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Veliss et al.

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(54) **INTERFACE INCLUDING A FOAM CUSHIONING ELEMENT**

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CPC ***A61M 16/06*** (2013.01); ***A61M 16/0622*** (2014.02); ***A61M 16/0633*** (2014.02); ***A61M 16/106*** (2014.02); ***A62B 18/084*** (2013.01)

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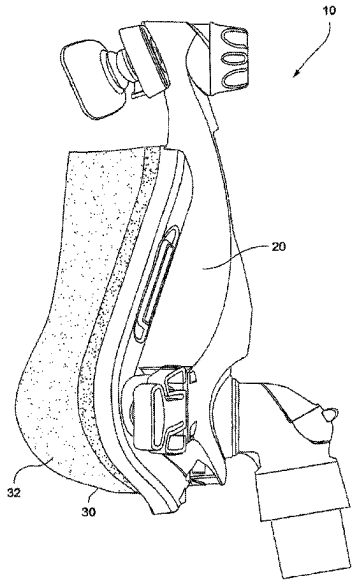
(57) **ABSTRACT**

A respiratory mask assembly includes a frame having a channel and a cushioning element including a clip portion adapted for interference seal and retention in the channel. The cushioning element includes an interfacing portion constructed from foam and having a wider width than the clip portion.

19 Claims, 9 Drawing Sheets



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(58) **Field of Classification Search**

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See application file for complete search history.

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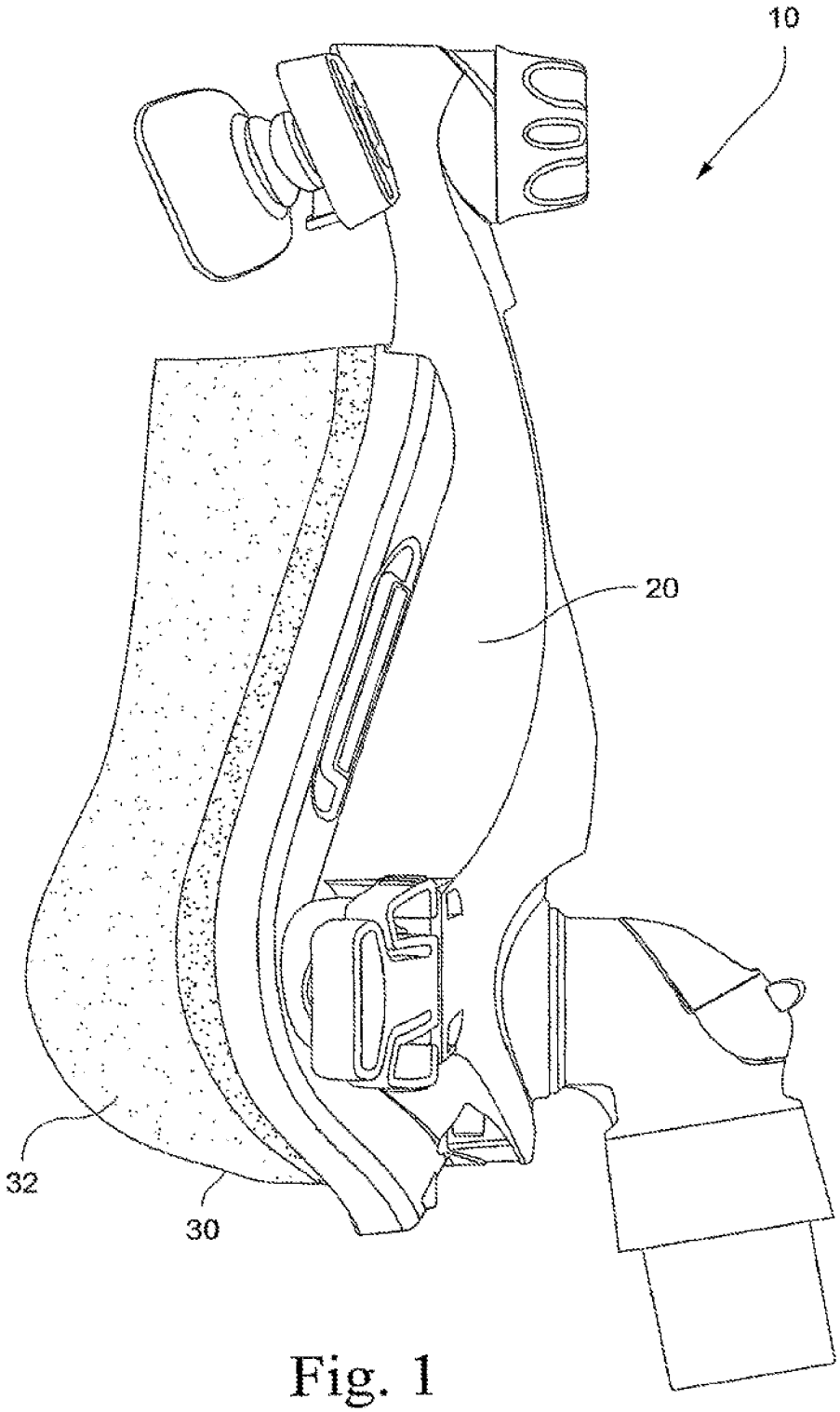

Fig. 1

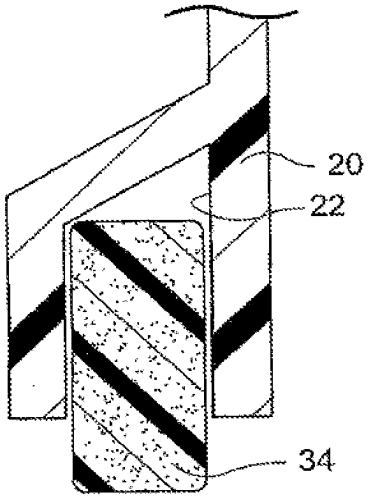

Fig. 2

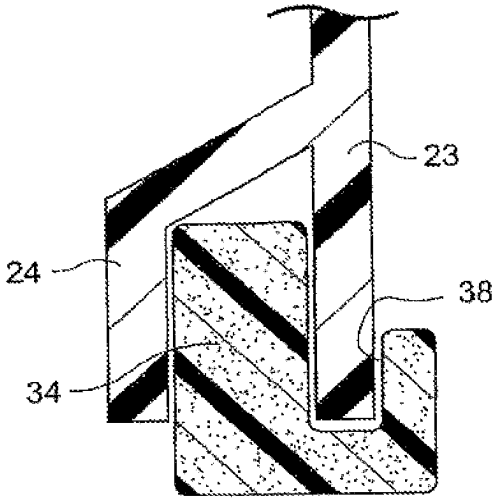

Fig. 3a

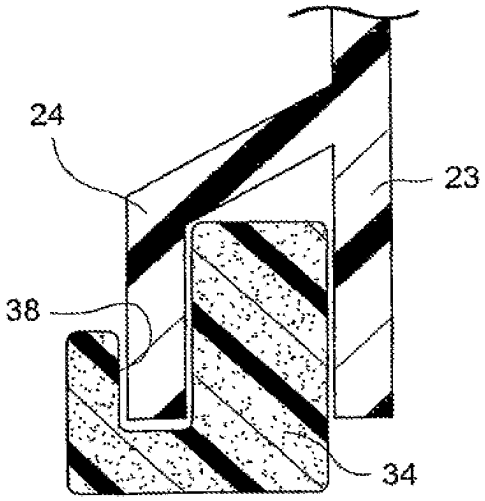

Fig. 3b

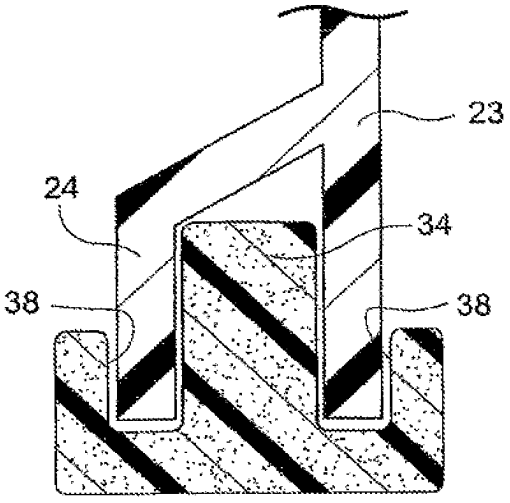

Fig. 3c

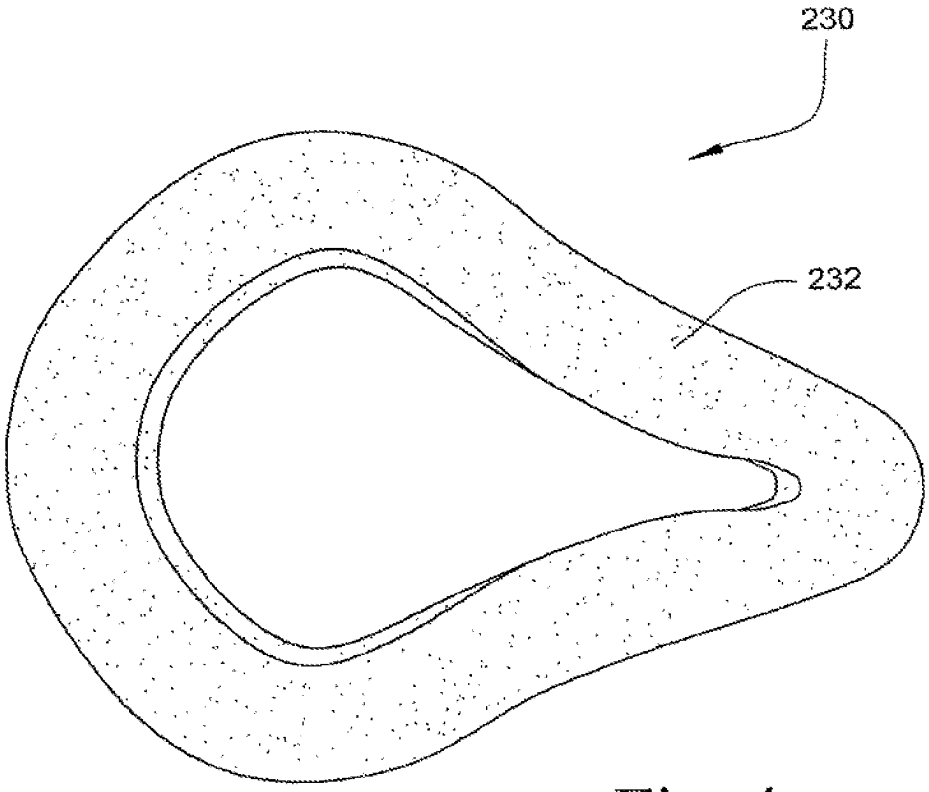

Fig. 4a

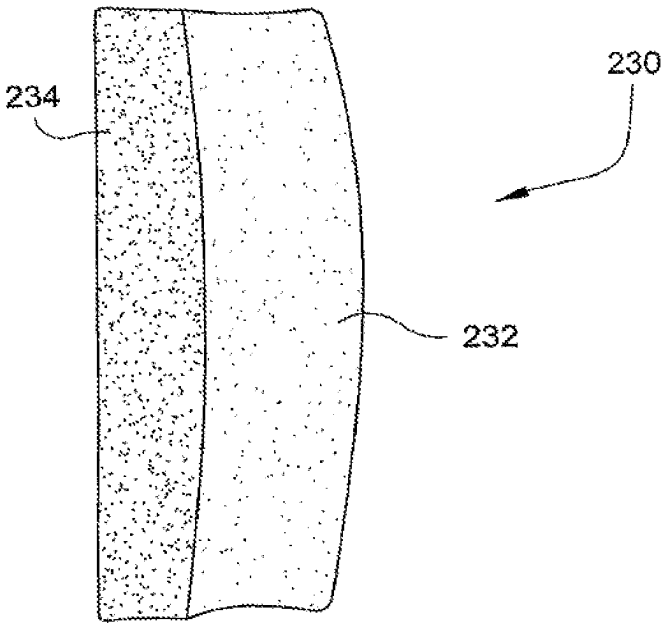

Fig. 4b

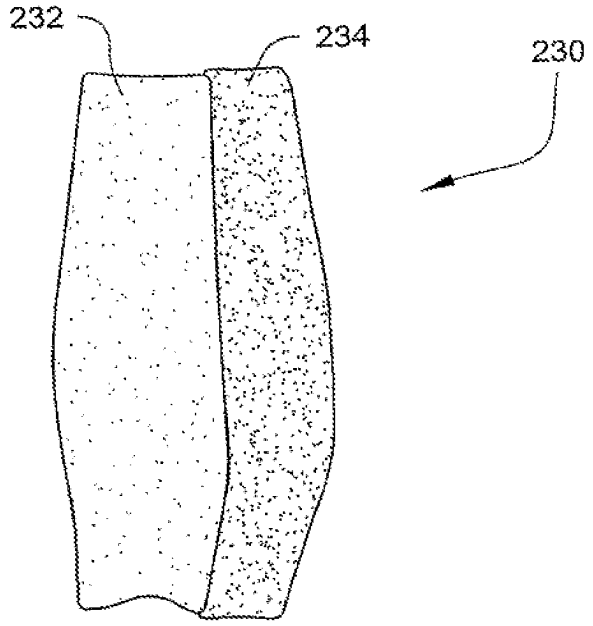

Fig. 4c

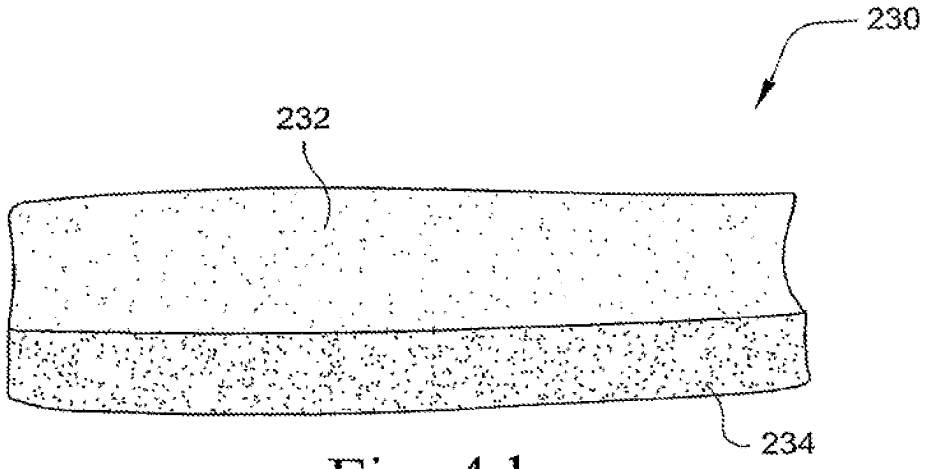

Fig. 4d

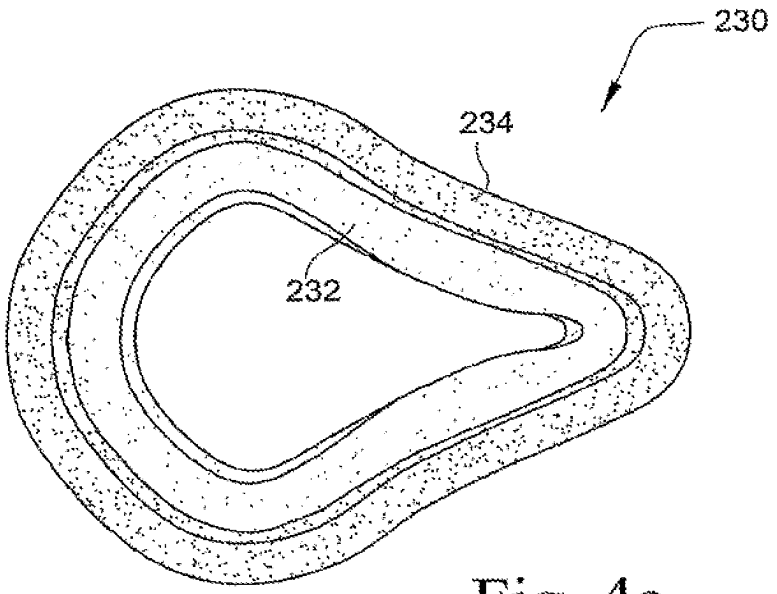

Fig. 4e

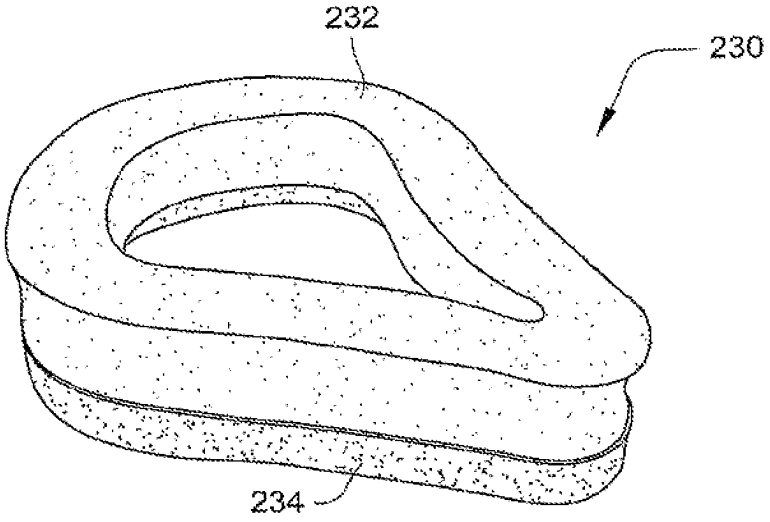

Fig. 4f

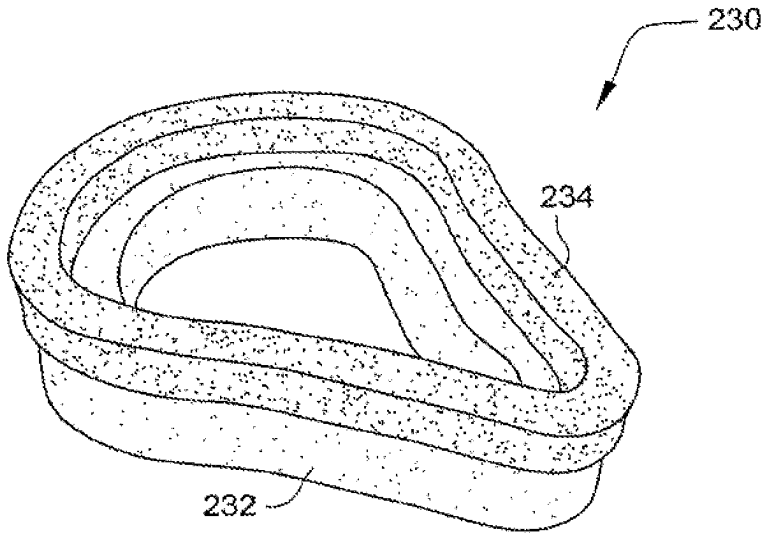

Fig. 4g

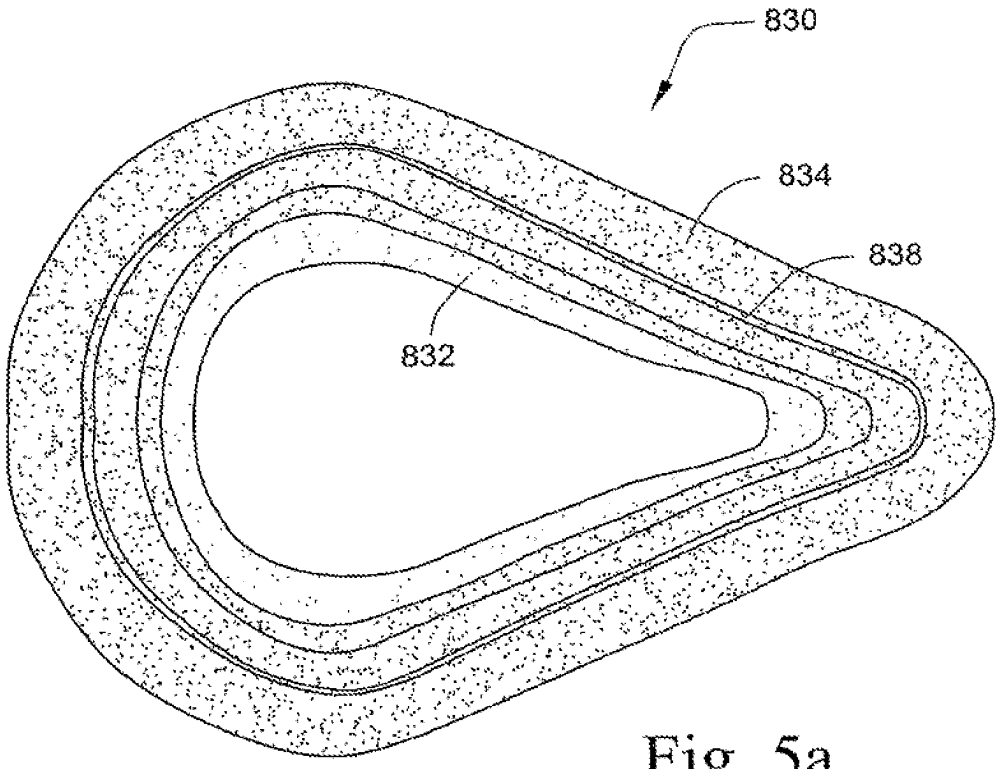

Fig. 5a

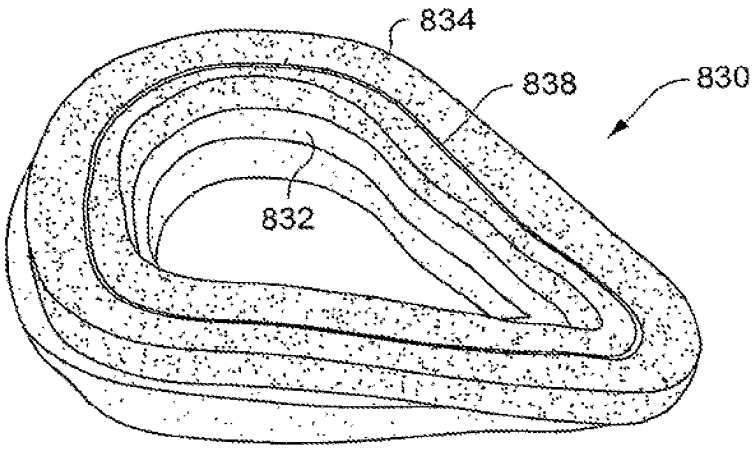

Fig. 5b

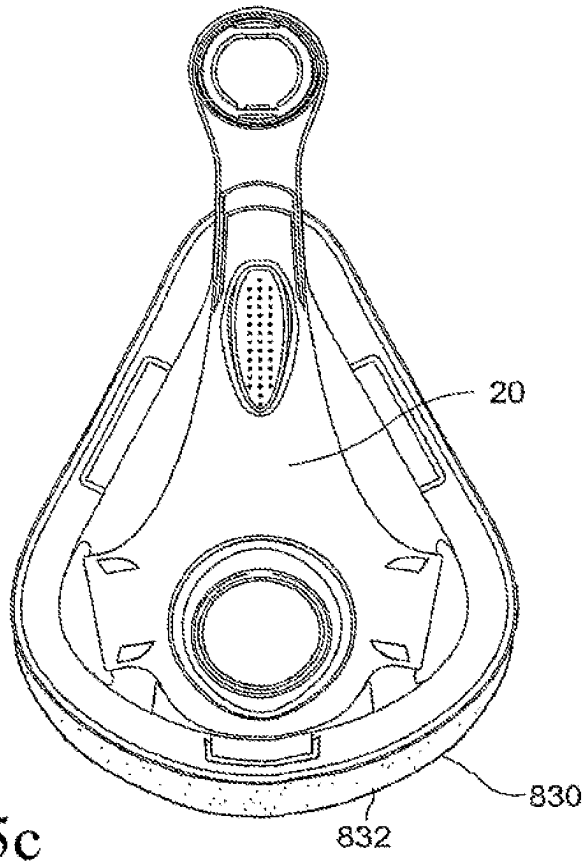

Fig. 5c

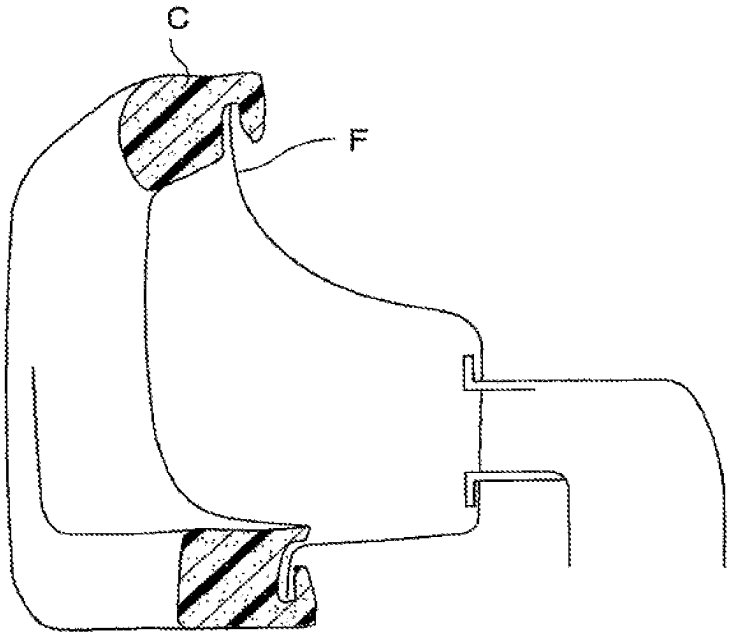

Fig. 6a
(PRIOR ART)

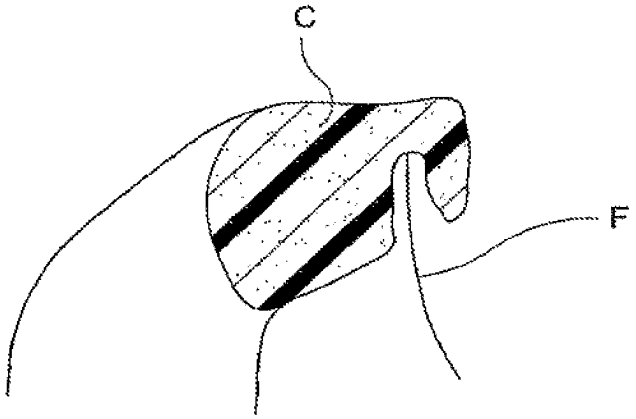

Fig. 6b
(PRIOR ART)

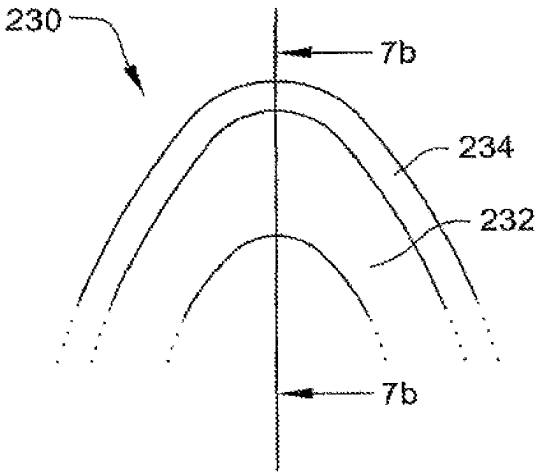

Fig. 7a

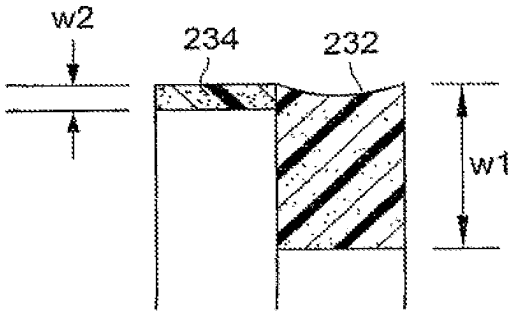

Fig. 7b

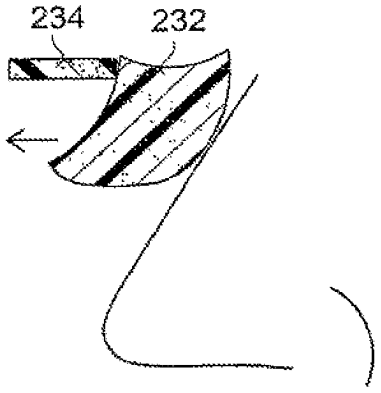

Fig. 7c

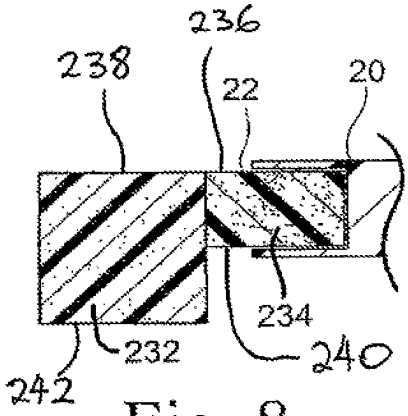

Fig. 8

INTERFACE INCLUDING A FOAM CUSHIONING ELEMENT

CROSS-REFERENCE TO APPLICATION

This application is a continuation of U.S. patent application Ser. No. 15/987,734, filed May 23, 2018, now allowed, which is a continuation of U.S. patent application Ser. No. 12/736,030, filed Sep. 2, 2010, issued as U.S. Pat. No. 9,987,450, which was the U.S. national phase of International Application No. PCT/AU2009/000262, filed Mar. 4, 2009, which designated the U.S. and claims the benefit of Australian Provisional Application No. AU 2008901056, filed Mar. 4, 2008, each of which is hereby incorporated herein by reference in its entirety.

FIELD OF THE INVENTION

The present invention relates to an interface between a human and a piece of equipment, for example a mask, that includes a foam-based cushioning element.

BACKGROUND OF THE INVENTION

In a number of fields, such as respiratory therapy, apparatus for delivery of therapy includes a more rigid component defining a structure and a soft, cushioning component positioned between the patient and the rigid component.

In the case of a respiratory device, the more rigid component may be a mask frame defining a nose-receiving chamber. The mask frame may include a flange around its periphery. The cushioning component may be glued to the flange. See U.S. Patent Application Publication US 2003/0168063.

The cushioning component may form an air tight seal with the skin of the patient in some forms of respiratory therapy. In other devices, for example headphones, it may not be necessary for an air tight seal to be formed.

Other known masks that include foam cushioning elements include the following Fisher and Paykel masks: ACLAIM mask, FLEX-FIT 405, FLEX-FIT 407, and FLEX-FIT 431.

SUMMARY OF THE INVENTION

A first aspect of the invention is to provide a patient interface with a foam cushioning element.

Another aspect of the invention is to provide a patient interface with a removable foam cushioning element.

Another aspect of the invention is to provide a patient interface system with at least two different types of removably replaceable cushioning elements.

Another aspect of the invention is to include a cushioning element having portion adapted for engagement with a more rigid component.

Another aspect of the invention is to provide a respiratory mask assembly including a frame and a cushioning element wherein the cushioning element includes a foam-based interfacing portion and a clip portion adapted for removable engagement with the frame portion.

Another aspect of the invention is to provide a support structure for a cushioning element that supports the cushioning element on one side and allows movement on another side.

Another aspect of the invention relates to a cushion for a respiratory mask including a clip portion and an interfacing portion wherein the interfacing portion is constructed from a foam material and the clip portion is narrower than the interfacing portion.

Another aspect of the invention relates to a respiratory mask assembly including a frame having a channel and a cushioning element including a clip portion adapted for interference seal and retention in the channel. The cushioning element includes an interfacing portion constructed from foam and having a wider width than the clip portion.

Another aspect of the invention relates to a respiratory mask assembly including a frame having a channel and a removably replaceable interfacing structure including a clip portion adapted for interference seal and retention in the channel. The interfacing structure includes a cushion component constructed from foam.

Another aspect of the invention relates to a mask system including a common frame and at least a first cushion constructed from foam and a second cushion constructed from silicone. The first and second cushions are each structured to removably attach to the frame.

Other aspects, features, and advantages of this invention will become apparent from the following detailed description when taken in conjunction with the accompanying drawings, which are a part of this disclosure and which illustrate, by way of example, principles of this invention.

BRIEF DESCRIPTION OF THE DRAWINGS

The accompanying drawings facilitate an understanding of the various embodiments of this invention. In such drawings:

FIG. **1** shows a side view of a mask assembly including a foam cushioning element according to an embodiment of the invention;

FIG. **2** shows a schematic diagram of a channel of a portion of a mask frame and a clip portion of a cushioning element retained by an interference fit according to an embodiment of the invention;

FIGS. **3***a*, **3***b*, and **3***c* show a range of rib engagement fitting arrangements between a mask frame and a clip portion of a cushioning element according to embodiments of the invention;

FIG. **4***a* shows a patient contacting side of a cushioning element according to an embodiment of the invention;

FIG. **4***b* shows a bottom view of the cushioning element of FIG. **4***a;*

FIG. **4***c* shows a top view of the cushioning element of FIG. **4***a;*

FIG. **4***d* shows a side view of the cushioning element of FIG. **4***a;*

FIG. **4***e* shows a frame contacting side of the cushioning element of FIG. **4***a;*

FIG. **4***f* shows a patient contacting side isometric view of the cushioning element of FIG. **4***a;*

FIG. **4***g* shows a frame contacting side isometric view of the cushioning element of FIG. **4***a;*

FIG. **5***a* is a plan view showing a die cut cushioning element wherein the clip portion includes a slot for engagement with the frame according to an embodiment of the invention;

FIG. **5***b* is an isometric view of the cushioning element shown in FIG. **5***a;*

FIG. **5***c* is an assembly view of the cushioning element shown in FIG. **5***a* with a mask frame;

FIG. **6***a* shows a cross-section from a prior art nasal mask with foam cushion;

FIG. **6***b* shows a detail in the nasal bridge region of the mask of FIG. **6***a;*

FIG. **7***a* shows an elevation view detail from the frame side of the cushioning element shown in FIG. **4***e;*

FIG. **7***b* is a cross-section along line **7***b*-**7***b* of FIG. **7***a;*

FIG. **7***c* is a cross-sectional view showing the cushioning element of FIGS. **7***a* and **7***b* in use; and

FIG. **8** is a cross-sectional view showing the assembly of the cushioning element of FIGS. **7***a* and **7***b* and a frame according to an embodiment of the invention.

DETAILED DESCRIPTION OF ILLUSTRATED EMBODIMENTS

The following description is provided in relation to several embodiments which may share common characteristics and features. It is to be understood that one or more features of any one embodiment may be combinable with one or more features of the other embodiments. In addition, any single feature or combination of features in any of the embodiments may constitute additional embodiments.

In this specification, the word "comprising" is to be understood in its "open" sense, that is, in the sense of "including", and thus not limited to its "closed" sense, that is the sense of "consisting only of". A corresponding meaning is to be attributed to the corresponding words "comprise", "comprised" and "comprises" where they appear.

The term "air" will be taken to include breathable gases, for example air with supplemental oxygen.

Interconnection of Cushioning Element and Apparatus

In accordance with an embodiment of the present invention, a removable interconnectable cushioning element (also referred to as a cushion element or cushion) is provided. The cushioning element preferably includes a soft resilient foam interfacing portion for contacting a human. The cushioning element is constructed and arranged for removable interconnection with the rest of the apparatus, for example a respiratory mask.

The ability to removably connect the cushioning element enables one to replace the cushioning element should it become soiled and/or uncomfortable. It also facilitates trial of different forms of cushioning element. One form of cushioning element, for example a foam-based cushioning element, may be used as a form of "training" system to allow a person to become accustomed to the sensation of wearing and using a mask. A foam-cushion based mask may provide an initially more appealing and comfortable surface for a new patient than a gel or silicone-based cushion. The patient may subsequently switch from the foam-based cushion to a silicone or gel based cushion. In this way, the patient may be more likely to adhere to therapy because they are used to the very soft comfortable feeling of foam.

When applied to respiratory equipment, the cushioning element is adapted for connection with a mask frame. In use, an air-tight seal is formed between the cushioning element and the frame. This arrangement could be used for both nasal and full-face masks.

For example, FIG. **1** illustrates a mask **10** including a mask frame **20** and a foam-based cushioning element **30** provided to the mask frame **20**. As illustrated, the foam-based cushioning element **30** provides a foam interfacing portion **32** adapted to contact the patient's face in use. In this embodiment, the foam-based cushioning element **30** is adapted for use with an existing mask (e.g., ResMed's Mirage Quattro mask), which allows the patient to switch from the foam-based cushioning element **30** to the mask's existing silicone-based cushion if desired.

Dual Foam Layers

In one form of device in accordance with an embodiment of the invention, the foam-based cushioning element has two layers, i.e., an interfacing portion and a clip portion.

In an embodiment, the interfacing portion or cushion is constructed from a soft unskinned resilient viscoelastic polyurethane foam. Such a foam is disclosed in PCT Publication Nos. WO 2008/011682, published Jan. 31, 2008, and WO 2008/070929, published Jun. 19, 2008, each of which is incorporated herein by reference in its entirety. In one form, the resilient foam may be formed by a known method such as die cutting.

FIGS. **4***a* to **4***g* show a foam-based cushioning element **230** according to an embodiment of the invention. As illustrated, the cushioning element **230** includes an interfacing portion (or face-contacting portion) **232** and a clip portion **234** provided to the interfacing portion **232**. In this embodiment, the clip portion **234** is adapted for an interference fit with a mask frame, and the width of the clip portion **234** is narrower than the width of the interfacing portion **232** (e.g., see FIGS. **4***e* and **4***g*).

In the illustrated embodiment, both an inside surface and an outside surface of the foam interfacing portion **232** are die cut. This typically results in straight cut edges, much like a kitchen sponge. The cushion may therefore have a square cross section.

In an embodiment, the clip portion of the cushioning element may be constructed from a more rigid foam than the interfacing portion. For example, the clip portion may be formed from nitrogen blown polyethylene, or some other clean, biocompatible foam having a fine cell-structure. Alternatively, the clip portion could be made from some other polymer or rubber. In an embodiment, the clip portion is adapted to form a cushion-to-frame engagement mechanism and to form a structural support for the interfacing portion.

The two layers (i.e., the interfacing portion and the clip portion) may be adhered to one another using polyurethane hot melt glue. This arrangement provides a one piece cushioning element with an interfacing portion adapted to engage the patient's face and a clip portion adapted to interface with the mask frame.

Cushion-to-Frame Engagement Mechanisms

According to an aspect of the invention, the cushion-to-frame engagement and connection mechanism provided by the clip portion may include a channel-type engagement or rib-type engagement.

As shown in FIG. **2**, the channel-type engagement includes a foam clip portion **34** that is adapted to be received within the channel **22** of a mask frame **20** with an interference fit. The foam clip portion **34** extends around the entire perimeter of the cushioning element so as to form an air-tight seal and retention with the mask frame.

As shown in FIGS. **3***a* to **3***c*, the rib-type engagement includes a foam clip portion **34** with one or more slots **38** to receive inner and/or outer ribs **23**, **24** of the mask frame **20**. For example, the slot to rib engagement may provide an inner frame rib engagement (see FIG. **3***a*), an outer frame rib engagement (see FIG. **3***b*), or an inner and outer frame rib engagement (see FIG. **3***c*). This arrangement provides a broader base of support for the sealing foam.

FIGS. **5***a* and **5***b* illustrate a foam-based cushioning element **830** including a foam interfacing portion **832** and a clip portion **834**, and FIG. **5***c* illustrates the cushioning element **830** provided to a mask frame **20**. As shown in FIGS. **5***a* and **5***b*, the clip portion **834** includes a slot **838** adapted to receive a rib of the mask frame **20**. Also,

providing a wider clip portion **834** allows more stiffness and structural integrity to be provided to the clip portion, making the clip portion easier to assemble to the mask frame.

When structured to form an interference fit with the mask frame, the clip portion may have the following properties: appropriate rigidity (e.g., less than that of the frame and in one form more rigid than the foam interfacing portion); non-porous; and/or low compression set (the amount of deformation expressed as a percentage of original dimensions) which a material retains after compressive stress is released (in this way, the clip portion maintains its retention force during its usage life).

Interfacing Portion Support Structure

In accordance with an embodiment of the invention, a range of different arrangements of clip portions and foam interfacing portions may be provided. For example, the width of the clip portion may match the interfacing portion, the width of the clip portion may be less than the width of the interfacing portion, or the width of the clip portion may be greater than the width of the interfacing portion.

When the width of the clip portion is less than the width of the interfacing portion, the clip portion and interfacing portion may be arranged such that (i) the outer perimeter of the clip portion and interfacing portion align (hides hardness of clip portion and provides desired freedom of movement in the interfacing portion), (ii) the inner perimeter of the clip portion and the interfacing portion align, or (iii) neither the inner or outer perimeter of the clip portion and the interfacing portion align.

Similarly, when the width of the clip portion is greater than the width of the interfacing portion, the clip portion and interfacing portion may be arranged such that (i) the outer perimeter of the clip portion and interfacing portion align, (ii) the inner perimeter of the clip portion and interfacing portion align, or (iii) neither the inner or outer perimeter of the clip portion and the interfacing portion align.

In these different configurations with different relative widths, the clip portion provides different forms of support of the interfacing portion.

When the width of the clip portion is less than the width of the interfacing portion and the outer perimeter of the clip portion aligns with the interfacing portion, the interfacing portion is more free to flex in regions not having a clip portion next to it than in regions having a clip portion adjacent to it. For example, where the interfacing portion overhangs the clip portion, that overhanging region of the interfacing portion has more freedom to move. This arrangement can be more comfortable and more able to adapt to different geometries of a person, and provide the correct vectors to seal the interfacing portion against the face.

When used as part of a respiratory mask, it may be preferable that the inner portion of the interfacing portion overhang the clip portion. In this arrangement in use, the face of the patient may engage with an unsupported inner edge of the softer interfacing portion causing it to bend and conform to the individual patient's shape.

FIG. **7***a* shows an elevation view detail from the frame side of the cushioning element **230** shown in FIG. **4***e* in a nasal bridge region. As shown in cross-section in FIG. **7***b*, it is apparent that the width w**2** of the clip portion **234** is less than the width w**1** of the interfacing portion **232** and that the outer perimeter of the clip portion **234** and the interfacing portion **232** are aligned. An advantage of this arrangement is illustrated in FIG. **7***c* where in use the nose is able to push the inner perimeter of the interfacing portion **232** in the direction shown by the arrow, in a cantilever manner as well as compressing.

FIG. **8** is a cross-section showing the clip portion **234** of the cushioning element **230** received within the channel **22** of a mask frame **20**. It can be seen that the width of the clip portion **234** is less than that of the interfacing portion **232**, and that the outer perimeter surfaces **236** and **238** respectively of the clip portion **234** and interfacing portion **232** are aligned while the respective inner perimeter surfaces **240**, **242** are offset.

This arrangement is in contrast to prior art cushions (such as the Lifecare mask shown in FIGS. **6***a* and **6***b*) where the inner perimeter of the cushion C abuts the frame F, and hence it is not free to move inwardly and can only compress.

In one form, a mask system may be provided that includes at least two different forms of cushioning element chosen from the set of foam-based cushion, silicone-based cushion, and gel-based cushion.

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

What is claimed is:

1. A mask system for delivery of respiratory therapy, comprising:

a common frame at least partially defining a breathing chamber, the common frame being rigid;

a first cushioning element configured to, in use, form a seal with the patient's skin, the first cushioning element being removably attachable to the common frame, the first cushioning element being a foam-based cushioning element including an interfacing portion comprising a resilient foam arranged to contact the patient's face in use; and

a second cushioning element configured to, in use, form a seal with the patient's skin, the second cushioning element being removably attachable to the common frame such that the first cushioning element and the second cushioning element are interchangeable on the common frame,

wherein the second cushioning element is a silicone-based cushioning element comprising a skin contacting surface formed of a silicone material.

2. The mask system of claim **1**, wherein each of the first cushioning element and the second cushioning element includes a clip portion for attachment to the common frame.

3. The mask system of claim **2**, wherein the clip portion of the first cushioning element has a first side configured for attachment to the common frame and a second side that is attached to the interfacing portion.

4. The mask system of claim **3**, wherein the second side of the clip portion is adhered to the interfacing portion.

5. The mask system of claim 2, wherein the common frame includes a channel formed by inner and outer ribs.

6. The mask system of claim 5, wherein each clip portion is adapted to be received in the channel with an interference seal to thereby removably attach a corresponding one of the first cushioning element and second cushioning element to the common frame.

7. The mask system of claim 5, wherein the clip portion of the first cushioning element comprises foam.

8. The mask system of claim 7, wherein the clip portion of the first cushioning element includes one or more slots formed in the foam of the clip portion to receive the inner and/or the outer ribs of the common frame.

9. The mask system of claim 2, wherein, in a cross-sectional view, the clip portion of the first cushioning element is narrower than the interfacing portion in a radial direction of the first cushioning element.

10. The mask system of claim 9, wherein an unsupported inner region of the interfacing portion overhangs the clip portion.

11. The mask system of claim 10, wherein the unsupported inner region of the interfacing portion is configured to, in use, bend and conform to the patient's face upon engagement with the patient's face.

12. The mask system of claim 11, wherein the unsupported inner region of the interfacing portion is configured to, in use, engage a nasal bridge region of the patient's face.

13. The mask system of claim 9, wherein the clip portion and the interfacing portion of the first cushioning element are aligned at their outer perimeters.

14. The mask system of claim 2, wherein neither-inner perimeters of the clip portion and the interfacing portion of the first cushioning element are not aligned with one another and outer perimeters of the clip portion and the interface portion of the first cushioning element are not aligned with one another.

15. The mask system of claim 1, wherein the resilient foam of the first cushioning element is an unskinned resilient viscoelastic polyurethane foam.

16. The mask system of claim 1, wherein the interfacing portion has an air permeability in the range of about 0 to about 50 $L/s/m^2$.

17. The mask system of claim 1, wherein the first cushioning element includes a clip portion,

wherein the clip portion has a first side adapted to couple with the common frame and a second side adhered to a contact region of the interfacing portion, and

wherein an overhanging region of the interfacing portion of the first cushioning element extends beyond the clip portion and is configured to flex over the clip portion when the patient's face engages with the interfacing portion in use.

18. The mask system of claim 17, wherein, in a cross-sectional view, a width of the clip portion is narrower than a width of the interfacing portion in a radial direction of the first cushioning element.

19. The mask system of claim 18, wherein an outer perimeter of the clip portion and an outer perimeter of the interfacing portion are aligned.

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