a socket opening in the frame **116**. The elbow **122** preferably defines an angle between flow in the conduit **120**, and flow through the aperture **170** of between 0° and 90° or between 30° and 60°. Alternatively, as described above, the elbow **122** could be unitarily or integrally formed with the frame **116**. In other configurations, the elbow **122** could be omitted entirely and the tube **120** or other breathing circuit could be directly connected to the frame **116**.

(242) In the illustrated arrangement, the bias flow vent **126** is defined by the frame **116**. In particular, the bias flow vent **126** is defined by the elbow connector **174** of the base **144** of the frame **116**. The illustrated elbow connector **174** comprises an enlarged diameter portion closest to the U-shaped body of the base **144** that defines a surface or shoulder **188** that faces or contacts an end surface of the elbow **122**. The bias flow vent **126** comprises a plurality of openings or vent bores **190** that extend in a generally radial direction through the enlarged diameter portion of the elbow connector **174**. Accordingly, the elbow **122** does not cover the vent holes **190** when the elbow **122** is connected to the base **144** and the vent holes **190** are located between the elbow **122** and the U-shaped body of the base **144**. In the illustrated arrangement, a longitudinal axis of the

individual vent holes **190** are canted or angled in a forward direction when moving along the axis in a direction from an interior of the elbow connector **174** toward an exterior of the elbow connector **174**. Such an arrangement can direct the flow of exhaust gases away from the face of the user. Alternatively, the bias flow vent **126** can be located on the elbow **122**, the frame **116** or at another suitable location.

(243) FIGS. **12-15** illustrate features that allow the mask **112** to transfer force from the seal **114** to the frame **116**. The illustrated mask **112** comprises a seal support, which can be a base, housing, shell or connector **202**, for example. The seal **114** is attached to the connector **202** such that the connector **202** provides some amount of support for the seal **114**. The connector **202** permits the mask **112** to be connected to the frame **116**. The illustrated connector **202** is generally annular in shape and, in at least some configurations, does not cover a substantial portion of a forward-facing surface of the seal **114**.

(244) The connector **202** can be constructed from a relatively rigid, semi-rigid or rigid material, such as polycarbonate, for example. Thus, in at least some configurations, the connector **202** is more rigid than the seal **114**. The material from which at least the thin-walled supple center portion of the seal **114** is formed may be a soft stretchable material such as a silicone material, or a TPE (thermoplastic elastomer), for example. In some configurations, the seal **114** is a one piece component all of the described parts and portions of which are integrally formed by injection moulding, for example. In an alternative arrangement, however, only a wearer side of the seal **114** may be formed of such a material, and may be bonded to a more rigid shell (rather than the connector **202**), which couples to or is integrally formed with the frame **116** of the interface. Alternatively or additionally, the seal **114** may be a foam or gel-filled seal.

(245) The illustrated mask **112** has a hollow interior which is filled with air under positive pressure in use and is configured to seal under the nose of the user, along a portion of the face extending lateral to the nose, as well as along the upper lip of the user. The mask **112** advantageously does not require contact with the bridge of the nose of the user. In the illustrated configuration, the mask **112** does not extend over the bridge of the nose of the user. More particularly, the illustrated mask **112** does not contact the bridge of the nose of the user.

(246) The mask **112** may or may not extend over the tip of the nose of the user. Thus, in some configurations, the mask **112** covers the tip of the nose. In some configurations, the seal **114** of the mask **112** covers the tip of the nose. In some configurations, the illustrated mask **112** preferably does not enshroud the tip of the nose of the user. In some configurations or with some facial geometries, the tip of the nose of the user extends over the adjoining portion of the mask **112**. In some configurations, the frame **116** and other portions of the mask **112** can accommodate deflection of the seal **114** by portions (e.g., the tip) of the user's nose such that the interface can accommodate a variety of nasal lengths.

(247) As illustrated, the mask **112** preferably is adapted to extend around and seal over the wing or alar of the nose, which flares out to form a rounded eminence around the nostril. The illustrated mask **112** is adapted to seal around the surfaces that define the opening to the nostril, which may include a portion or entirety of the fleshy external end of the nasal septum, sometimes called the columella. In some configurations, the mask **112** is adapted to extend upwardly to seal along at least a portion of the left and right dorsal side walls of the nose of the user. In some configurations, the mask **112** is adapted to extend upwardly along at least a portion of the left and right dorsal side walls without extending upwardly to the region of the bridge of the nose of the user. In some configurations, a primary sealing surface of the mask **112** contacts the underside of the nose of the user, the upper lip and/or a transition region between the underside of the nose and the upper lip. A secondary sealing surface of the mask can contact the side surfaces of the nose of the user, possibly along with the cheeks at a location near the nose. Such primary and secondary sealing surfaces may not make contact with the face of all users; however, such an arrangement can provide a suitable seal with a relatively large range of facial geometries.

(248) As described above, the seal **114** comprises at least one nasal opening or aperture **128**. In some configurations, the seal **114** can comprise more than one nasal aperture **128**. In some configurations, the seal **114** can comprise apertures **128** defined within superstructures, such as pillows, prongs or the like. In some configurations, the nasal aperture **128** can be defined by a nasal cushion or insert, which can be over-moulded or otherwise secured to a base structure of the seal **114**. Examples of suitable arrangements of the seal **114** are disclosed in Applicant's publication no. WO 2014/077708, the entirety of which is incorporated by reference herein.

(249) The seal **114** comprises an inward or rearward-facing central portion **204** that faces or contacts the user during use of the mask **112**. The seal **114** also comprises a pair of opposing inner lateral portions **206** and a pair of opposing outer lateral portions **208**. The inner lateral portions **206** are configured to contact the sides of the nose and/or the portion of the user's face on either side of the nose. The inner lateral portions **206** can comprise both inward-facing surfaces and rearward-facing surfaces. That is, each of the inner lateral portions **206** can wrap from an inward-facing surface of the seal **114** toward or to a rearward-facing surface of the seal **114**. The outer lateral portions **208** can comprise both rearward-facing surfaces and outward-facing surfaces. The rearward-facing surfaces of the outer lateral portions **208** can contact the face of the user during use of the mask **112**. The seal **114** can also comprise a nasal opening support or thickened rim **210** that partially or completely surrounds and provides support to the nasal aperture **128**. Preferably, the outer lateral portions **208** are not connected to the frame **116** such that the outer lateral portions **208** and/or the inner lateral portions **206** can move inwardly in response to pressure exerted on the central portion **204** of the seal **114** by the user. Such an arrangement allows the lateral portions of the seal **114** to move inwardly to facilitate sealing with the user's face.

(250) The seal **114** can comprise regions of varying thickness to provide the seal **114** with different properties or characteristics within the different regions. For example, the central portion **204** can have a relatively low thickness to allow the central portion **204** to conform to the particular facial geometry of the user. In some configurations, the relatively low thickness can allow the central portion **204** to stretch. In some configurations, the central portion **204** can have a thickness between 0.3 mm and 0.5 mm or 0.6 mm. In some configurations, the thickness of the central portion **204** is 0.3 mm. If desired, the central portion **204** could have a thickness as low as 0.15 mm. However, it has been determined that lower thicknesses can result in or increase the likelihood of creasing for some facial geometries and/or under some operational gas pressures. Keeping the thickness at or above 0.3 mm in a substantial portion or an entirety of the central portion **204** can reduce the incidence of creasing over a substantial range of operational pressures, which may comprise an entire range of normal operating pressures.

(251) The inner lateral portions **206** can have a thickness that is greater than the thickness of the central portion **204**. In some configurations, the thickness of the inner lateral portions **206** can be between 0.4 mm and 0.6 mm. In some configurations, the thickness of the inner lateral portions **206** is 0.5 mm. The nasal opening support **210** can have a thickness that is greater than one or both of the central portion **204** and the inner lateral portions **206**. The relatively greater thickness can protect the seal **114** from tearing at the nasal aperture **128** and can help the nasal aperture **128** maintain an opened shape. In some configurations, the thickness of the nasal opening support **210** is between 1 mm and 2.5 mm. In some configurations, the thickness of the nasal opening support **210** is 1.2 mm. The thicknesses can be constant or varied within any of the central portion **204**, inner lateral portions **206** or nasal opening support **210**.

(252) Lateral portions **212** of the mask **112**, including portions or entireties of the inner lateral portions **206** and the outer lateral portions **208**, can be referred to herein as paddles. Paddles **212** can refer to any portion of an interface seal that is positioned alongside the nose of the user during use of the interface. Paddles **212** are disclosed in the context of under-nose interfaces herein, but can be utilized in other types of interfaces, including those that contact, cover or seal against the bridge of the user's nose, unless otherwise indicated.

(253) The outer lateral portions **208** can comprise features that assist in maintaining a shape of the seal **114**. In some configurations, the outer lateral portions **208** comprise regions of increased thickness, rigidity or stiffness that assist in maintaining a shape of the seal **114**, which are referred to herein as support structures **214**. The support structures **214** of the mask **112** can inhibit or prevent overexpansion or undesired expansion of the lateral end portions of the seal **114**, which could result in leaks and/or undesirable pressure being applied to the user's nose by the central portion **204** of the seal **114**. The support structures **214** can also inhibit or prevent collapse of at least portions of the seal **114** when engaged with a nose in use. For example, the support structures **214** can inhibit or prevent collapse of the nasal region or central portion **204** of the seal **114**.

(254) The support structures **214** can also transfer forces from one portion of the seal **114** to another portion of the seal **114**. For example, the support structures **214** can transfer force applied to a rear portion of the seal **114** to a front portion of the seal **114**. In some configurations, the support structures **214** can transfer force applied to a rearward-facing surface of the seal **114** by the user's face to another portion of the seal **114** that can resist some or all of the transferred force. In some configurations, the support structures **214** transfer force from a rearward-facing or user-contacting surface of the seal **114** to the frame **116** or other structure that supports the seal **114** (e.g., the connector **202**). Thus, in some configurations, the support structures **214** extend between a rearward-facing surface of the seal **114** and a surface of the seal **114** that contacts or is overlapped by the frame **116** or other support structure for the seal **114**. Preferably, the support structures extend from the rearward-facing surface to the surface that is overlapped by the frame **116** or other support structure. However, as noted above, the support structures **214** can provide structure to the seal **114** and can be utilized to provide such support without necessarily transferring forces.

(255) In some configurations, the frame **116** includes a central portion and lateral portions on each side of the central portion. The lateral portions can function to provide support to the support structures **214** of the seal **114** and can be referred to as paddle covers **216** herein. The lateral portions or paddle covers **216** can be aligned with or overlap the portions of the seal **114** comprising the support structures **214** such that the support structures **214** can transfer loads to the lateral portions **216** of the frame **116**.

(256) The supports **214** can extend in a direction generally from the rearward or user-contacting surface of the seal **114** toward its respective lateral portion of cover **216** of the frame **116**. In some configurations, each of the supports **214** extends generally or substantially in a longitudinal direction of the seal **114**. The supports **214** can extend generally parallel to one another or can be closer at a forward end in comparison to a rearward end. In other words, the supports **214** can converge in a direction moving from the rearward or user-contacting surface of the seal **114** toward a front portion of the seal **114**. However, in other configurations, the supports **214** can diverge from rear to front.

(257) In the illustrated arrangement, each support structure **214** is shaped or otherwise configured to follow a portion or an entirety of a peripheral edge of the associated outer lateral portion **208**. Each support structure **214** can comprise a general C-shape (or reversed C-shape) when the seal **114** is viewed from the side, which comprises a rearward portion **218**, an upper extension or leg **220** and a lower extension or leg **222** that extend forward from the rearward portion **218**. In the illustrated arrangement, the support structures **214** are thickened regions of the seal **114**, each of which projects inwardly into the interior space of the seal **114**. Either one or both of the extensions **220**, **222** can extend to and/or contact the connector **202**. In the illustrated configuration, only the lower extension **220** extends to the connector **202** and the upper extension **220** is spaced rearward from the connector **202**. However, in other configurations, this arrangement could be reversed.

(258) Each of the illustrated support structures **214** comprises a cut-out or relief **224** that provides a region of less thickness, stiffness or rigidity within the support structure **214**. In the illustrated arrangement, the relief **224** is a region of less thickness relative to other portions of the support structure **214**. The illustrated relief **224** also comprises a general C-shape (or reverse C-shape)

when the seal **114** is viewed from the side. In some configurations, the relief **224** also follows a portion or an entirety of a peripheral edge of the associated outer lateral portion **208**. However, preferably, the relief **224** is spaced inwardly from the peripheral edge of the outer lateral portion **208**. In at least some configurations, the relief **224** is fully contained within the support structure **214**. The relief **224** can allow portions of the support structure **214** to move relative to one another. Accordingly, the relief **224** can allow corresponding portions of the seal **114** to move relative to one another. Thus, a portion of the support structure **214** and seal **114** rearward of the relief **224** can move toward a portion of the support structure **214** and seal **114** forward of the relief **224**.

(259) The support structure **214** can be of variable thickness to provide different levels of support to the seal **114**. For example, the upper extension **220** and/or lower extension **222** can have a thickness that is less than a thickness of at least a portion of the rearward portion **218**. In some configurations, a portion of the rearward portion **218** rearward of the relief **224** and/or located on or adjacent a rearward surface of the seal **114** has a thickness that is greater than a portion of the rearward portion **218** forward of the relief **224**. The relief **224** can have a thickness that is less than both the portion of the rearward portion **218** forward of the relief **224** and the portion of the rearward portion **218** rearward of the relief **224**. Furthermore, a portion of the outer lateral portions **208** outside (e.g., forward) of the support structure **214** can have a thickness that is less than a thickness of any portion of the support structure **214**. In some configurations, the thickness of the portion of the outer lateral portions **208** outside of the support structure **214** is equal to or substantially equal to the thickness of the relief **224**.

(260) In some configurations, the portion of the rearward portion **218** rearward of the relief **224** and/or located on or adjacent a rearward surface of the seal **114** has a thickness of between 2 mm and 5 mm. In some configurations, the thickness is 4 mm. In some configurations, the portion of the rearward portion **218** forward of the relief **224** has a thickness of between 1.5 mm and 3 mm. In some configurations, the thickness is 2 mm. In some configurations, the relief **224** has a thickness between 0.3 mm and 0.6 mm. In some configurations, the thickness is 0.5 mm. In some configurations, the portion of the outer lateral portions **208** outside of the support structure **214** can have a thickness of between 0.3 mm and 0.6 mm. In some configurations, the thickness is 0.5 mm. The seal **114** can also have thicknesses proportional to those disclosed herein, without having any or all of the particular thicknesses disclosed.

(261) As described, a face contacting or wearer side of the seal **114** comprises a supple lower-nose-receiving concave center part shaped to form a seal on the face of the wearer by receiving and sealingly contacting the tip, lower sides, and base of the nose and sealingly contacting the upper lip, and position the aperture **128** for gas flow beneath the nares of wearer. As shown in FIGS. **5** and **16**, the lower-nose-receiving supple center part comprises an upper wall portion **230** to contact the tip of the nose of the wearer, a lower wall portion **232** to contact the upper lip below the nose of the wearer, and left and right side wall portions defined by the previously-described inner lateral portions **206** to contact the left and right lower sides of the nose of the wearer. The lower wall portion **232** below the outlet aperture **128** is positioned rearward of or is closer to the left and right rearward-most extremities of the seal **114** than is the upper wall portion **230**.

(262) The left and right side wall portions defined by the inner lateral portions **206** extend from the aperture **128** away from one another. An angle between the left and right side wall portions **206** may be between about 20 and about 60 degrees or about 30 and about 50 degrees for example. Typically, the seal **114** has a greater width dimension than a height dimension. In at least some embodiments, the seal **114** may have an overall width of between 5 cm and 10 cm, or 6 cm and t 8 cm. In at least some embodiments, the seal **114** may have an overall height of less than 5 cm, less than 4.5 cm or less than 4 cm. The seal **114** can have a first texture on a user-contacting side and a second texture on the opposite side, which can be different from the first texture. For example, the texture on the user-contacting side can promote sealing with, friction against or comfort for the user's face. The texture on the opposite side can be configured to interact with the base **144** of the

frame **116** to increase friction to inhibit relative movement between the seal **114** and the frame **116**, decrease friction to promote relative movement between the seal **114** and the frame **116** or reduce adhesion between the seal **114** and the frame **116** so that the lateral portions of the seal **114** are free to move away from and out of contact with the frame **116**.

(263) The aperture **128** may be elongate in a width direction of the seal **114**. The aperture **128** may be somewhat bean-shaped or bowtie-shaped when viewed from the rear. In the illustrated configuration, a central portion of the aperture **128** has a smaller height than lateral portions of the aperture **128**. In addition, because the lower wall portion **232** is positioned rearward of the upper wall portion **230**, a lower edge **236** of the aperture **128** is spaced rearward in the depth direction of the seal **114** relative to an upper edge **234** of the aperture **128** with the seal **114** in an orientation as worn by a user with the user's head upright.

(264) FIG. 5 illustrates a sectioned view of the mask **112** taken along a vertical, central plane of the mask **112**. A portion of the upper wall portion **230** above and adjacent the aperture **128** can define a line **240** that lies within the central plane. Similarly, a portion of the lower wall portion **232** below and adjacent the aperture **128** can define a line **242** that lies within the central plane. The lines **240** and **242** define an angle **244** between them. In some configurations, the angle **244** is greater than or equal to 90 degrees and less than 180 degrees. In some configurations, the angle **244** is between 120 degrees and 150 degrees. In some configurations, the angle **244** is 135 degrees.

(265) The seal **114** can also define a line **246** that lies in the central plane and extends through a point on the lower edge **236** of the aperture and a point on the upper edge **234** of the aperture **128**. FIG. 16A illustrates the aperture **128** viewed from a rear of the seal **114** normal to the line **246**. As described above, the aperture **128** can have a bean-shape or a bowtie-shape with the central portion **250** having a smaller height **252** than a height **254** of the lateral portions **256**. The aperture **128** can be symmetrical about a central, vertical axis. In the illustrated arrangement, each lateral portion **256** is generally oval in shape, with a long axis of the oval shapes angled inward or toward one another in a direction from the lower edge **236** toward the upper edge **234**. The central portion **250** defines curved, concave transitions between the oval shapes of the lateral portions **256** on each of the lower edge **236** and the upper edge **234**.

(266) Each lateral portion **256** defines an uppermost point **260** and a lowermost point **262**. The uppermost points **260** of the lateral portions **256** are closer to one another and the central axis than the lowermost points **262**. The uppermost points **260** define a horizontal distance or width **264** between them that is smaller than a horizontal distance or width **266** between the lowermost points **262**. Each of the distances **264**, **266** can be equal to or greater than one-half and less than or equal to three-quarters of an overall width **268** of the aperture **128**. In some configurations, the distance **264** is between one-third and two-thirds of the width **268**, or one-half of the width **268**. In some configurations, the distance **266** is between one-half and seven-eighths of the width **268**, or three-quarters of the width **268**.

(267) The upper edge **234** of the aperture **128** defines a vertical distance **270** between the uppermost points **260** and a lowermost point **272** of the upper edge **234** within the central portion **250**, which can be located on the central axis. The vertical distance **270** can also be referred to as a depth of the central portion **250** on the upper edge **234**. Similarly, the lower edge **236** of the aperture **128** defines a vertical distance **274** between the lowermost points **262** and an uppermost point **276** of the lower edge **236** within the central portion **250**, which can be located on the central axis. The vertical distance **274** can be referred to as a depth of the central portion **250** on the lower edge **236**. In some configurations, the vertical distances **270**, **274** can be different from one another. In some configurations, the vertical distance **270** is less than the vertical distance **274**. In some configurations, the vertical distance **270** is between one-third and two-thirds of the vertical distance **274**, or is about one-half of the vertical distance **274**. In some configurations, the vertical distance **270** is less than the height **252** of the central portion **250** and/or the height **252** of the central portion **250** is equal to or less than the vertical distance **274**.

(268) In some configurations, the overall width **268** of the aperture **128** is between 20-25 mm, between 21-23 mm, or is about 22 mm. In some configurations, the overall height **254** of the aperture **128** is between 10-14 mm, between 11-13 mm, or is about 12 mm. In some configurations, the height **252** of the central portion **250** of the aperture **128** is between 4-6 mm, or is about 5 mm. In some configurations, the distance **270** is between 1.5-2.5 mm, or is about 2 mm. In some configurations, the distance **274** is between 4-6 mm, or is about 5 mm. In some configurations, the distance **264** between the uppermost points **260** of the upper edge **234** is between 8-12 mm, 9-11 mm or is about 10 mm. In some configurations, the distance **266** between the lowermost points **262** of the lower edge **236** is between 15-20 mm, between 16-18 mm, or is about 17 mm.

(269) With particular reference to FIGS. **5**, **10** and **17-22**, as described above, the illustrated mask **112** comprises the connector **202** that couples the seal **114** to the frame **116**. The connector **202** comprises a first portion **300** and a second portion **302** that capture the seal **114** between them. The first portion **300** and the second portion **302** can couple to one another to retain the seal **114** between the first portion **300** and the second portion **302**. In some configurations, the first portion **300** can connect to the second portion **302** by a snap-fit arrangement, which can be a permanent or removable connection.

(270) In the illustrated arrangement, the first portion **300** of the connector **202** comprises a hub portion **304** and a flange portion **306**. The hub portion **304** comprises an annular wall that extends in an axial direction and defines the aperture **175** that receives the connector **172** of the base **144** portion of the frame **116**. The flange portion **306** comprises an annular wall that extends outwardly from the hub portion **304**. In some configurations, the flange portion **306** extends in a radial direction and, thus, is perpendicular to the hub portion **304**. In the illustrated arrangement, the second portion **302** is an annular member that is sized and shaped to fit onto the hub portion **304** of the first portion **300**.

(271) As described above, the first portion **300** and the second portion **302** of the connector **202** are configured to be interlocked with one another in an axial direction. In the illustrated arrangement, an outer surface of the end portion of the hub portion **304** of the first portion **300** defines a recess **308** that extends partially or completely around the hub portion **304** in a circumferential direction. An interior surface of the second portion **302** defines a protrusion **310** that extends partially or completely around the second portion **302** in a circumferential direction and is configured to be received by the recess **308** of the first portion **300**. In other configurations, this arrangement could be reversed such that the protrusion **310** can be on the first portion **300** and the recess **308** can be on the second portion **302**.

(272) The first portion **300** and the second portion **302** can also be keyed to one another to ensure that the first portion **300** and the second portion **302** can only be connected in a single rotational orientation relative to one another and/or to inhibit or prevent relative rotation once connected. In some configurations, one of the first portion **300** and the second portion **302** comprises a key or protrusion and the other of the first portion **300** and the second portion **302** comprises a slot or recess configured to receive the key or protrusion. In the illustrated arrangement, the hub portion **304** of the first portion **300** comprises a slot or recess **312** and the second portion **302** comprises a key or protrusion **314** that is configured to engage the slot or recess **312**. At least a terminal end of the slot or recess **312** is semi-cylindrical in shape and the key or protrusion **314** comprises a complementary semi-cylindrical shape. In the illustrated arrangement, the slot **312** and the protrusion **314** are located on an upper portion of a respective one of the first portion **300** and the second portion **302** of the connector **202**. However, in other configurations, this location could be varied. In addition, the location of the recess **312** and the protrusion **314** can be reversed between the first portion **300** and the second portion **302** of the connector **202** from the locations shown.

(273) The seal **114** defines an aperture **316** that receives the first portion **300** and the second portion **302** of the connector **202**. When the connector **202** is assembled to the seal **114**, the flange portion **306** of the first portion **300** is positioned within an interior of the seal **114** and the hub portion **304**

extends through the aperture **316**. The second portion **302** of the connector **202** is positioned on the exterior of the seal **114**. The seal **114** can comprise an annular rim **318** that encircles the aperture **316** and is configured to be captured by the first portion **300** and the second portion **302** of the connector **202**. In particular, the rim **318** comprises a generally T-shaped cross-section having a narrow base **320**, a first lobe **322** that extends in a first axial direction from the base **320** and a second lobe **324** that extends in a second axial direction from the base **320** that is opposite the first axial direction. The first portion **300** defines an annular recess **326** configured to receive the first lobe **322** and the second portion **302** defines an annular recess **328** configured to receive the second lobe **324**. The base **320** extends between the first portion **300** and the second portion **302** toward a main portion of the seal **114**.

(274) In the illustrated arrangement, the connector **202** and the seal **114** comprise interference portions configured to inhibit or prevent rotational movement between the seal **114** and the connector **202**. In particular, the hub portion **304** of the first portion **300** comprises a first protrusion **330** and the second portion **302** comprises a second protrusion **332**. The first protrusion **330** and the second protrusion **332** face one another with a space between them that is configured to receive a portion of the annular rim **318** between them. The portion of the annular rim **318** defines a first recess **334** and a second recess **336** configured to receive the first protrusion **330** and the second protrusion **332**, respectively. In the illustrated arrangement, each of the protrusions **330**, **332** and the recesses **334**, **336** comprise a generally cuboid shape. The protrusions **330**, **332** and the recesses **334**, **336** are located on lower portions of the first portion **300** and the second portion **302** of the connector **202**. However, in other configurations, these locations could be varied.

(275) In some configurations, the connector **202** and the seal **114** also comprise a second set of interference portions configured to inhibit or prevent rotational movement between the seal **114** and the connector **202**. In particular, the first portion **300** comprises a third protrusion **338** and the seal **114** comprises a third recess **340** and a fourth recess **342**. The third recess **340** is configured to receive the third protrusion **338**. In the illustrated configuration, a portion of the key or protrusion **314** extends into the fourth recess **342**. The third protrusion **338**, the third recess **340** and the fourth recess **342** are located on an upper portion of a respective one of the connector **202** and the seal **114** and/or opposite the protrusions **330**, **332** and the recesses **334**, **336**. However, in other configurations, the third protrusion **338**, the third recess **340** and the fourth recess **342** can be located elsewhere.

(276) With reference to FIGS. **3** and **23**, in the illustrated arrangement, the headgear **118** can comprise a bifurcated headgear arrangement having a top or upper strap portion **350** and a rear strap portion **352**. The upper strap portion **350** is configured to pass over the top of the user's head from one side to the other. In some configurations, the upper strap portion **350** is a crown strap that lies over the parietal bone or at or near a junction between the parietal bone and the frontal bone. In other configurations, the upper strap portion **350** can comprise a forehead strap that lies over the frontal bone of the user. The rear strap portion **352** passes around the back of the user's head and, in some configurations, lies over the occipital bone of the user. However, in other configurations, the rear strap portion **352** could be positioned higher or lower on the head and/or neck of the user. In the illustrated arrangement, the upper strap portion **350** and the rear strap portion **352** join one another on each side of the headgear **118** at a junction **354**. Each one of a pair of forward extension straps **356** extends forwardly from the junction **354** toward and connects to a respective one of the side arms **130** of the frame **116**.

(277) In some configurations, at least some portions of the headgear **118** are rigid, semi-rigid, inelastic or substantially inextensible in response to normal or expected forces acting on the headgear **118** and other portion of the headgear **118** are elastic or extensible in response to normal or expected forces. In some configurations, one or more of the upper strap portion **350**, junctions **354** and forward extension straps **356** are rigid, semi-rigid, inelastic or substantially inextensible. In the illustrated configuration, each of the upper strap portion **350**, junctions **354** and forward

extension straps **356** are rigid, semi-rigid, inelastic or substantially inextensible. In the illustrated configuration, the rear strap portion **352** is elastic or extensible. Such an arrangement allows the rear strap portion **352** to stretch to adjust a circumferential length of the headgear **118**. The amount of stretch of the rear strap portion **352** can be limited and, thus, the rear strap portion **352** can also be adjustable in length. In some configurations, it is preferable for circumferential length adjustment to occur at the back of the user's head, which is less susceptible to lengthening in response to blow-off forces. The rigid, semi-rigid, inelastic or substantially inextensible nature of the junctions **354** and forward extension straps **356** positioned on the side and forward portions of the user's head assists in maintaining a desired circumferential length of the headgear **118** despite the elastic nature of the rear strap portion **352**. In some cases, frictional forces between the portions of the headgear **118** and the side and forward portions of the user's head inhibit movement or lengthening of the headgear **118** in response to blow-off forces. However, in other arrangements, the rear strap portion **352** can be rigid, semi-rigid, inelastic or substantially inextensible and, in such cases, may be adjustable in length.

(278) The upper strap portion **350** can comprise a length adjustment arrangement. In the illustrated arrangement, the upper strap portion **350** comprises a first portion **358** and a second portion **360** that are separate from one another and are capable of being adjustably connected to one another. A free end of the first portion **358** comprises a loop **362** through which the second portion **360** can pass. Thus, the first portion **358** and the second portion **360** can be slid relative to one another to vary an overlapping distance of the portions **358**, **360** and, thus, vary a length of the upper strap portion **350**. The second portion **360** can be coupled to the first portion **358** to secure the upper strap portion **350** in a desired adjusted length. In the illustrated arrangement, an inner surface of the second portion **360** can comprise a hook portion of a hook-and-loop fastener and the outer surface of the first portion **358** can comprise a loop portion of the hook-and-loop fastener. This arrangement can also be reversed. In some configurations, a material of the upper strap portion **350** can define the loop portion of the hook-and-loop fastener. In other words, the loop portion may not be a discrete element of the upper strap portion **350**.

(279) With the above-described arrangement, for a particular user, the upper strap portion **350** can be adjusted to an appropriate length such that the junctions **354** and/or forward extension straps **356** sit above the user's ears. Once adjusted, the upper strap portion **350** can be maintained in the adjusted position during donning and doffing of the headgear **118** and associated interface **110**. In other words, preferably, the first portion **358** and the second portion **360** do not have to be separated from one another for the user to put on or take off the interface **110**. Rather, the headgear **118** allows the interface **110** to be donned ('like a cap') by holding the frame **116** at the seal **114** or near the seal **114** (as one would hold a cap at its peak when lifting or flipping it onto the head) and moving the rear strap portion **352** over and to the rear of the user's head. The stretchable or extensible rear strap portion **352** can facilitate the passing of the headgear **118** over the user's head without opening the headgear **118** by separating the portions **358**, **360** of the upper strap portion **350** or separating one or both ends of the rear strap portion **352** from a remainder of the headgear **118**. The headgear **118** may be removed or doffed in a reverse action.

(280) In the illustrated configuration, the rear strap portion **352** is connected to each of the junctions **354** by an end portion of the rear strap portion **352** that is passed through a loop **364** carried by the junction **354** and doubled back on itself. The end portion of the rear strap portion **352** can be coupled to a relatively more central portion of the rear strap portion **352** by a suitable fastener, such as a hook-and-loop fastener, for example. The rear strap portion **352** can be adjustable at one or both ends.

(281) In some configurations, the rigid, semi-rigid, inelastic or substantially inextensible portions of the headgear **118** can be constructed by introducing a molten plastic material into a space defined by a textile or fabric material outer cover and allowed to cool to form a plastic core. The plastic material can adhere or be coupled to the textile or fabric material to form an integrated

structure. The textile or fabric material can be a tubular structure or separate layers of material, for example. Headgear structures having a plastic core and an outer textile or fabric cover and methods for producing such headgear structures are disclosed in Applicant's U.S. Provisional Application Nos. 62/050,925; 62/159,857; and 62/198,104, the entireties of which are incorporated by reference herein and made a part of the present disclosure. In some arrangements, some or all of the connectors **138** and loops **362**, **264** are formed as a unitary structure with the plastic core of the headgear **118**.

(282) Seals and masks disclosed herein may be used with headgear in other forms, such as headgear with two straps which attach to the mask on either side, i.e., headgear which comprises left and right side upper and lower straps. The frame of such an interface embodiment may or may not comprise side arms as described above. Left and right upper straps may pass downwardly (when the headgear is worn) between the eyes and ears of the wearer and left and right lower straps may extend from the lower rear of the head and beneath the ears to the mask (and attach to the mask each side below the upper straps). Alternatively, upper and lower straps may join for example in a stiffer yoke before attaching to the mask frame, or which is integral with the mask frame. Such a headgear may have buckle and tongue, loop and tongue or other adjustment in the upper or lower straps or both sides, part way along their length(s) or at the connection of the straps to the mask. In less preferred embodiments, the upper straps may attach to the top of a T-piece extending upwardly from the frame to the wearer's forehead. In another embodiment, again, the headgear may comprise a single strap which passes or loops from the mask on one side around the rear of the head and back to the mask on the other side. Such a headgear strap may be elastic or resiliently stretchable and/or may have a length adjustment device (e.g., buckle and tongue, loop and tongue, etc.) in the rear or at the sides or at the connection of the headgear to the mask on one or both sides. A variant of such headgear may also comprise a crown strap.

(283) Other suitable materials or configurations for the headgear **118** can also be used. For example, in some configurations, the headgear may be formed at least in part from a soft flexible material, which can be a cloth covered foam material, such as a BREATH-O-PRENE material, for example. The headgear **118** may be formed by cutting out the headgear **118** to shape from the sheet material by blade cutting or radio frequency cutting, for example. In one embodiment, the edges of the headgear are thermoformed, i.e., compressing under heat, to form rounded edges. That is, heat and pressure are applied along the headgear edges to compress the opposite outer surfaces of the headgear material towards one another at the edges and heat bond them together. This may be done simultaneously or in the same tool with cutting the headgear to shape for example, by cutting an outline of the headgear shape in the sheet material and theremoforming to define the rounded headgear edges in one operation, or instead by first cutting the headgear to shape and then rounding the edges in a second operation. The rounded edges or any joints in the headgear may alternatively be formed by ultrasonic or radio frequency welding, for example.

(284) As described above, the mask **112** comprises a bias flow vent **126** that allows expired gases from the user to be exhausted from the interface **110**. In the illustrated arrangement, the bias flow vent **126** is defined by the frame **116**. In particular, the bias flow vent **126** is defined by the elbow connector **174** of the base **144** of the frame **116**. The vent holes **190** of the bias flow vent extend in a generally radial direction through the elbow connector **174** between the elbow **122** and the U-shaped body of the base **144**. The location of the vent holes **190** can reduce noise produced by the interface **110**. In addition, other features of the interface **110** can facilitate noise reduction.

Examples of such features and arrangements are disclosed with particular reference to FIGS. **24-29**.

(285) Inspiration noise can be defined as the increased level of noise resulting from the breathing in or inspiration of a user wearing a CPAP mask. Inspiration noise is common to CPAP masks, especially smaller nasal masks or nasal pillow masks. Static bias noise can be defined as constant noise with no flow generated by patient breathing and is generally associated with bias hole geometry and can be reduced via a number of different hole shapes, patterns and configurations.

Dynamic inspiration noise (which is generally worse on inhalation) can be caused by geometry other than the bias holes. It is believed that this inspiration noise is, however, transmitted or heard through the bias holes and hence is closely associated with bias flow. When a patient is breathing on a CPAP machine, as he or she breathes in, the flow in the CPAP tube increases such that an approximately constant pressure is maintained within the mask. This has the result that bias flow on inhalation and exhalation is approximately constant and hence flow through the bias holes is a function of pressure only.

(286) Dynamic noise, and specifically inspiration noise, occurs when a patient is breathing in and hence when the flow from the CPAP is at a maximum. It is therefore believed that increased flow causes the inspiration noise. Methods to minimize the noise created on inspiration are discussed below. Noise is caused by a restriction in the breathing circuit upstream of the bias flow. The restriction causes increased velocity and turbulence, which in turn generates noise. The noise is heard through the bias holes. It has been determined that having a diameter less than approximately 15 mm within the breathing circuit can result in significant inspiration noise. Therefore, when possible or practical considering other factors, maintaining a diameter greater than approximately 15 mm within the breathing circuit can be desirable when designing a mask system that has reduced, minimal or no inspiration noise issues.

(287) In addition to maintaining a minimum diameter or cross-sectional area within the breathing circuit, another factor is the consideration of turbulence. Turbulence created in the airstream itself creates noise, which is subsequently heard by the patient. Sudden expansions in a pipe cause changes in pipe velocity, turbulence and, hence, noise. Expansion can either be a sudden expansion (wherein the expansion angle is equal to 180 degrees) or a more gradual expansion (wherein the expansion angle is greater than 0 degrees and less than 180 degrees). In order to reduce the noise, either the rate at which the fluid is slowing down can be reduced (i.e., utilize a shallow gradual expansion) or the velocity at which the air is travelling can be reduced. In order to reduce head loss, an expansion should preferably have an angle of $\Theta < 30^\circ$ or, alternatively, an angle of $120^\circ \leq \Theta < 180^\circ$ or $150^\circ \leq \Theta < 180^\circ$.

(288) In practice, noise can be reduced designing cross sections such that the peak air speed is reduced or minimized and/or designing of geometry to reduce or eliminate sudden changes in geometry that cause turbulence and thus noise. In some configurations, noise reductions can be achieved by careful consideration of tube and connection diameters within the breathing circuit. For example, a conventional CPAP hose to mask tube connection is shown in FIG. 24. The actual CPAP hose or breathing circuit is not shown in FIG. 24 (see, however, conduit 12 in FIG. 1), but would be coupled to the upstream end of the CPAP hose adapter 400. The CPAP hose adapter 400 is coupled to the connector 124 of the mask tube 120. The illustrated connector 124 of the mask tube 120 is a swivel connector that comprises a male swivel portion 402 and a female swivel portion 404. The male swivel portion 402 is coupled to the mask tube 120 and the female swivel portion 404 is coupled to the CPAP hose adapter 400. It can be seen in FIG. 24 that there are several restrictions and an expansion within the illustrated CPAP hose to mask tube connection. The restrictions cause the velocity of the air to increase which then causes increased turbulence when the air passes over the expansion. The restrictions are created as a result of several male to female connections between swivels 402, 404 and tube or hoses.

(289) With reference to FIG. 25, an improved CPAP hose to mask tube connection reduces one or more of the restrictions, such as by reducing or minimizing the wall thickness of the swivel components and changing the way in which the male swivel 402 is joined to the mask tube 120. In particular, in the illustrated configuration of FIG. 25, the male swivel 402 does not extend inside the mask tube 120. Rather, the male swivel 402 has a minimum diameter that is equal to or substantially equal to the internal diameter of the mask tube 120. In some configurations, this is achieved by using a coupling sleeve 406 or other suitable coupling to couple the male swivel 402 to the mask tube 120. The coupling sleeve 406 can be formed by, for example, overmoulding a

material that will chemically bond to the male swivel **402** and the mask tube **120** onto a portion of both the swivel **402** and the tube **120**. Such an arrangement reduces the size of the restriction within the male swivel **402** and also removes or substantially eliminates the expansion from the male swivel **402** to the mask tube **120**. In the illustrated arrangement, the diameters of the various components are labeled and can be as follows:

(290) Approximate Diameters:

(291) $D1 \approx 22$ mm $D2 \approx D3 \approx 19$ mm $D4 \approx 17$ mm $D5 \approx D6 \approx 15$ mm

In other configurations, the diameters may vary from the above values, but the proportions between two or more of the diameters can be the same or substantially the same. Furthermore, the differences between two or more of the diameters can be the same, substantially the same or less than the above values.

(292) In some applications or in some locations within a CPAP system, such as the interface **110**, for example, it can be difficult or impractical to avoid sudden changes in geometry. For example, to prevent sudden transitions in cross-sectional area, a small wall angle (e.g., less than) 30° is desirable. Such small wall angles require the transition between diameters or cross-sectional areas to occur over a greater length compared to a more sudden transition, which can increase the overall size of the mask. In many cases, it is desirable for the mask to be as small and unobtrusive as possible or practical, for user comfort. Thus, a sudden transition may be desirable in terms of the smaller mask geometry that it allows.

(293) To reduce the noise created over the unavoidable transitions from small diameters to large diameters (expansions), the location of the bias vent can be selected to reduce the flow rate across the transition. The bias flow, which is generally associated with the creation of noise, can actually be used to reduce noise. By having the bias flow on the side of the expansion with the smallest cross sectional area (before the expansion), the inspiration noise can be reduced as the flow rate over the expansion and thus the velocity is now reduced. Such an arrangement creates a less turbulent flow, as shown in FIGS. **26** and **27**. FIGS. **26A** and **27A** illustrate flow at an expansion when the bias flow vent is located before or upstream of the expansion. FIG. **26A** is a velocity plot and FIG. **27A** is a vector plot. FIGS. **26B** and **27B** illustrate flow at an expansion when the bias flow vent is located after the expansion. Again, FIG. **26B** is a velocity plot and FIG. **27B** is a vector plot. Comparing FIGS. **26A** and **26B**, it is apparent that the velocity at the expansion is lower when the bias flow vent is located before the expansion (FIG. **26A**) relative to the velocity at the expansion when the bias flow vent is located after the expansion (FIG. **26B**). The dark area in the relative upstream portions of the flows represents areas higher velocity. Thus, with the bias flow vent located before the expansion, velocity is lower and, accordingly, noise is lower. FIGS. **27A** and **27B** also illustrate that less recirculated flow is present when the bias flow vent is located before the expansion (FIG. **27A**) compared to the situation when the bias flow vent is located after the expansion (FIG. **27B**). Less recirculated flow means less turbulence, which means less noise.

(294) Different design options (A, B and C) illustrating how this principle can be implemented in a mask **112** are shown in FIGS. **28A**, **28B** and **28C**. The level of sound in each design option produces over 3 breaths is shown in the plot in FIG. **29**. Design C has the lowest peak inspiration noise and Design A has the highest peak inspiration noise, with Design B having a peak inspiration noise between Design C and Design A. Each sample has the same minimum internal diameter D. In the illustrated designs, the bias flow vents **126** are implemented in the elbow connectors **174**; however, in other arrangements, the bias flow vents **126** can be in other locations, as well. For example, in some configurations, the bias flow vents **126** can be in the elbow **122**, among other possible locations.

(295) In Design A, the vent holes **190** of the bias flow vent **126** are located after a sudden change in geometry. As a result, upon inhalation, there is a high flow rate of air over a sudden expansion which causes turbulence and noise.

(296) In Design B, the vent holes **190** of the bias flow vent **126** are located after a gradual transition

in geometry. The angle of the gradual transition in the geometry is greater than 30°. As a result, upon inhalation, some separation of flow from the walls of the flow path occurs due to the high flow over the gradual expansion. This separation of flow causes turbulence, which causes noise. (297) In Design C, the vent holes **190** of the bias flow vent **126** are located before or upstream of a sudden change in the geometry. This reduces the flow rate and, thus, the velocity of the air passing over the sudden expansion. As the head or pressure loss is proportional to the velocity squared, it is apparent that velocity is a significant factor in the amount of head losses, turbulence and, hence, noise that occurs when the fluid flows over a change in section. This shows the influence the position of the bias flow vent **126** has on the noise and turbulence generated. As there is a reduced velocity passing over the expansion, the turbulence and, hence, the noise is significantly lower in Design C than that observed in Design A.

(298) In an alternative arrangement, the principle illustrated in Design C can be applied to Design B by locating the bias flow vent **126** before or at the start of the gradual expansion. Due to the reduced flow over the gradual expansion, results similar to that in Design C are expected.

(299) The location of the vent holes **190** of the bias flow vent **126** relative to sudden expansions has a greater impact on noise than reducing the angle of the walls at the expansion. This is desirable as it can be impractical to optimize the expansion angle in an actual mask because the use of a desirable (small) angle requires an increased transition length in order to achieve the change in cross-sectional area, which may result in an overly large mask. In order to reduce dynamic (inhalation) noise, turbulence created within the air supply flow path can be reduced or minimized by avoiding, reducing or minimizing restrictions where possible or practical within the flow path from the CPAP machine to the patient. In addition or in the alternative, internal diameters (or cross-sectional areas) of swivels, elbows and/or other parts of the flow path can be increased or maximized, or made as close to the internal diameter (or cross sectional area) of the air supply (CPAP) hose as possible or practical. Such an arrangement will keep the flow velocity and, hence, turbulence to a minimum resulting in the creation of less noise. Design of a transition from a smaller section to a larger section, if required or desirable, is preferably located between the bias flow vent and the patient (after the bias flow) such that the volumetric flow rate over the transition is reduced. Design of a transition from a smaller section to a larger section, if required or desirable, preferably is such that the flow head loss over the transition is minimised. The flow path from the smaller section to the larger section preferably is a gradual expansion, with walls angles at less than 30 degrees. If such an arrangement is not practical, then a sudden transition with walls angled at 180° is preferred.

(300) FIGS. **30** and **31** illustrate an alternative connection arrangement between the headgear **118** and the frame **116** (or other portion of the mask **112**). In the illustrated arrangement, the forward extension straps **356** of the headgear **118** overlap the side arms **130** of the frame **116**. In the illustrated arrangement, the forward extension straps **356** can be positioned to the inside of the side arms **130**; however, in other arrangements, this arrangement can be reversed and the forward extension straps **356** can be positioned to the outside of the side arms **130**.

(301) In some configurations, the position of the headgear **118** relative to the frame **116** is adjustable such that the amount of overlap between the forward extension straps **356** can be adjusted. Such adjustment varies an effective circumferential length of the interface **110**. In some configurations, the headgear **118** and the frame **116** are adjustable into a selected one of two or more discrete adjustment positions. Any suitable coupling arrangement between the headgear **118** and the frame **116** can be used. In the illustrated arrangement, the headgear **118** comprises one or more posts **410** located on the forward extension straps **356** and the frame **116** comprises one or more corresponding openings **412** located on the side arms **130** and configured to removably receive the posts **410**. In the illustrated arrangement, the headgear **118** comprises two posts **410** on each side and each side arm **130** of the frame **116** comprises three openings **412**. Thus, the headgear **118** and frame **116** have two different length adjustment positions. However, in other

arrangements, other numbers of adjustment positions can be provided.

(302) The posts **410** and openings **412** are similar in structure and function to a baseball-cap style size adjustment arrangement. Each of the posts **410** comprises a stem **414** and a head or cap **416**. The illustrated posts **410** are generally T-shaped; however, other shapes can also be used, such as a cylindrical stem **414** and disc-shaped or spherical head **416**, for example. The openings **412** are sized, shaped and/or otherwise configured to allow the heads **416** of the posts **410** to pass therethrough and to retain the posts **410** once passed through the openings **412**, at least in response to normal or expected forces. However, the posts **410** can be deliberately removed from the openings **412** to permit separation of the headgear **118** and the frame **116**. Passing of the posts **410** through the openings **412** can be accomplished by deformation of one or both the posts **410** and openings **412**. That is, the heads **416** of the posts **410** can flex or otherwise deform and the openings **412** can stretch or enlarge to facilitate passage of the heads **416** of the posts **410**.

(303) In the illustrated arrangement, the openings **412** are elongated and each comprise a recessed flange **418** that is spaced inwardly from the outer surface of the side arms **130** of the frame **116**. The recessed flange **418** can extend around a portion or an entirety of a periphery of the openings **412**. The recessed flange **418** can be continuous or interrupted. For example, the recessed flange **418** can comprise portions on each end of the elongated opening **412**, wherein those portions are separate from one another. The recessed flange **418** can be configured to contact and retain a head **416** of the associated post **410**.

(304) The posts **410** can be formed by or connected to the headgear **118** by any suitable arrangement. For example, the posts **410** can be unitarily formed with a base member **420** that is coupled to the headgear **118**, such as by sewing, RF welding, adhesives or another suitable coupling arrangement. In some configurations, the posts **410** can be unitarily formed with a plastic core of the headgear **118**.

(305) FIGS. **32** and **33** illustrate yet another alternative connection arrangement between the headgear **118** and the frame **116** (or other portion of the mask **112**). In the illustrated arrangement, the forward extension straps **356** of the headgear **118** overlap the side arms **130** of the frame **116**. In the illustrated arrangement, the forward extension straps **356** can be positioned to the inside of the side arms **130**; however, in other arrangements, this arrangement can be reversed and the forward extension straps **356** can be positioned to the outside of the side arms **130**.

(306) In the illustrated configuration, the position of the headgear **118** relative to the frame **116** is fixed or non-adjustable when the frame **116** is connected to the headgear **118**. In alternative arrangements, the position of the headgear **118** relative to the frame **116** can be adjustable such that the effective circumferential length of the interface **110** can be adjusted. Any suitable coupling arrangement between the headgear **118** and the frame **116** can be used. In the illustrated arrangement, the headgear **118** comprises one or more posts **410** located on the forward extension straps **356** and the frame **116** comprises one or more corresponding openings **412** located on the side arms **130** and configured to removably receive the posts **410**. In the illustrated arrangement, the headgear **118** comprises two posts **410a**, **410b** on each side and each side arm **130** of the frame **116** comprises two complementary openings **412a**, **412b**. In some configurations, the two posts **410a** and **410b** are different from one another at least in shape. Similarly, the two openings **412a** and **412b** are different from one another at least in shape. In the illustrated arrangement, the rearward post **410a** is generally triangular in shape and the forward post **410b** is generally circular in shape. Similarly, the rearward opening **412a** is generally triangular in shape and the forward post **412b** is generally circular in shape. However, other suitable shapes can also be used. Furthermore, the shapes of different posts and/or openings can be the same or different.

(307) Similar to the arrangement of FIGS. **30** and **31**, the posts **410a**, **410b** and openings **412a**, **412b** of FIGS. **32** and **33** are similar in structure and function to a baseball-cap style size adjustment arrangement. Each of the posts **410a**, **410b** comprises a stem (not shown, but similar to stem **414** of FIGS. **30** and **31**) and a head or cap (visible portion of the posts **410a**, **410b**). The

openings **412a**, **412b** are sized, shaped and/or otherwise configured to allow the heads of the posts **410a**, **410b** to pass therethrough and to retain the posts **410a**, **410b** once passed through the openings **412a**, **412b**, at least in response to normal or expected forces. However, the posts **410a**, **410b** can be deliberately removed from the openings **412a**, **412b** to permit separation of the headgear **118** and the frame **116**. Passing of the posts **410a**, **410b** through the openings **412a**, **412b** can be accomplished by deformation of one or both the posts **410a**, **410b** and openings **412a**, **412b**. That is, the heads of the posts **410a**, **410b** can flex or otherwise deform and the openings **412a**, **412b** can stretch or enlarge to facilitate passage of the heads of the posts **410a**, **410b**.

(308) In some configurations, the openings **412a**, **412b** can each comprise a recessed flange that is spaced inwardly from the outer surface of the side arms **130** of the frame **116**. The recessed flange can extend around a portion or an entirety of a periphery of the openings **412a**, **412b**. The recessed flange can be continuous or interrupted. For example, the recessed flange **418** can comprise portions on each end of the elongated opening **412a**, **412b**, wherein those portions are separate from one another. The recessed flange can be configured to contact and retain the head of the associated post **410a**, **410b**. In other configurations, the heads of the posts **410a**, **410b** can abut against an outer surface of the side arms **130** (or other portion of the frame **116**) adjacent the openings **412a**, **412b** instead of a recessed flange.

(309) The posts **410a**, **410b** can be formed by or connected to the headgear **118** by any suitable arrangement. For example, the posts **410a**, **410b** can be unitarily formed with a base member that is coupled to the headgear **118**, such as by sewing, RF welding, adhesives or another suitable coupling arrangement. In some configurations, the posts **410a**, **410b** can be unitarily formed with a plastic core of the headgear **118**.

(310) FIG. **34** illustrates an alternative arrangement of a headgear **118**, which can be similar in many respects to the headgear **118** of FIGS. **3** and **23**. Accordingly, aspects of the headgear **118** not specifically described below can be assumed to be the same as or similar to the headgear **118** of FIGS. **2** and **23**, or can be of any other suitable arrangement. In the arrangement of FIG. **34**, the headgear **118** comprises a bifurcated headgear arrangement having a top or upper strap portion **350** and a rear strap portion **352**. The upper strap portion **350** is configured to pass over the top of the user's head from one side to the other. In some configurations, the upper strap portion **350** is a crown strap that lies over the parietal bone or at or near a junction between the parietal bone and the frontal bone. In other configurations, the upper strap portion **350** can comprise a forehead strap that lies over the frontal bone of the user.

(311) The rear strap portion **352** passes around the back of the user's head and, in some configurations, lies over the occipital bone of the user. However, in other configurations, the rear strap portion **352** could be positioned higher or lower on the head and/or neck of the user. In the illustrated arrangement, the upper strap portion **350** and the rear strap portion **352** join one another on each side of the headgear **118** at a junction **354**. Each one of a pair of forward extension straps **356** extends forwardly from the junction **354** toward and connects to a respective one of the side arms **130** of the frame **116**.

(312) In some configurations, at least some portions of the headgear **118** are rigid, semi-rigid, inelastic or substantially inextensible in response to normal or expected forces acting on the headgear **118** and other portion of the headgear **118** are elastic or extensible in response to normal or expected forces. In some configurations, one or more of the upper strap portion **350**, junctions **354** and forward extension straps **356** are rigid, semi-rigid, inelastic or substantially inextensible. In the illustrated configuration, each of the upper strap portion **350**, junctions **354** and forward extension straps **356** are rigid, semi-rigid, inelastic or substantially inextensible. In the illustrated configuration, the rear strap portion **352** is elastic or extensible. Such an arrangement allows the rear strap portion **352** to stretch to adjust a circumferential length of the headgear **118**. The amount of stretch of the rear strap portion **352** can be limited.

(313) In some configurations, the rear strap portion **352** can also be adjustable in length. In some

configurations, it is preferable for circumferential length adjustment to occur at the back of the user's head, which is less susceptible to lengthening in response to blow-off forces. The rigid, semi-rigid, inelastic or substantially inextensible nature of the junctions **354** and forward extension straps **356** positioned on the side and forward portions of the user's head assists in maintaining a desired circumferential length of the headgear **118** despite the elastic nature of the rear strap portion **352**. In some cases, frictional forces between the portions of the headgear **118** and the side and forward portions of the user's head inhibit movement or lengthening of the headgear **118** in response to blow-off forces. However, in other arrangements, the rear strap portion **352** can be rigid, semi-rigid, inelastic or substantially inextensible and, in such cases, may be adjustable in length.

(314) The upper strap portion **350** can comprise a length adjustment arrangement. In the illustrated arrangement, the upper strap portion **350** comprises a first portion **358** and a second portion **360** that are separate from one another and are capable of being adjustably connected to one another. A free end of the first portion **358** comprises a loop **362** through which the second portion **360** can pass. Thus, the first portion **358** and the second portion **360** can be slid relative to one another to vary an overlapping distance of the portions **358**, **360** and, thus, vary a length of the upper strap portion **350**. The second portion **360** can be coupled to the first portion **358** to secure the upper strap portion **350** in a desired adjusted length. In the illustrated arrangement, an inner surface of the second portion **360** can comprise at least one protrusion (not shown), which can be similar to any of the posts **410**, and the outer surface of the first portion **358** can comprise a plurality of openings **370** configured to removably receive the protrusion to provide a number of discrete adjustment positions. This arrangement can also be reversed.

(315) With the above-described arrangement, for a particular user, the upper strap portion **350** can be adjusted to an appropriate length such that the junctions **354** and/or forward extension straps **356** sit above the user's ears. Once adjusted, the upper strap portion **350** can be maintained in the adjusted position during donning and doffing of the headgear **118** and associated interface **110**. In other words, preferably, the first portion **358** and the second portion **360** do not have to be separated from one another for the user to put on or take off the interface **110**. Rather, the headgear **118** allows the interface **110** to be donned ('like a cap') by holding the frame **116** at the seal **114** or near the seal **114** (as one would hold a cap at its peak when lifting or flipping it onto the head) and moving the rear strap portion **352** over and to the rear of the user's head. The stretchable or extensible rear strap portion **352** can facilitate the passing of the headgear **118** over the user's head without opening the headgear **118** by separating the portions **358**, **360** of the upper strap portion **350** or separating one or both ends of the rear strap portion **352** from a remainder of the headgear **118**. The headgear **118** may be removed or doffed in a reverse action.

(316) In the illustrated configuration, the rear strap portion **352** is connected to each of the junctions **354** by an end portion of the rear strap portion **352** that is passed through a loop **364** carried by the junction **354** and doubled back on itself. The end portion of the rear strap portion **352** can be coupled to a relatively more central portion of the rear strap portion **352** by a suitable fastener, such as a book-and-loop fastener, for example. The rear strap portion **352** can be adjustable at one or both ends.

(317) FIGS. **36A** to **40C** illustrate interface arrangements having alternative side arm arrangements which are rotatable or compliant along a horizontal plane (i.e., horizontally across the user's face), substantially rigid along a vertical plane (i.e., vertically across the user's face). The horizontal and vertical planes across a user's face are illustrated in FIG. **35**. Providing side arms that are compliant along a horizontal plane allows the side arms to conform to the geometry of the user's face and/or change shape so as to not disturb the position of the seal on the user's face when external horizontal forces are applied to the side arms, for example, when the user sleeps on his/her side (e.g., a pillow contacting and exerting forces on the side arm). Further, providing side arms that are compliant along a horizontal plane allows the seal to be decoupled from the side arms and the frame such that

the seal can be correctly positioned on the user's face and will not move due to movement of the side arms. That is, external forces are not transmitted directly to the seal which allows the seal to be maintained in the correct operational position. The following illustrated interface arrangements provide side arms that are substantially rigid across a vertical plane to resist or inhibit rotation or rocking of the seal relative to the side arms, the headgear and the user's face caused by a blow-off force, thereby, ensuring a seal against the user's nose. In addition, the side arm arrangements in FIGS. 36A to 40C also limit or inhibit twist of the side arms which limits or inhibits rotation of the interface arrangements relative to the user's face (i.e., along an axis that is generally parallel to a plane that is perpendicular to both the horizontal and vertical planes, as shown in FIG. 35). More specifically, the side arms may be substantially rigid such that each side arm resists torsional bending along its length (i.e., about an axis defined by a lengthwise direction of the side arm). In some configurations, the side arms may allow a limited range of twist or rotation of the interface arrangements relative to the user's face to provide an amount of compliance which may improve user comfort while ensuring that the interface seals against the user's face.

(318) FIGS. 36A to 36D illustrate an interface 500 having a side arm arrangement having hinges 510 which allow the side arms 130 to rotate along a horizontal plane while remaining substantially rigid along a vertical plane (i.e., resisting bending caused by vertical forces). The side arms 130 may be formed from an injection moulded plastic material and are illustrated as having a rectangular cross-sectional shape. The rectangular cross-sectional shape of the side arms 130 have a height substantially greater than a thickness such that the resistance to bending in a direction parallel to the height direction is substantially greater than the resistance to bending in a direction parallel to the thickness direction. Accordingly, in the illustrated configuration and orientation of the side arms 130 in FIGS. 36A to 36D, the side arms 130 are substantially rigid along a vertical plane relative to the user and semi-rigid along a horizontal plane relative to the user (i.e., due to the rectangular cross-sectional shape). In some configurations, the side arms 130 may be rigid in both vertical and horizontal planes relative to the user. In addition, the geometry of the side arm, the cross-sectional shape and the type of material used to form the side arms may be configured to limit or inhibit twist of the side arms such that rotation of the interface arrangements relative to the user's face is limited or prevented.

(319) As shown FIGS. 36A and 36B, the side arms 130 have a two-piece design in which a seal-connecting portion 130A of the side arm 130 is connected to a headgear-connecting portion 130B of the side arm 130 by a hinge 510. The seal-connecting portion 130A is connected to the frame 116 of the seal 114 and the headgear-connecting portion 130B is connected to the headgear (not shown). The seal-connecting portion 130A may be permanently or removably coupled to the frame 116 such that the seal 114 is rigidly attached to the seal-connecting portion 130A. With such an arrangement, the seal 114 is less likely to rotate or rock relative to the seal-connecting portion 130A. The seal-connecting portion 130A on both the left side and the right side of the seal 114 may be formed with the frame 116 as a single unitary component. The seal 114 may be connected to the frame 116 using any of the seal and frame connection arrangements previously disclosed. Similarly, the headgear-connecting portion 130B may be permanently or removably coupled to the headgear using any of the side arm and headgear connection arrangements previously disclosed.

(320) As illustrated in FIG. 36B, the hinge 510 comprises a pin 512 that extends through holes 514 within the ends of the seal-connecting portion 130A and the headgear-connecting portion 130B. The end of the headgear-connecting portion 130B has a female connection portion 530 that includes outer knuckles 532 which define a slot 516 therebetween. The seal-connecting portion 130A has a male connection portion 520 that includes an inner knuckle 522 which is positioned within the slot 516 between the outer knuckles 532. As illustrated in FIG. 36A, the pin 512 and holes 514 are aligned with the height direction of the rectangular cross-section of the side arms 130, which is also substantially aligned with a vertical plane relative to the user. As such, the seal-connecting portion 130A and the headgear-connecting portion 130B rotate relative to each other

about the pin **512**. In other words, the seal-connecting portion **130A** and the headgear-connecting portion **130B** are rotatable across the user's face in the horizontal direction.

(321) The hinge **510** and a portion of the side arms **130** are covered by a concertina cover **550**. In some configurations, the concertina cover **550** provides resistance to rotation such that the seal-connecting and headgear-connecting portions **130A**, **130B** maintain their relative rotated positions. The concertina cover **550** may be formed from a semi-rigid plastic and have a deformable accordion-like geometry with ridges and bellows formed along its length. The concertina cover **550** may have a length that covers a portion of both the seal-connecting and headgear-connecting portions **130A**, **130B**. The concertina cover **550** has an inner cavity **552** through which the side arms **130** extend. The concertina cover **550** may have a size, shape and geometry similar to the side arms **130** such that the concertina cover **550** is tightly wrapped over the hinge **510** and around the side arms **130**. Inner ridges **554** of the inner cavity **552** may have a tight fit or interference fit with the side arms **130** so as to contact and be tightly wrapped around the outer surface of the side arms **130**. Accordingly, by having the concertina cover **550** wrapped around the side arms **130** and positioned over the hinge **510**, the concertina cover **550** resists rotation between the seal-connecting and headgear-connecting portions **130A**, **130B** until a predetermined threshold amount of force is applied to the side arm **130** which causes the concertina cover **550** to bend and deform to allow the seal-connecting and headgear-connecting portions **130A**, **130B** to rotate relative to each other.

(322) The hinge **510** is depicted as a butt- or mortise-type hinge having the inner knuckle **512** positioned between the outer knuckles **514**. However, it should be known to one of ordinary skill in the art that the hinge **510** may include different knuckle and/or hinge arrangements. Further, it should be known to one of ordinary skill in the art that the illustrated arrangement is not limited to a single hinge and may include multiple hinges and concertina covers. Even further, the illustrated arrangement is not limited to a hinge arrangement having a pin. Other hinge arrangements may be used such as, a protrusion that engages and rotates about a receptacle.

(323) FIGS. **37A** to **37C** illustrate an interface **600** having a side arm arrangement having side arms **130** formed from modular segments **610A**, **610B**, **610C** that are interlocked similar to a wristwatch band. Similar to the side arm arrangement in FIGS. **36A** to **36D**, a plurality of interlocking modular segments **610A**, **610B**, **610C** allow the side arms **130** to rotate along a horizontal plane while remaining substantially rigid along a vertical plane. More specifically, the segments **610A**, **610B**, **610C** allows the side arm **130** to articulate incrementally and conform to the shape of the user's face when an external horizontal force is applied, as depicted in FIG. **37C**. Further, the plurality of segments **610A**, **610B**, **610C** allow localized shape changes to the side arms **130** such that the side arms **130** conform to facial features or landmarks on a user's face. Similar the interface **500**, the segments **610A**, **610B**, **610C** of the side arm **130** resist rotation or rocking of the seal **114** caused by vertical forces acting on the seal **114** (e.g., the blow-off force). The segments **610A**, **610B**, **610C** may be formed from an injection moulded plastic material and have a rectangular cross-sectional shape similar to the side arms **130** in FIGS. **36A** to **36D**.

(324) As illustrated in FIG. **37A**, the segment **610A** may be permanently or removably coupled on one end to a connector portion or connector **146** of the seal frame **116**. The segment **610A** has a male connection portion **620** that includes an inner knuckle **622** positioned on an end opposite to the frame **116**. Similarly, the segment **610B** may be permanently or removably coupled to the headgear **118** on one end and has a female connection portion **630** on an end opposite the headgear **118** which includes outer knuckles **632** that define a slot **616** therebetween. In some configurations, the segments **610A** and **610B** are connected together by one or a series of segments **610C**. Each segment **610C** has a male connecting portion **620** on one end and a female connecting portion **630** on the opposite end in a lengthwise direction of the segment **610C**. The inner knuckle **622** of the male connecting portion **620** of each segment **610A**, **610C** is positioned within the slot **616** between the outer knuckles **632** of the female connection portion **630** of segments **610B**, **610C**. The male and female connecting portions **620**, **630** are connected by a pin **612** fitted within through

holes **614** extending through the male and female connecting portions **620**, **630**. As illustrated in FIG. **37B**, the pins **612** and holes **614** are aligned with the height direction of the rectangular cross-section of the side arms **130**, which is also substantially aligned with a vertical plane relative to the user.

(325) Similar to a wristwatch band, the pins **612** may be removable to allow segments **610C** to be added or removed such that the length of the side arms **130** may be adjusted. It should be known to one of ordinary skill in the art that the segments are not limited to male and female connection portions **620**, **630** having pins inserted through inner and outer knuckles **622**, **632** and may include alternative modular and interlocking connection arrangements.

(326) FIGS. **38A** to **38D** illustrate an interface **700** having a side arm arrangement having spring-loaded side arms **130** that deform or deflect to provide a temporary shape change when a momentary external horizontal force is applied to the side arms **130**. When the momentary external horizontal force is removed, the side arms **130** return back to or toward an undeformed shape. Further, the spring-loaded side arms **130** are extensible to extend and contract which allow the interface **700** to accommodate a wider range of facial geometries as well as to account for blow off force in the mask. The side arms **130** have a spring portion **710** positioned between a seal-connecting portion **130A** and a headgear-connecting portion **130B**. The seal-connecting portion **130A** may be permanently or removably coupled to the frame **116** such that the seal **114** is rigidly attached to the seal-connecting portion **130A** such that seal **114** does not rotate or rock relative to the seal-connecting portion **130A**. Similarly, the headgear-connecting portion **130B** may be permanently or removably coupled to the headgear. The seal-connecting portion **130A**, the headgear-connecting portion **130B** and the spring portion **710** may be unitarily-formed as integral one-piece side arms. The side arms **130** may be formed from an injection moulded plastic material and are illustrated as having a rectangular cross-sectional shape similar to the side arm arrangements in FIGS. **36A-D** and **37A-C**.

(327) As illustrated in FIG. **38B**, the spring portion **710** is illustrated as a linear accordion flat spring that is compressible, extendible, and horizontally rotatable. The spring portion **710** is formed as a series of straight segments **712** connected by bends **714**. The bends **714** may form an acute angle between the straight segments **712** as to allow the spring portion **710** to bend, shorten in length or extend in length. FIGS. **38C** and **38D** illustrate the spring portion **710** bending, shortening and lengthening along a horizontal plane to allow the side arms **130** to move relative to the seal **114** when a momentary external horizontal force is applied to the side arms **130**. The spring portion **710** absorbs at least a portion of and does not transfer an entirety of the momentary external horizontal force to the seal **114** such that the position of the seal **114** on the user's face remains undisturbed or is disturbed less than with other frame designs. The spring portion **710** may have an undeformed shape (i.e., when no momentary external horizontal force is applied) in which the seal-connecting portion **130A** and the headgear-connecting portion **130B** are substantially in-line or parallel on average in a length direction. However, the spring portions **710** may be formed so as to have a curved or non-linear undeformed shape on average in a length direction.

(328) Similar to FIGS. **38A** to **38D**, FIGS. **39A** and **39B** illustrate an alternative spring-loaded side arm arrangement which also deforms to provide a temporary shape change when a momentary external horizontal force is applied to the side arms **130**. However, in contrast to the side arms **130** in FIGS. **38A** to **38D**, the seal-connecting portion **130A** and headgear-connecting portion **130B** are connected to elastic segments **810** which provide a spring-loading effect similar to the spring portion **710**. The elastic segments **810** may be formed from rubber or Thermoplastic polyurethane (TPU). The elastic segments **810** are positioned between the seal-connecting portion **130A** and the headgear-connecting portion **130B** and separated by a rigid segment **812**. The seal-connecting portion **130A** and headgear-connecting portion **130B** are also rigid. As such, the elastic segments **810** bend and deform to allow the side arms **130** to be compliant within a horizontal plane to allow the side arms **130** to move relative to the seal **114** when a momentary external horizontal force is

applied. That is, the elastic segment **810** absorbs at least a portion of and does not transfer an entirety of the momentary external horizontal force to the seal **114** such that the position of the seal **114** on the user's face remains undisturbed or is disturbed less than with other frame designs. Further, when the momentary external horizontal force is removed, the elastic segments **810** return back to their neutral undeformed shape.

(329) As illustrated in FIG. **39B**, the elastic segments **810** have male connection portions **820** on each end and the rigid segment(s) **812** have female connection portions **830** on each end. An elastic segment **810** is connected to a rigid segment **812** by positioning the male connection portion **820** into the female connection portion **830**. The male connection portion **820** has a corresponding shape and size as the female connection portion **830** such that the male and female connection portions **820**, **830** are connected by a tight fit or interference fit. The seal-connecting portion **130A** and headgear-connecting portion **130B** each have a female connection portion **830** positioned on the end facing the rigid segment **812**. The rigid segment **812** has female connection portions **830** positioned on both ends. In some configurations, additional elastic and rigid segment **810**, **812** may be added or removed to adjust the length of the side arms **130**. Further, the male connection portion **820** is depicted as a cylindrical post and the female connection portion **830** is depicted as a cylindrical slot. It should be understood to one of ordinary skill in the art that the male and female connection portions **820**, **830** is not limited to cylindrical posts and slots and may include alternative connection arrangements.

(330) FIGS. **40A** to **40E** illustrate an interface **900** having a side arm arrangement having flexible side arms **130** that deform to provide a temporary shape change when a momentary external horizontal force is applied to the side arms **130** while remaining substantially rigid along a vertical plane. The side arms **130** have one or both of outer kerfing **910** and inner kerfing **920** along the length of the side arms **130**. The outer kerfing **910** is positioned on an outer surface of the side arm **130** (i.e., facing away from the user) and is positioned closest to the seal **114**. The inner kerfing **910** is positioned on an inner surface of the side arm **130** (i.e., facing toward the user) and is positioned closest to the headgear **118**. The side arms **130** is formed from an injection moulded plastic material and the kerfing **910**, **920** may be integrally and unitarily formed into the side arms **130**. Alternatively, the kerfing **910**, **920** may be formed by cutting, molding or otherwise creating vertical slots into the side arms **130**. As shown, the side arms **130** have a rectangular cross-sectional shape similar to the side arm arrangements in FIGS. **36A-D** and **37A-D**. Cheek pads **950** may be attached to the side arms **130** over the inner kerfing **920** to prevent the inner kerfing **920** from contacting the user's face. The cheek pads **950** may be formed from a soft padding material.

(331) As illustrated in FIGS. **40D** and **40E**, the kerfing **910**, **920** consists of a series of live hinges or slots **930** recessed into the side arms **130** along a thickness direction of the side arms **130**. The slots **930** extend through an entire width of the side arms **130**. Accordingly, the thickness of the side arms **130** is thinner at portions having slots **930** than at portions between the slots **930**. As a result, the side arm **130** is able to bend and rotate about the slots **930** when a momentary external horizontal force is applied to the side arms **130**. Further, the kerfing **910**, **920** allows the side arms **130** to return back to or toward an undeformed shape when the momentary external horizontal force is removed. As shown in FIG. **40D**, the slots **930** have a depth X , a width Y and are spaced apart by a spacing distance Z . The return force for urging the side arm **130** to return back to or toward its undeformed neutral shape (i.e., also the amount of resistance to bending) is controlled by, at least in part or primarily, the depth X of the slot **930** (i.e., relative to the thickness of the side arm **130**). Slots **930** having a greater depth X cause the side arm **130** to have a thinner thickness T at positions where the slots **930** are located. As a result, the thinner thickness T provides less resistance to bending and a smaller return force for returning the side arm **130** to an undeformed shape than slots **930** having a smaller depth X . The maximum amount of bending provided by a slot **930** is controlled by, at least in part or primarily, the width Y of the slot **930**. Generally, a slot **930** having a greater width Y allows a greater amount of bending of the side arm **130** about the slot

930. The maximum amount of bending allowed by a slot **930** occurs when the slot **930** narrows in width until the sidewalls **932** of the slot **930** contact each other, as shown in FIG. **40E**. Accordingly, providing slots **930** with a greater width **Y** provides a greater distance between the sidewalls **932**. However, the amount of bending may be limited to prevent the side arms **130** from contacting the user's face or detaching from the headgear **118**. FIG. **40C** illustrates the maximum amount of bending provided by both the inner and outer kerfing **910**, **920** relative to an undeformed shape shown in FIG. **40B**. The rate of bending of the side arm **130** (i.e., gradual or acute bending) is controlled by, at least in part or primarily, the spacing distance **Z** and the quantity of slots **930**. Closely spaced slots **930** having a narrow spacing distance **Z** will allow a greater rate of bending of the side arm **130** than widely spaced slots **930** having a wider spacing distance **Z**. As such, the amount and rate of curvature of the side arms **130** is determined by the depth **X**, width **Y** and spacing distance **Z** of the slots **930**. Further, although the side arms **130** are depicted as having slots **930** with identical geometry, in some configurations, the slots **930** may have varying depth **X**, width **Y** and spacing distance **Z** along the length of the side arms **130** such that the side arms **130** have variable amounts and rates of curvature and return force along its length. Further, the slots **930** are not limited to rectangular shapes and may include a variety of shapes such as trapezoidal, curved, or semicircular shapes.

(332) FIGS. **41A** to **41C** illustrate an interface **1000** having a hook and post connector arrangement that allows rotation and retains a rotation position between the seal **114** and the side arms **130** of the headgear **118**. In the illustrated configuration, the headgear **118** is separable from the seal **114**. The headgear **118** has a hook-shaped connector **1020** on each end of the side arms **130**. The hook-shaped connector **1020** may be unitarily-formed as integral with the side arms **130**. The side arms **130** and hook-shaped connector **1020** may be formed from an injection moulded plastic material and are illustrated as having a rectangular cross-sectional shape similar to the side arm arrangements in FIGS. **36A-D** and **37A-D**. The connector **146** of the frame **116** has a post **1010** on each end. The seal **114** is connected to the headgear **118** by attaching the hook-shaped connector **1020** to the post **1010**. The hook-shaped connector **1020** has a cavity **1022** which receives the post **1010** such that the hook-shaped connector **1020** wraps over and around the post **1010**. In other words, the post **1010** is positioned within the cavity **1022**. In the illustrated configuration, the connector **146** has an opening **1012** adjacent to the post **1012** through which the hook-shaped connector **1020** extends through to wrap around the post **1010**.

(333) As illustrated in FIG. **41B**, the post **1010** has teeth **1014** extending radially outward from the post **1010**. The hook-shaped connector **1020** has a pawl **1024** that extends in a direction towards the cavity **1022**. The pawl **1024** engages a valley **1016** between adjacent teeth **1014** such that rotation of the post **1010** within the cavity (i.e., rotation between the post **1010** and the hook-shaped connector **1020**) is inhibited or obstructed by the pawl **1024**. The pawl **1024** is semi-rigid and deflectable to allow rotation of the hook-shaped connector **1020** around the post **1010** (i.e., including rotation of the side arm **130** within a horizontal plane) when an external horizontal force is applied to the side arms **130**. That is, when the yield strength of the pawl **1024** is overcome by an external horizontal force applied to the side arms **130**, the pawl **1024** will deform and slide up the tooth **1014** from the valley **1016** as the hook-shaped connector **1020** rotates about the post **1010**. The pawl **1024** slides up and over the tooth **1014** and down an adjacent valley **1016**. The shape, thickness and geometry of the teeth **1014** and pawl **1024** may be varied to customize the force profile for allowing rotation of the post **1010** relative to the hook-shaped connector **1020**. Further, due to the teeth **1014** extending radially outward from the post **1010**, the hook-shaped connector **1020** may rotate clockwise or counterclockwise relative to the post **1010**. In the illustrated configuration, the teeth **1014** are formed on only the side or portion of the post **1010** that faces the headgear **118** to provide the post **1010** with a smooth corresponding surface in contact with the inner surface of the hook-shaped connector **1020**. In alternative configurations, the teeth **1014** may be formed entirely around the post **1010**. The hook and post connector arrangement provides

rotational resistance between the post **1010** and the hook-shaped connector **1020** such that the user may put on or remove the interface using traditional broken-loop don and doff methods. Further, the hook and post connector arrangement may also allow for alternative type don and doff methods, such as, a swing-fit type don and doff methods where one end of the headgear/frame is connected to the mask, and the other end of the headgear/frame is swung around the head and connected to the mask. The hook and post connector arrangement accommodates a variety of don and doff methods to improve usability of the interface.

(334) FIGS. **42A** to **42D** illustrates an alternative interface assembly or interface **1100** having a seal **1114** that rotates horizontally relative to side arms **1130** (i.e., across the user's face) and is biased to a rotatably centered position between the side arms **1130** by leaf springs **1140**. The rotating seal **1114** and the leaf springs **1140** allow the interface **1100** to absorb external horizontal forces to inhibit or prevent dislodging of the seal **1114** from under the user's nose, for example, when the user sleeps on his/her side and the interface **1100** is contacted by a pillow, as shown in FIG. **42B**. Further, the rotating seal **1114** allows the interface **1110** to fit users having crooked noses, as shown in FIG. **42C**. Similar to the above disclosed interfaces, the interface **1100** prevents or inhibits the seal **1114** from rotating along a vertical plane (i.e., vertically across the user's face). Further, the leaf springs **1140** center the seal **1114** when the external horizontal forces are removed.

(335) Similar to the interface **110** in FIGS. **1** to **11**, the interface comprises a seal **1114** attached to a frame assembly or frame **1116**. The frame **1116** supports the seal **1114**. A connector portion or connector **1146**, which includes the side arms **1130**, is attached to the frame **1116**. The frame **1116** and the connector **1146** may be formed from a relatively rigid, semi-rigid or rigid material, such as polycarbonate, for example. Thus, in at least some configurations, the frame **1116** and the connector **1146** are more rigid than the seal **1114**.

(336) Similar to the connector **146** in FIGS. **1** to **11**, the connector **1146** is a generally U-shaped member from a top-down view comprising the side arms **1130** and a central portion **1148** that connects the two side arms **1130** to one another. That is, side arms **1130** may be unitarily-formed as integral one-piece with the connector **1146** which provides greater vertical stability (i.e., resisting of movement of the seal vertically across the user's face). In contrast to the connector **146** in FIGS. **1** to **11**, the connector **1146** is pivotally attached to the frame **1116** to allow the frame **1116** to rotate relative to the connector **1146** about a vertical axis such that that the frame **1116** rotates along a horizontal plane. The connector **1146** may be pivotally connected to the frame **1116** by a pivoting mechanism such as, for example, a cylindrical post positioned vertically within a socket.

(337) As illustrated, the side arms **1130** extend outwardly (away from each other), rearwardly and upwardly at a shallow angle, past left and right extremities of the seal **1114** and along the left and right cheeks and in particular cheekbones of a user to connect to the headgear (not shown) for holding the seal **1114** on the face of a user. At their outer or free ends, the side arms **1130** include connector portions **1134** for detachably connecting the side arms **1130** to the headgear (not shown). The side arms **1130** are relatively inflexible in a horizontal and vertical plane (when worn).

(338) As shown in FIG. **42A**, each side arm **1130** has a leaf spring **1140** attached to and extending from an inner surface **1132** of the side arm **1130**. The leaf springs **1140** extend a distance toward the frame **1116** so as to be in slidingly contact with an outer surface **1118** of the frame **1116** when the frame **1116** is centered between the side arms. The leaf springs **1140** are positioned along the inner surface **1132** such that both the leaf springs **1140** contact the outer surface **1118** of the frame **1116** when the frame **1116** is rotatably centered between the side arms **1130**. The leaf springs **1140** act as cantilever springs to bias the frame **1116** away from the side arms **1130**. In other words, the leaf springs **1140** bias the frame **1116** such that the seal **1114** is rotationally centered relative to the connector **1146**. FIG. **42D** (center) illustrates a neutral position of the frame **1116** relative to the side arms **1130** that is maintained by the leaf springs **1140**. When the frame **1116** is centered between the side arms **1130**, the leaf springs **1140** may be in slight contact with the frame **1116** so as to be unloaded. However, in some configurations, both leaf springs **1140** may be preloaded when

the frame **1116** is centered between the side arms **1130** or slightly biased toward one of the side arms **1130**.

(339) When the seal **1114** and the frame **1116** are rotated from the centered position relative to the connector **1146**, the leaf springs **1140** provide a return force to center the seal **1114** and the frame **1116**. FIG. 42D (left, right) illustrates the seal **1114** and the frame **1116** rotated from the centered position relative to the connector **1146**. The leaf spring **1140**, which the frame **1116** rotates towards, deflects and exerts a return force to center the seal **1114** and the frame **1116**.

(340) In the illustrated configuration, the leaf springs **1140** only slidably contact with the frame **1116**. That is, the leaf springs **1140** are not fixed to the frame **1116**. As such, the leaf spring **1140**, which the frame **1116** is rotating away from, is not in contact with the frame **1116** and remains undeflected. In some configurations, the leaf springs **1140** may be attached to both the connector **1146** and the frame **1116** such that both leaf springs **1140** exert a return force on the frame **1116** to center the frame **1116** relative to the connector **1146**. The leaf springs **1140** may have a smooth curved shape and sliding surface to reduce sliding friction between the leaf springs **1140** and the frame **1116**. Further, the leaf springs **1140** may also be curved or include fillets or buttressing at the connection with the inner surface **1132** of the side arm **1130** to reinforce the connection between the side arm **1130** and the leaf springs **1140**. Even further, the shape and geometry of the leaf springs **1140** may be modified to provide various force profiles for biasing the frame **1116**. Still further, it should be understood to one of ordinary skill in the art that a variety of spring types may be used to absorb forces and bias the frame **1116**. In other words, the interface **1100** is not limited to use of only leaf springs **1140** and may employ alternative biasing arrangements such as coil springs or elastically deforming cushions, airbags, pads, etc.

(341) FIGS. 43A to 43C illustrate an alternative interface assembly or interface **2100** having a seal **2114** that slides horizontally or laterally between side arms **2130** (i.e., across the user's face). In contrast to the interface **1100** in FIGS. 42A to 42D, the seal **2114** slides horizontally or laterally across the user's face as opposed to rotating horizontally about an axis across the user's face. Having the seal **2114** slide horizontally between side arms **2130** allows the interface **2100** to absorb and adjust to external horizontal forces to inhibit or prevent dislodging of the seal **2114** from under the user's nose, for example, when the user sleeps on his/her side and the interface **2100** is contacted by a pillow, as illustrated in FIGS. 43B and 43C. Similar to the above disclosed interfaces, the interface **2100** prevents or inhibits the seal **1114** from rotating or flexing along a vertical plane (i.e., vertically across the user's face).

(342) As shown in FIG. 43A, the side arms **2130** are connected to each other by a bridge or central portion **2148**. That is, each side arm **2130** is connected to the central portion **2148** at its end, thereby forming a closed-loop with the headgear **2118**. The side arms **2130** may be permanently or removably coupled to the headgear **2118**. The side arms **2130** may be unitarily-formed as integral one-piece with the connector **2146** from a material such as polycarbonate such that the side arms **2130** and the central portion **2148** are rigid. Similar to the above-disclosed interfaces, the side arms **2130** and the central portion **2148** have an elongate cross-section having a height substantially greater than a thickness such that the side arms **2130** and the central portion **2148** resist vertical rotation (i.e., vertically across the user's face). The side arms **2130** and the central portion **2148** are connected to the frame **2116** by a connector portion or connector **2146**. The connector **2146** has a channel **2150** through which the central portion **2148** slides within. The channel **2150** has a corresponding shape and size with the side arms **2130** and the central portion **2148** such that the side arms **2130** and the central portion **2148** are able to slide within and travel through the channel **2150**. In operation, when the user sleeps on his/her side and the interface **2100** is contacted by a pillow which exerts a force on the side arms **2130**, the side arms **2130** and the central portion **2148** are shifted and pushed through the channel **2150** of the connector **2146** such that the seal **2114** does not move and the position of the seal **2114** on the user's nose is undisturbed.

(343) In some configurations, the range of travel between the side arms **2130** may be limited by

varying the cross-sectional size and shape of the central portion **2148** or the side arms **2130** such that enlarged regions of the central portion **2148** or the side arms **2130** are unable to enter the connector **2146**. For example, the height and/or the thickness of the end portions of the central portion **2148** may be increased such that the end portions of the central portion **2148** are larger than the height and/or width of the channel **2150**. Accordingly, the range of travel of the frame **2116** would be limited to between the ends of the central portion **2148**. In alternative configurations, protrusions extending from the surface of the central portion **2148** or the side arms **2130** may also be used to obstruct the central portion **2148** or the side arms **2130** from entering the connector **2146** such that the range of travel is limited.

(344) FIGS. **44A** to **49C** illustrate nasal seals having features that inhibit or preferably prevent incorrect fitment of the nasal seal and also indicate to the user that the seal is incorrectly fitted. A common fitment mistake is for users to insert their nose into the nasal port of the seal. As a result, the seal will not properly seal around the user's nose and the mask may not function properly. Further, the mask is uncomfortable to wear and the user may be discouraged from continuing to wear the mask. The features of the nasal seals of FIGS. **42A** to **49C** indicate to the user that the nasal seal is incorrectly fitted, prevent or inhibit the user from incorrectly fitting the nasal seal, or provide the user with guidance on how the nasal seal should be properly fitted.

(345) The illustrated configuration in FIGS. **44A** to **44D** depicts a nasal seal **114** that provides physical feedback indicating to the user that the seal **114** is incorrectly fitted which discourages the user from continuing to wear the seal **114** incorrectly. The nasal seal **114** is similar to the seal described in FIGS. **1-22** and, therefore, redundant discussion of similar structures will be largely omitted. The seal **114** has an inward or rearward-facing central portion **204** that faces or contacts the user during use of the seal **114**. The central portion **204** has a nasal opening or aperture **128** defined by an upper edge **234**, a lower edge **236**, and side edges **238**. As illustrated, the seal **114** has a thickened flange **1210** that causes the flange **1210** to be stiffer than the central portion **204** of the seal **114**. The flange **1210** is formed along the upper portion of the aperture **128** to define the upper edge **234** of the aperture **128** and extends toward an interior or dead space **228** of the seal **114** when the seal is not worn by the user and undeformed. The ends of the flange **1210** may extend so as to be connected to the side edges **238**, which may also increase the stiffness of the flange **1210**. In some configurations, the flange **1210** may extend to include the lower edge **236** to substantially or completely surround the nasal aperture **128**. The flange **1210** has a thickness that is greater than along the central portion **204** of the seal **114** such that the flange is stiffer and more rigid than the central portion **204**. The flange **1210** is illustrated as having a constant thickness but the thickness of the flange **1210** may vary along its length. The flange **1210** may be integrally formed with the seal **114**. The flange **1210** extends downward into the dead space **228** of the seal **114**. In some configurations, the nasal aperture **128** has an edge that includes a thickened bead at the upper edge **234** of the nasal aperture **128**.

(346) FIG. **44B** illustrates the seal **114** correctly fitted to the user. As shown, the user's nose is positioned on top of the seal **114** with the aperture **128** being positioned below the nares of the user and the tip of the user's nose being in contact with the central portion **204** of the seal. Further, the flange **1210** is not in contact with the user when the seal **114** is correctly fitted to the user. More specifically, the flange **1210** is positioned below the nares of the user's nose and extends in a direction away from the nose and into the seal **114**.

(347) FIG. **44C** illustrates the seal **114** incorrectly fitted to the user. In contrast to FIG. **42B**, the user's nose extends through the aperture **128** and is positioned inside the seal **114**. With the user's nose extending through the aperture **128**, the flange **1210** is positioned on top of the user's nose with a bottom edge **1212** of the flange **1210** pressing into the tip, supra tip or bridge of the user's nose. The stiffness of the flange **1210** (i.e., due to its thickness and having ends attached to the side edges **238** of the aperture **128**) prevents the flange **1210** from deforming or collapsing inward into the seal **114** due to the force of the user's nose pushing into the aperture **128**. As such, the user will

physically feel the flange **1210** pressing against his/her nose and causing discomfort which will provide haptic feedback or indication to the user that the seal is not correctly fitted. In other words, the discomfort caused by the flange **1210** that is felt by the user will be perceived as an indication that seal **114** is incorrectly fitted. The flange **1210** also prevents blow out because the flange **1210** is formed from thicker silicone and, therefore, stiffer and better able to hold its shape under blow out force applications.

(348) FIGS. **44D** to **44F** illustrate an alternative flange configuration comprising a flange **1210** with through-holes or blow holes **1214** that extend through the flange **1210**. The blow holes **1214** provide a pathway for pressurized air to escape from inside the seal to outside of the seal. Similar to FIG. **44B**, when the seal **114** is correctly fitted to the user as shown in FIG. **44E**, the user's nose is positioned on top of the seal **114** and the flange **1210** is not in contact with the user when the seal **114** is correctly fitted to the user. As shown in FIG. **44F**, when the seal **114** is incorrectly fitted to the user, the user's nose is pressed into the aperture **128** such that the bottom edge **1212** of the flange **1210** presses into the user's nose, similar to FIG. **44C**. In operation, when the seal **114** is filled with air under positive pressure, the pressurized air will flow through the blow holes **1214**. The flange **1210** and blow holes **1214** are positioned slightly above the user's nose such that the user will feel the flow of pressurized air blowing through the blow holes **1214**. Therefore, in addition to the discomfort of the flange **1210** pressing into the user's nose, the user will also feel the flow of air escaping the seal just above his/her nose. In some configurations, the blow holes may be positioned and/or angled such that the blow holes **1214** direct the flow of pressurized air towards the user's eyes. Further, the size and shape of the blow holes **1214** may be tuned to provide an audible sound such that the user is provided with an audible indicator when the seal **114** is incorrectly fitted. It should be understood to one of ordinary skill in the art that the blow holes **1214** are not limited to circular cross-sections and may be formed in various cross-sectional shapes and sizes.

(349) FIGS. **44G** and **44H** illustrate alternative flange configurations comprising a flange **1210** having a rounded bottom edge **1212**. Similar to the flanges in FIGS. **44A-F**, when the user's nose is pressed into the aperture **128**, the flange **1210** presses into the user's nose and the blow holes **1214** direct pressurized air towards the user's eyes to indicate to the user that the seal **114** is not correctly fitted. However, in contrast to the flange **1210** in FIGS. **44A-F**, the rounded bottom edge **1212** may provide a wider and rounded surface that contacts the user's nose without leaving a mark or indentation on the user's nose. FIG. **44G** illustrates a flange **1210** having a semi-circular cross-section. FIG. **44H** illustrates a flange **1210** having an upper portion that is rectangular in cross-section while the bottom portion of the flange is rounded. The rectangular upper portion allows the flange **1210** to flex such that the amount of force pressing down on the user's nose by the flange **1210** is distributed over a greater area so as to not leave a mark or indentation on the user's nose.

(350) FIG. **44I** illustrates an alternative flange configuration comprising a flange **1210** with recesses **1216** instead of the blow holes **1214** in FIGS. **44D-F**. The recesses **1216** may be formed into the bottom edge **1212** of the flange **1210** such that pressurized air will flow through the recesses **1216** when the user's nose is pressed into the aperture **128** and the seal **114** is pressurized (i.e., the seal **114** is incorrectly fitted to the user).

(351) The illustrated configuration in FIGS. **45A** to **45C** depicts a nasal seal **114** that physically prevents or inhibits the user from incorrectly wearing the seal **114**. More specifically, the seal **114** obstructs the user's nose from being inserted into the seal **114** through the aperture **128**. The nasal seal **114** is similar to the seal described in FIGS. **1-22** and FIGS. **44A-I** and, therefore, redundant discussion of similar structures will be largely omitted. As illustrated in FIG. **45A**, the seal **114** has a woven mesh **1310** over-moulded or otherwise affixed onto the upper, lower, and side edges **234**, **236**, **238** of the aperture **128** such that the woven mesh **1310** is flush with the sealing surface of the seal **114**. The woven mesh **1310** spans across and covers the aperture **128**. The woven mesh **1310** allows air to flow through the aperture **128** while preventing or inhibiting the user from inserting

his/her nose into the aperture **128**. The woven mesh **1310** may be over-moulded from a silicone material onto the aperture **128**. The woven mesh **1310** may be elastic to conform to the shape of the aperture **128** and deform with the seal **114**. However, the woven mesh **1310** may be taut so as to prevent or inhibit the user's nose from entering the seal **114**. Further, the strand width and the coarseness or fineness of the woven mesh **1310** may be varied so as to provide strength to withstand the force of the user's nose pushing into the aperture **128** while also minimizing any pressure drop caused by the woven mesh **1310** restricting the flow of air through the aperture **128**. (352) FIGS. **45B** and **45C** illustrate an alternative configuration of a nasal seal **114** having a woven mesh **1310** offset inward into the seal **114** by an offset flange **1320**. As shown in FIG. **45C**, the outer edges of the offset flange **1320** may be attached to the upper, lower, and side edges **234**, **236**, **238** of the aperture **128** and the offset flange **1320** extends inward in a direction towards the interior of the seal **114**. The inner edges of the offset flange **1320** are attached to the woven mesh **1310**. The offset flange **1320** positions the woven mesh **1310** away from the sealing surface so that the user's nose is not in direct skin contact with the woven mesh **1310** when the user's nose is positioned over the aperture **128**.

(353) FIGS. **45D** and **45E** illustrates an alternative configuration of a nasal seal **114** that obstructs the user's nose from being inserted into the seal **114** through the aperture **128**. In contrast to the woven mesh **1310** of FIGS. **45A-C**, the seal **114** has an aperture cover **1410** with an array of holes **1420** extending through the aperture cover. Similar to the woven mesh **1310**, the aperture cover **1410** obstructs the user's nose from being inserted into the seal **114** through the aperture **128**. The aperture cover **1410** is attached onto the upper, lower, and side edges **234**, **236**, **238** of the aperture **128** such that the aperture cover **1410** is flush with the sealing surface of the seal **114**. The aperture cover **1410** may be unitarily or integrally formed with the seal **114**. The holes **1420** extend through and are uniformly distributed across the aperture cover **1410**. The holes **1420** allow air to flow through the aperture cover **1410** while preventing or inhibiting the user from inserting his/her nose into the aperture **128**. The diameters and spacing of the holes **1420** may be configured to minimize noise and pressure drop. It should be understood to one of ordinary skill in the art that the holes **1420** may include an unlimited combination of holes having various shapes, sizes, and arrangements. FIG. **45E** illustrates examples of holes **1420** arranged on the aperture cover **1410**, such as, a combination of large and small holes, polygonal-shaped holes, wide holes spanning across the aperture, holes arranged in a fan configuration across the aperture.

(354) FIGS. **46A** to **46D** also illustrate an alternative configuration of a nasal seal **114** that obstructs the user's nose from being inserted into the seal **114** through the aperture **128**. In contrast to the woven mesh **1310** of FIGS. **45A-C** and the aperture cover **1410** of FIGS. **45D-E**, the aperture **128** has a series of tethers **1510** that are attached to the perimeter of the aperture **128** along the upper, lower, and side edges **234**, **236**, **238** of the aperture **128**. When the user attempts to insert his/her nose into the aperture **128**, the user's nose will contact one or more of the tethers **1510** which will indicate to the user that the seal **114** is not correctly fitted. If the user continues to insert his/her nose into the aperture **128**, the tethers **1510** will block or obstruct the user from pushing further into the aperture **128**.

(355) The tethers **1510** extend downward into the seal **114** and are attached to an inner surface **1520** of a bottom wall of the seal. The tethers **1510** are formed from elongated string-like strands of silicone that are bonded or integrally molded with a component part of the seal **114** or to the seal **114** itself. The tethers **1510** are evenly spaced around the perimeter of the aperture **128**.

(356) As illustrated in FIG. **46C**, the tethers **1510** are taut (i.e., tension within the tethers **1510**) when the seal **114** is undeformed (i.e., the seal **114** is not fitted on the user). As a result, the tethers **1510** anchor the central portion **204** of the seal **114** to an inner surface **1520** at the bottom of the seal **114** which allows the seal **114** to hold its undeformed shape. As such, the undeformed position of the edges of the aperture **128** may be controlled and maintained. As illustrated in FIG. **46D**, the tethers **1510** are slackened (i.e., no tension within the tethers **1510**) when the seal **114** is properly

fitted to the user. That is, when the seal **114** is worn by the user, the seal **114** is compressed such that the distance decreases between the aperture **128** and the inner surface **1520** at the bottom of the seal **114**. As a result, the tethers **1510** are compressed and slackened.

(357) FIGS. **46E** to **46H** illustrate another alternative configuration of a nasal seal **114** that obstructs the user's nose from being inserted into the seal **114** through the aperture **128**. In contrast to the tethers **1510** of FIGS. **46A-D**, the seal **114** has a bumper **1610** attached to the inner surface **1620** at the bottom of the seal **114** and positioned immediately below the aperture **128**. As illustrated in FIG. **46F**, when the user attempts to insert his/her nose into the aperture **128**, the seal **114** will compress and the user's nose will contact the bumper **1610**. When contacting the bumper **1610**, the user is provided feedback such that the user may realize that his/her nose should not be inserted into the aperture **128** and will try to refit the seal **114** with the user's nose positioned outside of the aperture **128**.

(358) The bumper comprises a vertical strut **1612** and a lateral beam **1614**. The strut **1612** is positioned below the aperture **128** and attached to the inner surface **1620** at the bottom of the seal **114**. The strut **1612** extends vertically upward towards the aperture **128**. The upper end of the strut **1612** is attached to the beam **1614**. The beam **1614** has an elongated shape that extends laterally across the width of the aperture **128**.

(359) The strut **1612** has a height such that the beam **1614** is positioned a distance below the aperture **128** when the seal **114** is correctly fitted to the user, as shown in FIG. **46C**. In other words, the beam **1614** is not in contact with the user's nose when the seal **114** is correctly fitted to the user. The seal **114** may compress slightly due to the force required to provide an airtight seal around the user's nose. However, strut **1612** has a height such that the beam **1614** is not in contact with the user's nose despite the seal **114** being compressed. The strut **1612** and beam **1614** may be formed from a silicone material such that the strut **1612** and the beam **1614** are flexible and do not cause pain or injury when contacting the user's nose. The strut **1612** and beam **1614** may be bonded or integrally molded with a component part of the seal **114** or the seal **114** itself. Further, the strut **1612** may have a curved shape such that the shape of the strut **1612** may provide an amount of flexibility so that the strut **1612** deforms when contacting the user's nose.

(360) The beam **1614** is illustrated as having a straight and elongated cylindrical shape. However, it should be understood to one of ordinary skill in the art that the beam **1614** may be one of a variety of shapes that obstruct the user's nose or other objects from descending deeper into the seal **114** through the aperture **128**. Further, in some configurations, the seal **114** may have a strut **1612** without a beam **1614** attached to the upper end of the strut **1612**. FIG. **46H** illustrates examples of strut arrangements having a strut **1612** without a beam.

(361) FIGS. **47A** to **47G** illustrate alternative configurations of an aperture **128** for a seal (not shown) that inhibits or prevents the user's nose from being inserted into the aperture **128** by providing distinct locations for the user's left and right nares over the aperture **128**. As shown, the upper and lower **234**, **236** edges of the aperture **128** narrow at a lateral midpoint of the aperture **128** to form a narrow central portion **1710** of the aperture **128** that is positioned between a left and right nares **1712**. The widest distance between the upper and lower **234**, **236** edges of the aperture **128** at the narrow central region **1710** is substantially narrower than the widest distance between the upper and lower **234**, **236** edges at the left and right nares **1712**. As a result, the narrow central portion **1710** defines distinct left and right nares **1712** such that the user may intuitively and unmistakably recognize that his/her nares should be positioned over the left and right nares **1712** because the user will recognize that the aperture **128** is too narrow at the narrow central portion **1710** for his/her nose to be inserted. Further, if the user attempts to insert his/her nose into the aperture **128**, portions of the seal **114** around the narrow central portion **1710** will contact the tip or septum of the user's nose to obstruct or block insertion into the aperture **128**. The left and right nares **1712** may be ovular in shape. The aperture **128** may be formed in a variety of shapes such as, but not limited to, a kidney shape (FIGS. **47A-D**) or a crescent shape (FIG. **47E**). The left and right nares **1712** may

be angled toward each other such that the upper-most edges of the left and right nares **1712** are closer together than the lower-most edges of the left and right nares **1712**. In some configurations, the left and right nares **1712** may be angled away from the narrow central region **1710**. Each of the left and right nares **1712** may have a shape such that a width of the upper-most portion of the left and right nares **1712** is narrower than a width of the lower-most portion of the left and right nares **1712**. In some configurations, the narrow central region **1710** may be positioned closer to the upper edge **234** of the aperture **128**, as shown in FIGS. **47A**, **47C** and **47D**. In other configurations, the narrow central region **1710** may be positioned closer to the lower edge **236** of the aperture **128**, as shown in FIG. **47B**.

(362) As illustrated in FIGS. **47A** to **47F**, the position, shape and size of the narrow central region **1710** may vary between the upper and lower **234**, **236** edges of the aperture **128** according to the size and shape of the user's nose and nares. Similarly, the size and shapes of the left and right nares **1712** may also vary according to the size and shape of the user's nose and nares. FIGS. **47F** and **47G** illustrate an aperture **128** having overlapping upper and lower edges **234**, **236**. As shown, the lower edge **236** extends over the upper edge **234** such that the left and right nares **1712** are entirely separated. Separate left and right nares **1712** provides explicitly distinct locations for placement of the user's left and right nares over the aperture **128**.

(363) In some configurations, the seal **114** may be configured such that an aperture **128** having overlapping upper and lower edges **234**, **236** provides a flush seating surface for the user's nose to be seated on. As illustrated in FIG. **47G**, an upper portion **1730** of the seal **114** may have a recess **1732** that receives a lower portion **1740** of the seal **114** such that the seating surface at the intersection of the upper and lower portions **1730**, **1740** is substantially flat. A substantially flat seating surface at the intersection of the upper and lower portions **1730**, **1740** inhibits or prevents a portion of the user's nose from becoming pinched in between the upper and lower portions **1730**, **1740**. The lower portion **1740** may also have a protrusion **1742** having a corresponding shape with the recess **1732** such that the upper and lower portions **1730**, **1740** are interlocked and provide a substantially flat seating surface when the seal **114** is fitted to the user.

(364) FIGS. **48A** to **48D** illustrate an alternative configuration of a nasal seal **114** that provides the user with visual guidance regarding how the seal **114** should be properly fitted to the nose. As illustrated in FIG. **48A**, the seal **114** has markings **1810** to visually indicate to the user where to position his/her nose over the aperture **128**. The markings **1810** are depicted as a circular target with a center “bulls-eye”. The markings **1810** are positioned on the central portion **204** of the seal **114** at a position where the tip of the user's nose should be positioned. The markings **1810** may be printed with ink on the inner or outer surface of the seal **114**. In some configurations, the ink may be a water-based washable ink that may be removed with water such that the user may remove the markings **1810** once learning how the seal **114** should be correctly fitted. In other configurations, the markings **1810** may be a sticker that is applied with an adhesive onto or on an interior surface of the seal **114** within the dead space such that the markings **1810** are visible through the surface of the seal **114**. FIG. **48B** illustrates alternative target-type markings **1810**. FIG. **48C** illustrates a combination of markings including markings **1810A** indicating the alignment of the user's nose on the seal **114** and markings **1810B** indicating the position of the underside of the user's nose on the aperture **128**. FIG. **48D** illustrates markings **1810** depicting an outline of the user's nose to indicate both the alignment of the user's nose on the seal **114** and the position of the user's nose over the aperture **128**.

(365) In contrast to explicit images indicating the exact position, placement, and/or alignment of the user's nose, the markings **1810** may include amusing or comical images to communicate the location of the seal **114** on the user's face. FIG. **48E** depicts markings **1810** in the form of a mustache that is printed below the aperture **128** onto the central portion **204** of the seal **114** that is positioned under the user's upper lip. The image of a mustache provided by the markings **1810** would indicate to the user where his/her upper lip should be positioned. Similarly, FIG. **48F** depicts

markings **1810** in the form of flowers that are printed above the aperture **128** onto the central portion **204** of the seal **114** that is positioned under the user's nose. In some configurations, the markings **1810** may also be scented (e.g., a floral scent) to further indicate how the seal **114** should be fitted. In other configurations, the markings **1810** may be a sticker that is applied with an adhesive onto the seal **114**. In other configurations, the markings **1810** may be applied using ink or stickers that change according to temperature such that regions of the seal **114** may change colors (e.g., red or green) when the seal **114** is incorrectly or correctly fitted. The changing colors may provide positive or negative feedback regarding the user's behavior.

(366) In contrast to printed markings **1810**, FIGS. **48G** to **48I** illustrate markings **1910** formed in frosted silicone. The markings **1910** may be integrally and unitarily molded into the seal **114** to provide frosted silicone markings **1910** having an opaque appearance that contrasts from the translucent appearance of the remaining portions of the seal **114**. Similar to FIG. **48D**, FIG. **48O** illustrates a frosted silicone marking **1910** that indicates both the position and alignment of the user's nose on the seal **114** and the position of the user's nares on the aperture **128**. FIG. **48H** illustrates a frosted silicone marking **1910** that indicates the position of the user's nares on the aperture **128** by outlining the shape of the user's nares in frosted silicone. Similar to FIG. **48A**, FIG. **48I** illustrates target-type markings **1910** in frosted silicone that may indicate where on the seal **114** the tip of the user's nose should be positioned.

(367) As another alternative to printed markings, FIGS. **49A** to **49C** illustrate a deformable marking or depressible dimple **2010** that deforms to indicate that the seal **114** is correctly fitted on the user. Similar to the markings **1810** in the shape of a target or “bulls-eye”, the dimple **2010** is positioned on the central portion **204** of the seal **114** at a position where the tip of the user's nose should be positioned. As illustrated in FIG. **49C**, the dimple **2010** deforms inward toward the inner cavity or dead space of the seal **114** when depressed. Accordingly, when the tip of the user's nose is positioned over the dimple **2010**, the dimple **2010** will deform inward to provide haptic positive feedback to the user that the seal **114** is positioned correctly. The dimple **2010** may also make an audible “popping” noise when the dimple **2010** deforms inward. The dimple **2010** may be reset to extend outward (i.e., away from an interior or dead space of the seal **114**) when the seal **114** is removed from the user's face such that dimple **2010** is repositioned for the next fitting. The dimple **2010** provides an easily recognizable mechanism for indicating where the user's nose should be placed on the seal **114** since deformable dimples are also used on consumer products (e.g., takeaway coffee lids).

(368) The dimple **2010** may also be used to indicate whether the seal **114** is sufficiently tight on the user. For example, the force profile or threshold amount of force required to deform the dimple **2010** may be determined based on the proper tightness of the seal **114** against the user's nose or face. Accordingly, the dimple **2010** will not deform unless a threshold force is applied which will indicate to the user whether the seal **114** is sufficiently tight against the user's nose or face.

(369) FIGS. **50A** to **50F** illustrate alternative configurations of an interface **3110** that adjusts the angle of the nasal seal **3114** according to the user's nose angle to comfortably fit user's noses within a wide range of upward or downward angles and minimize the amount of force applied to the user's subnasal region. Generally, the subnasal region of a user is sensitive to the upward force applied by the seal. However, in order to inhibit or prevent the seal from leaking, the seal must apply an upward force to the user's nose that is greater than the blow-off force. The blow-off force varies according to the upward or downward angle of the user's nose. As such, a seal that comfortably fits a user having an upwardly angled nose (i.e., by applying a minimum amount of force to the subnasal region of the user) may be uncomfortable for a user with a downwardly angled nose because the seal will not be aligned with the blow-off force thereby applying a greater amount of force to the subnasal region of the user. Therefore, to reduce or minimize the amount of force applied to the subnasal region, the interface **3110** provides a seal **3114** that is rotatable depending on the upward or downward angle of the user's nose to provide a sealing force that is aligned with

and directly opposes the user's blow-off force which reduces or minimizes the amount of force applied to the user's subnasal region.

(370) In FIG. 50A, the interface **3110** has a seal **3114** that is attached to a frame **3116**. The seal **3114** and frame **3116** are similar to the seal **114** and frame **116** described in FIGS. 1-22 and, therefore, redundant discussion of similar structures will be largely omitted. The frame **3116** is rotatably attached to an upper frame rail **3122** at an upper connection portion **3152** and rotatably attached to a lower frame rail **3124** at a lower connection portion **3154**. That is, the frame **3116** rotates relative to the upper frame rail **3122** about the upper connection portion **3152** and the frame **3116** also rotates relative to the lower frame rail **3124** about the lower connection portion **3154**. The upper and lower frame rails **3122**, **3124** may be formed from a relatively rigid, semi-rigid or rigid material, such as polycarbonate, for example. The ends of the upper and lower frame rails **3122**, **3124** are attached to forward straps **3140** of the headgear **3118**. That is, the ends of the upper frame rail **3122** are attached to an upper headgear strap **3142** and the ends of the lower frame rail **3124** are attached to a lower headgear strap **3144**. As such, the seal **3114** is supported at the upper and lower connection portions **3152**, **3154** by the headgear **3118**.

(371) The upper and lower frame rails **3122**, **3124** may be attached to the upper and lower headgear straps **3142**, **3144** by a connection mechanism **3160** such that the upper and lower frame rails **3122**, **3124** may extend or retract relative to the headgear **3118**, as illustrated in FIG. 50B. More specifically, the extension or retraction of the upper and lower frame rails **3122**, **3124** changes the relative positions of the upper and lower connection portions **3152**, **3154** which causes rotation of the seal **3114** and allows rotational adjustability of the seal **3114** within a range of angular rotation. A rotated position of the seal **3114** is depicted in dashed lines in FIG. 50B.

(372) For illustration, FIGS. 50C and 50D are schematic side views of the upper and lower frame rails **3122**, **3124** to show changes to the respective positions of the upper and lower connection portions **3152**, **3154** when the upper and lower frame rails **3122**, **3124** are extended or retracted from the upper and lower headgear straps **3142**, **3144**. As shown, a length **L1** is measured as a distance between the upper connection portion **3152** and an end of the upper headgear strap **3142**. Similarly, a length **L2** is measured a distance between the lower connection portion **3154** and an end of the lower headgear strap **3144**. Accordingly, extending or retracting the upper or lower frame rails **3122**, **3124** relative to the upper and lower connection portions **3152**, **3154** changes the lengths **L1**, **L2**. To further illustrate the effect of extending and retracting the upper and lower headgear straps **3142**, **3144**, a front plane projection line **FP** defined by the upper and lower connection portions **3152**, **3154** represents a front plane of the frame **3116**. As such, the angle of the front plane projection line **FP** changes depending upon the lengths **L1**, **L2** of the upper and lower frame rails **3122**, **3124**.

(373) When comparing FIGS. 50C and 50D, the length **L1** does not change between FIGS. 50C and 50D. However, the length **L2** increases from FIG. 50C to FIG. 50D. That is, the length **L2** in FIG. 50D is greater than in FIG. 50C. As a result, the lower connection portion **3154** is positioned further away from the headgear **3118** than in FIG. 50C which causes the seal **3114** to rotate downward, as depicted by the clockwise rotation of the front plane projection line **FP** in FIG. 50D. Similarly, although not depicted, the extension of the upper frame rail **3122** and the retraction of the lower frame rail **3124** would causes the seal **3114** to rotate upward and the front plane projection line **FP** to rotate counter clockwise. The range of angular rotation provided by the upper and lower frame rails **3122**, **3124** may depend upon the amount or range of extension and retraction provided to by the upper and lower frame rails **3122**, **3124** by both the connection mechanism **3160**. Accordingly, rotation of the seal **3114** within the range of angular rotation allows the seal **3114** to comfortably fit user's noses within a wide range of positive or negative nose angles in order to minimize the amount of force applied to the user's subnasal region.

(374) To illustrate the effect of the rotational adjustability of the seal **3114** provided by the interface **3110**, FIG. 50E illustrates a cross-sectional view of the seal **3114** fitted to the nose of a user with a

positive nose angle and FIG. 50F illustrates a cross-sectional view of the seal **3114** fitted to the nose of a user with a negative nose angle. The nose angle is determined based on an angle σ between a bottom plane BP of the user's nose and a horizontal reference plane H. A positive nose angle is defined as an angle σ above the horizontal reference plane H. A negative nose angle is defined as an angle σ below the horizontal reference plane H. FIGS. 50E-F also depict the blow-off force vector BOF for both positive and negative nose angles. As shown, the blow-off force vector BOF for the positive nose angle is angled closer to a horizontal plane than the blow-off force vector BOF for the negative nose angle. FIGS. 50E-F also depict the front plane projection line FP, which is defined by the upper and lower connection portions **3152**, **3154** and represents a front plane of the frame **3116**, illustrated in FIGS. 50A-D. The interface **3110** accommodates blow-off force vectors BOF of varying angles that are caused by positive and negative nose angles by allowing the seal **3114** to rotate according to the nose angle such that the front plane projection line FP is perpendicular to the blow-off force vector BOF. Aligning the front plane projection line FP to be perpendicular to the blow-off force vector BOF minimizes the amount of force applied to the user's subnasal region.

(375) As illustrated in FIG. 50E, the seal **3114** fitted to the positive nose angle is rotated clockwise compared to the seal **3114** fitted to the negative nose angle (FIG. 50F) such that the front plane projection line FP is perpendicular to the blow-off force. As a result, the amount of force applied to the user's subnasal region for the seal **3114** to seal against the user's nose is minimized. In FIG. 50F, the seal **3114** fitted to the negative nose angle is rotated counterclockwise compared to the seal **3114** fitted to the positive nose angle in FIG. 50E such that the front plane projection line FP is also perpendicular to the blow-off force. As a result, the amount of force applied to the user's subnasal region to provide a seal against the user's nose is minimized. To further illustrate the difference in rotation angle of the front plane projection line FP, an angle θ is shown between the front plane projection line FP and vertical reference plane V. As shown, the angle θ of the front plane projection line FP for the seal **3114** fitted to the positive nose angle in FIG. 50E is less than the angle θ of the front plane projection line FP for the seal **3114** fitted to the negative nose angle in FIG. 50F.

(376) The seal **3114** may be rotatably attached to the upper frame rail **3122** and the lower frame rail **3124** by any connection arrangement that allows rotation of the frame **3116**. In other words, the upper and lower connection portions **3152**, **3154** may include a variety of any connection arrangement that allows rotation of the frame **3116**. In some configurations, the frame **3116** may have loops or through holes positioned on a front portion of the frame **3116** through which the upper frame rail **3122** and the lower frame rail **3124** pass through, thereby, allowing the frame **3116** to rotate about the upper and lower frame rails **3122**, **3124**.

(377) The connection mechanism **3160** may include any connection mechanism arrangement between the headgear **3118** and the upper and lower frame rails **3122**, **3124** that provide extension and retraction of the upper and lower frame rails **3122**, **3124** such that the seal **3114** is rotatable through a range of angular rotation. The connection mechanism **3160** may include the rigid adjustment mechanisms as described in U.S. provisional patent application 61/261,715, which is incorporated herein by reference.

(378) FIGS. 51A to 51G illustrate alternative connection mechanisms that allow the seal **3114** to rotate through a range of angular rotation. FIGS. 51A-B illustrate a connection mechanism **3260** comprising an endless or closed-loop cable **3220** and pulleys **3230**. The closed-loop cable **3220** has an upper loop portion **3222** and a lower loop portion **3224**. Similar to the upper and lower frame rails **3122**, **3124**, the closed-loop cable **3220** is connected to the frame **3116** at upper and lower connection portions **3152**, **3154**. The upper and lower connection portions **3152**, **3154** may comprise loops or through holes positioned on a front portion of the frame **3116** through which the closed-loop cable **3220** passes therethrough, thereby, allowing the frame **3116** to rotate about the upper and lower frame rails **3222**, **3224**.

(379) As shown in FIGS. 51A-B, the closed-loop cable **3220** is wrapped around the pulleys **3230**. The pulleys **3230** are attached to forward straps **3240** of the headgear **3118**. The pulleys **3230** rotate clockwise or counterclockwise to allow the upper and lower loop portions **3222**, **3224** to increase or decrease in length such that the seal **3114** rotates. That is, rotation of the pulleys **3230** pulls the upper or lower connection portions **3152**, **3154** closer to the headgear **3118**. Accordingly, the user may rotate the pulleys **3230** to rotate and adjust the seal **3114** until the seal **3114** is comfortably fitted.

(380) In some configurations, the pulley **3230** may have a recessed groove around its circumference to receive the closed-loop cable **3220**. Further, the user may don and doff the seal **3114** by separating the closed-loop cable **3220** from the pulley **3230**. Even further, the pulleys **3230** may be adjustably attached to the forward straps **3240** of the headgear **3118** to allow the slack within the closed loop cable **3220** and, hence, the tightness of the seal **3114** against the user's face, to be adjusted. More specifically, the position of the pulleys **3230** may be moved along the forward straps **3240** (i.e., closer or further away from the frame **3114**) such that the tightness of the seal **3114** against the user's face may be adjusted. Alternatively, closed-loop cable **3220** having different lengths may be provided such that the tightness of the seal **3114** against the user's face may be adjusted.

(381) FIGS. 51C-D illustrate an alternative connection mechanism comprising upper and lower yokes **3322**, **3324** that are attached to a pulley **3330**. In contrast to the closed-loop cable **3220**, the upper and lower yokes **3322**, **3324** have fixed lengths and may be rigid or semi-rigid in construction. As a result, the upper and lower yokes **3322**, **3324** may be sufficiently rigid to resist yielding to vertical forces such as, for example, vertical components of the blow-off force. The upper and lower yokes **3322**, **3324** are rotatably attached to the pulley **3230** to allow the upper and lower yokes **3322**, **3324** to rotate relative to the pulley **3230**. As shown, the user may rotate the pulley **3230** to rotate the seal **3114** in a clockwise or counterclockwise direction. More specifically, rotation of the pulley **3230** may push or pull the upper and lower yokes **3322**, **3324** which pushes or pulls the upper and lower connection portions **3152**, **3154** further or closer to the headgear **3118**. As a result, the seal **3114** rotates upward or downward.

(382) As shown in FIG. 51E, the pulley **3430** may have a gear **3460** positioned on a side of the pulley **3430**. The gear **3460** may engage a tooth **3462** that is attached to the headgear **3118**. The tooth **3462** engages the teeth of the gear **3460** to inhibit or prevent rotation of the pulley **3430** such that the rotational orientation of seal **3114** is maintained. In some configurations, the pulley **3460** may have a toothed outer circumference. The pulley **3430** and the tooth **3462** may be formed from plastic such as Thermoplastic polyurethane (TPU).

(383) FIG. 51F illustrates a pulley **3430** having a knurled outer circumference **3470**. The texture provided by the knurled outer circumference **3270** provides increased grip to allow the user to overcome the retaining force of the tooth **3462** and rotate the pulley **3430**. Similarly, FIG. 51G illustrates a pulley **3430** having a lever **3480** extending radially outward from a perimeter of the pulley **3430**. Accordingly, the pulley **3430** may be rotated by turning the lever **3480**.

(384) FIGS. 52A to 52C illustrate an alternative configuration of a rolling seal **4114** that deforms to comfortably fit user's noses within a wide range of upwardly or downwardly angles in order to minimize the amount of force applied to the user's subnasal region. In contrast to a mechanism that rotates the seal upward or downward in alignment with the angle of user's nose, the seal **4114** deforms and rolls downward over onto itself, which allows the seal **4114** to conform to the shape and angle of the user's nose. More specifically, the seal **4114** has regions of varying thickness or stiffness such that the deformation of the seal **4114** may be controlled and provided in predetermined regions of the seal **4114** when force is applied to the seal **4114** thereby minimizing the amount of force applied to the user's subnasal region. When the seal **4114** is removed, the upper outer peripheral region **4250** reverts back to its undeformed shape.

(385) The seal **4114** has an aperture **4128** surrounded by an inward or rearward-facing central

portion **4204** that faces or contacts the lower portion of the user's nose during use of the seal **4114**. The central portion **4204** is connected to an upper outer peripheral region **4250** that surrounds the central portion **4204** and extends along lateral portions of the outer periphery of the seal **4114**. A lower outer peripheral region **4252** is positioned below the upper outer peripheral region **4250** and also extends along a lower lateral portion of the outer periphery of the seal **4114**. The upper outer peripheral region **4250** is connected to an inner upper edge of the lower outer peripheral region **4252** that is adjacent to the dead space **4206** of the seal **4114**. A seal port **4172** may be formed at a center midpoint region of the lower outer peripheral region **4252**.

(386) FIG. 52B illustrates a vertical cross-section of the seal **4114**. As shown, the thickness of the lower outer peripheral region **4252** (i.e., wall thickness of the seal **4114** at the lower outer peripheral region **4252**) is much greater than the thickness of the upper outer peripheral region **4250**. Accordingly, the lower outer peripheral region **4252** has significantly greater stiffness and rigidity than the upper outer peripheral region **4250**. In some configurations, the lower outer peripheral region **4252** may be formed from a rigid plastic material upon which silicone portions of the seal **4114** is overmoulded thereon. As a result, when a downward force is applied to the central portion **4204** of the seal **4114** (i.e., if the user has a downwardly angled nose), the upper outer peripheral region **4250** rolls inward and downward onto itself and/or the lower outer peripheral region **4252**, as shown in FIG. 52C. More specifically, the central portion **4204** moves downward and/or inward into the dead space **4206** of the seal **4114** in reaction to the force applied, which causes the upper outer peripheral region **4250** to collapse and roll inward into the dead space **4206** of the seal **4114** and downward onto itself and/or the lower outer peripheral region **4252**. The rolling of the upper outer peripheral region **4250** allows the seal **4114** to move downward and/or inward to conform to the shape and angle of the bottom plane of the user's nose such that the force applied to the subnasal region of the user is reduced. In addition, by adjusting the thickness and stiffness of the upper outer peripheral region **4250**, the force required to induce rolling of the upper outer peripheral region **4250** can be controlled, which controls the force applied against the nose of the user. For example, by progressively varying the thickness or stiffness, rolling of the upper outer peripheral region **4250** can become increasingly or decreasingly resisted over the range of movement.

(387) The seal **4114** may include a stiffening portion or thickened band **4240** positioned between the upper outer peripheral region **4250** and the central portion **4204**. The band **4240** may extend along the upper outer edge of the central portion **4204** on an inner wall of the seal **4114**. The band **4240** reduces the prevalence of ballooning and provides additional structure between the upper outer peripheral region **4250** and the central portion **4204** to inhibit or prevent rolling of the central portion **4204** and facilitate rolling of the upper outer peripheral region **4250**. The band **4240** can be a component formed of a material that is more rigid than, or that features increased stiffness relative to, the silicone or other material forming the seal **4114**.

(388) The seal **4114** may also include a thickened or stiffened aperture region **4242** around the aperture **4128**. The reinforced aperture region **4242** may extend around or enclose the aperture **4128** to inhibit or prevent the edges of the aperture **4128** from deforming and collapsing into the dead space **4206** of the seal **4114**. Further, the reinforced aperture region **4242** may also aid in transferring the downward force applied by the user's nose to the upper outer peripheral region **4250**. Similar to the band **4240**, the reinforced aperture region **4242** can be a component formed of a material that is more rigid than, or that features increased stiffness relative to, the silicone or other material forming the seal **4114**.

(389) In the illustrated configuration, the thickness of the upper outer peripheral region **4250** may be similar in thickness compared to the central portion **4204** and other regions of the seal **4114**, except the lower outer peripheral region **4252** which is significantly thicker. However, in such a case, the central portion **4204** is reinforced by the thickened band **4240** to inhibit or prevent collapsing or rolling of the central portion **4204**. In some configurations, the thickness of the seal

4114 along the upper outer peripheral region **4250** may be thinner than all other portions of the seal **4114** to provide a region of reduced stiffness relative to all other regions of the seal **4114** such that deformation and rolling is limited to only the upper outer peripheral region **4250**.

(390) While the illustrated configuration uses regions of varying thickness, other methods for providing regions of varied stiffness also can be used to induce rolling of the seal **4114**. For example, the material of the seal **4114** can be configured to have regions of relative increased or decreased stiffness through material selection or material properties. In addition, a composite of materials can be used to provide regions of varying stiffness or rigidity. Moreover, a combination of any suitable techniques can be used. Nevertheless, the upper outer peripheral region **4250**, which is configured with decreased thickness, provides a simple manner of achieving the region of increased stiffness.

(391) FIGS. **53A** to **53D** illustrates an alternative configuration of a rolling seal **5114** that adjusts by deforming to accommodate users having a wide range of under nose angles, which is a combination of a user's nose angle and upper lip angle. Similar to the seal **4114** in FIGS. **52A-C**, the seal **5114** has an upper outer peripheral region **5250** that rolls downward onto itself to accommodate users with negative nose angles. However, the seal **5114** also has a lower outer peripheral region **5252** that rolls upward onto itself to accommodate users with a protruding upper lip angle. That is, the upper and lower outer peripheral region **5250**, **5252** rolls downward and upward, respectively, such that the seal **4114** is compressed to fit between the space between the user's nose and upper lip. When the seal **4114** is removed from the space between the user's nose and upper lip, the upper and lower outer peripheral region **5250**, **5252** revert back to their undeformed shape.

(392) The upper and lower outer peripheral regions **5250**, **5252** may be separated by a rigid frame portion **5260**. The rigid frame portion **5260** may be formed from thick silicone such the rigid frame portion **5260** is substantially inflexible. Alternatively, the rigid frame portion **5260** may be formed from a rigid plastic material upon which the upper and lower outer peripheral regions **5250**, **5252** may be overmoulded thereon from a flexible material such as silicone. A seal port **5172** may be formed at a center midpoint region of the frontal region of rigid frame portion **5260**. The rigid frame portion **5260** is illustrated as recessed inward relative to the outer lateral perimeter of the upper and lower outer peripheral regions **5250**, **5252**. However, in some configurations, it should be understood to one of ordinary skill in the art that the rigid frame portion **5260** may be flush with or protruding from the outer lateral perimeter of the upper and/or lower outer peripheral regions **5250**, **5252**.

(393) The seal **5114** having rolling upper and lower outer peripheral regions **5250**, **5252** accommodates users having a wide range of under nose angles (i.e., nose angle and upper lip angle combinations). FIG. **53B** is a comparative illustration showing a side profile of a user having a positive nose angle and a shallow upper lip angle that is overlaid over a side profile of a user having a negative nose angle and a protruding upper lip angle. An under nose angle is measured between the subnasal region and the upper lip. The user having a positive nose angle and a shallow upper lip angle is shown as having an under nose angle of $\theta_{\text{sub.MAX}}$. The user having a negative nose angle and a protruding upper lip angle is shown as having an under nose angle of $\theta_{\text{sub.MIN}}$. In other words, the under nose angle is greater for users having a positive nose angle and a shallow upper lip angle than for users having a negative nose angle and a protruding upper lip angle.

(394) The seal **5114** accommodates users having under nose angles within the range of $\theta_{\text{sub.MIN}}$ to $\theta_{\text{sub.MAX}}$. FIG. **53C** is a side view orientation of the seal **5114** configured to fit a user having an under nose angle $\theta_{\text{sub.MAX}}$. As illustrated, the upper and lower outer peripheral regions **5250**, **5252** are undeformed such that the seal **5114** may span the under nose angle $\theta_{\text{sub.MAX}}$ and seal against the user's nose. FIG. **53D** is a side view orientation of the seal **5114** configured to fit a user having an under nose angle $\theta_{\text{sub.MIN}}$. In contrast, the upper and lower outer peripheral regions **5250**, **5252** are deformed and rolled onto themselves such that the seal **5114** conforms to fit the under nose angle $\theta_{\text{sub.MIN}}$ and seal against the user's nose while minimizing the amount of force

applied to the user's subnasal region.

(395) The upper and lower outer peripheral regions **5250**, **5252** may be substantially similar in structure with the upper outer peripheral region **4250** and each other. As such, the upper and lower outer peripheral regions **5250**, **5252** may deform similarly under similar forces. Accordingly, the seal port **5172** is balanced between the upper and lower outer peripheral regions **5250**, **5252**. Further, sustained vertical external forces are absorbed by the upper and lower outer peripheral regions **5250**, **5252** as they roll and equalize at a new position. Temporary vertical external forces caused by, for example, incidental hose pulls, are absorbed by the upper and lower outer peripheral regions **5250**, **5252** and the upper and lower outer peripheral regions **5250**, **5252** will return toward or to their equalized position. In some configurations, the upper and lower outer peripheral regions **5250**, **5252** may have different size, geometry and/or structure such that the upper outer peripheral region **5250** may provide a different force profile than the lower outer peripheral region **5252**.

(396) Similar to the seal **4114**, stiffening portions or thickened bands **5240** extend around the outer uppermost edge of the upper outer peripheral region **5250** and the outer lowermost edge of the lower outer peripheral region **5252** on inner walls of the seal **5114**. Further, the seal **5114** may also include a thickened or stiffened aperture region **5242** around the aperture **5128**. The bands **5240** and the stiffened aperture region **5242** aid in transferring force applied by the user's nose and upper lip to the upper and lower outer peripheral regions **5250**, **5252**. FIG. 53E illustrates an alternative to the stiffening bands **5240**. As shown, the seal **5114** may have a spring steel strip **5340** upon which the upper and lower outer peripheral regions **5250**, **5252** are overmoulded. The spring steel strip **5340** facilitates rolling of the upper outer peripheral region **4250** by inhibiting or preventing rolling at other regions of the seal **5114**.

(397) FIGS. 54A to 54G illustrates an alternative configuration of a seal **6114** having a bellowing region **6202** that allows the seal **6114** to adjust to fit a range of nose lengths. The bellowing region **6202** is a deformable region of the seal **6114** that receives the user's nose and deforms to accommodate the length and shape of the user's nose and bellows outward and/or upward to relieve and reduce the amount of force acting against the user's nose. As shown in FIGS. 54A-B, the bellowing region **6202** is a flexible region formed from a thin-walled portion of the seal **6114**. The bellowing region **6202** may have the thinnest wall thickness compared to all other portions of the seal **6114** such that the deformation occurs only in the bellowing region **6202**. The thin wall thickness provides flexibility which allows the bellowing region **6202** to change shape by deforming inward and expanding outward. The bellowing region **6202** may include the central portion **6204** such that the bellowing region **6202** surrounds the aperture **6128**. Further, the bellowing region **6202** may extend to include portions of the upper outer peripheral regions **6250**. The seal **6114** may also include a thickened or stiffened aperture region **6242** around the aperture **6128**. That is, the aperture **6128** may have thickened or stiffened aperture region **6242** that is formed from thickened silicone (i.e., relative to other portions of the seal **6114**) such that the aperture **6128** is stiffened and strengthened so as to inhibit or prevent collapsing of the seal **6114** around the aperture **6128**. Accordingly, the stiffened aperture region **6242** may ensure that the bellowing region **6202** of the seal **6114** deforms, as opposed to the regions around the aperture **6128**, when the seal **6114** is fitted to the user.

(398) FIG. 54C is a comparative illustration showing a side cross-sectional view of the seal **6114** fitted to a user having a longer nose overlaid over a side cross-sectional view of the seal **6114** fitted to a user having a shorter nose with an upward angle. As illustrated, the longer nose extends deeper into the seal **6114** compared to the shorter nose. As a result, the bellowing region **6202L** deforms inward to receive the longer nose. Further, the bellowing region **6202L** protrudes outwardly in forward and upward directions to increase the volume within the seal **6114** such that a pressure increase inside the seal **6114** is minimized. As a result, the amount of force acting against the longer nose decreases which increases comfort of the seal **6114**. In addition, the thin surface provided by the bellowing region **6202L** that extends up the user's nose improves the comfort of the

seal **6114** because the amount of force is distributed over a greater amount of contact area with the nose. In contrast, the bellowing region **6202S** inflates or extends toward the user to receive the shorter nose. The shorter nose does not extend deep into the seal **6114**. As such, the bellowing region **6202S** does not protrude outwardly in forward and upward directions as the bellowing region **6202L**.

(399) FIG. **54D** illustrates the seal **6114** fitted to a user having a longer nose with a level plane nose angle. FIG. **54E** illustrates the seal **6114** fitted to a user having a longer nose with a negative nose angle. As shown, the bellowing region **6202** of the seal **6114** protrudes outwardly in forward and upward directions to accommodate both nose angles. Similarly, FIG. **54F** illustrates the seal **6114** fitted to a user having a shorter nose with a positive nose angle. FIG. **54G** illustrates the seal **6114** fitted to a user having a shorter nose with a negative nose angle. As shown, the bellowing region **6202** of the seal **6114** extends in the upward directions to accommodate both nose angles. In some configurations, the thickness and stiffness along the bellowing region **6202** may vary such that the seal **6114** may initially bellow or protrude upward along the user's nose to improve comfort of the seal **6114** against the user's nose. After a threshold pressure or force is applied, the bellowing region **6202** may then bellow or protrude forward to relieve pressure within the seal **6114**.

(400) The comfort of a nasal pillow seal can be improved by avoiding having the nasal seal protrude into the nostrils of the user. Nasal seals that do not protrude into the user's nostrils may form a seal with the user by having surfaces that compress against the lower portion of the user's nose and upper lip. This can give the nasal seal a larger profile compared to a seal that protrudes into the nostrils of the patient. A problem with large-profile nasal pillow seals is that the seal can dislodge if the seal comes into contact with another surface, for example, when the user changes position onto their side. Reducing the profile of the nasal seal can reduce the perceived obtrusiveness of the seal and can reduce the negative effects experienced when sleeping on one's side. As a low-profile respiratory interface is smaller, it is less likely to come into contact with a pillow or another surface associated with sleeping that may dislodge the respiratory interface and break the seal on the patient's nose. However, a low-profile respiratory interface may have less surface area to form a seal with the user's skin. The respiratory interfaces disclosed herein provide a low-profile nasal seal that is comfortable to wear and maintains a good seal between the interface and the user.

(401) FIG. **55** is a perspective view of another example of an interface assembly or respiratory mask system **110** that can be used with or incorporated into the system **10** of FIG. **1**. The mask system **110** can be similar in at least some respect to the mask system **110** of FIGS. **2-22** and is described in the context of differences relative to the prior mask system **110**. Components or features of the present mask system **110** that are not discussed in detail can be the same as or similar to the corresponding components or features of the prior mask system **110**, or can be of another suitable arrangement. Accordingly, in some instances, the same reference numerals are used to refer to the same, corresponding or similar components or features. The respiratory mask system **110** comprises a mask **112**, which in some configurations includes a seal **114** and a frame assembly or frame **116**. The seal **114** can be connected to the frame **116** by a connector **7222**. The respiratory mask system **110** also includes headgear **118** for securing the mask **112** to the user. The headgear **118** can include a yoke **127** that extends along the front of the mask **112**. The yoke **127** can be integrally formed with the headgear **118**. In some embodiments, the yoke **127** is removably connected to the frame **116**. In certain variants, the yoke **127** is integrated with the frame **116**. In the illustrated embodiment, the headgear **118** forms a closed loop from behind the head of the user to the front of the frame **116** and/or from the front of the frame **116** to the top of the head of the user. In preferred embodiments, the respiratory mask system **110** does not comprise a T-piece from the frame **116** extending upwardly (when worn) to connect to the headgear **118** at the user's forehead. However, if desired, aspects, features or components of the disclosed respiratory mask system **110** can be utilized in a design that incorporates a T-piece. The seal **114** does not rest on the

bridge of the nose, thereby reducing the size and profile of the seal and making the seal less obtrusive. Also, by not resting on the bridge of the nose, the seal **114** is adapted to reduce any chance of pressure damage on the sensitive nasal bridge region.

(402) In some configurations, the respiratory mask system **110** also comprises a short flexible tube or gas delivery conduit **120** that allows fluid communication with an interior of the seal **114** and which connects to the supply conduit **12** of the CPAP system **10** or other respiratory system. The gas delivery conduit **120** is connected to the mask **112** either directly or via a suitable connector, such as a hollow connector **122**, which can be of any desirable or suitable shape, such as curved or bent (e.g., an elbow) or straight. In some configurations, the connector **122** can swivel about one or more swivel axes relative to the mask **112** so that the path of the gas delivery conduit **120** relative to the positioning of the mask **112** on the face of the user can adapt to the sleeping position of the user. However, in other arrangements, the connector **122** can be integral or unitary with the mask **112**. In the illustrated embodiment, there is no connector **122**, and the gas delivery conduit **120** is fixedly connected to the frame **116**. The end of the gas delivery conduit **120** opposite the connector **122** can comprise a suitable connector **124** for connecting the gas delivery conduit **120** to the supply conduit **12**. In some configurations, the connector **124** can be or comprise a swivel connector that allows relative rotation between the gas delivery conduit **120** and the supply conduit **12**.

(403) The respiratory mask system **110** preferably includes a limited flow outlet or bias flow vent **126** for providing gas washout from the respiratory mask system **110**. In some configurations, the bias flow vent **126** is in the form of a collection of small apertures. The bias flow vent **126** may be provided in the frame **116**, as shown, in the connector **122** or elsewhere on the respiratory mask system **110**.

(404) In some configurations, the mask **112** can comprise the seal **114**, the frame **116**, and the connector **122**. In some configurations, the frame **116** (and, if desired, the connector **122**) can be stiffer than at least a portion of the seal **114**, such as the portion that defines a user-contacting surface. In some configurations, the seal **114** is removably coupled to the frame **116** around a passage through the frame **116** from the interior of connector **122**. In the illustrated embodiment, the frame **116** acts as a hub or a connector between the seal **114**, the gas delivery conduit **120**, and the headgear **118**. The frame **116** also provides rigid support to the seal **114** and/or connector **122**. The frame **116** is preferably rigid or semi-rigid, and can also be formed from a thickened silicone or other plastic material. Thus, the seal **114** and the frame **116** together can form an enclosure having a gas flow inlet from the CPAP system **10** and an aperture **7128** (see, e.g., FIG. **58A**) through the seal **114** to the user.

(405) In some configurations, the headgear **118** comprises side arms **130** that extend outwardly (away from each other), rearwardly and upwardly at a shallow angle, past left and right extremities of the seal **114** and along the left and right cheeks and in particular cheekbones of a user to connect to the headgear **118** for holding the seal **114** on the face of a user. Such side arms **130** may be longer than they are deep or thick and may be resiliently flexibly connected to the frame and/or resiliently flexible along their length (widthwise but not heightwise). In some configurations, the side arms **130** extend toward or to a location between the ears and eyes of the user and/or to or near the temple of the user. In some embodiments, the side arms **130** extend along the cheeks and upward toward the top of the head to form a closed-loop headgear **118**.

(406) FIG. **56** shows an embodiment of the seal **114** and the frame **116**. For clarity, the yoke **127** retaining structure is not shown. The yoke **127** would extend across the front or distal-facing surface of the frame **116**. In the illustrated arrangement, the frame **116** defines a general U-shape when viewed from above. As discussed below, a connector **7222** can connect the seal **114** to the frame **116**. The connector **7222** can function to provide support to the seal **114** and can resist deformation of the seal **114** when the seal **114** is under positive pressure in use.

(407) FIG. **57** depicts a non-limiting embodiment of the frame **116**. FIGS. **58A-C** depict non-

limiting embodiments of a seal **114**. With reference to FIG. 57, the central portion of the frame **116** defines an aperture **7170** through which gases can flow. A first annular wall surrounds the aperture **7170** and projects in a rearward direction to define a support or connector **7172** for the seal **114**. A second annular wall (containing the bias flow vent **126** and shown in FIG. 56) of the frame **116** surrounds the aperture **7170** and projects in a forward direction to define a support for the connector **122**. With reference to FIGS. 58A-C, the seal **114** defines a gas inlet aperture **7175** configured to receive the connector **7172** of the frame **116**. The seal **114** and the frame **116** can be removably coupled by any suitable arrangement, such as a friction-fit or snap-fit, for example. In the illustrated arrangement, the connector **7172** includes one or more recesses **7176** configured to receive a corresponding protrusion (not shown) of the seal **114** to create a snap-fit engagement between the seal **114** and the frame **116**. However, this arrangement could also be reversed. Moreover, the entire arrangement could be reversed between the seal **114** and the frame **116** in that the seal **114** could include a male connector portion and the frame **116** could include a corresponding female connector portion. In some configurations, the seal **114** can include a connector **7222**, as shown in FIGS. 72 and 73, that is formed around the gas inlet aperture **7175** of the seal **114**. The connector **7222** can be formed from a rigid plastic (e.g., polycarbonate). The connector **7222** can be formed as part of the seal **114**. For example, the seal **114** can be overmolded onto the connector **7222**. In some embodiments, the connector **7222** is adhered to the seal **114** with adhesive or is connected to the seal **114** with a coupling or a fastener. In some configurations, the connector **7222** includes multiple pieces that capture the seal **114** therebetween. The connector **7222** allows connection between the frame **116** and the seal **114**. In some embodiments, the frame **116** does not provide structural support for the seal **114**. Rather, the frame **116** acts as a manifold that enables the headgear **118**, gas delivery conduit **120**, and the seal **114** in combination with the connector **7222** to be combined into a single respiratory mask system **110**. The structural support for the seal **114** is provided on the distal face of the seal **114** by the connector **7222**.

(408) Preferably, the seal **114** and the frame **116** include an alignment or key arrangement such that the seal **114** and the frame **116** can only be assembled in the correct orientation relative to one another. Any suitable arrangement can be used. For example, the seal connector **7172** can include a recess **7180** configured to receive a key or protrusion (not shown) of the seal **114**. The recess **7180** and protrusion can be located on an upper, central portion of the aperture **7170** and/or other locations along the perimeter of the aperture **7170**. This arrangement could also be reversed. Moreover, other suitable arrangements could also be used, such as a non-circular shape of the connector **7172** and the gas inlet aperture **7175**, for example. In some embodiments, the gas inlet aperture **7175** can have a general D-shape, with a bottom portion of the gas inlet aperture **7175** being flattened or closer than the other portions of the gas inlet aperture **7175** to a central point of the gas inlet aperture **7175**. The frame **116** can include a D-shaped seal connector **7172** that mates with the D-shaped gas inlet aperture **7175** to ensure correct alignment and prevent rotation of the seal **114** relative to the frame **116**. The D-shaped or non-circular gas inlet aperture **7175** can also reduce the overall height of the respiratory mask system **110**, thereby making the respiratory mask system **110** less obtrusive and more desirable to use.

(409) In the embodiment of FIG. 58A, the gas inlet aperture **7175a** of the seal **114a** is largely circular in shape with a diameter of about 29.7 mm to accommodate a circular gas delivery conduit. In some variants, the gas inlet aperture **7175a** is between 28-34 mm. In the embodiment of FIG. 58B, the gas inlet aperture **7175b** is largely circular in shape with a diameter of about 26.5 mm, but the lower edge of the gas inlet aperture **7175b** includes a truncated portion **7177** having a marginally reduced diameter (FIG. 59B). This truncated portion **7177** can provide an intuitive indication of the orientation of a seal connector (FIGS. 72 and 73), discussed below. The truncated portion **7177** can be located on either or both lateral edges of the gas inlet aperture **7175**, the upper edge, or any location about the perimeter of the gas inlet aperture **7175**. In some variants, the gas inlet aperture **7175b** is between 26-30 mm. In the embodiment of FIG. 58C, the gas inlet aperture

7175c is largely circular in shape with a diameter of about 28.4 mm. The lower edge of the gas inlet aperture **7175c** includes a truncated portion **7177**, discussed above. In some variants, the gas inlet aperture **7175c** is between 28-32 mm.

(410) The seal **114** has a hollow interior which is filled with air under positive pressure in use and is configured to seal under the nose of the user, along a portion of the face extending lateral to the nose, as well as along the upper lip of the user (FIGS. **63A-C**). FIGS. **58A-C** depict non-limiting embodiments of the seal **114**. The seal **114** comprises at least one nasal opening or aperture **7128**. The nasal aperture **7128** communicates between the hollow interior of the seal **114** and the rear wall **7202** (FIG. **66A-C**) of the seal **114**. The gas inlet aperture **7175** provides an opening between the hollow interior of the seal **114** and the front wall **7212** of the seal **114**. In some configurations, the seal **114** can comprise more than one nasal aperture **7128**. In some configurations, the seal **114** can comprise apertures **7128** defined within superstructures, such as pillows, prongs or the like. In some configurations, the nasal aperture **7128** can be defined by a nasal cushion or insert, which can be over-molded or otherwise secured to a base structure of the seal **114**. Examples of suitable arrangements of the seal **114** are disclosed in Applicant's publication no. WO 2014/077708, the entirety of which is incorporated by reference herein.

(411) As discussed in more detail below, the seal **114** can be designed so that the seal has a low-profile and maintains good sealing characteristics under positive pressures up to and including 18-20 mm H.sub.2O. The profile of the seal **114** can be characterized by the distance the seal **114** extends beyond the user's nose. Generally speaking, the seal **114** in FIG. **58C** has a lower profile compared to the seal **114** in FIG. **58A**. The profile of the seal **114** of FIG. **58B** is intermediate to the profiles of the seals in FIGS. **58A** and **58C**.

(412) FIGS. **59A-C** show front views of the seals **114** shown in FIGS. **58A-C**. The seal **114** can have an overall height **7140** and an overall width **7142**, as shown in FIGS. **59A-C**. FIGS. **60A-C** show left views of the seals **114** of FIGS. **59A-C**. The seal **114** can have an overall depth **7144**, as shown in FIGS. **60A-C**. In some embodiments, the profile of the seal **7144** can be reduced by reducing one or more of the overall height **7140**, overall width **7142**, and/or overall depth **7144** of the seal **114**. While specific dimensions are discussed herein, the proportions of the specific dimension relative to one another are considered within the scope of the present disclosure as well. For example, a disclosure of a height and a depth includes a disclosure of the ratio of the height to the depth.

(413) In the illustrated embodiment of FIGS. **59A** and **60A**, the overall height **7140a** is 42.1 mm, the overall width **7142a** is 75.8 mm and the overall depth **7144a** is 45.6 mm. In some configurations, the overall height **7140a** is between 37-47 mm, between 40-44 mm, or is about 42 mm. In some configurations, the overall width **7142a** of the seal **114a** is between 72-82 mm, between 75-77 mm, or is about 76 mm. In some embodiments, the overall depth **7144a** is between 40-50 mm, between 44-48 mm, or is about 46 mm.

(414) In the illustrated embodiment of FIGS. **59B** and **60B**, the overall height **7140b** is 41.0 mm, the overall width **7142b** is 59.0 mm and the overall depth **7144b** is 43.0 mm. In some configurations, the overall height **7140a** is between 36-46 mm, between 39-43 mm, or is about 41 mm. In some configurations, the overall width **7142b** of the seal **114b** is between 54-64 mm, between 57-61 mm, or is about 59 mm. In some embodiments, the overall depth **7144** is between 38-48 mm, between 41-45 mm, or is about 43 mm.

(415) In the illustrated embodiment of FIGS. **59C** and **60C**, the overall height **7140c** is 35.6 mm, the overall width **7142c** is 59.0 mm and the overall depth **7144c** is 43.2 mm. In some configurations, the overall height **7140c** is between 30-40 mm, between 33-37 mm, or is about 35 mm. In some configurations, the overall width **7142c** of the seal **114c** is between 54-64 mm, between 57-61 mm, or is about 59 mm. In some embodiments, the overall depth **7144c** is between 38-48 mm, between 41-45 mm, or is about 43 mm.

(416) In some configurations, the seal **114** is sized to fit different nasal structures. For example, the

seal **114** can be provided in Small, Medium, Large, and Wide Models. In some embodiments, the seal **114** can be sized to fit the nasal structures of different ethnicities (e.g., Caucasians, Asians, African Americans). The aforementioned overall height **7140**, width **7142**, and depth **7144** ranges can be representative of a Medium Model of the different embodiments shown in FIGS. **59A-C**. For the embodiment shown in FIG. **59C**, the overall width **7142c** may be from about 45 mm for a Small model to about 80 mm for a Large Model. The Large Model of the embodiment in FIG. **59C** can have a similar height **7140c** and depth **7144c** as those of the Medium Model shown in FIG. **59C**. In certain variants, the Large Model of the embodiment in FIG. **59C** has a larger height **7140c** and/or depth **7144c** compared to the Medium Model shown in FIG. **59C**. The Small Model of the embodiment in FIG. **59C** can have a similar width **7142c** as the Medium Model shown in FIG. **59C**. In certain variants, the Small Model has a smaller width **7142c**, height **140c** and/or depth **7144c** compared to the Medium Model shown in FIG. **6C**. The Wide Model of the embodiment in FIG. **59C** can have a width **7142c** between 70-80 mm, between 73-77, or about 75 mm. The Wide Model of the embodiment of FIG. **59C** can have a larger height **7140c** and/or depth **7144c** that is similar to those of the Medium model shown in FIG. **59C**.

(417) Referring to FIGS. **60A-C**, the uppermost point **7182** of the gas inlet aperture **7175** can be disposed distal to the bottommost point **7184** of the gas inlet aperture **7175** when the bottom wall of the seal **114** is horizontal. As illustrated, a line passing through the uppermost and bottommost points **7182**, **7184** of the gas inlet aperture **7175** can form an angle **7186** with a vertical line passing through the bottommost point **7184**. This angle **7186** can be referred to as the gas inlet angle **7186**. In the embodiment of FIG. **60A** the gas inlet angle **7186a** is 8.75° and the uppermost point **7182a** is 4.65 mm distal of the bottommost point **7184a**. In the embodiment of FIG. **60B** the gas inlet angle **7186b** is 13.2° and the uppermost point **7182b** is 7.1 mm distal of the bottommost point **7184b**. In the embodiment of FIG. **60C** the gas inlet angle **7186c** is 15.5° and the uppermost point **7182c** is 8.1 mm distal of the bottommost point **7184c**.

(418) In some configurations, the gas inlet angle **7186** can range from between 5-30°, between 7-20°, or between 8-16°. In some variants, the gas inlet angle **7186** can be selected to reduce the volume within the hollow interior space of the seal **114**. Reduction of the volume within the hollow interior space of the seal **114** can reduce the obtrusiveness of the seal **114**. The volume within the hollow interior of the seal **114** can also be known as dead space. Reduction of the dead space can improve the flushing of expired air and carbon dioxide. The gas inlet angle **7186** can be selected to tilt the gas inlet aperture **7175** (and the gas delivery conduit that protrudes therefrom) toward the horizontal axis. Angling the gas delivery conduit that protrudes from the mask **112** toward the horizontal axis can allow the gas delivery conduit **120** to be connected to the supply conduit **12** without the use of an elbow connector. Angling the gas delivery conduit **120** toward the horizontal axis can reduce hose pull.

(419) In addition to reducing the overall height **7140**, width **7142**, and depth **7144** dimensions of the seal **114**, the profile of the seal **114** can be reduced by changing the shape of the seal **114**. FIGS. **61A-C** are rear views of the seals **114** shown in FIGS. **58A-C**. Referring to FIGS. **61A-C**, the rear wall **7202c** of the embodiment of FIG. **61C** has a more triangular shape compared to the rear surfaces **7202a,b** of the embodiments of FIGS. **61A** and **61B**. As shown in FIGS. **61A-C**, a rearward projection of the rear wall **7202** can define a perimeter that circumferentially surrounds the nasal aperture **7128**. This perimeter can be referred to as a rear perimeter. The seal **114** shown in FIG. **61C** has a rear perimeter that is smaller than that of the seal shown in FIG. **61A**. In some variants, the profile of the seal **114** is reduced by reducing the rear perimeter of the seal **114**.

(420) The nasal aperture **7128** of the seal **114** is disposed in a central portion of the rear wall **7202**. The central portion of the rear wall **7202** is distal to the lateral portions of the rear wall **7202**, thereby forming a nasal recess **7214**. In use, the nasal recess **7214** receives the tip portion of the user's nose. The seal **114** has a bottom wall **7216** that extends proximally upward to meet the rear wall **7202**. In the embodiments of FIGS. **61B** and **61C**, the bottom wall **7216b,c** and the rear wall

7202b,c meet to form a shelf **7218b,c** near the bottom of the nasal recess **7214**. The seal shown in FIG. **61A** has a less well defined shelf. As described below, a more defined shelf **7218** can reduce the profile of the seal **114** by allowing the bottom portion of the seal **114** to tilt closer to the user's face, as shown in FIGS. **63A-C**. A well-defined shelf **7218** can allow the volume of the hollow interior of the seal **114** to be reduced, thereby reducing the profile of the seal **114**. The shelf **7218** can also improve the stability of the seal **114**, allowing the size of the seal **114** to be reduced while maintaining good performance (e.g., sealing) of the seal **114**.

(421) FIGS. **62A-C** are top views of the seals **114** shown in FIGS. **58A-C**. Referring to FIGS. **62A-C**, the rear wall **7202c** of the embodiment of FIG. **62C** extends distally further than do the rear surfaces **7202a,b** of embodiments of FIGS. **62A** and **62B**. When the seal **114** is viewed from the top, the aperture **7128c** of the seal **114c** shown in FIG. **62C** is closer to a distal-most point **7230c** of the seal **114c** than to a proximal-most point **7232c** of the seal **114c**. In the embodiment of FIG. **62A**, the aperture **7128a** is closer to a proximal-most point **7232a** of the seal **114a** than to a distal-most point **7230a** of the seal **114a**. In the embodiment shown in FIG. **62A**, the front wall **7212a** flares out more as it extends in the rear-ward direction compared to the front surfaces **7212b,c** of the seals **114b,c** shown in FIGS. **62B** and **62C**. The front surfaces **7212b,c** maintain a parabolic form as the front surfaces **7212b,c** extend in the rear-ward direction and, in some configurations, may continuously curve in one direction without a point of inflection. In contrast, the front wall **7212a** of the seal **114a** has a point of inflection **7201**, as indicated in FIG. **62A**. In some configurations, the proximal-most point of the rear surface **7202c** is located within a distal half of the seal **114c** or is located less than halfway from the distal-most point **7230c** to the proximal-most point **7232a** in a fore-aft direction of the seal **114c**. In some configurations, the proximal-most point of the rear surface **7202c** is located between about 30-50% or at about 40% of the distance from the distal-most point **7230c** to the proximal-most point **7232a**.

(422) FIGS. **63A-C** are side views of the seals **114** of FIGS. **58A-C** positioned in use on a user's face. The seal **114** advantageously does not require contact with the bridge of the nose of the user. In the illustrated configuration, the seal **114** does not extend over the bridge of the nose of the user. More particularly, the illustrated seal **114** does not contact the bridge of the nose of the user.

(423) With continued reference to FIGS. **63A-C**, the profile of the seal **114** can be lowered by aligning the seal **114** along the base of the user's nose within the space between the user's nose and cheek. In the embodiment of FIG. **63C**, the lateral portions of the seal **114c** tuck further up into the space between the user's cheek and nose than do the lateral portions of the embodiments of the seal **114a,b** shown in FIGS. **63A** and **63B**. In addition or in the alternative, a lower portion of the seals **114b** and **114c** are positioned closer to the face (e.g., upper lip) of the user in use than the lower portion of the seal **114a** (with the lower portion of seal **114c** being closer than the lower portion of seal **114b**). Such an arrangement can provide for an advantageous orientation or angle of a gases delivery tube or conduit and/or of the frame or headgear. The orientation of the gas inlet aperture **7175** can be characterized by an angle **7240**, also referred to as the use angle **7240**. The use angle **7240** is the angle between the horizontal axis and a line that is normal to the line that extends between the uppermost and bottommost points **7182**, **7184** of the gas inlet aperture **7175** when the nasal aperture **7128** is directed towards the nasal passage of the user. In the embodiment of the seal **114a** of FIG. **63A**, the use angle **7240a** is about 30.0°. In other arrangements, such as the embodiments of FIGS. **63B** and **63C**, the use angle **7240b,c** is greater than about 35° or greater than about 40°. In the embodiment of FIG. **63B**, the use angle **7240b** is about 43.7°. In the embodiment of FIG. **63C**, the use angle **7240c** is about 45.6°. Due to the variety of nasal shapes among the human population, the use angle **7240** may be subject to significant variation for a given seal. For example, the use angle **7240** can vary from about 0° to about 70°. However, it can be advantageous for the use angle **7240** to be relatively large to reduce the negative effects of hose pull. In some variants, the use angle **7240** can range from about 70° to about 90°.

(424) The seal **114** can have an effective taper that is defined as a ratio of the depth **7144** (FIGS.

60A-C) of the seal **114** to the projected area of the lateral portion of the front wall **7212** when the seal **114** is viewed from the side. In calculating the effective taper, the front wall **7212** is considered to extend to the line extending between the uppermost and bottommost points **7182**, **7184** of the gas inlet aperture **7175**. In the embodiment of FIG. **63A**, the effective taper has a value of about 0.37. In the embodiment of FIG. **63C**, the effective taper has a value of about 0.39. In some variants, the profile of the seal **114** is reduced by increasing the use angle **7240**, and/or by increasing the effective taper of the seal **114**.

(425) Referring to FIG. **64**, the seal **114** can have a variable wall thickness. The thickened wall portions can be designed to provide a support structure that helps the seal **114** maintain contact with the user's skin when the seal **114** is in use. In some variants, the thickened wall portions help the seal **114** resist deformation when the seal **114** is in use. The thickened wall portions can allow less material to be used to make the seal **114**, thereby reducing the profile of the seal **114**. The thickened wall portions can extend into the hollow interior of the seal. For example, the thickened wall portions may extend proximally from the front wall **7212** and/or distally from the rear wall **7202**.

(426) The seal **114** can have regions of varying thickness. For example, each lateral side portion of the seal **114** can have a top region **7302**, a back region **7304**, a front region **7306**, and a central region **7308**. Only one side portion has the regions identified in FIG. **11**. The regions of the other side can be a mirror image of the illustrated side. The back region **7304** can have a thickness that is greater than the thickness of all the other regions. The top region **7302** and/or the central region **7308** can have a thickness that is less than the thickness of all other regions. In the illustrated embodiment, the top region **7302** and the central region **7308** have a thickness of about 0.3 mm, the front region **7306** has a thickness of about 2.6 mm and the back region **7304** has a thickness of about 3.9 mm.

(427) FIGS. **65A** and **65B** show the thickened wall portions or regions of the embodiment of the seal **114c** shown in FIG. **58C**. The regions shown in FIGS. **65A** and **65B** can be the same as or similar to the regions shown in FIG. **64**. The thickened wall portions extend into the hollow interior of the seal **114c**. In FIG. **65A**, the outline of the seal **114c** profile is shown for clarity. The top region **7302c** and the central region **7308c** have a thickness of about 0.3 mm, and the front region **7306c** has a thickness of about 1.0 mm. The back region **7304c** has a variable thickness, with a maximum thickness of about 1.45 mm. In some variants, the thickness of the top region **7302c** and the central region **7308c** is between about 0.2 mm and about 0.4 mm. The thickness of the front region **7306c** is between about 0.7 mm and about 1.3 mm. The maximum thickness of the back region **7304c** is between about 1.2 mm and about 1.7 mm.

(428) As shown in FIGS. **65A** and **65B**, the back region **7304c** is the shape of a “U” with the bottom of the “U” being disposed near the proximal-most point of the front wall **7212**. The front region **7306c** extends across the top of the “U”-like structure formed by the back region **7304c**. The central region **7308c** is enclosed by the front region **7302c** and the back region **7304c**. The top region **7302c** extends from the back region **7304c** away from the central region **7308c**.

(429) The thickness of the thickened wall portions in the seal **114c** shown in FIG. **58C** have been decreased compared to those of the seal **114a** shown in FIG. **58A**. Reducing the thickness of the wall portions assists in reducing the weight and/or the obtrusiveness of the seal **114**. The thickness of the thickened wall portions can be increased to increase rigidity and friction between the seal **114** and the frame **116**. In some variants, the thickness of the thickened wall portions is increased to increase the vertical stability of the seal **114**.

(430) FIGS. **66A-C** show a sagittal cross-sectional view of the seal **114**. In particular, FIGS. **66A-C** show the seal **114c**; however, certain features can be found in other arrangements of the seal **114**, such as seals **114a** and **114b**. For the sake of comparison, the seals **114a**, **b**, **c** are illustrated in FIGS. **67A-C**. The thickness of the bottom wall **7216** of the seal **114** can vary. The bottom wall **7216** can have a distal thickness **7316** near the front wall **7212**. The bottom wall **7216** can have a

proximal thickness **7318** near the rear wall **7202**. The bottom wall **7216** can have a central thickness **7320** disposed within a longitudinally central portion of the bottom wall **7216**. In some arrangements, two or more of the distal thickness **7316**, the proximal thickness **7318** and the central thickness **7320** vary relative to one another.

(431) FIGS. **67A-C** show sagittal cross-sectional views of the seal embodiments depicted in FIGS. **58A-C**. The seal **114a** shown in FIG. **67A** has a distal thickness **7316a** of about 1.5 mm and a central thickness **7320a** of about 0.3 mm. The seal **114b** shown in FIG. **67B** has a distal thickness **7316b** of about 2.4 mm and a central thickness **7320b** of about 0.5 mm, and a proximal thickness **7318b** of about 2.9 mm. The seal **114c** shown in FIG. **67C** has a distal thickness **7316c** of about 1.35 mm and a central thickness **7320c** of about 0.5 mm, and a proximal thickness **7318c** of about 3.1 mm. As mentioned above, the seals **114b,c** shown in FIGS. **67B** and **67C** have a clear distinction between the bottom wall **7216** and the rear wall **7202**, forming a shelf **7218** in the form of a rounded edge on the proximal side of the bottom wall **7216**. The seal **114a** in FIG. **67A** has a curved bottom wall **7216a** with no clearly defined interface with the rear wall **7202a**.

(432) With continued reference to FIGS. **67A-C**, the rear wall **7202** can have a thickened portion **7330** that surrounds the nasal aperture **7128**. The thickened portion **7330** can extend distally from the distal-facing surface of the rear wall **7202** and can have a maximum thickness **7332**. The thickened portion **7330** can be adapted to prevent the edges of the aperture **7128** from deforming (e.g., “blowing out”) when the seal **114** is under pressure in use. Deformation of the aperture **7128** can reduce the effectiveness of the seal **114** and increase discomfort of the user. The thickened portion **7330** can improve effectiveness of the seal **114**.

(433) The seal **114a** in FIG. **67A** has an oval, pad-like thickened portion **7330a**. The thickened portion **7330a** has a maximum thickness **7332a** of about 1.5 mm. The thickened portion **7330a** gradually tapers as it extends away from the nasal aperture **7128**. The seal **114b** in FIG. **67B** has a thickened portion **7330b** that is similar to the thickened portion **7330a** of the seal **114a** shown in FIG. **67A**.

(434) Referring to FIG. **68**, the seal **114b** can include a thickened ridge **7340** that extends distally about 1.0 mm from the distal-facing surface of the rear wall **7202b**. The ridge **7340** can be disposed between the interface of the thickened portion **7330b** and the top region **7302b** of the seal **114b**. In some variants, the ridge **7340** reinforces the seal **114b** to prevent the seal **114b** from creasing as air pressure is increased in the hollow interior of the seal **114b**. In some embodiments, the thickened portion **7330** can contribute to some distortion of the seal **114b** as it is inflated. The ridge **7340** can allow the seal **114b** to inflate smoothly. In some embodiments, the seal **114** having a thickened portion **7330** can inflate smoothly without the seal **114** having a ridge **7340**. In certain variants, the seal **114c** that has a thickened portion **7330c** that closely matches the nasal aperture **7128** can inflate smoothly without the seal **114c** having a ridge **7340**.

(435) FIG. **69** shows in greater detail the thickened portion **7330b** of the seal **114b** in FIG. **14B**. The thickened portion **7330b** extends a maximum distance **7334b** of about 7.9 mm from the edge of the nasal aperture **7128**. The thickened portion extends from the distal-facing surface of the rear wall **7202** a maximum thickness **7332b** of about 1.5 mm.

(436) FIG. **70** shows a detailed front view of the thickened portion **7330c** of the seal **114c** shown in FIG. **67C**. The thickened portion **7330c** matches the periphery of the nasal aperture **7128** more closely than do the thickened portions **7330a,b** shown in FIGS. **67A** and **67B**. The thickened portion **7330c** extends distally into the hollow interior of the seal **114c** from the rear wall **7202c**. The thickened portion **7330c** has a maximum width of about 3.3 mm.

(437) In many embodiments, the surface portion of the seal **114** surrounding or defining the nasal aperture **7128** is not in direct contact with the nose of the user. Instead, a volume of air separates the surface portion of the seal **114** surrounding or defining the nasal aperture **7128** and the portion of the user's nose that is within nasal recess **7214** of the seal **114**. This separation between the seal **114** and the user's nose allows the area of the nasal aperture **7128** to be reduced without users

feeling that the flow through the aperture **7128** is constricted. Referring to FIGS. **71A-C**, the area of the nasal aperture **7128** can be evaluated by comparing the areas of rear-ward projections of the nasal aperture **7128**. The rear-ward projection of the nasal aperture **7128** can have a minimum height **7342**, a maximum height **7344**, and an overall width **7346**. The seal **144a** in FIG. **71A** has a minimum height **7342a** of about 4.0 mm, a maximum height **7344a** of about 12.0 mm, and an overall width **7346a** of about 18.8 mm. The seal **144b** in FIG. **71B** has a minimum height **7342b** of about 4.0 mm, a maximum height **7344b** of about 11.0 mm, and an overall width **7346b** of about 17.1 mm. The seal **144c** in FIG. **71C** has a minimum height **7342c** of about 4.5 mm, a maximum height **7344c** of about 11.0 mm, and an overall width **7346c** of about 16.9 mm. Each of these aforementioned minimum heights **7342**, maximum heights **7344**, and overall widths **7346** can be increased or reduced by at least 20% in certain variants.

(438) Another method of comparing the reduction in size of the nasal aperture **7128** for the seals **114** shown in FIGS. **71A-C** is by comparing the surface area changes between the aperture **7128a** shown in FIG. **71A** to that of the aperture **7128c** shown in FIG. **71C**. The surface area of the aperture **7128** can be measured along the curved surface of the nasal recess **7214** to get a more accurate measurement than that obtained from the 2D rearward projection data discussed above. For the seal **114a** in FIG. **71A**, the surface area of the aperture **7128a** along the curved surface of the nasal recess **7214a** is approximately 161 mm.^{sup.2}. For the seal **114c** in FIG. **71C**, the surface area of the aperture **7128c** along the curved surface of the nasal recess **7214c** is approximately 141 mm.^{sup.2}. In some configurations, the surface area of the aperture **7128** is less than or equal to about 160 mm.^{sup.2}, less than or equal to about 150 mm.^{sup.2} or less than or equal to about 141 mm.^{sup.2} or 140 mm.^{sup.2}.

(439) With reference to FIGS. **72** and **73**, the seal **114** can include a connector **7222** (also referred to as a seal clip) that couples to the seal **114**. In some embodiments, the connector **7222** can be a portion of the frame **116**. For example, the connector **7222** can be a portion of the frame **116** that is permanently integrated with the seal **114** (e.g., overmolding the seal **114** over the connector **7222** portion of the frame **116**). In certain embodiments, the connector **7222** includes a clip portion that allows connection to another frame **116** or to the yoke **127** or headgear **118**. The connector **7222** can be configured to provide lateral support to the seal **114**. The connector **7222** can have a front flange **7224**, a rear flange **7226**, and a hub portion **7228** disposed between the front and rear flanges **7224**, **7226**. The connector **7222** can be configured to capture a portion of the seal **114** between the front flange **7224** and the rear flange **7226**. In some embodiments, the connector **7222** is over-molded onto the seal **114**. In some embodiments, the seal **114** is over-molded onto the connector **7222**. In some configurations, the front flange **7224** can connect to the rear flange **7226** by a snap-fit arrangement, which can be a permanent or removable connection.

(440) When the connector **7222** is assembled to the seal **114**, the rear flange **7226** is positioned within an interior of the seal **114** and the hub portion **7228** extends through the gas inlet aperture **7175** of the seal **114**. The front flange **7224** of the connector **7222** is positioned on the exterior of the seal **114**. The seal **114** can comprise an annular rim that encircles the gas inlet aperture **7175** and is configured to be captured by the front flange **7224** and the rear flange **7226** of the connector **7222**.

(441) The connector **7222** can have a central opening **7250** that aligns with the gas inlet aperture **7175** of the seal **114** when the connector **7222** is attached to the seal **114**. The central opening **7250** can be configured to couple to a frame **116**, a gas delivery conduit **120**, an elbow connector **122**, or other suitable means for connecting the connector **7222** to a CPAP system.

(442) The connector **7222** can have side arms **7252** that extend proximally and laterally from the central opening **7250**. The side arms **7252** can be configured to be more resistant to lateral deformation than the seal **114**. The side arms **7252** can provide lateral support for the seal **114**. The connector **7222** can ensure the seal **114** maintains its shape under pressure, enabling the seal **114** to effectively encompass the nose of the patient. In some variants, the front wall **7212** of the seal **114**

may include a recess for receiving the side arms 7252 of the connector 7222. The profile of the seal 114 can be reduced by positioning the side arms 7252 to sit within the recess on the front wall 7212 of the seal 114. In some embodiments the side arms 7252 can be overmolded, chemically bonded or otherwise affixed to the seal 114. The side arms 7252 prevent the seal 114 from over expanding and losing a seal with the patient's nose. The side arms 7252 can prevent the seal 114 from severely deforming due to inflation from the pressure from the gases flowing through the patient interface 112.

(443) FIG. 74 shows another embodiment of a seal 114d that is similar to the seal 114, 144a, 114b, 114c except as described differently below. The features of the seal 114d can be combined or included with the seal 114 or any other embodiment discussed herein. The illustrated embodiment has a connector 7222d attached to the seal 114d. The connector 7222d is similar to the connector 7222 except as described differently below. As discussed, the connector 7222d has side arms 7252d that extend proximally and laterally from the central opening 7250d and provide lateral support to the seal 114d. The connector 7222d has a rear flange 7226d that is positioned within an interior of the seal 114d. In the illustrated embodiment, the rear flange 7226d has a blue color and is visible through the translucent seal 114d. The color of the rear flange 7226d can help guide a user to connect properly the seal 114d with another component of the interface (e.g., gas delivery conduit 120). For example, the color of the rear flange 7226d may match the color of a portion of the gas delivery conduit 120, making intuitive for a user the connection of the gas delivery conduit 120 to the connector 7222d. In some embodiments, it is intended for coloring to be used as an indication of components in the seal 114. For example, the front flange 7224d can be completely transparent while the rear flange 7226d can be colored a transparent blue.

(444) FIG. 75 shows another embodiment of a connector 7222e attached to a seal 114e. The seal 114e is similar to the seal 114 or any other embodiment discussed herein except as described differently below. The connector 7222e is similar to the connector 7222 or any other embodiment discussed herein except as described differently below. The features of the seal 114e and connector 7222e can be combined or included with the seal 114, or the connector 7222, or any other embodiment discussed herein. In the illustrated embodiment, a front wall 7254e of the connector 7222e is substantially flush with the front wall 7212e of the seal 114e. In some embodiments, at least a portion of the front wall 7254e of the connector 7222e can protrude laterally and/or distally beyond the front wall 7212e of the seal 114e. In some embodiments, at least a portion of the front wall 7212e of the seal 114e can protrude laterally and/or distally beyond the front wall 7254e of the connector 7222e.

(445) As discussed above, the seal 114 can be made in different sizes to allow at least one of the seals 114 to fit a wider variety of nasal structures. For example, the seal 114 can be made in four different sizes: small, medium, large, and wide. The four sizes of the seal 114 can be configured to allow one or more of the available seals 114 to be suitable for as wide a variety of users. In some configurations, the four seal sizes can allow the seal 114 to be viable for a substantial portion or a maximum portion of the population. The seal 114 can be made in more than four different sizes (e.g., extra-large, medium-wide, extra-small).

(446) FIGS. 76A-E show different views of the medium-sized seal 114e that is shown in FIG. 75. FIG. 76A is a front view of the seal 114e and is similar to the view shown in FIGS. 59A-C for the seals 114a-c. FIG. 76B is a left, side view of the seal 114e and is similar to the view shown in FIGS. 60A-C for the seals 114a-c. FIG. 76C is a rear view of the seal 114e and is similar to the view shown in FIGS. 61A-C for the seals 114a-c. FIG. 76D is a top view of the seal 114e and is similar to the view shown in FIGS. 62A-C for the seals 114a-c. FIG. 76E is a bottom view of the seal 114e.

(447) As shown in FIG. 76A, the seal 114e can be symmetric relative to a vertical axis 7256. The vertical axis 7256 passes through a midline of the seal 114e and aligns with a sagittal plane that extends from the front of the seal to the rear of the seal 114e. As discussed above, the front wall

7212e of the seal **114e** can have a recessed portion **7258e**. The recessed portion **7258e** can be configured to receive a portion of the connector **7222e**. For example, the recessed portion **7258e** can receive the front flange **7224** of the connector **7222**. Referring to FIGS. **76A-B**, the seal **114e** can have an overall height **7140e**, an overall width **7142e**, and an overall depth **7144e** that are similar to those described for the seals **114a-c** shown in FIGS. **59A-7C** above. Table 1 below shows an example of the approximate dimensions of the overall height **7140**, the overall width **7142**, and the overall depth **7144** for different sizes (e.g., small, medium, large, wide) of the seal **114**. In some embodiments, one or more of the dimensions of a seal **114** may vary by $\pm 10\%$ of the dimension listed in Table 1. The present disclosure includes the ratios that can be derived from the dimensions herein disclosed. For example, the present disclosure includes not only the disclosed overall widths of the small and large seals but also the ratio of the width of the small seal to the width of the large seal and any other ratio that can be derived from the dimensions disclosed herein.

(448) TABLE-US-00001 TABLE 1 Approximate dimensions of Small, Medium, Large, and Wide seal sizes. Seal Overall Overall Overall Size Height (mm) Width (mm) Depth (mm) Small 36.2 59.0 43.2 Medium 38.0 58.6 41.2 Large 38.0 72.0 42.7 Wide 38.0 72.0 43.9

(449) In some embodiments, the small- and medium-sized seals **114** are designed to be appropriate for approximately the same nose widths (also referred to herein as breadths), and are tailored to size experimentally according to a subnasal to pronasal dimension. For example, the small-sized seal **114** has a greater width than the medium-sized seal **114** because users of the small-sized seal **114** tend to have similar width or wider noses than users of the medium-sized seal **114**. However, in the embodiments presented in Table 1, the difference in the overall widths **7142** between the small- and medium-sized seals **114** is minimal (0.4 mm).

(450) FIG. **77** shows a perspective view of the medium-sized seal **114e** shown in FIG. **76A**. FIG. **78** shows a perspective view of an embodiment of a wide-sized seal **114f**. As shown in FIGS. **77** and **78**, the recessed portion **7258e** of the medium-sized seal **114e** can be more blunted compared to the recessed portion **7258f** of the wide-sized seal. For example, in the illustrated embodiments, the recessed portions **7258e,f** of the medium- and wide-sized seals **114e,f** can be said to have a height dimension that is measured parallel to the vertical axis **7256**. Compared to the height dimension of the medium-sized seal **114e**, the height dimension of the wide-sized seal **114f** decreases more slowly toward the lateral aspect **7260e,f** of the recessed portion **7258e,f**.

(451) FIGS. **79A-B** are left, side views of the medium-sized seal **114e** shown in FIG. **77**. Referring to FIG. **79A**, a gas inlet angle **7186e** can be formed by the vertical axis **7256** and the line passing through the uppermost point **7182e** and the bottommost point **7184e** of the gas inlet aperture **7175e** when the bottom wall **7216e** is aligned approximately horizontally, as described above with regard to FIGS. **60A-C**. Because the bottom wall **7216e** is curved, the whole bottom wall **7216e** is not aligned horizontally, nor is the entire forward portion of the bottom wall **7216e**. In the illustrated embodiment, the gas inlet angle **186e** is 14.0° . In some embodiments, the gas inlet angle **7186e** can be an angle other than 14.0° . A front wall distal displacement **7261e** can be defined as the distance of a distal-most point of the seal **114e** (which corresponds to the uppermost point **7182e** in the illustrated arrangement) from the vertical axis **7256**. In the illustrated embodiment, the front wall distal displacement **7261e** is 7.9 mm. In some embodiments, the front wall distal displacement **7261e** can be a value other than 7.9 mm. Angling the gas inlet aperture **7175** downward helps resist hose tug when the seal **114** is in use. For example, angling the gas inlet aperture **7175** downward can reduce tug from a gas delivery conduit **120** that is connected to the seal **114**.

(452) FIG. **79B** illustrates another way of characterizing the size or shape of the seal **114** relative to the gas inlet aperture **7175**. In FIG. **79B**, the seal **114e** is rotated to align the uppermost point **7182e** and the bottommost point **7184e** of the gas inlet aperture **7175e** along the vertical axis **7256**. A perpendicular distance **7262e** (or another way to characterize a depth of the seal **114e**) can be defined as the distance of a proximal-most point **7232e** of the seal **114e** from the vertical axis **7256**. In the illustrated embodiment, the perpendicular distance **7262e** is 35.2 mm. In some embodiments,

the perpendicular distance **7262e** can be a value other than 35.2 mm.

(453) Table 2 shows a comparison of approximate perpendicular distances **7262** for seals **114** of different sizes (e.g., small, medium, large, wide). In some embodiments, one or more of the dimensions of a seal **114** may vary by +10% of the dimension listed in Table 2. As discussed above, the present disclosure includes the ratios that can be derived from the dimensions disclosed herein. As with Table 1 above, the medium-sized seal **114** can have a slightly smaller perpendicular distance **7262** compared to that of the small-sized seal **114** due to the applied anthropometric data set.

(454) TABLE-US-00002 TABLE 2 Approximate front wall displacement for Small, Medium, Large, and Wide seal sizes. Front Wall Seal Size Displacement (mm) Small 36.2 Medium 35.2 Large 37.0 Wide 37.2

(455) FIG. **80** depicts a side view of the seal **114e** positioned in use on a user's face. As described above with regard to FIGS. **63A-C**, the orientation of the gas inlet aperture **7175e** can be characterized by a use angle **7240e**. The use angle **7240e** can characterize the angle the seal **114** sits at on a user's nose with respect to the transverse plane of the user's head. In the illustrated embodiment, the use angle **7240e** is approximately 45°. In other embodiments, the gas inlet aperture **7175e** can be at different orientations. In some variants, the orientation of the gas inlet aperture **7175e** can be dependent on the user's nose size and physical characteristics.

(456) FIG. **81** shows a front view of the seal **114e** shown in FIG. **76A**. The orientation of the front view shown in FIG. **81** is different from the front view of the seal **114e** shown in FIG. **76A** because the view shown in FIG. **81** is aligned with a plane that is perpendicular to the axial direction of the gas inlet aperture **7175e**. As discussed in more detail below, the seal **114e** can include a connector engagement structure or a connector retaining structure **7262e** that surrounds the gas inlet aperture **7175e**. The other embodiments of the seal **114** disclosed herein can also include a connector retaining structure **7262** that is similar to the connector retaining structure **7262e** described below. The connector retaining structure **7262e** defines the gas inlet aperture **7175e** and provides a structure that allows the connector **7222** (shown in FIG. **72**) to be connected to the body of the seal **114**.

(457) The gas inlet aperture **7175e** can include a truncated portion **7177e**, as described with regard to FIGS. **59B** and **59C**. The truncated portion **7177e** can provide an intuitive indication for the orientation of the connector **7222** of the seal **114**. In the illustrated embodiment, the truncated portion **7177e** is positioned on the bottom edge of the connector retaining structure **7262e**. In some embodiments, the truncated portion **7177e** can be positioned on the top edge of the connector retaining structure **7262e**, on either or both of the lateral edges of the connector retaining structure **7262e**, or on any combination thereof.

(458) Because of the truncated portion **7177e** of the connector retaining structure **7262e**, the gas inlet aperture **7175e** can have a vertical dimension **7264e** that is different from a lateral dimension **7266e** of the gas inlet aperture **7175e**. For example, in FIG. **81**, the truncated portion **7177e** is positioned on the bottom edge of the connector retaining structure **7262e** making vertical dimension **7264e** of the gas inlet aperture **7175e** smaller than the lateral dimension **7266e** of the gas inlet aperture **7175e**. In the illustrated embodiment, the gas inlet aperture **7175e** has a vertical dimension **7264e** that is 26.5 mm and a lateral dimension **7266e** that is 31.17 mm. However, these dimensions are illustrative only and not intended to be limiting. In some embodiments, the vertical dimension **7264e** has a value other than 26.5 mm, and the lateral dimension **7266e** has a value other than 31.17 mm.

(459) The seal **114e** can have regions of differing thickness, as describe above with regard to FIG. **64**. FIG. **82A** shows an isometric view of the seal **114e**. FIG. **82B** shows that the seal **114e** can have an apical region **7268e**, a core region **7270e**, and an intermediate region **7272e** disposed between the apical region **7268e** and the core region **7270e**. The apical region **7268e** of the seal **114e** can have a thickness of approximately 0.3 mm. In the illustrated embodiment, the thickness of the

apical region **7268e** is reduced compared to that of other embodiments of the seal **114** (e.g., the seal **114** of FIG. **64**). In the illustrated embodiment, the reduced thickness of the apical region **7268e** increases the extent the seal **114e** can flex and be compressed in use. Reducing the thickness of the apical region **7268e** can reduce the forces imposed on the face of the user by the seal **114** when the seal **114** is in use.

(460) With continued reference to FIG. **82B**, the thickness of the intermediate region **7272e** can be non-constant. In some embodiments, the thickness of the intermediate region **7272e** can increase non-linearly as the seal **114e** is traversed laterally along the intermediate region **7272e** from a first point **7276e** near the top of the seal **114e** to a second point **7278e** near the bottom of the seal **114e**. In the illustrated embodiment, the thickness of the intermediate region **7272e** is approximately 0.3 mm at the first point **7276e** and approximately 3.4 mm at the second point **7278e**. In some embodiments, the thickness of the intermediate region **7272e** may simply vary (e.g., increase and decrease multiple times along the path between the first point **7276e** and the second point **7278e**) between approximately 0.3 mm and approximately 3.8 mm at various locations along the profile of the intermediate region **7272e**. In the illustrated embodiment, the core region **7270e** corresponds to the recessed portion **7258e** of the front wall **7212e** and has a wall thickness of approximately 1.00 mm. The thicknesses indicated above are the seal thickness as measured in a direction that is normal to the surface of the seal **114e**. In some embodiments, one or more of the aforementioned thicknesses can vary by $\pm 10\%$ of these stated values.

(461) FIG. **83** shows a left side view of a cross-section of a lateral portion of the seal **114e**. In FIG. **83**, the front portion of the seal **114e** is shown in light shading to indicate the location of the selected cross-section with respect to the rest of the seal **114e**. FIG. **83** shows an inner surface **7274e** of the front wall **7212e** of the seal **114e**. The inner surface **7274e** faces the hollow interior space of the seal **7114e**. The differing thicknesses of the apical region **7268e**, the core region **7270e**, and the intermediate region **7272e** are viewable in the cross-section of the front wall **7212e**. The thickness profile of the front wall **7212e** of the illustrated seal **114e** allows the seal **114e** to perform better when in use, as discussed below. The thin regions of the seal **114e** allow the seal **114e** to deform where required to better fit a user's nose. The thick regions of the seal **114e** provide and transmit reinforcement forces that keep the seal **114e** from blowing out when the seal **114e** is under pressure in use.

(462) FIG. **84** shows a left side view of a sagittal cross-section of the seal **114e**, as described above with regard to FIGS. **66A-67C**. The seal **114e** can include a thickened portion **7330e** that encompasses the nasal aperture **7128e**, as described above with regard to FIGS. **69** and **70**.

(463) FIG. **85** shows a front view of the inner surface of the rear wall of the seal **114e**. In the illustrated embodiment, the thickened portion **7330e** can closely approximate the contours of the nasal aperture **7128e** at the lateral edges of the nasal aperture **7128e** and extends further away from the nasal aperture **7128e** at the medial portions of the nasal aperture **7128e**. As discussed above, the thickened portion **7330e** can assist in preventing blow out of the seal **114e** when the seal **114e** is under pressure in use.

(464) Referring back to FIG. **84**, the maximum thickness of the thickened portion **7330e** of the illustrated embodiment is 1.8 mm and is located on the central axis of the seal **114e** immediately adjacent to the nasal aperture **7128e**. In some embodiments, the maximum thickness of the thickened portion **7330e** is greater than 1.8 mm. In some embodiments, the maximum thickness of the thickened portion **7330e** is less than 1.8 mm. The ratio of the maximum thickness of the thickened portion **7330e** to the adjacent portion of the rear wall **7202e** can be 1.8:0.3 or 6:1.

(465) With continued reference to FIG. **84**, the bottom wall **7216e** of the seal **114e** has a forward portion **7280e**, a rear portion **7282e**, and a central portion **7284e** interposed between the forward portion **7280e** and the rear portion **7282e**. The forward portion **7280e** is characterized by an area of relatively high thickness adjacent to the connector retaining structure **7262e**. As discussed below, at least a portion of the central portion **7284e** can be characterized by a region of relatively low

thickness. The region of the central portion **7284e** that characterized by a region of relatively low thickness is referred to herein as a sub-nasal window **7285e** (shown in FIG. **87**). The rear portion **7282e** is characterized again by an area of relatively high thickness with respect to the central portion **7284e**. In the illustrated embodiment, the rear portion **7282e** forms a clear distinction between the bottom wall **7216e** and the rear wall **7202e**. In the illustrated embodiment, the thickness of the forward portion **7280e** is 2.7 mm, the thickness of the central portion **7284e** is 0.3 mm, and the thickness of the rear portion **7282e** is 2.7 mm, where the thickness is measured along a direction that is normal to the outer surface of the bottom wall **7216e**. In some embodiments, one or more of the aforementioned thicknesses can vary by +10% of these stated values.

(466) The sub-nasal window **7285e** (shown in FIG. **87**) of the central portion **7284e** can be said to be a recessed surface on the inner face of the bottom wall **7216e**. In some embodiments, the central portion **7284e** can include a band of decreased thickness along a portion of the surface of the bottom wall **7216e** that faces the hollow interior of the seal **114e**. In the illustrated embodiment, the central portion **7284e** is recessed approximately 2.4 mm with respect to the forward portion **7280e** and the rear portion **7282e** at the central axis of the seal **114e**. In some embodiments, the entire central portion **7284e** can be recessed with respect to the forward portion **7280e** and the rear portion **7282e** by a constant dimension.

(467) Reducing the thickness of the central portion **7284e** can improve the comfort of the seal **114e** during prolonged use. An issue that can occur with some nasal seal designs or some users is sub-nasal discomfort after periods of extended use. It was found that reducing the thickness of the central portion **7284e** of the bottom wall **7216e** improved the comfort of the seal **114**. As mentioned, the reduced thickness of the central portion **7284e** creates a sub-nasal window **7285e** between the thickened forward and rear portions **7280e**, **7282e** of the bottom wall **7216e**. The sub-nasal window **7285e** allows increased deformation of the bottom wall **7216e** of the seal **114e** during use and does not compromise the effectiveness of the seal **114e**. The increased thickness of the forward portion **7280e** and the rear portion **7282e** of the bottom wall **7216e** increases the structural integrity of the seal **114e** and allows the formation of an approximately air-tight seal with the user's face. The rear portion **7282e** of the bottom wall **7216e** assists in the formation of this air-tight seal against the user's lip and/or sub-nasal region.

(468) In some variants, the extent to which the central portion **7284e** is recessed can vary. For example, the central portion **7284e** can be recessed a maximum amount at the central axis (shown in cross-section in FIG. **84**) and recessed a minimum amount at the lateral ends of the central portion **7284e**. In some embodiments, the central portion **7284e** can include a combination of regions of adjacent increased or decreased thickness, thereby creating a plurality of regions that are recessed to different extents with respect to the forward and rear portions **7280e**, **7282e**. The boundaries between these adjacent regions can resemble step-wise function (e.g., abrupt changes in thickness). The boundaries between the adjacent regions can be smooth curves that transition in a continuous fashion from one level of recess to another. In some embodiments, the central portion **7284e** can have an undulating thickness as the central portion **7284e** extends laterally away from the central axis. For another example, the central portion **7284e** can include a plurality of raised ridges that extend parallel to one another laterally away from the central axis.

(469) FIG. **86** shows a bottom view of an embodiment of the seal **114g** that is similar to the seal **114** or any other embodiment discussed herein except as described differently below. The sub-nasal window **7285g** of the seal **114g** can have a proximal dimension **7286g** that extends along the medial plane of the seal **114g** from the distal most point of the sub-nasal window **7285g** to the proximal most point of the sub-nasal window **7285g**, as shown in FIG. **86**. The sub-nasal window **7285g** can have a lateral dimension **7288g** that extends from the right most point of the sub-nasal window **7285g** to the left most point of the sub-nasal window **7285g**, as shown in FIG. **86**. In the illustrated embodiment, the seal **114g** has a sub-nasal window **7285g** that has a proximal dimension **7286g** of approximately 15.72 mm and a lateral dimension **7288g** of approximately 32.45 mm. The

overall depth **7144g** of the seal **114e** is 41.2 mm, making the ratio between the proximal dimension **7286g** and the overall depth **7144g** of the illustrated embodiment 1:2.6. The proximal dimension **7286g** constitutes approximately 38% of the overall depth **7144g** of the seal **114g**. The overall width **7142g** of the seal **114g** is 58.6 mm, making the ratio between the lateral dimension **7288g** and the overall width **7142g** of the illustrated embodiment 1:1.8. The lateral dimension **7288g** constitutes approximately 55% of the overall width **7142g** of the seal **114g**. These dimensions are illustrative and not meant to be limiting. In some embodiments, the dimensions and ratios can alter depending on the size of the seal **114**.

(470) FIG. **87** shows a top view of a cross-section of the seal **114e** shown in FIG. **76A**. The top view is taken along a plane that is perpendicular to the sagittal plane. Accordingly, the surface of the bottom wall **7216e** that faces the hollow interior of the seal **114e** is viewable in FIG. **87**. As shown, the sub-nasal window **7285e** can have a first width **7290e** that is a measurement of the length of the sub-nasal window **7285e** that intersects a proximal axis **7292** that extends along the midline of the seal **114e** from the front wall **7212e** to the rear wall **7202e** of the seal **114e**. As illustrated in FIG. **87**, a reference line **7296e** can be defined normal to the proximal axis **7292** and passing through the rearmost point of the sub-nasal window **7285e** that lies on the proximal axis **7292**. The sub-nasal window **7285e** can have a second width **7294e** that is a measurement of the width of the sub-nasal window **7285e** at the lateral most point of the sub-nasal window **7285e** that lies on the reference line **7296e**, with the second width **7294e** being aligned to cross the sub-nasal window **7285e** in as short a distance as possible, as shown in FIG. **87**. In the illustrated embodiment, the first width **7290e** is approximately 5.9 mm and the second width **7294e** is approximately 7.1 mm, making the ratio of the first width **7290e** to the second width **7294e** 1.0:1.2. These dimensions correspond to a medium-sized seal **114** and are meant to be illustrative and non-limiting. In some embodiments, the dimensions and ratios can alter depending on the size (e.g., small, medium, large, wide) of the seal **114**.

(471) In some embodiments, the second width **7294e** can be the maximum width of the sub-nasal window **7285e**. As discussed, the second width **7294e** can be measured at a point of the sub-nasal window **7285e** that is laterally displaced from the proximal axis **7292**. In some embodiments, the sub-nasal window **7285e** can maintain approximately the same width as the sub-nasal window **7285e** extends laterally away from the proximal axis **7292**.

(472) FIG. **88** shows a bottom view of an embodiment of the seal **114h** that is similar to the seal **114** or any other embodiment discussed herein except as described differently below. The illustrated embodiment is a wide-sized seal **114h**. In the seal **114h** shown in FIG. **88**, the sub-nasal window **7285h** spans the bottom wall **7216h** of the seal **114h**. Having the sub-nasal window **7285h** extend across the entire length of the bottom wall **7216h** can be beneficial when compared to a sub-nasal window **7285** that only partially spans the length of the bottom wall **7216** (e.g., the sub-nasal window **7285e** shown in FIG. **87**) because a sub-nasal window **7285h** with a longer lateral profile allows a longer length of the seal **114h** to be compressed when in use. Accordingly, this can assist to further reduce potential sub-nasal discomfort.

(473) FIG. **89** shows a top view of a cross-section of an embodiment of a wide-sized seal **114i**. The top view is taken along a plane that is perpendicular to the sagittal plane. Accordingly, the surface of the bottom wall **7216i** that faces the hollow interior of the seal **114i** is viewable in FIG. **89**. The first width **7290i** of the seal **114i** that is shown in FIG. **89** is greater than the first width **7290e** of the seal **114e** that is shown in FIG. **87**. In the illustrated embodiment, the first width **7290i** can be approximately 6.9 mm. As shown in FIG. **89**, the sub-nasal window **7285i** spans the length of the bottom wall **7216i**. The seal **114i** is similar to the seal **114e** or any other embodiment discussed herein except as described differently below. The features of the seal **114i** can be combined or included with the seal **114e** or any other embodiment discussed herein. Accordingly, the sub-nasal window **7285i** can have absolute dimensions and/or ratios and/or configurations similar to those described for the sub-nasal window **7285e** or any other embodiment discussed herein.

(474) FIG. 90 shows a rear perspective view of an embodiment of a medium-sized seal **114j**. The sub-nasal window **7285j** shown in FIG. 90 is similar to the sub-nasal window **7285h** shown in FIG. 89 in that the sub-nasal window **7285j** spans across the length of the bottom wall **7216j**. The recessed portion **7285j** of the central portion **7284j** (also referred to herein as the sub-nasal window **7285j**) can be seen extending laterally along the bottom wall **7216j** and into a region between the front wall **7212j** and rear wall **7202j** of the seal **114j**. Accordingly, the sub-nasal window **7285j** can be said to laterally extend beyond what could strictly be referred to as the bottom wall **7216j** of the seal **114j**.

(475) FIG. 91 shows a top view of a cross-section of an embodiment of a seal **114k**. The top view is taken along a plane that is substantially perpendicular to the sagittal plane. Accordingly, the surface of the bottom wall **7216k** that faces the hollow interior of the seal **114i** is viewable in FIG. 91. In the illustrated embodiment, the central portion **7284k** includes three sub-nasal windows **7285k** characterized by a reduced wall thickness of the bottom wall **7216k** of the seal **114k**. In the illustrated embodiment, the three sub-nasal windows **7285k** are partitioned by two struts **7287k**, which are characterized by regions of increased thickness. The partitioned sub-nasal windows **7285k** can improve the behavior of the seal **114k** when the seal **114k** is under compression. The sub-nasal windows **7285k**, being regions of reduced thickness, can compress when the seal **114k** is worn, thereby reducing the pressure imposed on the upper lip of the user. The struts **7287k**, being thickened portions, can improve the ability of the seal **114k** to retain its shape when deformed around a user's nose in the distal-to-proximal direction. In the illustrated embodiment, the struts **7287k** have the same wall thickness as the adjacent front and rear portions **7280k**, **7282k**. In some embodiments, the struts **7287k** can have a wall thickness that is different than the wall thickness of the adjacent front and rear portions **7280k**, **7282k**. For example, the struts **7287k** can have a wall thickness that is greater than or less than the adjacent front and rear portions **7280k**, **7282k**. In some embodiments, the wall thickness of the sub-nasal window **7285k** can vary across the sub-nasal window **7285k**. For example, the wall thickness of the sub-nasal window **7285k** can gradually increase over the length of the sub-nasal window **7285k** so that the region of the sub-nasal window **7285k** that is adjacent to the strut **7287k** has the same wall thickness as the strut **7287k**.

Accordingly, the transition of the wall thickness between the sub-nasal window **7285k** and the strut **7287k** can be gradual over a length of the bottom wall **7216k** rather than step-wise as shown in the embodiment of FIG. 91. The illustrated embodiment, has three sub-nasal windows **7285k**.

However, some embodiments may have four or more sub-nasal windows **7285k**. Additionally, the struts **7287k** of the illustrated embodiment are of approximately constant width (e.g., the dimension of the strut **7287k** adjacent the front wall **7212k** of the seal **114k** is approximately the same as the dimension of the strut **7287k** adjacent the rear wall **7202k** of the seal **114k**). In some embodiments, the width of the struts **7287k** may not remain approximately constant. For example, the dimension of the strut **7287k** adjacent the front wall **7212k** of the seal **114k** can be smaller than the dimension of the strut **7287k** adjacent the rear wall **7202k** of the seal **114k** (e.g., the width of the strut **7287k** increases when translating from the front wall **7212k** to the rear wall **7202k** of the seal **114k** along the bottom wall **7216k** of the seal **114k**). In some embodiments, the opposite could also be the case (e.g., the width of the strut **7287k** decreases when translating from the front wall **7212k** to the rear wall **7202k** of the seal **114k** along the bottom wall **7216k** of the seal **114k**).

(476) As discussed above with regard to FIG. 55, the seal **114** can be attached to a connector **7222** that assists in providing structure to the seal **114** when the seal **114** is under pressure in use. In addition, the connector **7222** can provide a means for connecting the seal **114** to a frame **116** of a mask **112**. As shown in FIG. 72, the connector **7222** can include a front flange **7224** and a rear flange **7226**. The front flange **7224** and rear flange **7226** can include cooperating structures to retain between them the connector retaining structure **7262** of the seal **114**.

(477) FIGS. 92A-G show different views of the embodiment of a front flange **7224e** shown in FIG. 75. The front flange **7224e** is similar to the front flange **7224** except as described differently below.

The features of the front flange 7224e can be combined or included with the front flange 7224 or any other embodiment discussed herein. FIG. 92A shows a front perspective view of the front flange 7224e. FIG. 92B shows a rear perspective view of the front flange 7224e shown in FIG. 92A.

(478) As shown in FIG. 92A, the front flange 7224e can include a forward surface 7350e, a rearward surface 7352e, a central opening 7250e, and side arms 7252e that extend proximally and laterally away from the central opening 7250e. In the illustrated embodiment, the front flange 7224e is symmetric with respect to a sagittal plane of the front flange 7224e. As shown in FIG. 92B, the front flange 7224e can include a first clip retaining projection 7354e and a second clip retaining projection 7356e. In the illustrated embodiment, the first and a second clip retaining projections 7354e, 7356e have a semi-circular shape and are located on the rearward surface 7352e, adjacent to the central opening 7250e of the front flange 7224e. The first clip retaining projection 7354e is spaced apart vertically from a second clip retaining projection 7356a. The rearward surface 7352e of the side arms 7252e is configured to cooperate with the recessed portion 7258e of the seal 114e. As shown, each of the side arms 7252e twists slightly as it extends proximally away from the central opening 7250e. The twist of the side arms 7252e is configured to match the profile of the recessed portion 7258e of the seal 114e. As discussed above, the side arms 7252e of the front flange 7224e act to provide rigidity and a form of structural integrity to the seal 114e.

(479) FIG. 92C is a front view of the front flange 7224e. FIG. 92D is a left side view of the front flange 7224e. FIG. 92E is a rear view of the front flange 7224e. As shown in FIG. 92E, the front flange 7224e can include a rim 360e that surrounds the central opening 7250e of the front flange 7224c. FIG. 92F is a top view of the front flange 7224e. FIG. 92G is a bottom view of the front flange 7224c.

(480) FIGS. 93A-G show different views of an embodiment of a rear flange 7226e. The rear flange 7226e is similar to the rear flange 7226 except as described differently below. The features of the rear flange 7226e can be combined or included with the rear flange 7226 or any other embodiment discussed herein. FIG. 93A shows a front perspective view of the rear flange 7226e. FIG. 93B shows a rear perspective view of the rear flange 7226e shown in FIG. 93A.

(481) Referring to FIGS. 93A-B, the rear flange 7226e can include a collar 7362e, a first clip retaining recess 7364e, a second clip retaining recess 7336e, a plurality of locating features 7368e, a plurality of frame retaining members 7370e, and a rim 7372e to secure the seal 114e. In the illustrated embodiment, the locating features 7368e are similarly sized. However, this does not need to be the case. In some embodiments, the locating features 7368e are shaped differently from one another. In some embodiments, the locating features 7368e can be shaped differently from each other to reduce material used in manufacturing. The first clip retaining recess 7364e and the second clip retaining recess 7336e are adapted to cooperate with the first clip retaining projections 7354e and the second clip retaining projections 7356e respectively to allow the front and rear flanges 7224e, 7226e to be aligned and secured together with the correct spacing between the front and rear flanges 7224c, 7226e. The front and rear flanges 7224e, 7226e can then be welded together. In some embodiments, the first clip retaining projection 7354e is sized differently than the second clip retaining projection 7356e to prevent inversion or positioning upside down of the rear flange 7226e relative to the front flange 7224e.

(482) The orientation of one or more of the clip retaining projections and recesses can be reversed, with one or more of the projections being disposed on the rear flange 7226e and one or more of the recesses being disposed on the front flange 7224e. In some embodiments, the rear flange 7226e can include retaining projections instead of retaining recesses, and the front flange 7224e can include cooperating retaining recesses. In certain variants, there can be less than two corresponding recesses and projections to secure the front and rear flanges 7224e, 7226e.

(483) The frame retaining members 7370e allow the frame 116 (shown in FIG. 55) to be secured to the connector 7222e and the seal 114e via a push fit or interference fit system. The front flange

7224e and the rear flange 7226e can be closed together so that they secure the connector retaining structure 7262e of the seal 114e within the connector 7222e, as described below. In at least one embodiment, the rear flange 7226e can include only one frame retaining member 7370e. In some embodiments, the rear flange 7226e can include 3 or more frame retaining members 7370e.

(484) The locating features 7368e assist the manufacturing of the completed seal 114e and frame 116. The locating features 7368e fit into corresponding recesses adjacent to the perimeter of the gas inlet aperture 7175e of the seal 114e. The presence of these cooperating features allows the rear flange 7226e and the seal 114e to be easily aligned with one another. In at least one embodiment, the rear flange 7226e can include 2 or less locating features 7368e. In some embodiments, the rear flange 7226e can include 4 or more locating features 7368e.

(485) In at least one embodiment, after the rear flange 7226e, the seal 114e, and the front flange 7224e have been secured together, the rear flange 7226e can be bonded to the front flange 7224e so that the configuration of the connector 7222e and the seal 114e is substantially difficult to disassemble. The rear flange 7226e and the front flange 7224e can be bonded together through any appropriate means (e.g., RF welding, adhesive bonding, etc.).

(486) FIG. 93C is a front view of the rear flange 7226e. FIG. 93D is a left side view of the rear flange 7226e. FIG. 93E is a rear view of the rear flange 7226e. FIG. 93F is a top view of the rear flange 7226e. FIG. 93G is a bottom view of the rear flange 7226e.

(487) FIG. 94 shows a rear perspective view of the front flange 7224e attached to the rear flange 7226e. In the illustrated embodiment, the connector 7222e is formed by assembling the front flange 7224e and the rear flange 7226e. The seal 114e is not shown in FIG. 94.

(488) FIG. 95 shows a left side view of a cross-section of the assembled seal 114e and connector 7222e. The cross-sectional plane is the sagittal plane described above with regard to FIGS. 65A-C and 84. As shown in FIG. 95, the connector retaining structure 7262e of the seal 114e is secured between the front flange 7224e and the rear flange 7226e when the connector 7222e is assembled onto the seal 114e.

(489) FIG. 96 shows a zoomed in cross-section of an embodiment of the seal 114m on a plane parallel to the sagittal plane of a user. In the illustrated embodiment, the front flange 7224m and the rear flange 7226m fit together to secure the connector retaining structure 7262m of the seal 114m via interference fit. As a result, a user can disassemble the seal 114m, the front flange 7224m, and the rear flange 7226m as desired.

(490) FIG. 97 shows a cross section of an embodiment of a seal 114n, a front flange 7224n, and a rear flange 7226n. In the illustrated embodiment, the rear flange 7226n is welded to the front flange 7224n as shown by the weld 7380n. The connector 7222n is designed to be assembled in such a way that no plastic parts can break in normal use. This reduces the risk that a plastic component could break and be inhaled. The weld 7380n assists this because the connector 7222n must be broken to detach the connector 7222n from the seal 114n. The rear flange 7226n is sized such that an interference fit 7382n is formed with the seal 114n as indicated. The seal 114n is compressed at the indicated point of the interference fit 7382n to form the fit. This fit is beneficial in preventing foreign material from becoming lodged in crevasses of the apparatus. The weld 7380n shown in FIG. 97 can be a “shear weld.”

(491) FIG. 98 shows a cross section of an embodiment of a seal 114p, a front flange 7224p, and a rear flange 7226p. The rear flange 7226p is welded to the front flange 7224p, however the weld 7380p in the illustrated embodiment is a “face weld.”

(492) FIG. 99 shows a cross section of an embodiment of a seal 114q, a front flange 7224q, and a rear flange 7226q. The rear flange 7226q is welded to the front flange 7224q, however the weld 7380q is configured as shown. In the illustrated embodiment, the weld 7380q is a “shear weld.”

(493) A benefit of the connectors 7222 shown in FIGS. 96 and 97 is that gas flowing through central opening 7250 of the front flange 7224 can enter and exit the hollow interior of the seal 114 without encountering a ledge of the rear flange 7226. By contrast, in the connectors 7222 shown in

FIGS. 98 and 99, gas flowing through the central opening 7250 of the front flange 7224 will encounter a ledge or gap formed between the front flange 7224 and the rear flange 7226 in the vicinity of the weld 7380.

(494) Unless the context clearly requires otherwise, throughout the description and the claims, the words “comprise”, “comprising”, and the like, are to be construed in an inclusive sense as opposed to an exclusive or exhaustive sense, that is to say, in the sense of “including, but not limited to”. Conditional language used herein, such as, among others, “can,” “could,” “might,” “may,” “e.g.,” and the like, unless specifically stated otherwise, or otherwise understood within the context as used, is generally intended to convey that certain embodiments include, while other embodiments do not include, certain features, elements and/or states. Thus, such conditional language is not generally intended to imply that features, elements and/or states are in any way required for one or more embodiments or that one or more embodiments necessarily include logic for deciding, with or without author input or prompting, whether these features, elements and/or states are included or are to be performed in any particular embodiment.

(495) The term “plurality” refers to two or more of an item. Recitations of quantities, dimensions, sizes, formulations, parameters, shapes and other characteristics should be construed as if the term “about” or “approximately” precedes the quantity, dimension, size, formulation, parameter, shape or other characteristic. The terms “about” or “approximately” mean that quantities, dimensions, sizes, formulations, parameters, shapes and other characteristics need not be exact, but may be approximated and/or larger or smaller, as desired, reflecting acceptable tolerances, conversion factors, rounding off, measurement error and the like and other factors known to those of skill in the art. Recitations of quantities, dimensions, sizes, formulations, parameters, shapes and other characteristics should also be construed as if the term “substantially” precedes the quantity, dimension, size, formulation, parameter, shape or other characteristic. The term “substantially” means that the recited characteristic, parameter, or value need not be achieved exactly, but that deviations or variations, including for example, tolerances, measurement error, measurement accuracy limitations and other factors known to those of skill in the art, may occur in amounts that do not preclude the effect the characteristic was intended to provide.

(496) Numerical data may be expressed or presented herein in a range format. It is to be understood that such a range format is used merely for convenience and brevity and thus should be interpreted flexibly to include not only the numerical values explicitly recited as the limits of the range, but also interpreted to include all of the individual numerical values or sub-ranges encompassed within that range as if each numerical value and sub-range is explicitly recited. As an illustration, a numerical range of “1 to 5” should be interpreted to include not only the explicitly recited values of about 1 to about 5, but should also be interpreted to also include individual values and sub-ranges within the indicated range. Thus, included in this numerical range are individual values such as 2, 3 and 4 and sub-ranges such as “1 to 3,” “2 to 4” and “3 to 5,” etc. This same principle applies to ranges reciting only one numerical value (e.g., “greater than 1”) and should apply regardless of the breadth of the range or the characteristics being described.

(497) A plurality of items may be presented in a common list for convenience. However, these lists should be construed as though each member of the list is individually identified as a separate and unique member. Thus, no individual member of such list should be construed as a de facto equivalent of any other member of the same list solely based on their presentation in a common group without indications to the contrary. Furthermore, where the terms “and” and “or” are used in conjunction with a list of items, they are to be interpreted broadly, in that any one or more of the listed items may be used alone or in combination with other listed items. The term “alternatively” refers to selection of one of two or more alternatives, and is not intended to limit the selection to only those listed alternatives or to only one of the listed alternatives at a time, unless the context clearly indicates otherwise.

(498) Reference to any prior art in this specification is not, and should not be taken as, an

acknowledgement or any form of suggestion that that prior art forms part of the common general knowledge in the field of endeavour in any country in the world.

(499) Where, in the foregoing description reference has been made to integers or components having known equivalents thereof, those integers are herein incorporated as if individually set forth.

(500) The invention may also be said broadly to consist in the parts, elements and features referred to or indicated in the specification of the application, individually or collectively, in any or all combinations of two or more of said parts, elements or features.

(501) It should be noted that various changes and modifications to the presently preferred embodiments described herein will be apparent to those skilled in the art. Such changes and modifications may be made without departing from the spirit and scope of the invention and without diminishing its attendant advantages. For instance, various components may be repositioned as desired. It is therefore intended that such changes and modifications be included within the scope of the invention. Moreover, not all of the features, aspects and advantages are necessarily required to practice the present invention. Accordingly, the scope of the present invention is intended to be defined only by the claims that follow.

Claims

1. A nasal seal, comprising: a seal body defining a breathing chamber, the seal body configured to receive a user's nose and sealingly contact an underside of the user's nose; a nasal port in the seal body positioned beneath the nares of wearer; and wherein the nasal seal comprises a pair of thickened wall portions that, in use, contact the user's cheeks, wherein the pair of thickened wall portions each extend into a bottom wall of the seal body, the thickened wall portions each having a wall thickness that is greater than a wall thickness of adjacent portions of the seal body, the thickened wall portions each comprising a groove defined within the thickened wall portion that allows decoupled movement of portions of the thickened wall portion on opposing sides of the groove, wherein each groove extends laterally into and has an end located within the bottom wall of the seal body, wherein the ends of the grooves are separated from one another by a region of increased thickness in the bottom wall.
2. The nasal seal of claim 1, wherein the nasal port comprises a central portion positioned between a pair of lateral portions, the nasal port further comprising an upper edge and a lower edge; wherein the lower edge defines an inwardly projecting portion within the central portion.
3. The nasal seal of claim 2, wherein the inwardly projecting portion is curved.
4. The nasal seal of claim 1, wherein the nasal port is kidney-shaped or bowtie-shaped.
5. The nasal seal of claim 1, further comprising a thickened rim portion extending around a portion or an entirety of a periphery of the nasal port, the thickened rim portion having a larger wall thickness than a portion of the seal body immediately adjacent the thickened rim portion.
6. The nasal seal of claim 1, wherein the seal body comprises a central portion positioned between a pair of lateral portions, wherein in use the seal body is configured such that the lateral portions move inwardly when pressure is applied to the central portion by a user.
7. The nasal seal of claim 1, wherein a user-facing surface of the nasal seal comprises a thinned wall portion.
8. The nasal seal of claim 7, wherein the thinned wall portion of the user-facing surface has or is equal to the smallest wall thickness of the seal body.
9. The nasal seal of claim 1, wherein the wall thickness of the thickened wall portions define or are equal to a largest wall thickness of the seal body.
10. The nasal seal of claim 1, further comprising a connector configured to allow the nasal seal to be coupled to a frame, wherein the connector comprises a first portion within the seal body and a second portion outside of the seal body, wherein the first portion and the second portion are

coupled to one another.

11. The nasal seal of claim 10, wherein the first portion comprises a flange and a hub, wherein the hub extends through an aperture of the seal body and wherein the second portion is coupled to the hub of the first portion.

12. The nasal seal of claim 11, wherein the seal body comprises a rim extending partially or entirely around the aperture, wherein the rim is captured between the first portion and the second portion.

13. The nasal seal of claim 12, wherein the rim comprises a generally T-shaped cross-section having a base, a first lobe extending in a first direction from the base and a second lobe extending in a second direction from the base opposite the first direction.

14. The nasal seal of claim 13, wherein each of the first portion and the second portion of the connector comprises a recess configured to receive a respective one of the first lobe and the second lobe.

15. The nasal seal of claim 10, wherein the seal body and the connector comprise interfering portions that inhibit or prevent relative rotation between the seal body and the connector.

16. The nasal seal of claim 1, wherein the seal body has a first texture on a user-contacting side and a second texture on the opposite side, wherein the second texture is different from the first texture.

17. The nasal seal of claim 1, wherein a portion of each of the thickened wall portions define a rearward-facing surface of the seal body configured to contact the user's cheeks.

18. The nasal seal of claim 1, wherein a depth of the groove is less than the wall thickness of the thickened wall portion.

19. The nasal seal of claim 1, wherein the region of increased thickness in the bottom wall comprises a pair of struts.

20. The nasal seal of claim 19, wherein each of the pair of struts is located at the end of one of the grooves.

21. The nasal seal of claim 20, further comprising a sub-nasal groove located in the bottom wall of the seal body between the pair of struts.

22. The nasal seal of claim 19, wherein each of the pair of struts has a wall thickness that is different than a wall thickness of an adjacent portion of a front wall and a rear wall of the seal body.
