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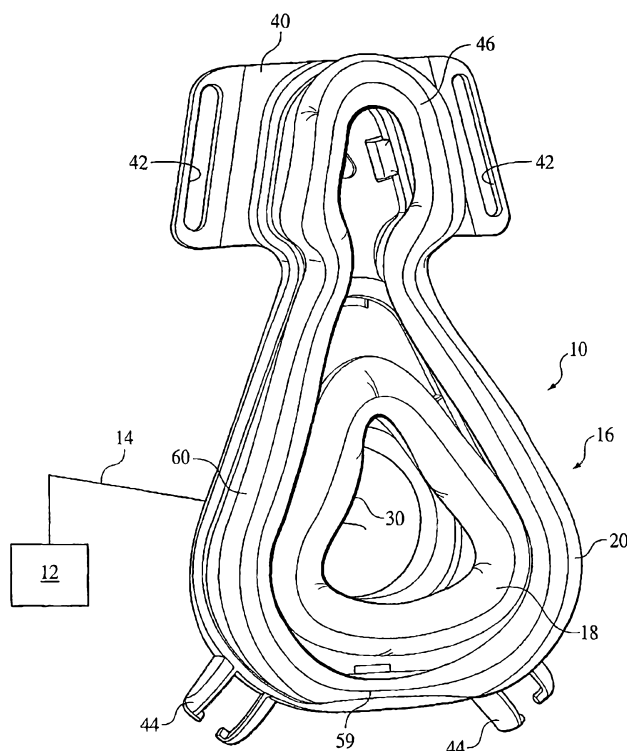
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[Continued on next page]

(54) Title: CUSHION INSIDE A CUSHION PATIENT INTERFACE



(57) Abstract: A patient interface device (10, 87, 120, 200) including a cushion assembly having a cushion-in-a-cushion arrangement and a system for supplying a flow of gas to a patient using such an interface device. The patient interface includes a mask shell (22, 122, 222) having a patient side and an outer side opposite the patient side adapted for receiving a supply of gas. A seal cushion (18, 136, 218) contacts a first area of a patient's face to form a seal therewith. A support cushion (20, 138, 220) encircles at least a portion of the seal cushion and includes a first end portion that contacts a second area of a patient's face.



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CUSHION INSIDE A CUSHION PATIENT INTERFACE

PRIORITY CLAIM

- [01] Under the provisions of 35 U.S.C. § 119(e), this application claims the benefit of U.S. Provisional Application Serial No. 60/670,806, filed April 13, 2005.

TECHNICAL FIELD

- [02] The present invention generally relates to a patient interface device for use in a pressure support system that supplies a flow of gas to the airway of a patient, and, in particular to a patient interface device that includes dual-cushion support and to a pressure support system that includes such a patient interface device.

BACKGROUND OF THE INVENTION

- [03] There are numerous situations where it is necessary or desirable to deliver a flow of breathing gas non-invasively to the airway of a patient, i.e., without intubating the patient or surgically inserting a tracheal tube in their esophagus. For example, it is known to ventilate a patient using a technique known as non-invasive ventilation (NIV). It is also known to deliver continuous positive airway pressure (CPAP) or variable airway pressure, such as a bi-level pressure that varies with the patient's respiratory cycle or an auto-titrating pressure that varies with the monitored condition of the patient. Typical pressure support therapies are provided to treat a medical disorder, such as sleep apnea syndrome, in particular, obstructive sleep apnea (OSA), chronic obstructive pulmonary disease (COPD), or congestive heart failure (CHF).

- [04] Non-invasive ventilation and pressure support therapies involve the placement of a patient interface device, which is typically a nasal or nasal/oral mask, on the face of a patient to interface the ventilator or pressure support system with the airway of the patient so that a flow of breathing gas can be delivered from the pressure/flow generating device to the airway of the patient. It is known to maintain such masks on the face of a patient by a headgear having upper and lower straps, each having opposite ends threaded through connecting elements provided on the opposite sides and top of a mask.

- [05] Typically patient interface devices include a mask shell having a cushion attached to the shell that contacts the surface of the patient. The mask shell and cushion are held in place by a headgear that wraps around the head of the patient. The mask and

headgear form the patient interface assembly. A typical headgear includes flexible, adjustable straps that extend from the mask to attach the mask to the patient.

[06]

Because such masks are typically worn for an extended period of time, a variety of concerns must be taken into consideration. For example, in providing CPAP to treat OSA, the patient normally wears the patient interface device all night long while he or she sleeps. One concern in such a situation is that the patient interface device is as comfortable as possible, otherwise the patient may avoid wearing the interface device, defeating the purpose of the prescribed pressure support therapy. It is also important that the interface device provide a tight enough seal against a patient's face without discomfort. A problem arises in that in order for the mask to maintain a seal without any undue gas leaks around the periphery of the mask, the mask may be compressed against the patient's face.

[07]

Many patient interface devices have been developed that attempt to balance the competing interests of patient comfort versus minimizing leakage. In addressing this issue, many patient interface devices have focused on the design of the cushion. Early cushion designs were typically a flap of material or a balloon, i.e., air-filled cushion, that contacted the face of the user. Further design developments including contouring the patient contacting portion of the cushion and/or making the seal customizable to the surface or underlying tissues of the user. Still further cushions have employed multiple flaps so that the outermost flap provides a sealing function. See, e.g., U.S. Patent No. 4,791,051 to Toffolon.

[08]

Although these conventional patient interface devices have advanced the art, the need still exists for a patient interface device that improves upon existing devices, for example, to maximize patient comfort while minimizing leak, during delivery of a positive airway pressure or flow of gas to the airway of the user. For example, many conventional patient interface devices tend to focus the strapping force applied on the patient to a relative small area of the patient's face around the nose, mouth, or both. Existing patient interfaces also may not provide a stable platform that supports the cushion on the patient's face.

[08a]

Throughout this specification the word "comprise", or variations such as "comprises" or "comprising", will be understood to imply the inclusion of a stated

element, integer or step, or group of elements, integers or steps, but not the exclusion of any other element, integer or step, or group of elements, integers or steps.

[08b]

Any discussion of documents, acts, materials, devices, articles or the like which has been included in the present specification is not to be taken as an admission that any or all of these matters form part of the prior art base or were common general knowledge in the field relevant to the present invention as it existed before the priority date of each claim of this application.

DISCLOSURE OF THE INVENTION

[09]

In a first aspect the invention provides a patient interface device for use in delivering a flow of gas to an airway of a patient, the patient interface device comprising:

a mask shell having a patient side and an outer side opposite the patient side adapted for receiving a flow of gas;

a seal cushion having a first end portion defining a first perimeter and adapted to contact a first area of a patient's face to form a seal therewith and a second end portion opposite the first end portion, the seal cushion further including a cavity adapted to receive a portion of the patient's face, wherein the flow of gas communicates with the cavity; and

a support cushion having a first end portion defining a second perimeter and adapted to contact a second area of a patient's face and a second end portion opposite the first end portion, wherein the first perimeter is disposed within the second perimeter, and wherein the second end portion of the seal cushion and the second end portion of the support cushion are coupled to the patient side of the mask shell. In particular, the gas entering the mask for delivery to the user is received in this cavity. The support cushion may encircle the first perimeter.

[10]

In a second aspect, the invention provides a system for delivering a flow of gas to a patient comprising:

(a) a gas flow generating device that produces a flow of gas;

(b) a conduit having a first end portion operatively coupled to the gas flow generating device and a second end portion, wherein the conduit carries the flow of gas from the gas flow generating device during operation of the system; and

(c) a patient interface device comprising:

(1) a mask shell having a patient side and an outer side opposite the patient side, wherein the second end portion of the conduit is coupled to the mask shell,

(2) a seal cushion having a first end portion defining a first perimeter and adapted to contact a first area of a patient's face to form a seal therewith and a second end portion opposite the first end portion, the seal cushion further including a cavity adapted to receive a portion of the patient's face, wherein the flow of gas communicates with the cavity, and

(3) a support cushion having a first end portion defining a second perimeter and adapted to contact a second area of a patient's face and a second end portion opposite the first end portion, wherein the first perimeter is disposed within the second perimeter, and wherein the second end portion of the seal cushion and the second end portion of the support cushion are coupled to the patient side of the mask shell.

10a] In a third aspect, the invention provides a patient interface device for use in delivering a flow of gas to an airway of a patient, the patient interface device comprising:

a mask shell having a patient side and an outer side opposite the patient side adapted for receiving a flow of gas;

a seal cushion having a first end portion defining a first perimeter and adapted to contact a first area of a patient's face to form a seal therewith and a second end portion opposite the first end portion, the seal cushion further including a cavity adapted to receive a portion of the patient's face, wherein the flow of gas communicates with the cavity, and wherein the seal cushion overlies a first area on such patient when donned by such a patient; and

a support cushion having a first end portion defining a second perimeter and adapted to contact a second area of a patient's face and a second end portion opposite the first end portion, wherein the first perimeter is disposed within the second perimeter, wherein the second end portion of the seal cushion and the second end portion of the support cushion are coupled to the patient side of the mask shell, wherein the support cushion overlies a second area on such patient when donned by such a patient, and wherein the second area overlaps at least a major portion of the first area.

10b)

In a further aspect, the invention provides a patient interface device for use in delivering a flow of gas to an airway of a patient, the patient interface device comprising:

a mask shell having a patient side and an outer side opposite the patient side adapted for receiving a flow of gas;

a seal cushion having a first end portion adapted to contact a first area of a patient's face to form a seal therewith and a second end portion opposite the first end portion, wherein a first opening is defined in the first end portion, wherein the seal cushion further includes a cavity adapted to receive a portion of the patient's face through the first opening, and wherein the flow of gas communicates with the cavity; and

a support cushion having a first end portion adapted to contact a second area of a patient's face and a second end portion opposite the first end portion, wherein a second opening is defined in the first end portion of the support cushion, wherein the second end portion of the seal cushion and the second end portion of the support cushion are coupled to the patient side of the mask shell, and wherein the first opening is disposed within the second opening.

[11]

These features and characteristics of the present invention, as well as the methods of operation and functions of the related elements of structure and the combination of parts and economies of manufacture, will become more apparent upon consideration of the following description and the appended claims with reference to the accompanying drawings, all of which form a part of this specification, wherein like reference numerals designate corresponding parts in the various figures. It is to be expressly understood, however, that the drawings are for the purpose of illustration and description only and are not intended as a definition of the limits of the invention. As used in the specification and in the claims, the singular form of "a", "an", and "the" include plural referents unless the context clearly dictates otherwise.

BRIEF DESCRIPTION OF THE DRAWINGS

[12]

FIG. 1 is a perspective view of a patient interface device according to the principles of the present invention shown (schematically) connected to a gas flow/pressure generating system;

[13]

FIG. 2 is an exploded view of the patient interface device of FIG. 1;

[14]

FIG. 3 is a front view of the patient interface device of FIG. 1;

15]

FIG. 4 is a sectional view of the patient interface device of FIG. 1 taken along line 4-4 of FIG. 3;

16]

FIG. 5 is an exploded view of a patient interface device according to a second embodiment of the present invention;

- [17] FIG. 6 is a front view of the patient interface device of FIG. 5;
- [18] FIG. 7 is a sectional view of the patient interface device of FIG. 5 taken along line 7-7 of FIG. 6;
- [19] FIG. 8 is a side sectional view of the patient interface device of FIG. 5;
- [20] FIGS. 9 and 10 are front and rear perspective views, respectively, of a patient interface device according to third embodiment of the present invention;
- [21] FIG. 11 is a detailed sectional view showing an exemplary technique for attaching a seal member to a flexible connecting member; and
- [22] FIG. 12 is a side sectional view of a patient interface device according to fourth embodiment of the present invention.

BEST MODE(S) FOR CARRYING OUT THE INVENTION

- [23] In describing the illustrated exemplary embodiments of the present invention, the terms “upper” and “lower” refer to the orientation of the mask as illustrated in the accompanying drawings. FIGS. 1-4 illustrate an exemplary first embodiment of a patient interface device 10 according to the principles of the present invention. Patient interface device 10 communicates a flow of breathing gas between the patient's airway and a pressure/flow generating system 12, such as a ventilator, CPAP device, or variable pressure device, e.g., a BiPAP® device manufactured and distributed by Respirationics, Inc. of Pittsburgh, PA, or an auto-titration pressure support system.
- [24] A BiPAP® device is a bi-level device in which the pressure provided to the patient varies with the patient's respiratory cycle, so that a higher pressure is delivered during inspiration than during expiration. An auto-titration pressure support system is a system in which the pressure varies with the condition of the patient, such as whether the patient is snoring or experiencing an apnea or hypopnea. For present purposes, pressure/flow generating system 12 is also referred to as a gas flow generating device, because flow results when a pressure gradient is generated. The present invention contemplates that pressure/flow generating system 12 is any conventional system for delivering a flow of gas to an airway of a patient or for elevating a pressure of gas at an airway of the patient, including the pressure support systems summarized above and non-invasive ventilation systems.
- [25] Communicating a flow of breathing gas between the patient's airway and pressure/flow generating system 12 includes delivering a flow of breathing gas to the

patient from the pressure/flow generating device and exhausting a flow of gas from the patient to ambient atmosphere. The system for delivering a breathing gas to a patient according to the present invention comprises the pressure/flow generating system that produces a flow of gas, and a conduit 14, which is also referred to as a patient circuit, having a first end portion operatively coupled to the gas flow generating device and a second end portion. Conduit 14 carries the flow of gas from pressure/flow generating device 12 during operation of the system to patient interface device 10, which is coupled to the second end portion of the conduit. Conduit 14 corresponds to any conduit suitable for communicating the flow of gas from the pressure/flow generating system to the patient interface device. A typical conduit is a flexible tube. A headgear assembly, which is not shown in the figures, attaches patient interface device 10 to the patient's head.

[26] Patient interface device 10 includes a cushion assembly, generally indicated at 16, that includes an inner seal member or seal cushion 18 and an outer support member or support cushion 20. The patient interface device also includes a mask shell 22 and a conduit coupling member (not illustrated) that couples the mask shell to conduit 14 so that a flow of gas is communicated to the interior of the patient interface device for subsequent delivery to the patient. Conversely, gas from the patient is communicated from the patient interface device into the conduit, where an exhaust port is located.

[27] In the illustrated exemplary embodiment, seal cushion 18 corresponds, in general, to the cushion described in U.S. Patent Nos. 6,651,663 and 6,729,333, the contents of which are incorporated herein by reference. As perhaps best shown in FIG. 2, seal cushion 18 has a generally triangular shape and is defined from a unitary piece of soft, cushiony, elastomeric material, such as silicone, appropriately soft thermoplastic elastomers, closed cell foam, thin materials, or any combination of such materials. Seal cushion 18 has a first end portion 24 and a second end portion 26 generally opposite the first end portion. A nose receiving cavity 28 is defined in the interior of the inner seal member by a side walls 29.

[28] First end portion 24 is adapted to contact an inner perimeter area of the patient's face and includes a first opening 30 to allow passage of at least a portion of the patient's nose into nose receiving cavity 28. In the illustrated exemplary embodiment, first end portion 24 is contoured to match the generally facial features of a human. Seal cushion 18 includes a base portion 32 defined in second end portion 26 and a second

opening 34 defined in base portion 32. First end portion 24 of seal cushion 18 includes a first in-turned flap 35 that has a distal edge, which is generally turned into nose receiving cavity 28, and a second in-turned flap 37, which also has a distal edge that is generally turned into the nose receiving cavity. In the illustrated exemplary embodiment, flap 35 contacts the surface of the patient and deflects toward the nose receiving cavity.

[29] Flap 35 extends around the perimeter of the first end portion and is relatively flexible to provide a leak resistant seal over the patient contacting area of the seal cushion. Flap 37 extends around a large portion of the perimeter of the first end portion, but is not present or is reduced in the area of the seal cushion that overlies the bridge of the user's nose. Flap 37 is relatively more stiff than flap 35 to provide support for seal cushion as it is compressed. The stiffness of flap 37 and its separation from flap 35 establish the degree of support provided by flap 37. Where less support is needed, such as at the bridge of the nose (and where sealing can be difficult) the distance between flap 35 and flap 37 is increased, for example by removing flap 37 in this area. It can thus be appreciated that a variety of different configurations for flaps 35 and 37 can be employed in the cushions of the present invention.

[30] Mask shell 22 is a generally rigid shell, and, in an exemplary embodiment of the present invention is formed from rigid plastic, such as polycarbonate. Mask shell 22 includes a patient side 36 and opposite thereto, an outer side 38. Attached to outer side 38 of mask shell 22 is a conduit coupling member (not illustrated) for coupling the patient interface device to delivery conduit 14.

[31] In this embodiment, mask shell 22 has a generally triangular shape having a forehead support portion 40 that includes headgear attaching elements in the form of receiving holes or slots 42 disposed on either side of the upper forehead support portion for receiving headgear straps (not illustrated). In the illustrated embodiment, the lower corners of mask shell 22 also include headgear attaching elements in the form of socket attachment elements 44, which cooperate with corresponding ball elements (not illustrated) on headgear straps. The ball and socket configuration, and other headgear attachment configurations suitable for use with the present invention, are disclosed in co-pending U.S. Patent Application No. 10/629,366 (U.S. Pub. No. US-2004-0025883-A1), the contents of which are incorporated herein by reference. It is to be understood that the

present invention contemplates using any conventional connection assembly to attach a headgear or headgear strap to mask shell 22 in this or any of the other embodiments.

[32] The present invention contemplates that the headgear suitable for use with patient interface device 10 is any conventional headgear used in the patient interface field. For example, a typical headgear assembly comprises a headpiece that overlies a portion of the patient's crania and with headgear straps extending therefrom to adjustably connect the headgear to the mask.

[33] In the illustrated embodiment, seal cushion 18 is a nasal cushion, meaning that it seals around the nose of the user. It is to be understood, however, that the present invention contemplates that the seal cushion can seal around any portion of the patient. For example, the seal cushion can be a nasal pillow or nasal cannula that seal against the nose, an oral/nasal seal that seals around the mouth and nose, or an oral seal that seals around the mouth.

[34] Support cushion 20 has a generally triangular shape having an elongated upper corner. Support cushion 20 surrounds or encircles side walls 29 of seal cushion 18 and includes an integrated forehead support portion 46 at its upper extent. Support cushion 20 is preferably similar in form to a conventional mask cushion, such as a nasal or oral/nasal mask, which contacts the perimeter of a patient's facial area. Support cushion 20 is preferably formed from a unitary piece of soft, cushiony, elastomeric material, such as silicone, appropriately soft thermoplastic elastomers, or gel materials. The flexibility of the material as well as the geometry will allow support cushion 20 to conform to the patient's facial contours in a passive manner without noticeable adjustment.

[35] Seal cushion 18 is structured to have a slightly higher profile than support cushion 20, see, e.g., FIG. 4. In use, seal cushion 18 will compress slightly to form a seal with the patient's face, while support cushion 20 will provide support over a relatively larger perimeter area on the patient. This relatively large patient contacting area of the support cushion widely distributes the compressive forces acting on the patient interface device to secure the patient interface device against the surface of the user.

[36] Integrated forehead support portion 46 of support cushion 20 eliminates the need for a separate forehead cushion, as found in many commercially available masks. Forehead support portion 46 achieves a comfortable support for the forehead passively and without active adjustment, allowing an infinite number of position adjustments. The

present invention, however, contemplates that support cushion 20 is formed without a forehead support portion such that the support stands-alone supporting the nose or oral-nasal perimeter areas only.

[37] Support cushion 20 has a first end portion 48 and a second end portion 50 generally opposite the first end portion. A seal cushion receiving cavity 52 is defined by side walls 54. First end portion 48 is adapted to generally contact an outer perimeter area of the patient's face, but is not necessarily in contact with the entire outer perimeter. That is, support cushion 20 need not serve as sealing member and does not provide a leak resistant seal for the flow of gas to the airway of the patient. Nevertheless, the present invention contemplates that the support cushion and the seal cushion can have similar configurations and be made from similar materials or combinations of materials. For example, support cushion 20 can include multiple flaps, lips, or rims at first end portion 48 and the first end portion can be contoured to match the facial features of a human, in general.

[38] First end portion 48 also includes an in-turned flap 56, which is generally turned into seal cushion receiving cavity 52. The present invention also contemplates forming support cushion 20 from a solid formation, for example, from a gel material, or from a combination of materials. First end portion 48 also includes a dip portion 58 between forehead support portion 46 and a lower portion 60 of support cushion 20. Dip portion 58 segregates forehead portion 46 and lower portion 60 from each other to provide individual passive adjustment of the two portions. Dip portion 58 does not need to be in sealing contact with the patient's facial area. Support cushion 20 further includes a bottom portion 59 having a contoured area that also does not need to be in sealing contact with the patient's facial area. The two side areas of lower portion 60 provide most of the support.

[39] Forehead support portion 46 further includes an integrated grooved area 62 or pleat defined in side wall 54 of forehead support portion 46 of support cushion 20. Grooved area 62 provides a floating affect to provide stability. Side wall 54 has an area 64 below grooved area 62 that is substantially thicker than the area above it to provide support. A cushion having this type of grooved area is described in co-pending U.S. provisional patent application no. 11/312,026, the contents of which are incorporated herein by reference.

[40] In the embodiment illustrated in FIGS. 1-4, seal cushion 18 and support cushion 20 are coupled together and are coupled to mask shell 22 by a mounting member 66. Mounting member 66 has a shape corresponding generally to that of support cushion 20 and mask shell 22, and includes a patient side 68 and opposite thereto, an outer side 70 with a sidewall 72 therebetween. Outer side 70 includes multiple snap attachment features 74a, which are receivable in corresponding snap attachment features 74b on patient side 36 of mask shell 22. In the present embodiment, mounting member 66 is defined from a relative rigid material.

[41] Mounting member 66 includes a forehead portion 76 and a lower portion 78. The sidewall 72 of lower portion 78 includes an outwardly extending lip 80. Sidewall 72 of forehead portion 76 also includes an outwardly extending lip 82. The inner perimeter of support cushion 20 is coupled to the outer perimeter of mounting member 66, and lips 80, 82 are insertable into corresponding grooves provided on forehead portion 46 and lower portion 60 of support cushion 20. These grooves correspond to grooves 84, 85 shown in FIG. 6. The present invention contemplates using any suitable numbers of snap attachment features and other mechanical or non-mechanical means for attaching the mounting member to mask shell 22. The present invention further contemplates other mechanical or non-mechanical means for attaching support cushion 20 to mounting member 66, such as by gluing.

[42] Mounting member 66 further includes a triangular-shaped angled wall 86 extending from its patient side. Angled wall 86 is insertable into the interior of base portion 32 of seal cushion 18 to secure the seal cushion to the mounting member. The present invention contemplates other mechanical or non-mechanical means for attaching seal cushion 18 to mounting member 66 such as by gluing.

[43] The arrangement between mounting member 66 and mask shell 22 provides a reservoir 69 between these two elements. This reservoir effectively functions as a water trap for any water or other fluid that may enter the mask from conduit 14. This is perhaps best illustrated in FIG. 8. Water or other fluid may condense on the walls of conduit 14, especially when a humidifier is used in the pressure/flow generating system. This fluid may flow toward the mask as indicated by arrow A and collect in reservoir 69. Thus, reservoir 69 effectively functions as a water trap to prevent or minimize the change of fluid contacting the user. A mask having such features is disclosed in copending U.S.

provisional patent application no. 11/300,052, the contents of which are incorporated herein by reference.

[44] An alternative exemplary embodiment of a patient interface device 87 according to the principles of the present invention is illustrated in FIGS. 5-8. In this embodiment, many features are similar to those illustrated in FIGS. 1-4. Thus, the description of this embodiment will focus primarily on the features of the patient interface device unique to each embodiment. This alternative embodiment is provided primarily to show a different possible configuration for coupling the cushions to the mask shell. It is to be understood, however, that the present invention contemplates other configurations for the patient interface components and mixing and matching of the features of the patient interface devices illustrated in all of these embodiments.

[45] Like in the embodiment of FIGS. 1-4, patient interface device 87 includes a seal cushion 18, support cushion 20, and a mask shell 22. In this exemplary embodiment, seal cushion 18 and support cushion 20 are coupled together and to mask shell 22 by a rigid holding member 88, a retaining ring 90, and a flexible connecting member or rolling diaphragm 100. Rolling diaphragm 100 corresponds to the rolling diaphragm disclosed in co-pending U.S. provisional patent application no. 11/374,580 (the '580 application), the contents of which is incorporated by reference herein.

[46] Rolling diaphragm 100 according to the present invention is operatively connected between seal cushion 18 and mask shell 22. In the illustrated embodiment, rolling diaphragm 100 is generally triangular in shape and includes a substantially concentric outer rim 102 and inner rim 104. A rolling element in the form of a flexible wall or membrane 106 extends between the outer and inner rims. Rolling diaphragm 100 is preferably molded of a high modulus thermal plastic elastomer or rubbery material to provide the desired flexibility. The material may be the same or different material than the one used for the seal cushion 18 or support cushion 20. In the illustrated embodiment, flexible wall or membrane 106 has a generally uniform thickness and a substantially U-shaped cross-section when not under pressure, e.g., when a flow of gas is not being delivered to the patient interface device. Rolling diaphragm 100 changes its shape depending on the force imparted to it through seal cushion 18 or mask shell 22 so that the position of the seal cushion relative to the mask shell can change. The U-shaped flexible membrane 106 is pointed away from mask shell 22.

- [47] Rolling diaphragm 100 isolates the forces and acts as a buffer between seal cushion 18 and mask shell 22. Rolling diaphragm 100 also acts as a flexible joint allowing relative angular and displacement movement between seal cushion 18 and mask shell 22. This allows the seal cushion to self-align on the surface of the patient when the patient interface device is donned by the user. Rolling diaphragm 100 also isolates seal cushion 18 from movement of the patient's head or support cushion 20 and displacement of the conduit tubing or headgear.
- [48] Outer rim 102 of rolling diaphragm 100 includes an annular flange 108 extending substantially perpendicularly from flexible wall membrane 106 of rolling diaphragm 100. Rolling diaphragm 100 of this illustrated embodiment further includes a plurality of rectangular holes or slots 112 spaced on annular flange 108. Seal cushion 18 is attached to rolling diaphragm 100 by retaining ring 90, which also has an outer annular groove 114 for receiving inner rim 104 of rolling diaphragm 100. Holding member 88 includes a plurality of snap attachment features 116, some of which are insertable through rectangular holes 112 and then receivable in corresponding snap attachment features 74c on patient side 36 of mask shell 22. Other snap attachment features 116 on a forehead portion 118 of holding member 88 are receivable directly in the corresponding snap attachment features 74d on forehead support portion 40 of mask shell 22.
- [49] The present invention contemplates alternative techniques for coupling the rolling diaphragm to the mask shell, many of which are described in the '580 application. The present invention further contemplates that rolling diaphragm 100 can have alternative shapes, can be formed from different materials or combinations of materials, and/or can have variations in dimensions over the overall diaphragm. Many such alternatives are disclosed in the '580 application.
- [50] FIGS. 9 and 10 illustrate a third exemplary embodiment of a patient interface device 120 according to the principles of the present invention. In this embodiment, many features are similar to those illustrated in FIGS. 1-8. Thus, the description of this embodiment will focus primarily on the features of the patient interface device unique to each embodiment. This alternative embodiment is provided primarily to show a different possible configuration for the mask shell. This embodiment also shows that the cushion inside a cushion arrangement can be provided without the forehead portion. That is the cushion inside a cushion technique can be limited to a seal used to seal

the supply of gas to the user's airway, and need not extend to the forehead as shown in previous embodiments. Again, it should be noted that the present invention contemplates other configurations for the patient interface components and mixing and matching of the features of the patient interface devices illustrated in all of these embodiments.

[51] Patient interface device 120 includes a mask shell 122 having a forehead support assembly 124. In the illustrated embodiment, forehead support 124 includes a support arm 126, a forehead support bracket 128 coupled to the support arm, and a forehead pad 130 coupled to the support bracket. In the illustrated exemplary embodiment, support arm 126 is adjustably coupled to mask shell 122 such that the arm is movable along an arcuate path with respect to the mask shell, as indicated by arrow B. This allows the position of the forehead support bracket to be adjusted by the user for optimum comfort. Forehead support bracket 128 is also movable relative to the support arm as indicated by arrow C. This allows the forehead pad to automatically move the optimum patient contacting position when the patient interface device is donned by the user. Headgear attachments 132 are provided on each side of the forehead support bracket.

[52] A patient interface device having many similar, if not identical features (other than the cushion inside a cushion concept of the present invention), is described in U.S. patent application no. 10/654,379 (U.S. Pub. No. US-2004-0045551-A1) the contents of which are incorporated herein by reference. It can further be appreciated that the forehead support and the components thereof, can any one of a variety of different, shapes, sizes, and configurations so long as the forehead support function is achieved. For example, the forehead pad can have other shapes, materials, combination of materials, sizes, and configuration. Similarly, the mask shell can have any one of a variety of different, shapes, sizes, and configurations, and can include additional features, such as headgear attachment portions, one or more exhaust assemblies, patient circuit connectors, or any combination thereof. Moreover, the present invention also contemplates a rigid coupling between support arm 126 and mask shell 122, between support arm 126 and support bracket 128, or both.

[53] The present invention also contemplates eliminating the forehead support entirely, so that the patient interface device is supported on the patient by a cushion assembly 134, which is attached to the mask shell. If the forehead support is eliminated, a

headgear attachment can be provided at the upper apex of the mask shell. The present invention also contemplates providing a post or other protrusion at the upper portion of the shell, i.e., the portion overlying the bridge of the nose, to which the headgear can be attached.

[54] The present invention further contemplated providing a chin support assembly (not shown) that extends from the mask shell and contacts the user's chin or mandible. The chin support assembly can be have the same or a similar configuration to the forehead support, but extending from the lower portion of the mask to contact the user below the lips, i.e., on the chin or mandible. U.S. patent application no. 10/953,642 (U.S. Pub. No. US-2005-0072428-A1), the contents of which are incorporated herein by reference, describes examples of such chin support assemblies suitable for use in the present invention. The chin support assembly can be used alone or in combination with the forehead support assembly.

[55] A cushion assembly 134 is coupled to mask shell 122. Cushion assembly 134 corresponds to any of the cushion assemblies described above, and includes an inner seal member or seal cushion 136 and an outer support member or support cushion 138. The seal cushion and support cushion can be coupled together using any of the techniques described herein, including a relatively rigid attachment (see FIG. 1-4) or a flexible attachment (see FIGS. 5-8).

[56] FIG. 11 is a detailed sectional view showing another technique for attaching a seal member 150 to a flexible connecting member 152. In this embodiment, the seal member is molded or otherwise bonded to a seal ring 154, and the flexible connecting member is molded or otherwise bonded to a connecting member ring 156. In an exemplary embodiment, the present invention contemplates overmolding seal 150 on ring 154 and overmolding flexible connecting member 152 on connecting member ring 156. Seal ring 154 and connecting member ring 156 are sized, configured, and arranged such that a wall of the seal ring abuts or is close to a wall of the connecting member ring at a junction indicated by reference numeral 158. These walls are joined together using any conventional technique, such as sonic welding. Of course, friction alone can be used to maintain the rings in an assembled relation. It is to be understood that other configurations for the rings and ring/seal or ring/flexible member coupling are contemplated by the present invention.

[57] A fourth embodiment of a patient interface device 200 according to the principles of the present invention is illustrated in FIG. 12. Patient interface device 200 is generally similar to that shown in FIG. 8 except for the at rest positioning of seal cushion 218 relative to support cushion 220. In this exemplary embodiment, seal cushion 218 is defined in a plane 216 that is disposed at an angle θ with respect to a plane 219 defined by another portion of the patient interface device, such as shell 222 or support cushion 220. This is done to preposition seal cushion 218 so that the angle of attack on the face of the user is optimized. In an exemplary embodiment of the present invention, angle θ ranges from zero to fifteen degrees (0-15°). In this embodiment, the angle is provided by configuring a rolling diaphragm 230 in such a way that causes the tilt. Of course, other techniques for controlling the position of and/or pre-positioning the seal cushion relative to the support cushion, the shell, or other portion of the patient interface device are contemplated by the present invention.

[58] In the illustrated embodiments, the seal cushion and support cushion are configured/arranged such that an outer (distal) edge of the seal cushion extends beyond the outer (distal) edge of the support cushion. This protrusion of the seal cushion out from the rim of the support cushion is illustrated by distance x in FIG. 8. It should be understood, however, that the present invention also contemplates configuring/arranging the seal cushion and support cushion such that the seal cushion does not extend beyond the outer edge of the support cushion in the at rest (non-deflected) position.

[59] The patient interface device or any or all of the embodiments of the present invention communicates a flow of breathing gas between the patient's airway and pressure generating device 12, such as a ventilator, CPAP device, or variable pressure device, e.g., an auto-titrating pressure support device or a BiPAP[®] device manufactured and distributed by Respironics, Inc. of Pittsburgh, PA, in which the pressure provided to the patient varies with the patient's respiratory cycle so that a higher pressure is delivered during inspiration than during expiration or an auto-titration pressure support system where the pressure varies with the condition of the patient, such as whether the patient is snoring or experiencing an apnea or hypopnea.

[60] Communicating a flow of breathing gas between the patient's airway and a pressure/flow generating device 12 includes delivering a flow of breathing gas to the patient from the pressure generating device 12 and exhausting a flow of gas from the

patient to ambient atmosphere in the case of single-limb circuit. The system for delivering a pressurized flow of breathing gas to a patient according to the present invention comprises a pressure or gas flow generating device 12 that produces a flow of gas, a conduit 14 having a first end portion operatively coupled to the gas flow generating device 12 and a second end portion, wherein conduit 14 carries the flow of gas from gas flow generating device 12 during operation of the system; a patient interface device 10 coupled to the second end portion of the conduit; and a headgear. The interior of seal cushion 18 is exposed to the pressurized breathable gas. It is to be understood that other accessories used in a pressure support system, such as a humidifier, pressure sensor, flow sensor, temperature sensor, humidity sensor, bacteria filter, etc. can be used in conjunction with the patient interface device of the present invention.

[61] It can also be appreciated that the description of the present invention, while discussing some different embodiments for the seal and mask, is not intended to be an exhaustive listing of the seals and masks suitable for use with the patient interface device of the present invention. On the contrary, those skilled in the art can appreciate that the mask shell, the seal cushion, the support cushion, and the components used to connect these elements to one another can have almost any configuration or size and still be used in conjunction with the patient interface device of the present invention.

[62] It should be understood that the present invention contemplates that the seal cushion and the support cushion can a variety of configurations, including those of conventional cushions. For example, the present invention contemplates from either of these cushions from a gel material, as disclosed, for example, in U.S. Patent Nos. 5,647,357 and 5,884,624, the contents of which are incorporated herein by reference, or from a gel material that is customizable, as disclosed, for example, in U.S. Patent No. 6,397,847, the contents of which are incorporated herein by reference. The present invention also contemplates that seal cushion, the support cushion, or both can be an air-filled cushion and can include an optional sealing flap. See, e.g., U.S. Patent No. 4,791,051. These cushions can include features typically found in conventional cushion, such as stiffening devices, materials, and/or geometries and can be formed from any one of a variety of materials, such as silicone, or a combination of materials.

[63] Although the invention has been described in detail for the purpose of illustration based on what is currently considered to be the most practical and preferred

embodiments, it is to be understood that such detail is solely for that purpose and that the invention is not limited to the disclosed embodiments, but, on the contrary, is intended to cover modifications and equivalent arrangements that are within the spirit and scope of the appended claims. For example, it is to be understood that the present invention contemplates that, to the extent possible, one or more features of any embodiment can be combined with one or more features of any other embodiment.

What is Claimed is:

1. A patient interface device for use in delivering a flow of gas to an airway of a patient, the patient interface device comprising:

a mask shell having a patient side and an outer side opposite the patient side adapted for receiving a flow of gas;

a seal cushion having a first end portion defining a first perimeter and adapted to contact a first area of a patient's face to form a seal therewith and a second end portion opposite the first end portion, the seal cushion further including a cavity adapted to receive a portion of the patient's face, wherein the flow of gas communicates with the cavity; and

a support cushion having a first end portion defining a second perimeter and adapted to contact a second area of a patient's face and a second end portion opposite the first end portion, wherein the first perimeter is disposed within the second perimeter, and wherein the second end portion of the seal cushion and the second end portion of the support cushion are coupled to the patient side of the mask shell.

2. The patient interface device of claim 1, wherein the support cushion further comprises a forehead support portion.

3. The patient interface device of claim 1 or 2, further comprising a flexible connecting member positioned between the patient side of the mask shell and the second end portion of the seal member to allow angular movement between the seal member and the mask shell.

4. The patient interface device of claim 1, 2 or 3, wherein the seal cushion, the support cushion, or both include a grooved area defined in a portion thereof.

5. The patient interface device of any one of the preceding claims, wherein the first end portion of the seal cushion, the first end portion of the support cushion, or both include at least one flap, two flaps at least partially overlying one another, and gas filled cushion, a gel material, or any combination thereof.

6. The patient interface device of any one of the preceding claims, wherein the first end portion of the seal cushion, the first end portion of the support cushion, or both are contoured.

7. The patient interface device of any one of the preceding claims, further comprising a connecting member coupling the mask shell with the seal cushion, and wherein a reservoir is defined between the connecting member and the mask shell.

8. A system for delivering a flow of gas to a patient, comprising:

(a) a gas flow generating device that produces a flow of gas;

(b) a conduit having a first end portion operatively coupled to the gas flow generating device and a second end portion, wherein the conduit carries the flow of gas from the gas flow generating device during operation of the system; and

(c) a patient interface device comprising:

(1) a mask shell having a patient side and an outer side opposite the patient side, wherein the second end portion of the conduit is coupled to the mask shell,

(2) a seal cushion having a first end portion defining a first perimeter and adapted to contact a first area of a patient's face to form a seal therewith and a second end portion opposite the first end portion, the seal cushion further including a cavity adapted to receive a portion of the patient's face, wherein the flow of gas communicates with the cavity, and

(3) a support cushion having a first end portion defining a second perimeter and adapted to contact a second area of a patient's face and a second end portion opposite the first end portion, wherein the first perimeter is disposed within the second perimeter, and wherein the second end portion of the seal cushion and the second end portion of the support cushion are coupled to the patient side of the mask shell.

9. The system of claim 8, wherein the support cushion further comprises a forehead support portion.

10. The system of claim 8 or 9, further comprising a flexible connecting member positioned between the patient side of the mask shell and the second end portion of the seal member allowing angular movement between the seal member and the mask shell.

11. The system of claim 8, 9 or 10, wherein the seal cushion, the support cushion, or both include a grooved area defined in a portion thereof.

12. The system of any one of claims 8 to 11, wherein the first end portion of the seal cushion, the first end portion of the support cushion, or both include a rim, multiple rims, and gas filled cushion, a gel material, or any combination thereof.

13. The system of any one of claims 8 to 12, wherein the first end portion of the seal cushion, the first end portion of the support cushion, or both are contoured.

14. A patient interface device for use in delivering a flow of gas to an airway of a patient, the patient interface device comprising:

a mask shell having a patient side and an outer side opposite the patient side adapted for receiving a flow of gas;

a seal cushion having a first end portion defining a first perimeter and adapted to contact a first area of a patient's face to form a seal therewith and a second end portion opposite the first end portion, the seal cushion further including a cavity adapted to receive a portion of the patient's face, wherein the flow of gas communicates with the cavity, and wherein the seal cushion overlies a first area on such patient when donned by such a patient; and

a support cushion having a first end portion defining a second perimeter and adapted to contact a second area of a patient's face and a second end portion opposite the first end portion, wherein the first perimeter is disposed within the second perimeter, wherein the second end portion of the seal cushion and the second end portion of the support cushion are coupled to the patient side of the mask shell, wherein the support

cushion overlies a second area on such patient when donned by such a patient, and wherein the second area overlaps at least a major portion of the first area.

15. The patient interface device of claim 14, wherein the support cushion further comprises a forehead support portion.

16. The patient interface device of claim 14 or 15, further comprising a flexible connecting member positioned between the patient side of the mask shell and the second end portion of the seal member allowing angular movement between the seal member and the mask shell.

17. The patient interface device of claim 14, 15 or 16, wherein the seal cushion, the support cushion, or both include a grooved area defined in a portion thereof.

18. The patient interface device of any one of claims 14 to 17, wherein the first end portion of the seal cushion, the first end portion of the support cushion, or both include a rim, multiple rims, and gas filled cushion, a gel material, or any combination thereof.

19. The patient interface device of any one of claims 14 to 18, wherein the first end portion of the seal cushion, the first end portion of the support cushion, or both are contoured.

20. A patient interface device for use in delivering a flow of gas to an airway of a patient, the patient interface device comprising:

a mask shell having a patient side and an outer side opposite the patient side adapted for receiving a flow of gas;

a seal cushion having a first end portion adapted to contact a first area of a patient's face to form a seal therewith and a second end portion opposite the first end portion, wherein a first opening is defined in the first end portion, wherein the seal cushion further includes a cavity adapted to receive a portion of the patient's face through the first opening, and wherein the flow of gas communicates with the cavity; and

a support cushion having a first end portion adapted to contact a second area of a patient's face and a second end portion opposite the first end portion, wherein a second opening is defined in the first end portion of the support cushion, wherein the second end portion of the seal cushion and the second end portion of the support cushion are coupled to the patient side of the mask shell, and wherein the first opening is disposed within the second opening.

21. The patient interface device of claim 20, wherein the support cushion further comprises a forehead support portion.

22. The patient interface device of claim 20 or 21, further comprising a flexible connecting member positioned between the patient side of the mask shell and the second end portion of the seal member allowing angular movement between the seal member and the mask shell.

23. The patient interface device of claim 20, 21 or 22, wherein the seal cushion, the support cushion, or both include a grooved area defined in a portion thereof.

24. The patient interface device of any one of claims 20 to 23, wherein the first end portion of the seal cushion, the first end portion of the support cushion, or both include a rim, multiple rims, and gas filled cushion, a gel material, or any combination thereof.

25. The patient interface device of any one of claims 20 to 24, wherein the first end portion of the seal cushion, the first end portion of the support cushion, or both are contoured.

26. A patient interface device of claim 1, 14 or 20 substantially as hereinbefore described with reference to the accompanying drawings.

27. A system for delivering a flow of gas to a patient substantially as hereinbefore described with reference to the accompanying drawings.

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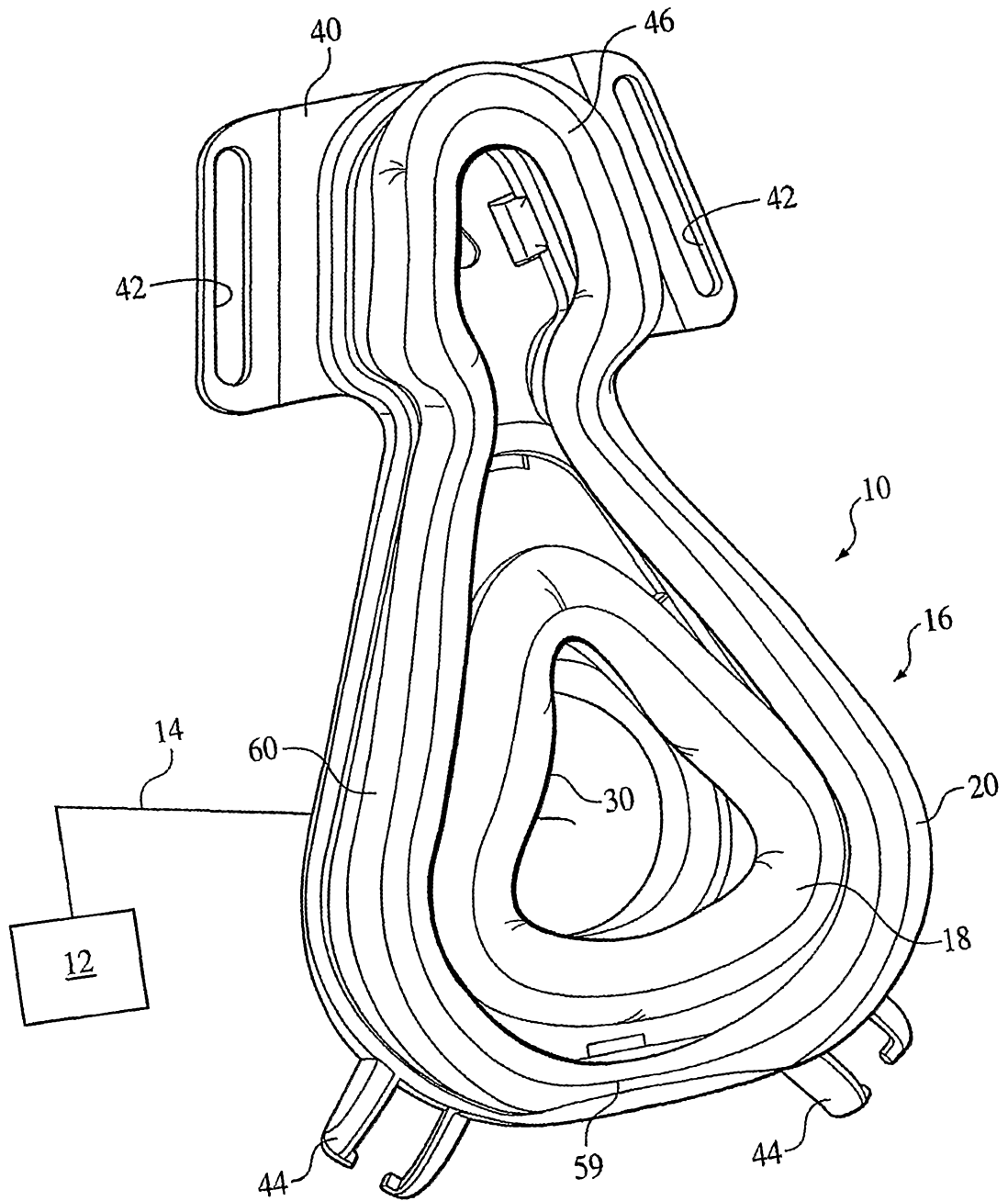


FIG. 1

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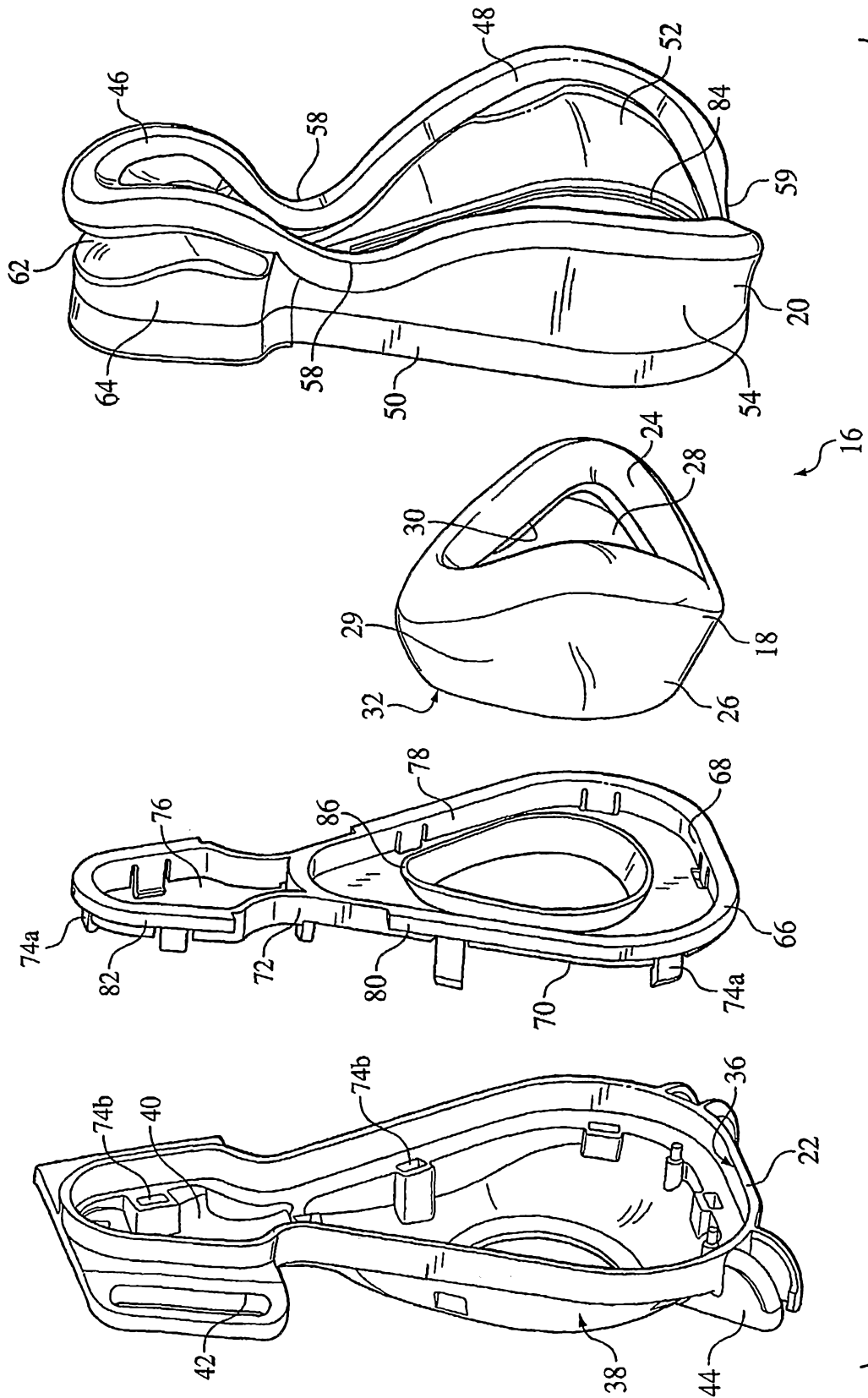


FIG. 2

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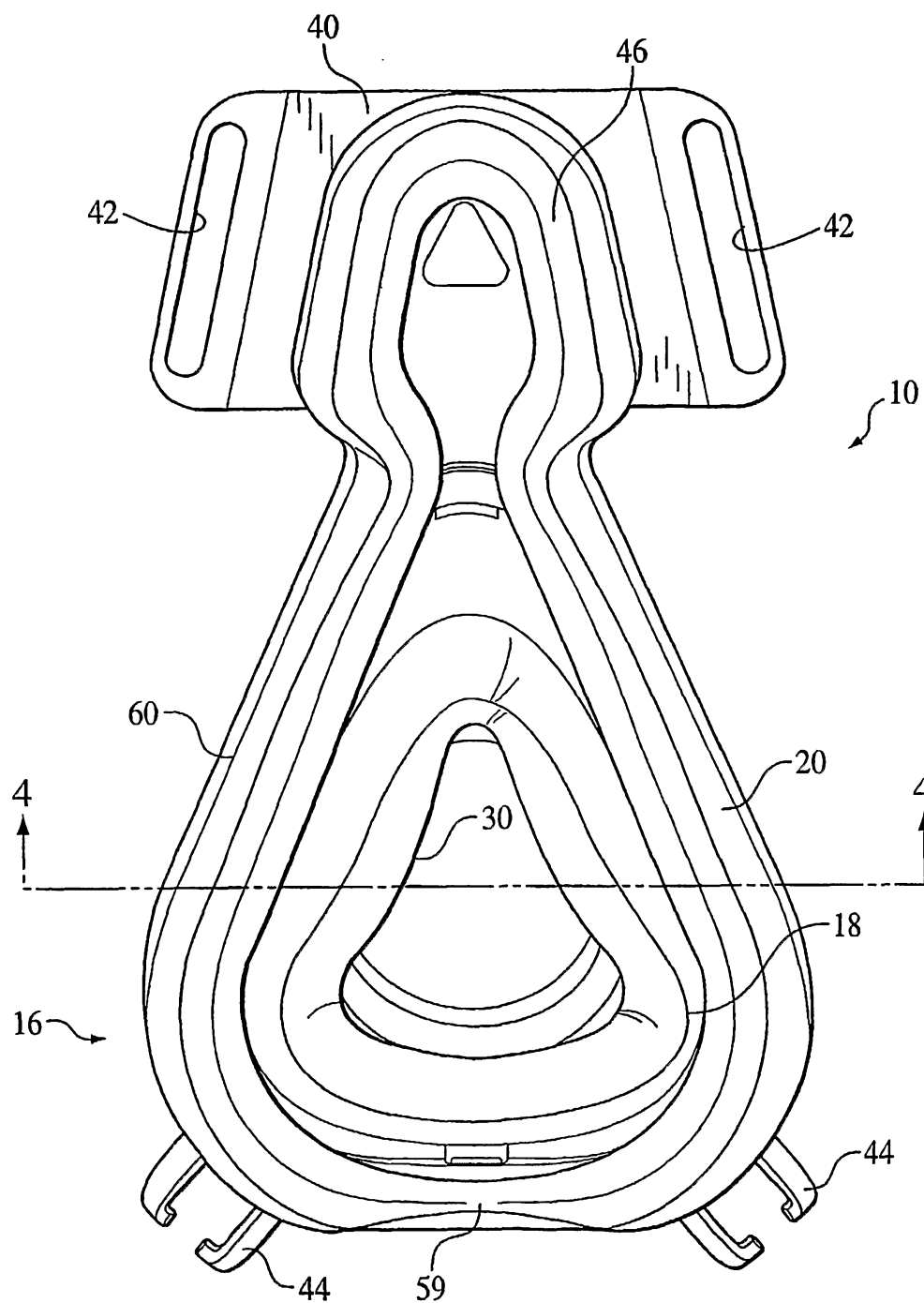


FIG. 3

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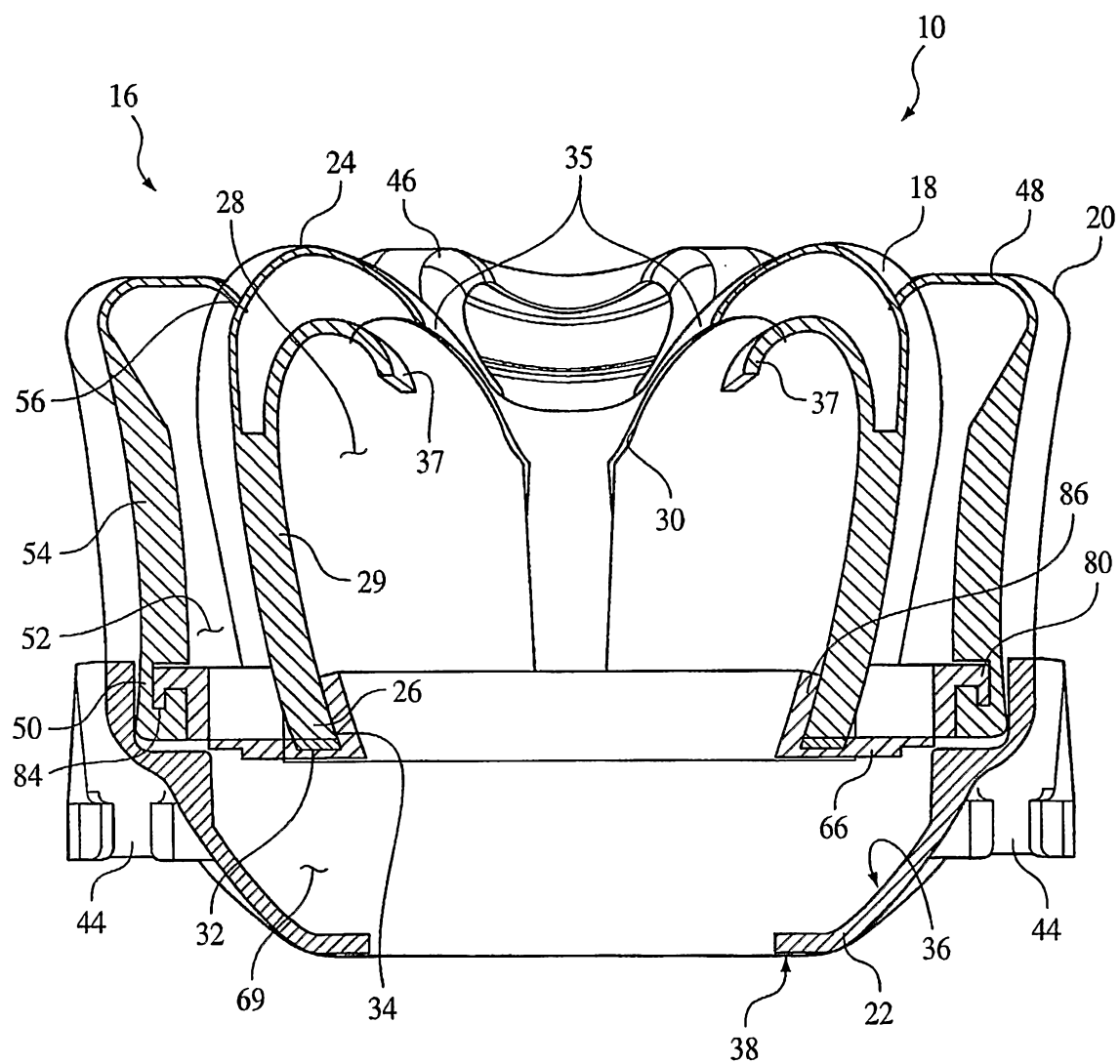


FIG. 4

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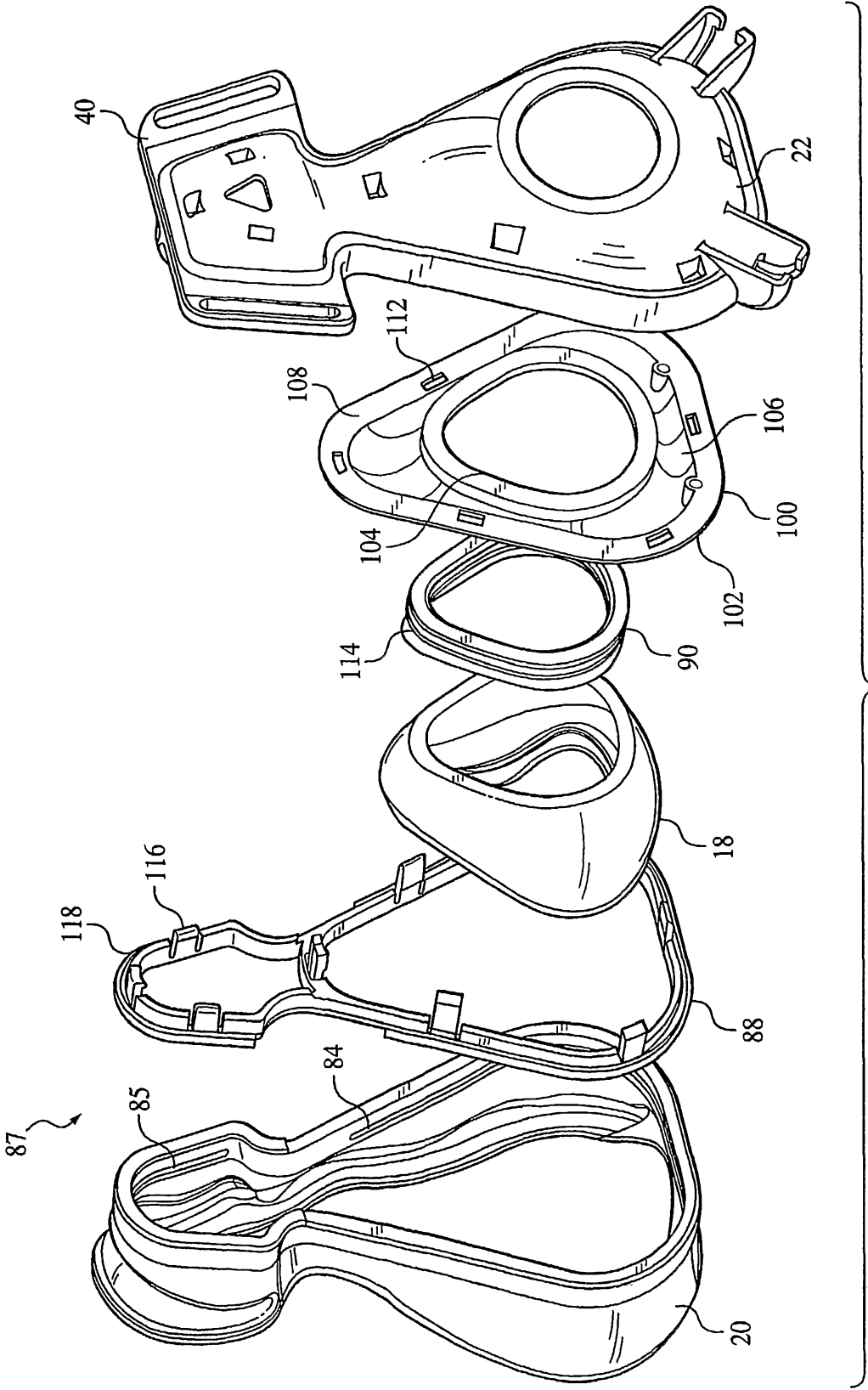


FIG. 5

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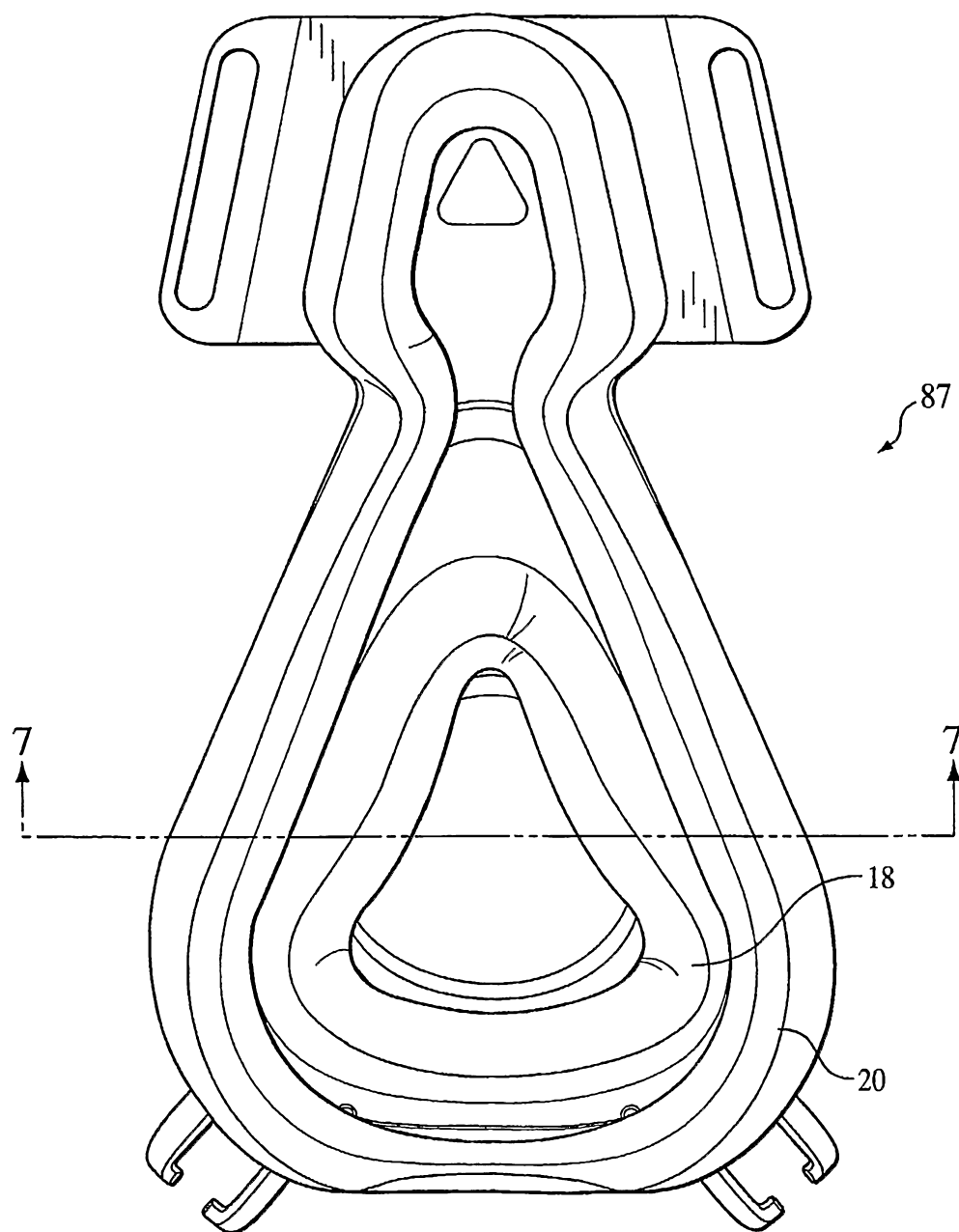


FIG. 6

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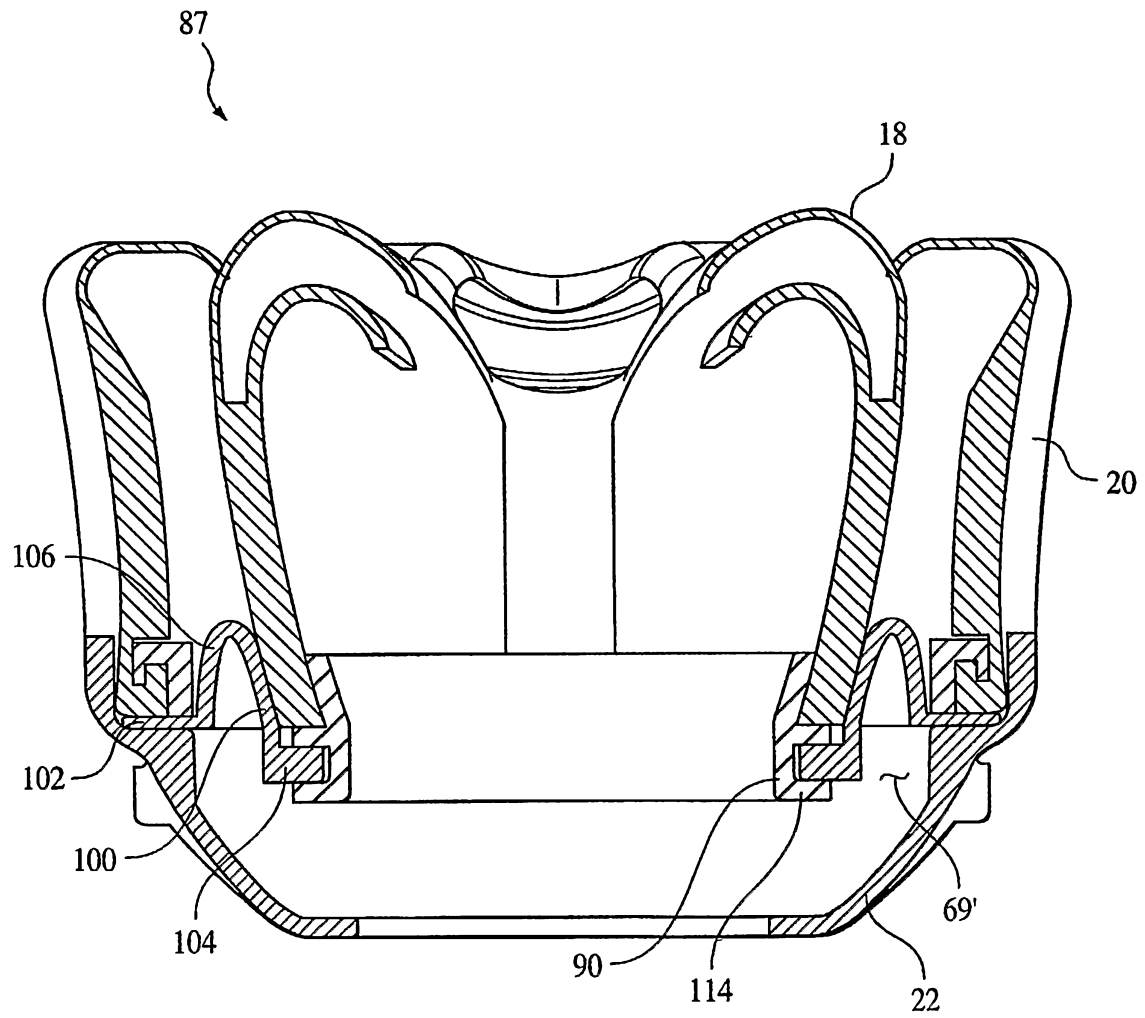


FIG. 7

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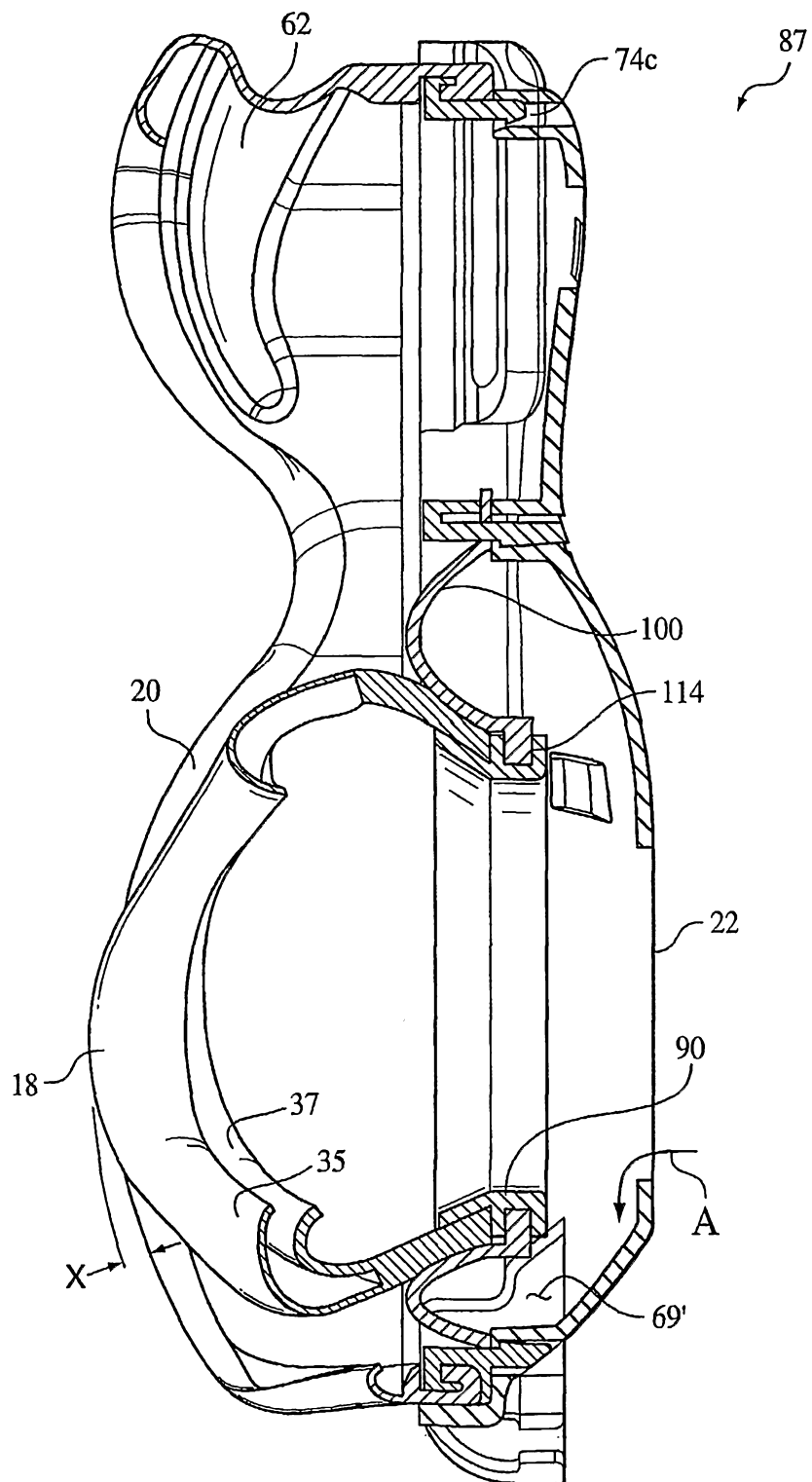


FIG. 8

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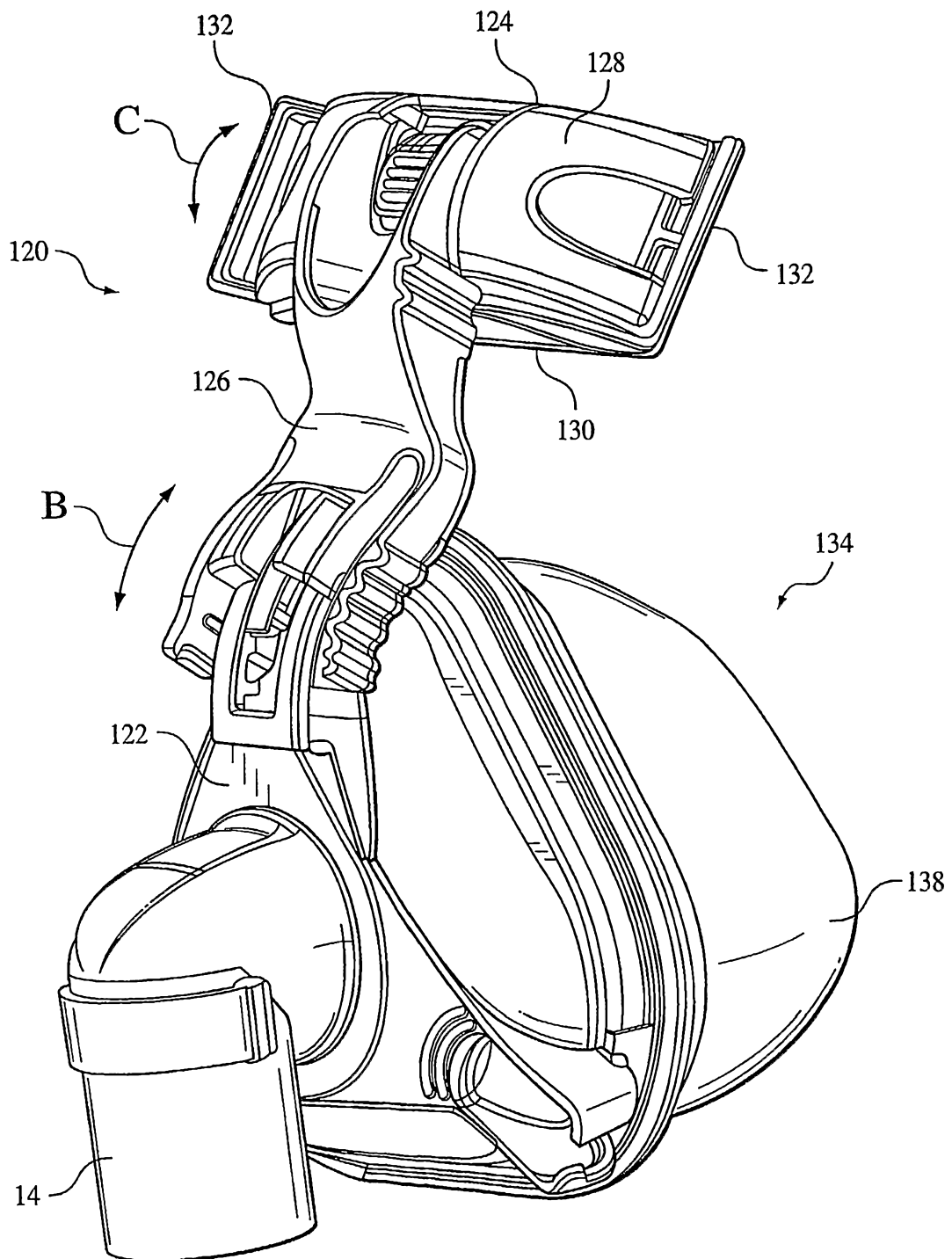


FIG. 9

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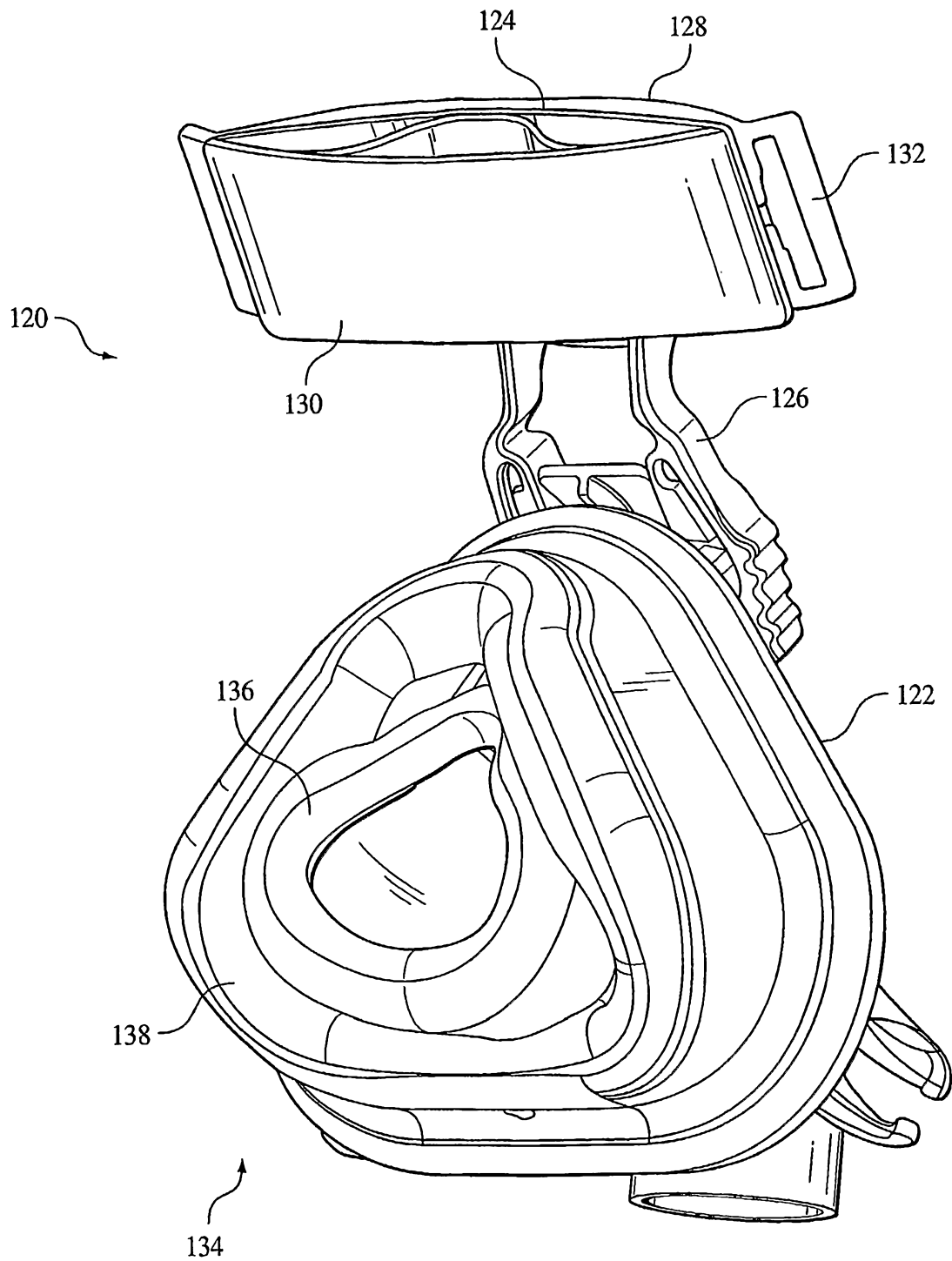


FIG. 10

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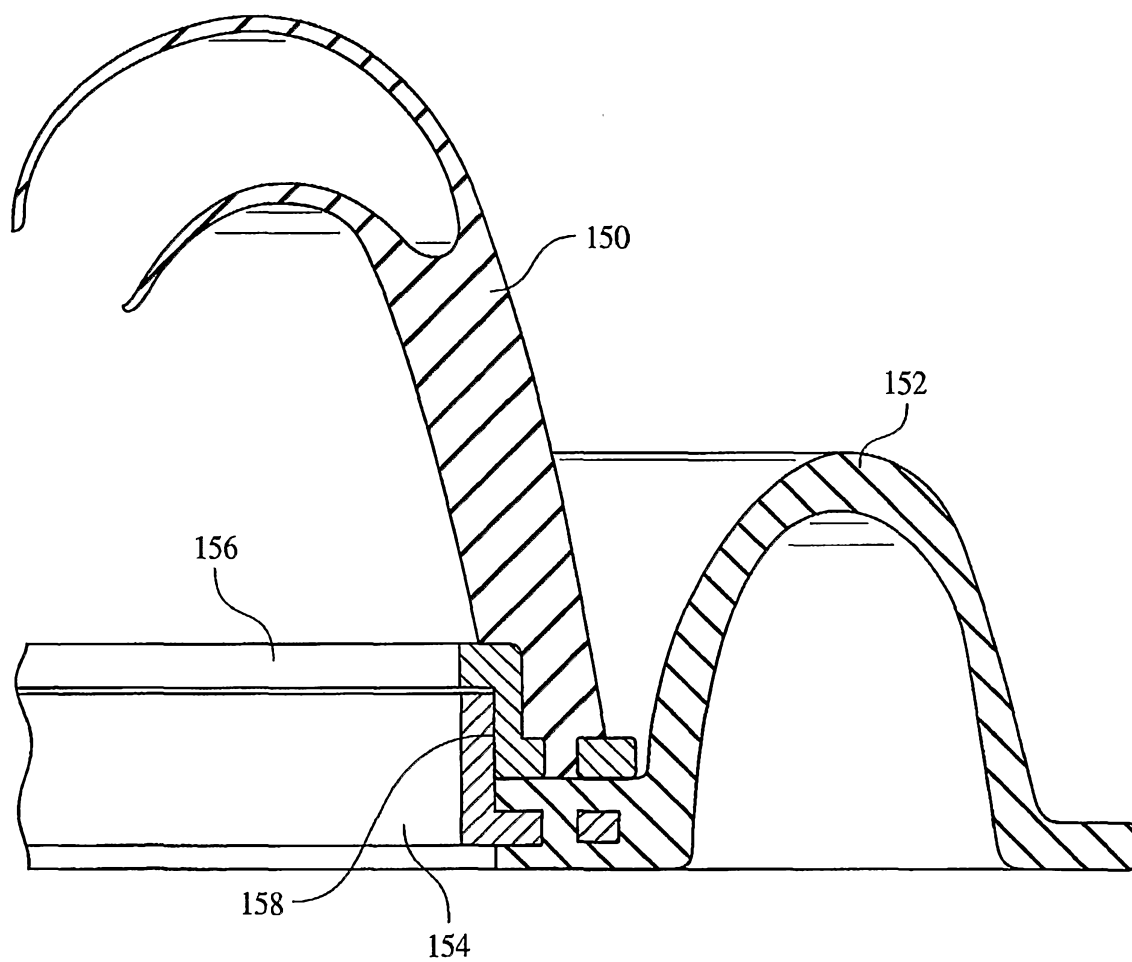


FIG. 11

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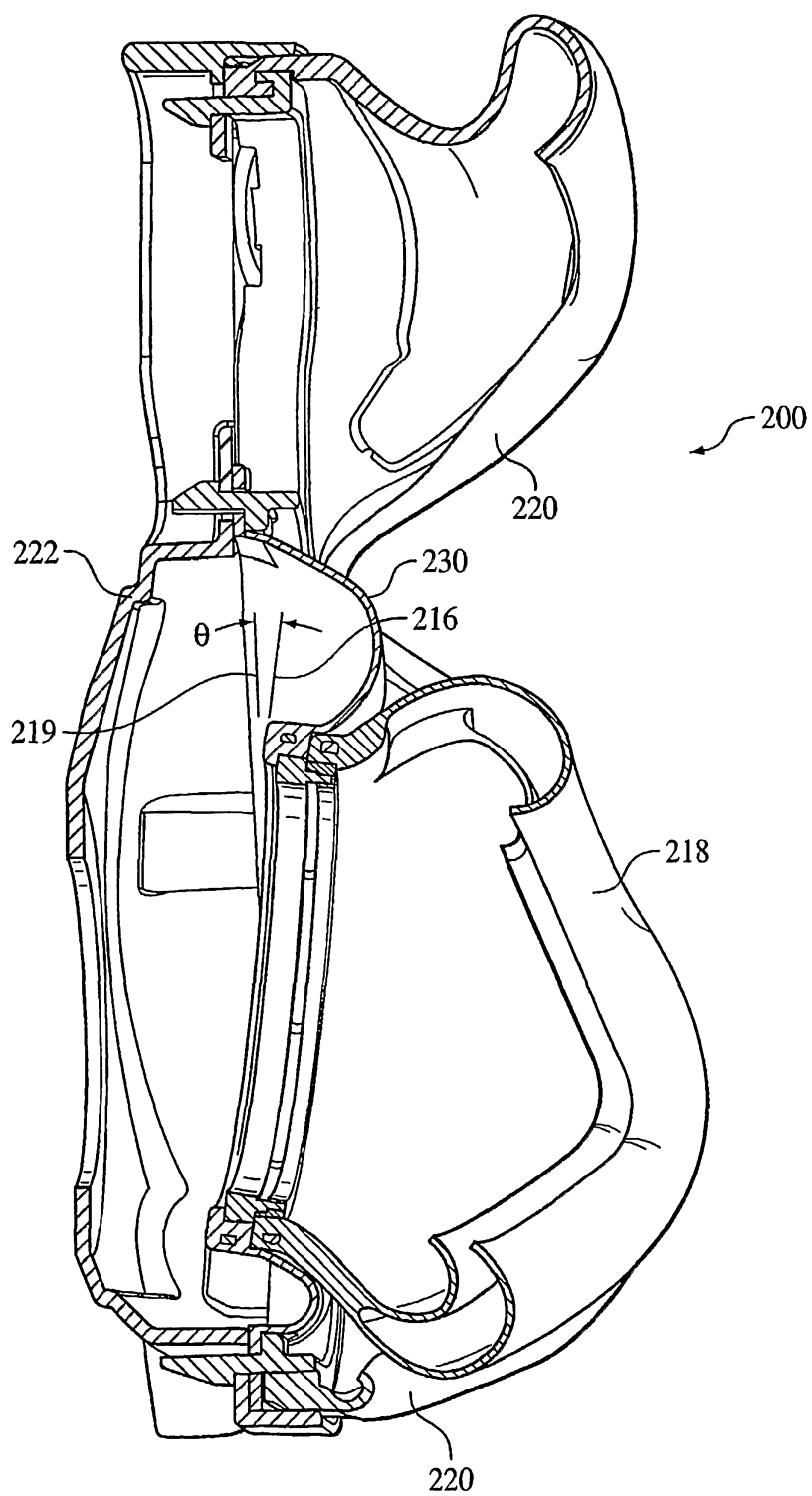


FIG. 12

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