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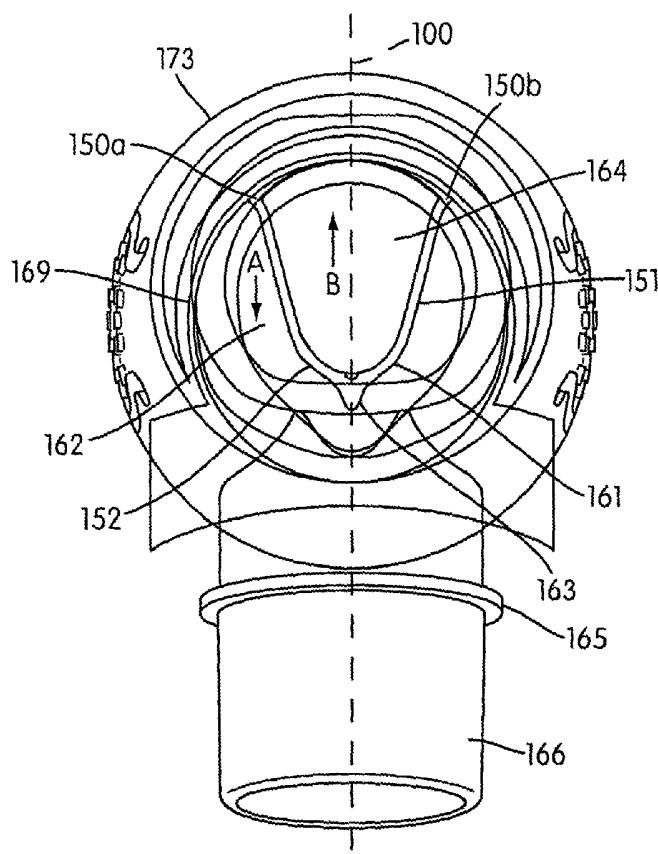
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[Continued on next page]

(54) Title: ELBOW FOR MASK ASSEMBLY



(57) Abstract: An elbow assembly for use in a respiratory mask, which includes an elbow, (160), an inlet port (162), an exhaust port (164) and a baffle (161) separating the inlet port from the exhaust port. A mask assembly includes a cushion (30) comprising at least one gusset and an aperture (42) for connection to the elbow assembly (20).



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## **ELBOW FOR MASK ASSEMBLY**

### **CROSS-REFERENCE TO PRIORITY APPLICATIONS**

The present application claims priority to U.S. Provisional Application Serial No. 60/424,695 filed November 8, 2002, U.S. Provisional Application Serial No. 60/474,928 filed 5 June 3, 2003, and U.S. Non-Provisional Application Serial No. 10/235,846 filed September 6, 2002, which in turn claims priority to U.S. Provisional Application No. 60/317,486 filed September 7, 2001 and U.S. Provisional Application Serial No. 60/342,854 filed December 28, 2001. Each of the above identified applications is incorporated herein by reference in its entirety.

10

### **BACKGROUND OF THE INVENTION**

#### 1. Field of the Invention

The invention relates to a mask frame and elbow for use with a mask system for Non-invasive Positive Pressure Ventilation (NPPV) and for continuous positive airway pressure (CPAP) therapy of sleep disordered breathing (SDB) conditions such as obstructive sleep apnea 15 (OSA).

#### 2. Background of the Invention

The use of NPPV for treatment of SDB, such as OSA was pioneered by Sullivan (see, for example, U.S. Pat. No. 4,944,310, the contents of which are hereby incorporated in their entirety by reference). Apparatus for this treatment involves a blower which delivers a supply 20 of air at positive pressure to a patient interface via an air delivery conduit. The patient interface may take several forms such as nasal masks and nose and mouth masks. Patients must wear a mask all night while sleeping to receive the therapy.

Masks typically comprise a rigid shell or frame and a soft face-contacting cushion that spaces the frame away from the face and forms a seal with the patient's face. The frame and 25 cushion define a cavity which receives the nose, or nose and mouth. The mask is held in position by headgear, which usually comprises an arrangement of straps that passes along the side of the face to the back or crown of the head.

Kwok *et al.* (U.S. Pat. No. 6,112,746), the contents of which are hereby incorporated in their entirety by reference, describe a nasal mask and mask cushion. The mask cushion is a substantially triangularly shaped frame from which extends a membrane. The mask frame has a scalloped edge by which the mask cushion is affixed to a mask frame. The membrane has an 5 aperture into which the user's nose is received. The membrane is spaced away from the rim of the frame, and its outer surface has substantially the same shape as the rim.

Frater *et al.* (PCT Patent Application AU01/00746, published as WO 01/97893), the contents of which are hereby incorporated in their entirety by reference, describes a mask system for delivering air to a user includes a suspension mechanism to allow relative 10 movement between a face-contacting cushion and a mask frame. The suspension mechanism also provides a predetermined force to the cushion that is a function of mask pressure, displacement of the cushion, or both.

During the course of the respiratory cycle patients inhale air, largely comprising a mixture of nitrogen and oxygen, and exhale a mixture of gases including a relatively higher 15 fraction of CO<sub>2</sub>. In a nasal mask system where the patient breathes through the nose, there can be a build-up of CO<sub>2</sub> in the mask cavity which can lead to undesirable CO<sub>2</sub> re-breathing. Hence a variety of vents have been developed for use with masks. The amount of CO<sub>2</sub> in the mask cavity is a function of vent geometry, mask geometry, flow patterns within the mask and the amount of dead-space within the mask cavity.

20 The mask is typically joined to the air delivery conduit using a friction fit. Since the blower is typically placed beside a patient's bed, it is typical that the air delivery conduit be at least 1 meter long. Occasionally, movement of the air delivery conduit can disrupt the seal. Furthermore, some patients prefer to have the conduit in one position (for example passing over their heads), whereas other patients prefer to have it in another position (for example to 25 the left or right side). Hence swivel elbows were developed for some masks.

Swivel elbows typically include: (i) a cylindrical first portion, having an axis aligned in a first direction and being adapted for connection to an air delivery conduit; and (ii) a cylindrical second portion, having an axis aligned in a second direction and being adapted for connection to a frame of a mask.

The first and second directions typically are at right angles to one another. The first portion has an outer diameter slightly smaller than the inner diameter of typical air delivery conduit tubing, so that the tubing can overfit the first portion and be held in position by friction. A free end of the second portion is adapted to pass through an orifice in the mask frame. Such known swivel elbows typically include a vent. While some vents are simply holes, such as those in the Puritan-Bennett SOFTFIT mask (Figure 10a), others are more sophisticated, such as those used with the ResMed ULTRA MIRAGE® mask.

A problem with the prior art swivel elbows incorporating a simple vent, such as the Puritan-Bennett SOFTFIT (Figure 10a), the Resironics CONTOUR-DELUXE (Figure 10c) and the related art Tiara ADVANTAGE elbows (Figure 10b), is that air from the blower can simply short-circuit the mask and pass straight out of the vent. This is a particular problem when a patient is being given supplemental oxygen, which is expensive. A significant portion of the oxygen being fed to the elbow simply passes out the vent without entering the mask.

Figures 8a, 8b, 9a, and 9b show prior art elbows manufactured by ResMed Limited for the STANDARD and MODULAR masks respectively. Figures 8c, 8d, 9c, and 9d show related art elbows manufactured by ResMed Limited for the ULTRA MIRAGE® and MIRAGE® VISTA masks respectively. Figures 11a to 11f show prior art elbows in the WHISPER swivel I and swivel II masks manufactured by Resironics. Figures 12 and 13 show a prior art mask SERENITY mask manufactured by DeVilbiss in which the interior of the nasal cavity includes a baffle B for redirecting incoming gas.

A mask that includes a cushion with a gusset will have a larger cavity, and hence more dead-space than a mask without a gusset, everything else being equal. Hence in a mask assembly with a gusset, particular attention needs to be paid to venting the mask to ensure that sufficient CO<sub>2</sub> is washed out by a continuous influx of fresh air.

Since the mask is to be used by sleeping users, it is also desirable to reduce or eliminate noise from all sources, including those caused by the venting of gases from the mask.

Kwok (PCT/AU98/00067, published as WO 98/34665), the contents of which are hereby incorporated in their entirety by reference, describes a mask and a vent. In one form the vent comprises a soft flexible insert piece with a series of orifices.

Drew *et al.* (PCT/AU00/00636 published as WO 00/78381), the contents of which are hereby incorporated in their entirety by reference, disclose a connector that comprises a mask end for connecting, in fluid communication, with the interior of a respiratory mask and a supply conduit end disposed at an angle to the mask end for connecting, in fluid communication, with the outlet of a breathable gas supply conduit. The connector also includes a gas washout vent passage having an inlet adjacent to, or forming part of, the mask end in fluid communication with the interior of the respiratory mask and an outlet in fluid communication with the atmosphere. The outlet includes an interior surface that forms a smooth prolongation with an adjacent exterior surface of the connector. The vent outlet is disposed on the side of the connector remote the mask end, has a generally part-annular cross section and is adapted to direct the washout gas in a direction substantially perpendicular to the longitudinal axis of the mask end and substantially parallel to the longitudinal axis of the supply conduit end towards the supply conduit end.

Moore *et al.* (co-pending provisional application serial no. 60/502,509, filed August 12, 2002), the contents of which are hereby incorporated in their entirety by reference, describe a mask system including a swivel elbow with a vent.

Correa *et al.* (U.S. Pat. No. 6,119,694) discloses a nasal mask assembly with a miniature nare seal. The mask assembly includes a conduit receptor that attaches to a gas delivery tube. Downstream of the conduit receptor is a bore that receives a stem having opposed flanges. The flanges separate the incoming gas into a plurality of channels, such that the gas is provided to one of a plurality of spatial regions in the interior of the nare seal.

While the vents and connectors described in the previous references provide adequate intake of breathable air/gas and venting for masks that have a small amount of dead-space, e.g., without gussets, they may be inadequate to provide air intake and CO<sub>2</sub> removal in masks that have larger amounts of dead-space, e.g., with gussets. Therefore, there exists a need in the art for a swivel elbow and mask assembly that overcome the problems listed above.

### SUMMARY OF THE INVENTION

A first aspect of the invention is directed towards providing an elbow for a mask which provides improved flow patterns for inlet and exhaust flows.

A second aspect of the invention is directed towards providing an elbow, comprising a baffle.

A third aspect of the invention is directed towards providing an elbow for a mask that includes an exhaust port for a mask and a baffle that extends from the elbow into the mask cavity.

Another aspect of the invention is directed towards providing a swivel elbow including an exhaust port for a mask, wherein the swivel elbow includes structure for ensuring that fresh air from the blower does not directly reach the vent.

Another aspect of the invention is directed towards a swivel elbow assembly that is easy to assemble and disassemble.

Another aspect of the invention is directed towards a mask assembly using an elbow assembly that permits better intake of breathable air and/or better removal of exhaust air.

Another aspect of the invention is directed towards a mask assembly using an elbow assembly that is quieter for the user and/or bed partner.

Another aspect of the invention is directed towards an elbow assembly for a respiratory mask comprising an elbow, including a portion adapted to engage a gas delivery tube and another portion that is detachable and is coupled to the mask. The elbow further defines an inlet port to deliver incoming gas into a nasal breathing cavity defined by the mask and an exhaust port separated from the inlet port by a curved baffle.

Another aspect of the invention is directed towards providing an elbow for a mask comprising: (i) a portion for connecting to a gas delivery tube; (ii) a portion that is connected to a mask cavity; (iii) an inlet port to deliver incoming gas into the breathing cavity; (iv) an exhaust port to washout CO<sub>2</sub>; and (v) a baffle that separates the inlet and exhaust ports.

Another aspect of the invention is directed towards a baffle for use with an elbow and mask assembly, for directing the inlet and outlet flows of the mask assembly.

A further aspect of the invention is directed towards a mask assembly comprising a mask frame, a mask cushion, and an elbow assembly.

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 FIGURES**

5 Figure 1 is an exploded cross-sectional view of a respiratory mask assembly according to one embodiment of the present invention;

Figure 2 is an assembled cross-sectional view of the respiratory mask assembly shown in Figure 1;

10 Figure 3a is a perspective view of a ring according to one embodiment of the present invention;

Figure 3b is a cross-sectional view of a frame portion of the respiratory mask assembly shown in Figure 2;

Figure 4a is a cross-sectional view of one embodiment of the swivel elbow according to the present invention;

15 Figure 4b is a front view of the swivel elbow shown in Figure 4a;

Figure 4c is a detailed cross-sectional view of the lower portion of the baffle shown in the swivel elbow of Figure 4b;

Figure 4d is a perspective view of a swivel elbow according to another embodiment of the present invention;

20 Figure 4e is a perspective view of a swivel elbow according to another embodiment of the present invention;

Figure 5a is a front view of the respiratory mask assembly shown in Figure 2;

Figure 5b is a left side view of the respiratory mask assembly shown in Figure 5a;

Figure 5c is a right side view of the respiratory mask assembly shown in Figure 5a;

- Figure 5d is a top view of the respiratory mask assembly shown in Figure 5a;
- Figure 6a is a front view of the respiratory mask frame shown in Figure 5a;
- Figure 6b is a rear view of the respiratory mask frame shown in Figure 6a;
- Figure 6c is a front perspective view of the respiratory mask frame shown in Figure 6a;
- 5 Figure 6d is a rear perspective view of the respiratory mask frame shown in Figure 6a;
- Figure 6e is a cross-sectional view along line 6e-6e of the respiratory mask frame shown in Figure 6a;
- Figure 6f is a right side view of the respiratory mask frame shown in Figure 6a;
- 10 Figure 6g is a cross-sectional view along line 6g-6g of the respiratory mask frame shown in Figure 6b;
- Figure 6h is a cross-sectional view along line 6h-6h of the respiratory mask frame shown in Figure 6a;
- Figure 6i is a cross-sectional view along line 6i-6i of the respiratory mask frame shown in Figure 6b;
- 15 Figure 6j is a cross-sectional view along line 6j-6j of the respiratory mask frame shown in Figure 6g;
- Figure 6k is a cross-sectional view along line 6k-6k of the respiratory mask frame shown in Figure 6a;
- Figure 6l is a bottom view of the respiratory mask frame shown in Figure 6b;
- 20 Figure 6m is a detailed cross-sectional view of an exhaust port according to the embodiment of the respiratory mask frame shown in Figure 6g;
- Figure 7a is a front view of the front of the swivel elbow shown in Figure 4a;
- Figure 7b is an alternative front view of the swivel elbow shown in Figure 7a;

Figure 7c is a cross-sectional view along line 7c-7c of the swivel elbow shown in Figure 7a;

Figure 7d is a right side view of the swivel elbow shown in Figure 7a;

Figure 7e is a top view of the top of the swivel elbow shown in Figure 7a;

5 Figure 7f a cross-sectional view along line 7f-7f of the swivel elbow shown in Figure 7b;

Figure 7g is a rear perspective view of the swivel elbow shown in Figure 7a;

Figure 7h is a front perspective view of the swivel elbow shown in Figure 7a;

Figure 7i is a bottom view of the swivel elbow shown in Figure 7a;

10 Figure 8a is a rear view of a prior art swivel elbow;

Figure 8b is a rear view of a prior art swivel elbow;

Figure 8c is a rear view of a related art swivel elbow;

Figure 8d is a rear view of a related art swivel elbow;

Figure 9a is a cross-sectional view of the front of the swivel elbow shown in Figure 8a;

15 Figure 9b is a cross-sectional view of the front of the swivel elbow shown in Figure 8b;

Figure 9c is a cross-sectional view of the front of the swivel elbow shown in Figure 8c;

Figure 9d is a cross-sectional view of the front of the swivel elbow shown in Figure 8d;

Figure 10a is a cross-sectional view of a prior art swivel elbow;

Figure 10b is a cross-sectional view of a related art swivel elbow;

20 Figure 10c is a cross-sectional view of a prior art swivel elbow;

Figure 11a is a front view of a side of a part of a prior art swivel elbow;

Figure 11b is a left side view of the swivel elbow shown in Figure 11a;

Figure 11c is a detailed cross-sectional view of vents on the swivel elbow shown in Figure 11a;

Figure 11d is an exploded view of a part of another prior art swivel elbow;

5 Figure 11e is a cross-sectional view of the swivel elbow shown in Figure 11d in an assembled state;

Figure 11f is a bottom view of the swivel elbow shown in Figure 11e;

Figure 12 is a rear view of a prior art respiratory mask assembly;

10 Figure 13 is a cross-sectional view along line 13-13 of the respiratory mask assembly shown in Figure 12;

Figure 14 is a front perspective view of a swivel elbow according to another embodiment of the invention;

Figure 15a is a front view of the swivel elbow shown in Figure 14;

Figure 15b is a top view of the swivel elbow shown in Figure 15a;

15 Figure 15c is a bottom view of the swivel elbow shown in Figure 15a;

Figure 15d is a right side view of the swivel elbow shown in Figure 15a;

Figure 15e is a right side view of the swivel elbow shown in Figure 15d;

Figure 15f is a cross-sectional view along line 15f-15f of the swivel elbow shown in Figure 15e;

20 Figure 15g is a cross-sectional view along line 15g-15g of the swivel elbow shown in Figure 15a;

Figure 15h is a detailed view of a portion of the swivel elbow shown in Figure 15g;

Figure 15i is a front perspective view of the swivel elbow shown in Figure 15a;

Figure 15j is a rear perspective view of the swivel elbow shown in Figure 15a;

Figure 16a is a front perspective view of a swivel elbow according to another embodiment of the invention;

Figure 16b is a rear perspective view of the swivel elbow shown in Figure 16a;

5 Figure 17a is a front view of the swivel elbow shown in Figure 16a;

Figure 17b is a top view of the swivel elbow shown in Figure 17a;

Figure 17c is a bottom view of the swivel elbow shown in Figure 17a;

Figure 17d is a right side view of the swivel elbow shown in Figure 17a;

Figure 17e is a rear view of the swivel elbow shown in Figure 17a;

10 Figure 17f is a cross-sectional view along line 17f-17f of the swivel elbow shown in Figure 17e;

Figure 17g is a cross-sectional view along line 17g-17g of the swivel elbow shown in Figure 17a;

Figure 17h is a detailed view of a portion of the swivel elbow shown in Figure 17g;

15 Figure 17i is another front perspective view of the swivel elbow shown in Figure 16a at a slightly different angle;

Figure 17j is a rear perspective view of the swivel elbow shown in Figure 16b at a slightly different angle;

20 Figure 18a is a front perspective view of a swivel elbow according to another embodiment of the invention;

Figure 18b is a rear perspective view of the swivel elbow shown in Figure 18a;

Figure 19a is a front view of the swivel elbow shown in Figure 18a;

Figure 19b is a top view of the swivel elbow shown in Figure 19a;

- Figure 19c is a bottom view of the swivel elbow shown in Figure 19a;
- Figure 19d is a right side view of the swivel elbow shown in Figure 19a;
- Figure 19e is a rear view of the swivel elbow shown in Figure 19a;
- Figure 19f is a cross-sectional view along line 19f-19f of the swivel elbow shown in  
5 Figure 19e;
- Figure 19g is a cross-sectional view along line 19g-19g of the swivel elbow shown in  
Figure 19a;
- Figure 19h is a detailed view of a portion of the swivel elbow shown in Figure 19g;
- Figure 19i is another front perspective view of the swivel elbow shown in Figure 18a at  
10 a slightly different angle;
- Figure 19j is another rear perspective view of the swivel elbow shown in Figure 18b at  
a slightly different angle;
- Figure 20a is a front perspective view of a swivel elbow according to another  
embodiment of the invention;
- 15 Figure 20b is a rear perspective view of the swivel elbow shown in Figure 20a;
- Figure 21a is a front view of the swivel elbow shown in Figure 20a;
- Figure 21b is a top view of the swivel elbow shown in Figure 21a;
- Figure 21c is a bottom view of the swivel elbow shown in Figure 21a;
- Figure 21d is a right side view of the swivel elbow shown in Figure 21a;
- 20 Figure 21e is a rear view of the swivel elbow shown in Figure 21a;
- Figure 21f is a cross-sectional view along line 21f-21f of the swivel elbow shown in  
Figure 21e;

Figure 21g is a cross-sectional view along line 21g-21g of the swivel elbow shown in Figure 21a;

Figure 21h is a detailed view of a portion of the swivel elbow shown in Figure 21g;

5 Figure 21i is another front perspective view of the swivel elbow shown in Figure 20a at a slightly different angle;

Figure 21j is another rear perspective view of the swivel elbow shown in Figure 20b at a slightly different angle;

Figure 22a is a front perspective view of a swivel elbow according to another embodiment of the invention;

10 Figure 22b is a rear perspective view of the swivel elbow shown in Figure 22a;

Figure 23a is a front view of the swivel elbow shown in Figure 22a;

Figure 23b is a top view of the swivel elbow shown in Figure 23a;

Figure 23c is a bottom view of the swivel elbow shown in Figure 23a;

Figure 23d is a right side view of the swivel elbow shown in Figure 23a;

15 Figure 23e is a rear view of the swivel elbow shown in Figure 23a;

Figure 23f is a cross-sectional view along line 23f-23f of the swivel elbow shown in Figure 23e;

Figure 23g is a cross-sectional view along line 23g-23g of the swivel elbow shown in Figure 23a;

20 Figure 23h is a detailed view of a portion of the swivel elbow shown in Figure 23g;

Figure 23i is another front perspective view of the swivel elbow shown in Figure 22a at a slightly different angle;

Figure 23j is another rear perspective view of the swivel elbow shown in Figure 22b at a slightly different angle;

Figure 24a is a front perspective view of a swivel elbow according to another embodiment of the invention;

Figure 24b is a rear perspective view of the swivel elbow shown in Figure 24a;

Figure 25a is a front view of the swivel elbow shown in Figure 24a;

5 Figure 25b is a top view of the swivel elbow shown in Figure 25a;

Figure 25c is a bottom view of the swivel elbow shown in Figure 25a;

Figure 25d is a right side view of the swivel elbow shown in Figure 25a;

Figure 25e is a rear view of the swivel elbow shown in Figure 25a;

10 Figure 25f is a cross-sectional view along line 25f-25f of the swivel elbow shown in Figure 25e;

Figure 25g is a cross-sectional view along line 25g-25g of the swivel elbow shown in Figure 25a;

Figure 25h is a detailed view of a portion of the swivel elbow shown in Figure 25g;

15 Figure 25i is another front perspective view of the swivel elbow shown in Figure 24a at a slightly different angle;

Figure 25j is another rear perspective view of the swivel elbow shown in Figure 24b at a slightly different angle;

Figure 26a is a front perspective view of a swivel elbow according to another embodiment of the invention;

20 Figure 26b is a rear perspective view of the swivel elbow shown in Figure 26a;

Figure 27a is a front view of the swivel elbow shown in Figure 26a;

Figure 27b is a top view of the swivel elbow shown in Figure 27a;

Figure 27c is a bottom view of the swivel elbow shown in Figure 27a;

- Figure 27d is a right side view of the swivel elbow shown in Figure 27a;
- Figure 27e is a rear view of the swivel elbow shown in Figure 27a;
- Figure 27f is a cross-sectional view along line 27f-27f of the swivel elbow shown in Figure 27e;
- 5 Figure 27g is a cross-sectional view along line 27g-27g of the swivel elbow shown in Figure 27a;
- Figure 27h is a detailed view of a portion of the swivel elbow shown in Figure 27g;
- Figure 27i is another front perspective view of the swivel elbow shown in Figure 26a at a slightly different angle;
- 10 Figure 27j is another rear perspective view of the swivel elbow shown in Figure 26b at a slightly different angle;
- Figure 28a is a front perspective view of a swivel elbow according to another embodiment of the invention;
- Figure 28b is a rear perspective view of the swivel elbow shown in Figure 28a;
- 15 Figure 29a is a front view of the swivel elbow shown in Figure 28a;
- Figure 29b is a top view of the swivel elbow shown in Figure 29a;
- Figure 29c is a bottom view of the swivel elbow shown in Figure 29a;
- Figure 29d is a right side view of the swivel elbow shown in Figure 29a;
- Figure 29e is a rear view of the swivel elbow shown in Figure 29a;
- 20 Figure 29f is a cross-sectional view along line 29f-29f of the swivel elbow shown in Figure 29e;
- Figure 29g is a cross-sectional view along line 29g-29g of the swivel elbow shown in Figure 29a;

Figure 29h is a detailed view of a portion of the swivel elbow shown in Figure 29g;

Figure 29i is another front perspective view of the swivel elbow shown in Figure 28a at a slightly different angle;

Figure 29j is another rear perspective view of the swivel elbow shown in Figure 28b at 5 a slightly different angle;

Figure 30a is a side view of a swivel elbow according to another embodiment of the invention;

Figure 30b is a right side view of the swivel elbow shown in Figure 30a;

Figure 30c is a top view of the swivel elbow shown in Figure 30a; and

10 Figure 30d is a partial bottom view of the swivel elbow shown in Figure 30a.

#### **DETAILED DESCRIPTION OF ILLUSTRATED EMBODIMENTS**

Figure 1 shows an exploded cross-sectional view of a mask assembly 5 according to one embodiment of the present invention. The mask assembly 5 is intended to be worn by a user 1 and substantially surrounds the nose 3 of the user 1. The mask assembly 5 includes, for example, a mask frame 10, a swivel elbow assembly 20 connected to the mask frame 10, and a cushion 30 connected to the mask frame 10. The swivel elbow assembly is adapted to be 15 connected to an air tube 168 that delivers breathable gas to the user 1.

The cushion 30 is designed to substantially surround the user's nose 3 and apply pressure around the cushion's 30 perimeter while minimizing and/or avoiding contact with pressure sensitive regions on the user's face. Some parts of the user's face, for example, the 20 nasal bridge region, require special attention to achieve a balance between pressure and seal. It is also desirable to provide a low profile mask to improve the comfort level of the user 1 by improving stability, and to reduce the forces which may tend to pivot the mask assembly 5 relative to the user's face. While the cushion 30 is shown as being used with a nasal mask assembly, it can also be designed for use with a full face mask or a nasal/oro mask assembly.

25 The cushion 30 has a face-contacting side 38 and a non face-contacting side 39. The non-face contacting side 39 of the cushion 30 engages the mask frame 10 at points 34a and

34b. Any type of connection system can be used for connecting the cushion 30 to the mask frame 10 in the mask assembly 5. Some examples include interior cushion clips or exterior cushion clips, which are used in ResMed's Ultra Mirage® mask, which is described in U.S. Patent No. 6,412,487, incorporated in its entirety herein by reference. The cushion 30 can be 5 permanently or detachably and/or reattachably connected to the mask frame 10. Other forms of cushion connection may be used such as friction fits, gluing and tongue and groove mechanisms.

The mask frame 10 includes at least one aperture 42, adapted to fit the elbow assembly 20. The aperture 42 has a diameter in its broadest aspect between about 20 mm to about 40 10 mm, more preferably a diameter between about 25 mm to about 30 mm, and most preferably a diameter of about 28 mm. The aperture 42 preferably has a generally circular shape. However, the aperture 42 may have a non-circular shape. Further, the mask frame 10 may have a plurality of apertures therethrough with the elbow assembly 20 coupled to the mask frame 10 15 such that it surrounds the plurality of apertures.

15 Figure 2 is a cross-sectional view of the mask assembly 5, showing one embodiment of the mask frame 10, one embodiment of the cushion 30, and one embodiment of the elbow assembly 20, connected together according to one embodiment of the present invention. Figure 2 also shows a vent cover 180 attached to the swivel elbow 160. The vent cover 180 directs 20 exhaust air along the air tube therefore avoiding disturbance of a bed partner and minimizing noise.

The aperture 42 may optionally include a ring 400. Figure 3a is a perspective view of the ring 400. Ring 400 includes an outer ring 310 and an inner ring 307 defining a passage 306 which directs exhaust through the vent cover 180, e.g., via a vent cavity 308. The outer ring 310 is attached to the inner ring 307 by at least one connecting arm 304. In the embodiment 25 shown in Figure 3a, ring 400 has three connecting arms 304. It would be evident to a person skilled in the art that different numbers of connecting arms 304 can be used.

In one embodiment, the ring 400 is fabricated as one piece with the mask frame 10. In this embodiment, the inner diameter of the aperture 42 is co-incident with the outer ring 310 (i.e., the outer ring 310 is the inner diameter of the aperture 42). In another embodiment, the 30 ring 400 is fabricated separately and adapted to be detachable engaged with the mask frame 10.

Each connecting arm 304 can be essentially straight or can include depressions, notches, and/or projections. In the embodiment shown in Figure 3a, the connecting arm 304 includes one notch 303 and a projection 305. The profile of the ring 400 is shown in Figure 3b.

Figure 3b is a cross-sectional view of the area surrounding the aperture 42 in the mask frame 10. The aperture 42 is surrounded by a flange 301 and a lip 300. The mask frame 10 in this embodiment also includes a bump 302. The flange 301, lip 300, and bump 302 are adapted to engage the elbow assembly 20.

In the embodiment shown in Figure 3b, the outer ring 310 of the ring 400 is integrated with the flange 301. This causes a through channel defined by the aperture 42 in the mask frame 10 and the passage 306 in the ring 400. The outer ring 310 has a diameter in its broadest aspect between about 20 mm to about 40 mm, more preferably a diameter between about 25 mm to about 30 mm, and most preferably a diameter about 24 mm. The passage 306 has a diameter in its broadest aspect between about 4 mm to about 12 mm, more preferably a diameter between about 6 mm to about 10 mm, and most preferably a diameter about 8 mm.

Figures 4a and 4b show one embodiment of a swivel elbow 160 in greater detail. The swivel elbow 160 is rotationally connected to the mask frame 10 and includes a stem 166 which is adapted to receive the air tube 168 to supply pressurized breathable air or gas from a blower (not shown). In the embodiment shown, the stem 166 includes an element 165. A top of element 165 is adapted to engage a bottom of the vent cover 180.

Figure 4a is a cross-sectional view of one embodiment of the swivel elbow 160. It shows that the swivel elbow 160 includes a collar 173 that surrounds the end portion 169 of the elbow 160. The end portion 169 of the elbow 160 extends beyond the collar 173 to improve alignment when assembled into the mask frame 10. In particular, the end portion 169 is adapted to engage notch 303 in the ring 400 (if used). The collar 173 is spaced away from the end portion 169 in concentric relation so as to form a receiving space 183 between the collar 173 and the end portion 169. Collar 173 is adapted to engage bump 302 when the swivel elbow assembly 20 is attached to the mask frame 10. One example of a detachable swivel elbow connection is described in U.S. Patent Application No. 60/402,509, filed August 12, 2002, the contents of which are incorporated in their entirety by reference herein.

In order to improve CO<sub>2</sub> washout in a mask assembly 5, especially with a large breathing cavity 35 such as a full-face mask or a cushion with gusset, a baffle 161 to separate inlet port 162 from the exhaust port 164 has been developed. The exhaust cavity 308 is shown in Fig. 4a as well. The exhaust cavity 308 directs gas washout to the vent cover 180, which is not shown in Fig. 4a. The depth of the baffle 161 is one design parameter that has been manipulated to improve CO<sub>2</sub> washout. A number of different forms of the elbow 160 and the mask frame 10 can be produced to create the desired baffle depth. In one embodiment of the invention, the mask frame 10 does not form the baffle 161, but the whole baffle depth is formed by the elbow 160. In another embodiment, the ring 400 increases the depth of the baffle 161, which also improves CO<sub>2</sub> washout in mask assemblies 5 with large breathing cavities 35.

The swivel elbow 160 includes an intake port 162 and an exhaust port 164. The exhaust port 164 is separated from the intake port 162 by the baffle 161 provided within the interior portion of the elbow 160, as shown in Figures 4a and 4b. The orientation of the intake 162 and exhaust 164 ports is selected such that the incoming gas, indicated by the directional arrow A in the intake port 162, less directly impacts the flow of gas washout indicated by the directional arrow B, along the exhaust port 164. Further, the air/gas entering the elbow 160 is less likely to flow directly into the exhaust port 164 since the baffle 161 forces the incoming air to take a tortuous path, e.g., turn around about 180°, before being able to exit through the exhaust port 20 164.

The baffle 161 is generally curved. Figure 4b shows the baffle 161 according to one embodiment of the present invention. The baffle 161 is generally sinusoidally-shaped and disposed about a center line 100 in a generally symmetric manner. The baffle 161 includes two points 150a and 150b of attachment to the end portion 169, a central portion 152, and a bottom 25 155. The center line 100 intersects the bottom 155 of the baffle 161. The baffle 161 has an inner surface 153 and an outer surface 154, shown in greater detail in Figure 4c.

The baffle 161 includes at least one protrusion 163 that extends from the outer surface 154. The baffle 161 is disposed in a manner such that when the elbow assembly 20 is engaged with the mask frame 10, the inner ring 305 of the ring 400 is situated such that the inner surface 30 153 is in close proximity with the inner ring 305.

The shape of the baffle 161 has several advantages, some of which are: (i) the incoming gas/air supply in the inlet port 162 is directed by the bottom 155 and/or the protrusion 163, which provides a more even flow to the user 1; (ii) the bottom 155 is generally situated under the user's nostrils such that the exhaust air (rich in CO<sub>2</sub>) vented out the exhaust port 164 efficiently; and/or (iii) the noise produced by the user 1 is reduced.

Other embodiments of the baffle 161 are shown in Figures 4d and 4e. In the embodiment shown in Figure 4d, the baffle 161 does not contain the protrusion 163. In the embodiment shown in Figure 4e, the baffle 161 is inverted with respect to Figures 4b and 4d. In the embodiments shown in Figures 4b, 4d, and 4e, the center line 100 is disposed vertically. 10 However, it is within the scope of this invention that additional center lines be disposed horizontally or at any angle between vertical and horizontal.

A variety of other baffle shapes are possible. For example, the baffle 161 may be M-, C-, or V-shaped. A further advantage of a baffle 161 in accordance with an embodiment of the invention is that the cross-sectional area of the exhaust flow path increases from a first end in 15 the interior of the mask to a second end, near the exhaust port 164. In this way, the velocity of the air exhausted via the exhaust port 164 is slowed down, or at least not increased, as it flows out of the elbow 160. This contributes to decreasing the noise of the vent. It is also within the scope of the invention for the elbow 160 to be or be devoid of a vent cavity.

An embodiment of the invention with an M-shaped baffle and increasing vent cavity is 20 shown in Figures 18a to 19j. An embodiment of the invention with a V-shaped baffle and no vent cavity is shown in Figures 22a to 23j. An embodiment of the invention with a C-shaped baffle and increasing vent cavity is shown in Figures 24a to 25j. An embodiment of the invention with a V-shaped baffle and increasing vent cavity is shown in Figures 28a to 29j. All 25 the baffle shapes described provide noise reduction, increased CO<sub>2</sub> washout, and/or optimized and/or low flow impedance. Additional baffle 161 shapes and orientations are possible and within the scope of the present invention.

As mentioned earlier the baffle 161 defines an inlet port 162, through which air from a blower can enter, and an exhaust port 164 within the elbow 160. Air from the blower passes through the air tube 168 to the elbow 160, where it passes through the inlet port 161 and is

"injected" into the cavity 35 of the mask 10. Air continually flows from the mask cavity 35 out to atmosphere via the ring 400 to the exhaust port 164 of the elbow 160.

5 While the embodiment shown in Figures 14a to 15j does not include a baffle 161, it does incorporate other advantages of the invention, including its low profile. An embodiment of the present invention, a "deep" baffle 161 for use in mask assemblies 5 with large breathing cavities 35, is shown in Figures 16a and 16b.

Figures 30a-30d show a swivel elbow in accordance with an alternative embodiment of the invention similar to the embodiment shown in Figures 26a, 26b, 27a-27j. In this embodiment there are two "C"-shaped baffles 161 (Figure 30c). Air enters the elbow from a 10 blower via a stem 166 and is directed to turn through approximately 90 degrees and passes into the mask cavity via the intake port 162 which is located in the center of the elbow. (Figures 30b and 30d). Air from the mask cavity passes out through the exhaust ports 164 which are located on the sides of the elbow and into vent cavity 308 (Figures 30a and 30d).

15 In order to provide sufficient exhaust flow, it is desirable that the exhaust port 164 have a low flow impedance. One way to achieve this is to have as large a cross-sectional area for the exhaust port 164 as possible. However, within a given elbow design, increasing the cross-sectional area of the exhaust port 164 comes at the expense of the inlet port 162. It is also desirable to have as low a flow impedance in the inlet port 162 as possible. Hence in designing the elbow 160, one must take into account the two apparently conflicting design goals.

20 In one embodiment the baffle 161 of the elbow 160 extends into the mask frame 10 and is molded in one piece. In another embodiment, the baffle 161 is split between the swivel elbow 160 and the mask frame 10, and the combination of the two provides a baffle 161 of sufficient length. In the latter embodiment, the swivel elbow 160 is suitable for use with shallow mask frames 10 that do not require a long overall baffle 161.

25 In another form, the baffle 161 is partly formed by the elbow 160 and partly by the frame 10. This configuration can be created in different forms or baffle shapes. When the baffle 161 is formed from the combination of elbow 160 and frame 10, it is possible to create a modular elbow design which can be used with a variety of different mask systems. In order to

form a baffle 161 from the combination of frame 10 and elbow 160, a circular ring 400 is added to the frame.

The ring 400 extends the depth of a baffle 161 into the cavity 35 of the mask frame 10. In this way, the likelihood that fresh inlet air short circuits the mask cavity 35 is reduced. An 5 end of the ring is close to the edge of the user's nose and hence this configuration assists to direct exhaled air from the nose towards the exhaust port 164. The use of a ring 400 molded into the frame 10 obviates the need to extend the baffle 161 of the swivel elbow 160 into the mask frame 10. While a long baffled elbow is suitable for mask assemblies with large cavities, it may not be suitable for mask assemblies with shallow cavities, since it may interfere with a 10 patient's nose. Hence by the use of the combination of mask frame 10 with ring 400 and an elbow 160 with a short baffle, the same elbow 160 can be used on both shallow and large cavitied mask assemblies.

In one form of the invention, the baffle 161 is formed within a cylindrical portion of the elbow 160 adapted for connection to the frame. In the embodiment of the invention, shown in 15 Figures 20a and 21a to 21j, the baffle 161 defines a centrally located exhaust port 164. Air from the blower passes around the outside of the exhaust port 164.

The construction of the elbow 160 in combination with the angle between the two generally cylindrical portions of the elbow 160 leads to a potential dead spot within the blower airflow path. Potential dead spots within the blower flow path represent an opportunity for an 20 exhaust flow path. Hence in one form of the invention, e.g., see Figs. 4a-4c, the exhaust flow path is positioned within the elbow 160 in what would otherwise be a dead spot for blower flow. Thus the cross-sectional area of the exhaust flow path can be increased without having a significant impact on the impedance of the blower flow path and/or an adverse effect on the undesirable noise that may be produced during washout. In this way, it is possible to increase 25 the cross-sectional area of the exhaust flow path from 40% to 60% of the total cross-sectional area (equal to the area of the exhaust flow path and the area of blower flow path) at the entrance to the mask cavity 35.

Another advantage of the baffle 161 in accordance with the invention is that it does not present a significant flow impedance for the blower flow. While a variety of different baffle 30 designs are possible, those which impede the flow path create a resistance to flow from the

blower, causing a large pressure drop along the elbow 160 than would otherwise be the case. The larger the pressure drop in the elbow, the harder the blower must work in order to provide air at a given positive pressure. The harder the blower must work, the more noise is created by the blower, which makes it more difficult for a patient to sleep.

5 In one form of the invention, the elbow 160 comprises two cylindrical portions, a first portion adapted for connection to an air delivery tube 168 and having a first axis; and a second portion adapted for connection to the mask frame 10 and having a second axis, wherein the two axes are disposed at an interior angle of about 100 degrees. This contrasts with prior art elbows where two corresponding axes are disposed at an interior angle of 90 degrees.

10 A further advantage of a swivel elbow 160 in accordance with the invention is that it has a low height (the perpendicular distance it extends from the frame). This reduces the visual impact of the swivel elbow 160, reduces the bending moment of the swivel elbow 160 and reduces the "lever arm" effect of the swivel elbow 160.

15 Figures 5a to 5d show various views of the respiratory mask assembly 10 according to one embodiment of the present invention. Figure 6a to 6m show several views of the respiratory mask assembly 10. Figures 7a to 7i show several views of the swivel elbow 160. The dimensions shown in Figures 5a to 7i are preferred illustrative embodiments that may be varied up to  $\pm 20\%$ , and preferably  $\pm 10\%$ , in embodiments.

20 Other advantages of a swivel elbow and mask frame 10 in accordance with a preferred embodiment of the invention include providing: (i) sufficient inlet area and optimized shape such that flow into the mask assembly 5 is not impeded; and (ii) sufficient outlet flow area that has, in addition, a smooth profile and no restrictions other than a final smooth tapered exit to provide a quiet vent. The latter advantage has been difficult to achieve prior to the present invention.

25 While the invention has been described with reference to a nasal mask, it is applicable to a nose and mouth mask, or mouth mask. Furthermore, while the invention has been described with reference to a swivel elbow 160, it is applicable to fixed elbows. In addition, while one form of the invention is applicable to a cushion 30 which includes a gusset portion

32, other forms of the invention can be used with cushions 30 that do not include a gusset portion 32.

It can thus be appreciated that the aspects of the present invention have been fully and effectively described. The foregoing specific embodiments have been provided to illustrate the 5 structural and functional principles of the present invention, and are not intended to be limiting. To the contrary, the present invention is intended to encompass all modifications, alterations and substitutions within the spirit and scope of the detailed description.

**WHAT IS CLAIMED IS:**

1        1. An elbow assembly for a respiratory mask comprising an elbow, wherein the  
2        elbow comprises:

3                a) a first end portion comprising a surface adapted to engage a surface of  
4        a gas delivery tube; and

5                b) a second end portion provided to the mask,

6        wherein the elbow further defines:

7                i) an inlet port to deliver incoming gas in a first direction to a  
8        nasal breathing cavity defined by the mask, and

9                ii) an exhaust port separated from the inlet port by at least one  
10      baffle,

11        wherein the baffle has at least one arcuate portion, as viewed along the second  
12      end, and the baffle is configured to direct exhaust gas away from the nasal breathing cavity in  
13      a second direction that is substantially opposite to the first direction.

1        2. The elbow assembly according to claim 1, wherein the at least one baffle  
2        comprises a first and a second baffle situated across from one another.

1        3. The elbow assembly according to any one of claims 1 or 2, wherein the baffle  
2        is oriented in the elbow about a center line passing from a top of the elbow to a bottom of the  
3        elbow such that a bottom of the baffle is aligned with the bottom of the elbow.

1        4. The elbow assembly according to any one of claims 1-3, wherein the exhaust  
2        port is completely surrounded by the inlet port.

1        5. The elbow assembly according to any one of claims 1-4, wherein the baffle is  
2        substantially circular.

1           6.       The elbow assembly according to any one of claims 1-5, wherein the baffle is  
2 oriented in the elbow about a center line passing from a right side of the elbow to a left side  
3 of the elbow.

1           7.       The elbow assembly according to any one of claims 1-6, wherein the baffle  
2 further comprises a protrusion adapted to protrude into a breathing cavity of the mask.

1           8.       The elbow assembly according to any one of claims 1-7, wherein the second  
2 end portion of the elbow further comprises:

3                   iii)       a resilient collar that substantially surrounds a mating portion to  
4 define a receiving space between the collar and the mating portion, and wherein the collar is  
5 configured to flex outwardly upon entry of a flange, formed on the mask, into the receiving  
6 space until the second end portion reaches an operative position in which the collar flexes  
7 inwardly by virtue of the resiliency thereof so as to lock the flange with respect to the collar  
8 and thereby detachably couple the elbow to the mask.

1           9.       The elbow assembly according to claim 8, wherein the mating portion extends  
2 beyond the collar to facilitate alignment of the second end portion of the elbow with respect  
3 to the mask.

1           10.      The elbow assembly according to any one of claims 8 or 9, wherein the elbow  
2 further comprises release portions on each side of the collar that are flexed towards one  
3 another to move the collar outwardly so as to allow the flange to move out of the receiving  
4 space to detach the elbow from the mask.

1           11.      The elbow assembly according to any one of claims 1-10, further comprising:  
2                   c)       a removable vent cover detachably connected to the elbow, wherein the  
3 vent cover includes a main body and at least one vent aperture for gas washout.

1           12.      The elbow assembly according to claim 11, wherein the vent cover is made of  
2 a resilient material.

1           13.    The elbow assembly according to any one of claims 1-12, wherein the at least  
2    one baffle is M-shaped, V-shaped or C-shaped.

1           14.    The elbow assembly according to any one of claims 1-12, wherein the exhaust  
2    port increases in area along the second direction.

1           15.    A respiratory mask assembly comprising:  
2               a)    a mask frame further comprising at least one aperture;  
3               b)    a cushion, and  
4               c)    an elbow assembly according to any one of claims 1-14.

1           16.    The mask assembly according to claim 15, wherein the aperture has a diameter  
2    between about 20 mm to about 40 mm, preferably between about 25 mm to about 30 mm, and  
3    more preferably about 28 mm.

1           17.    The mask assembly according to any one of claims 15-16, wherein the aperture  
2    has a generally circular shape.

1           18.    The mask assembly according to any one of claims 16-17, wherein the aperture  
2    further comprises a ring.

1           19.    The mask assembly according to claim 18, wherein the ring further comprises  
2    an inner ring.

1           20.    The mask assembly according to claim 19, wherein the inner ring is linked to  
2    an inner diameter of the aperture by at least one connector.

1           21.    The mask assembly according to claim 20, wherein the at least one connector  
2    comprises at least one notch adapted to engage the elbow.

1           22.    The mask assembly according to claim 19, wherein the ring further comprises  
2    an outer ring surrounding the inner ring.

1           23.    The mask assembly according to claim 22, wherein the outer ring has a  
2    diameter between about 20 mm to about 40 mm, preferably between about 25 mm to about 30  
3    mm, and most preferably about 24 mm.

1           24.    The mask assembly according to claim 19, wherein the inner ring defines a  
2    cavity.

1           25.    The mask assembly according to claim 24, wherein the cavity has a diameter  
2    between about 4 mm to about 12 mm.

1           26.    The mask assembly according to claim 25, wherein the cavity has a diameter  
2    between about 6 mm to about 10 mm, preferably about 8 mm.

1           27.    The mask assembly according to any one of claims 15-26, wherein the cushion  
2    is adapted to be inserted into the mask frame to define a cavity surrounding a user's nose.

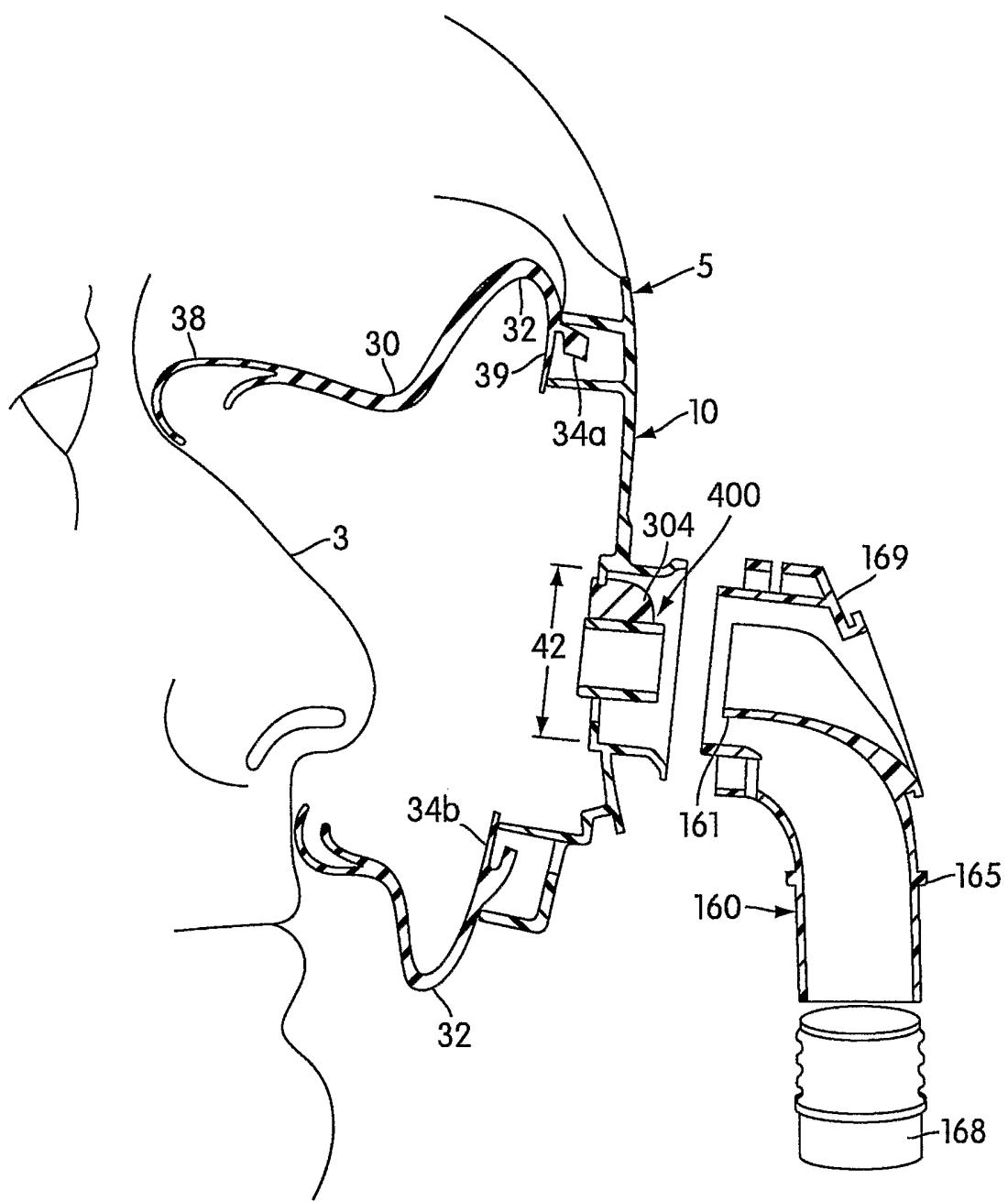


FIG. 1

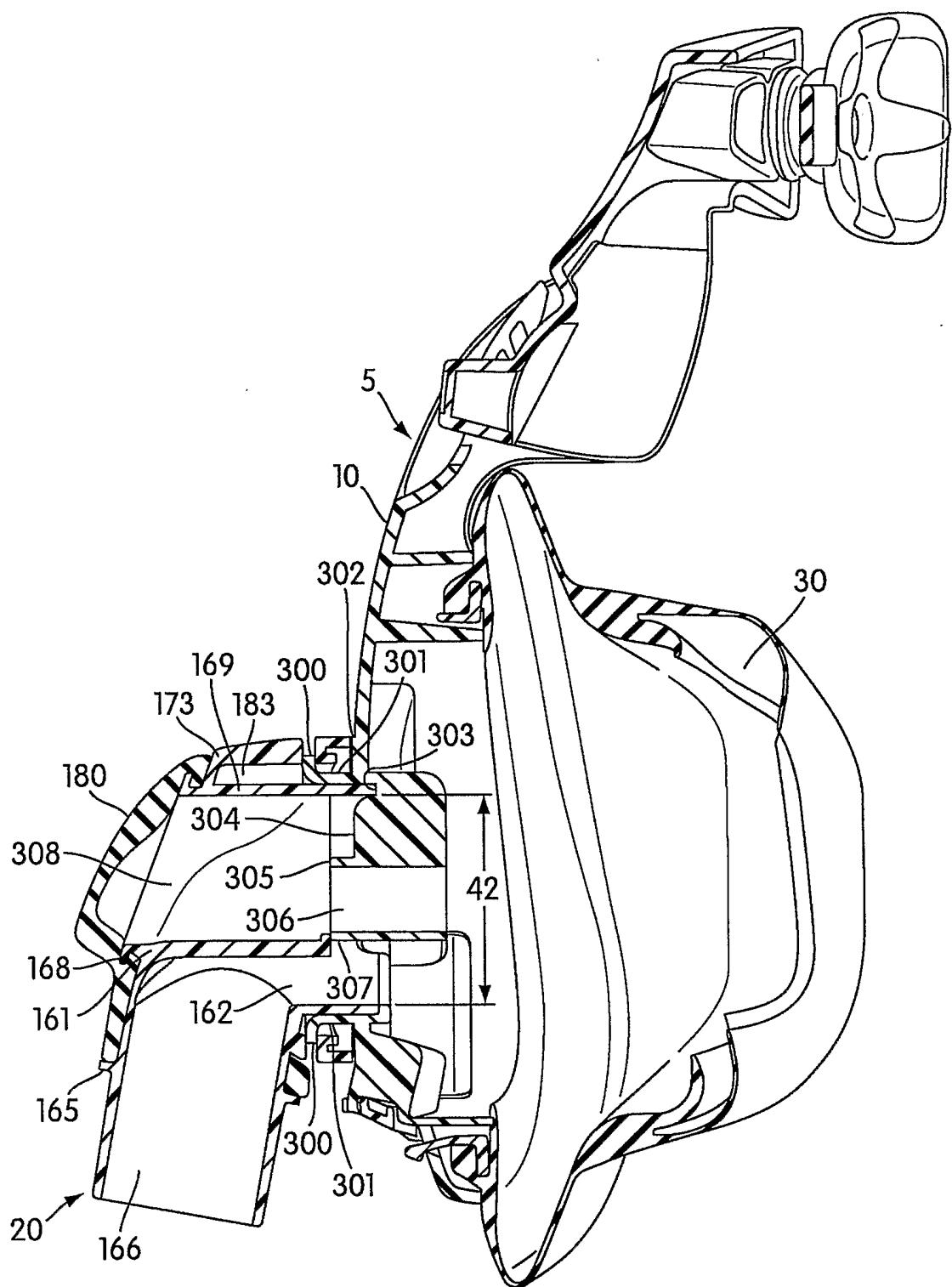
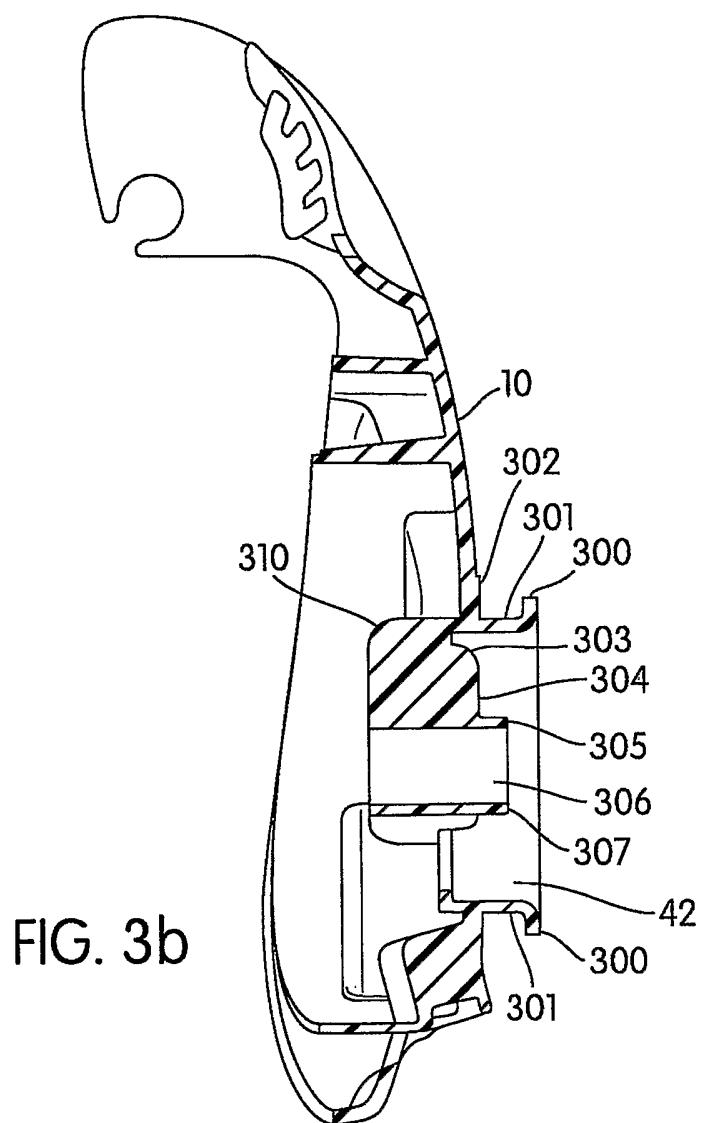
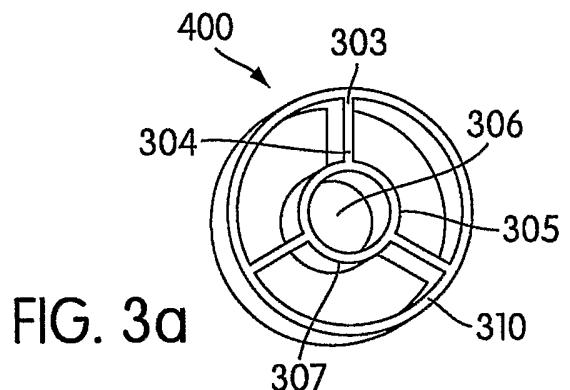


FIG. 2

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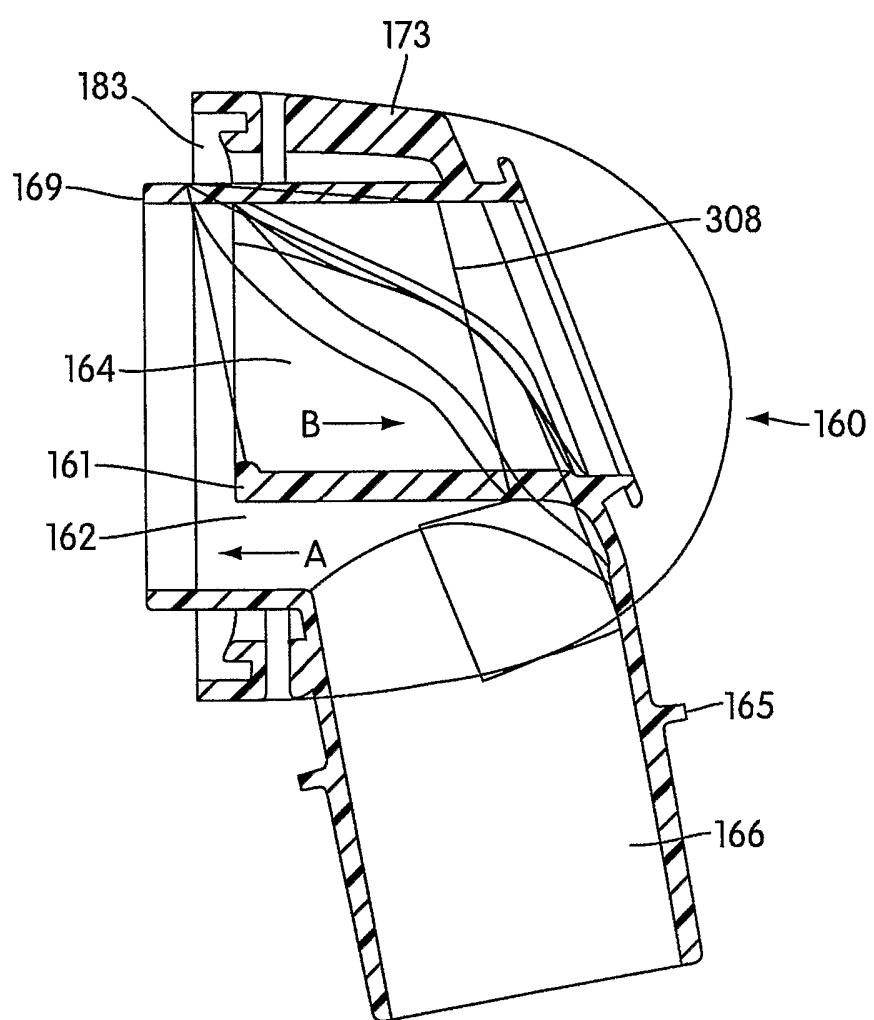


FIG. 4a

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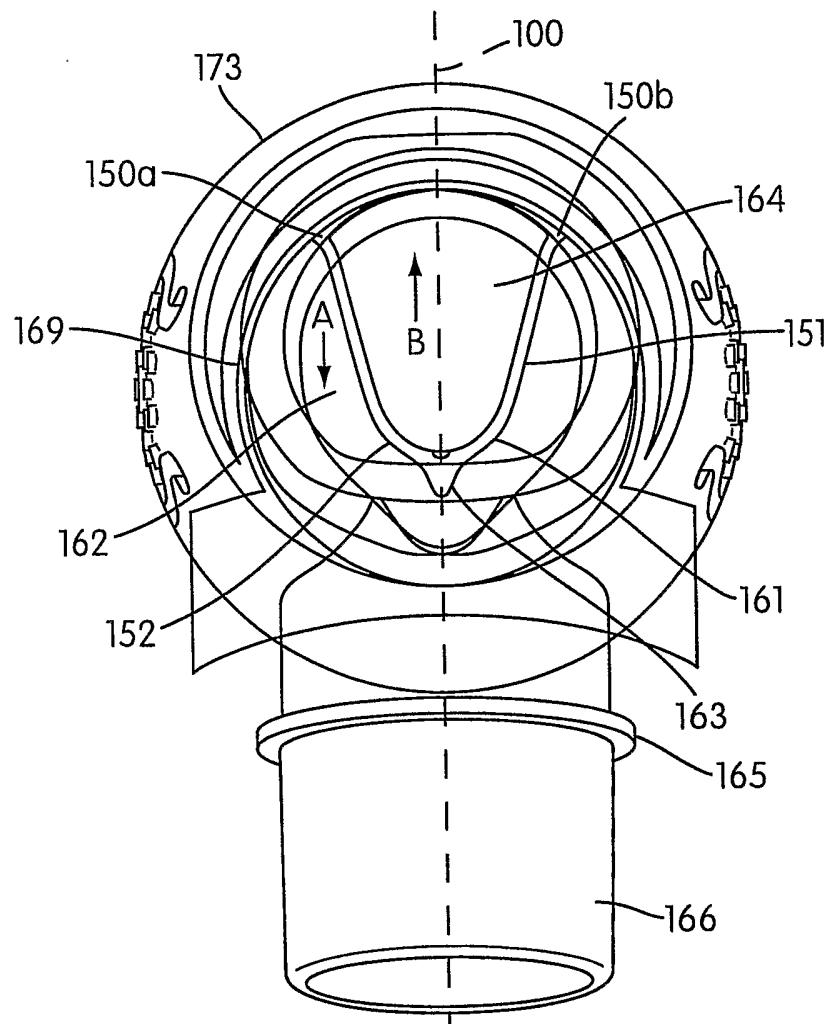


FIG. 4b

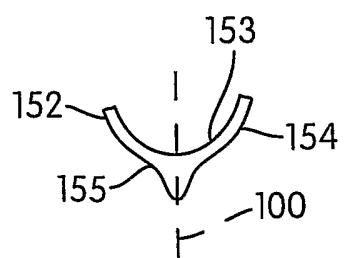


FIG. 4c

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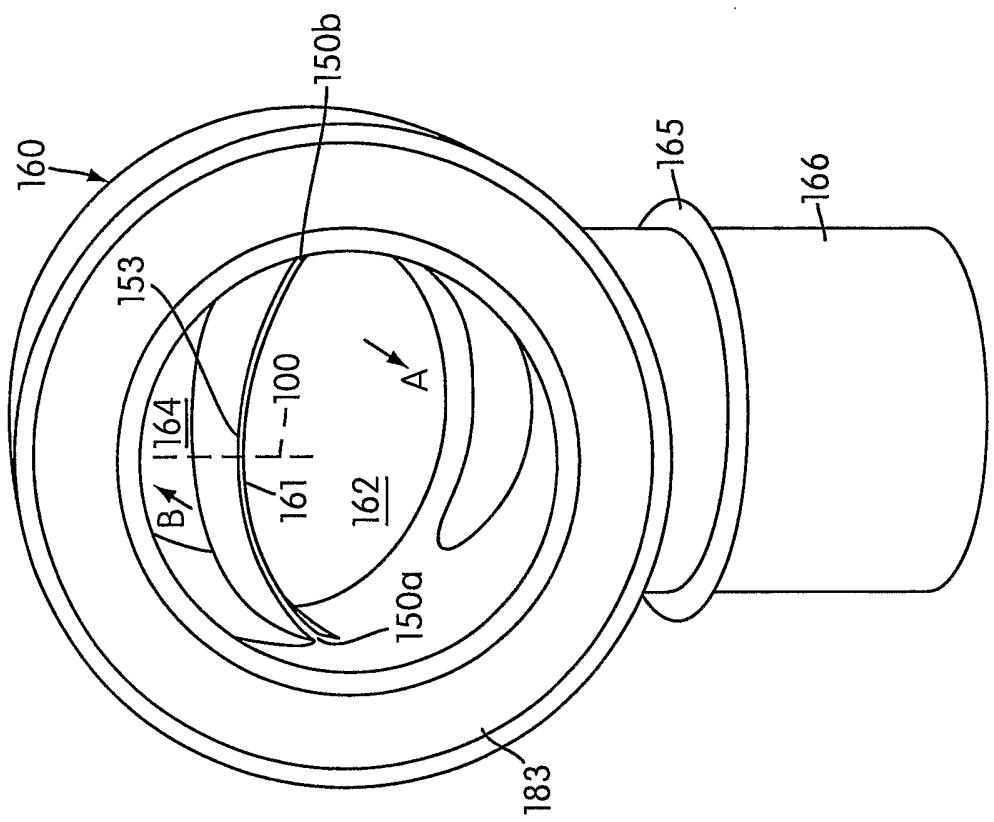


FIG. 4e

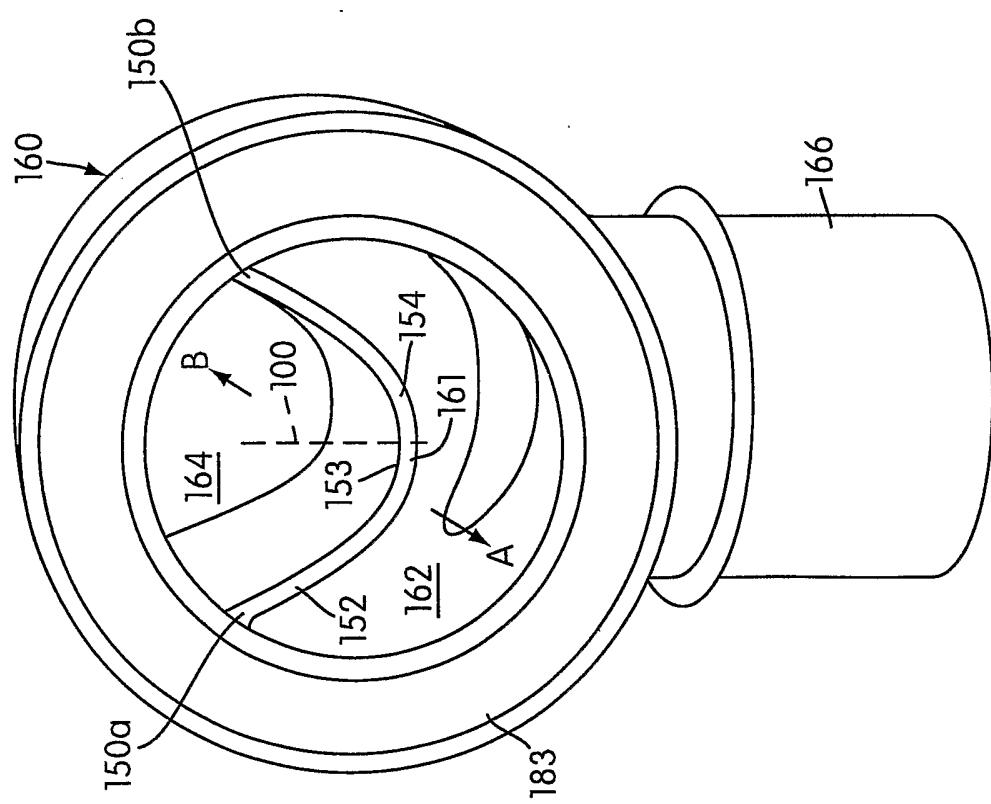


FIG. 4d

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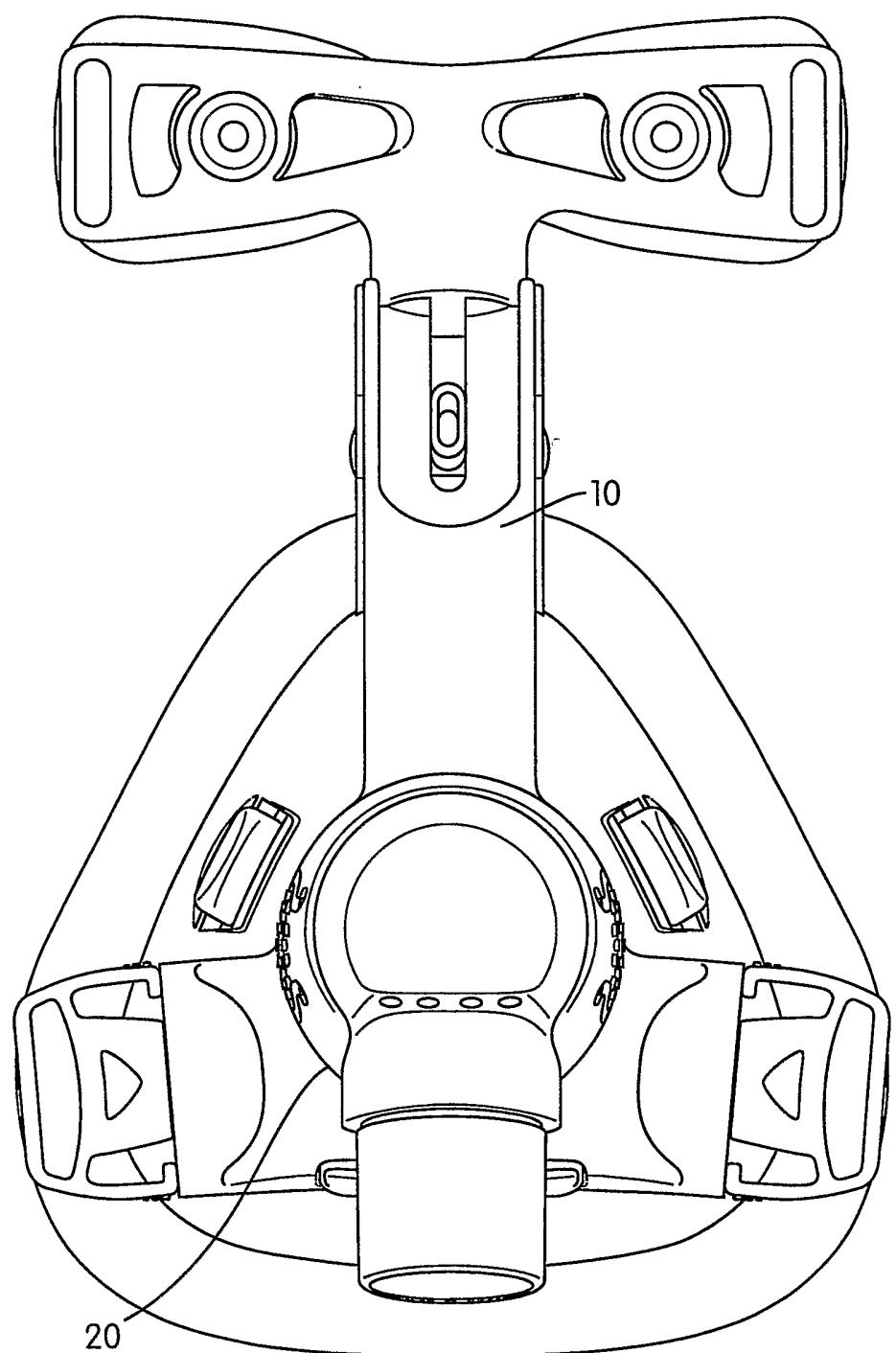


FIG. 5a

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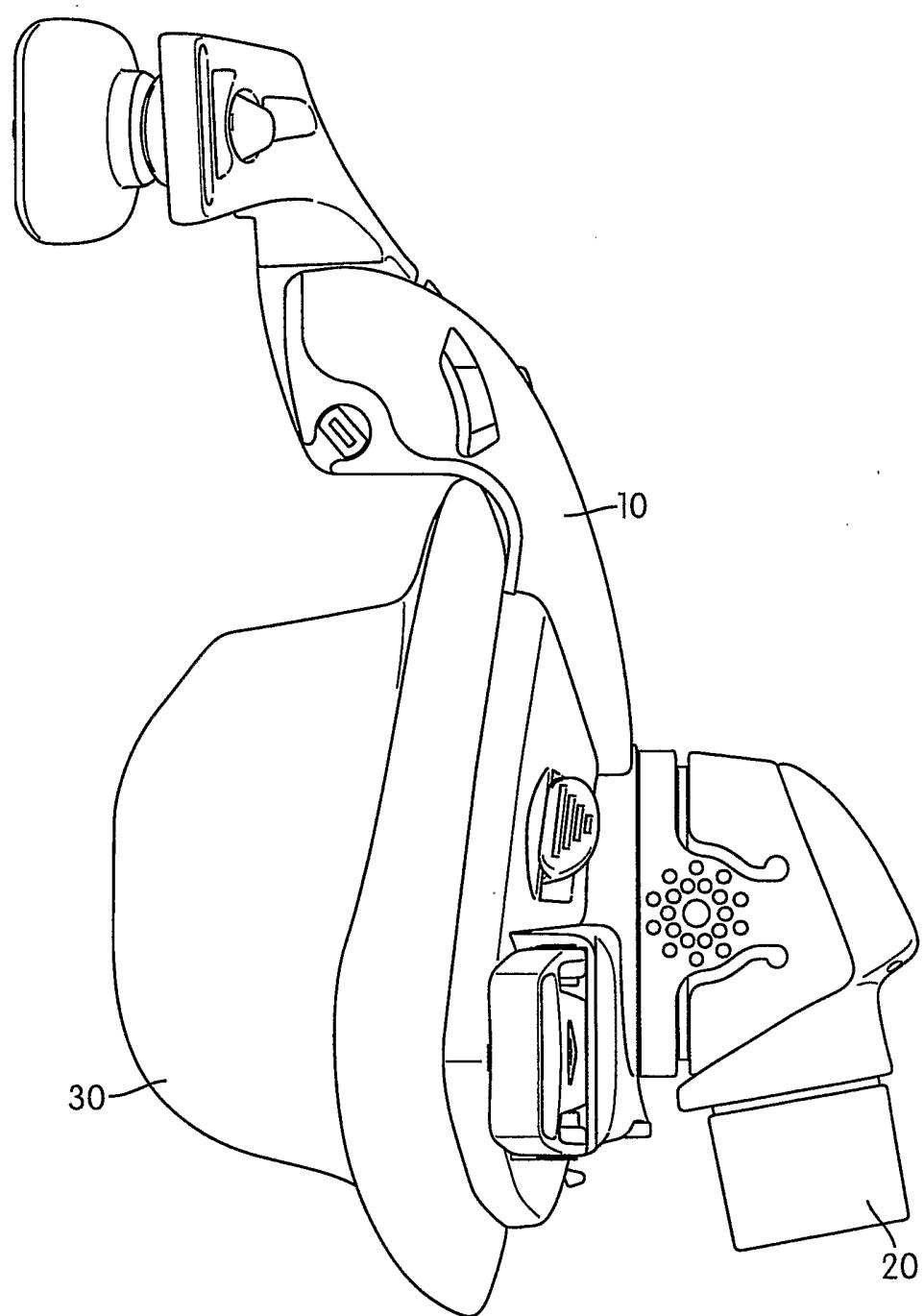


FIG. 5b

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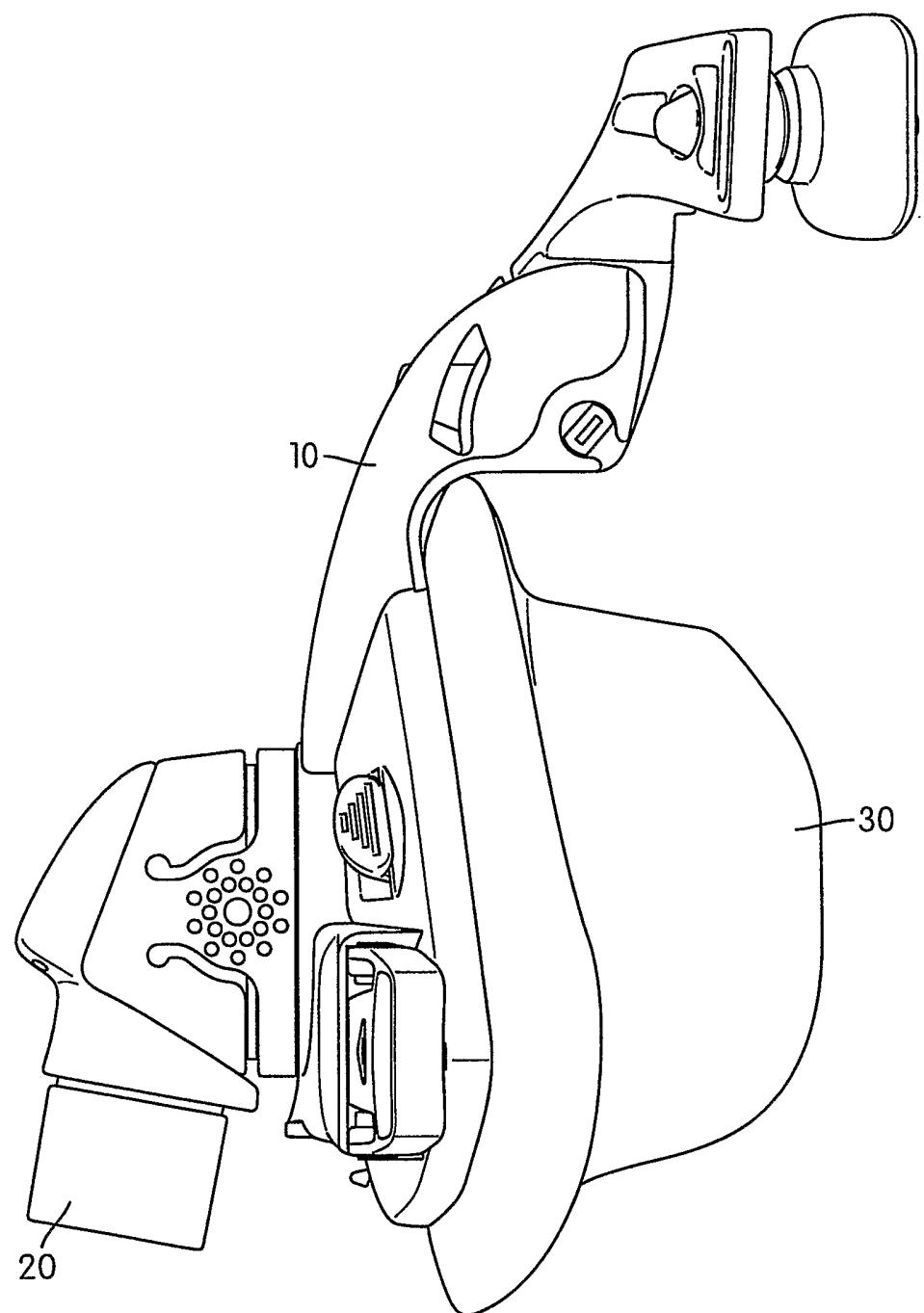


FIG. 5c

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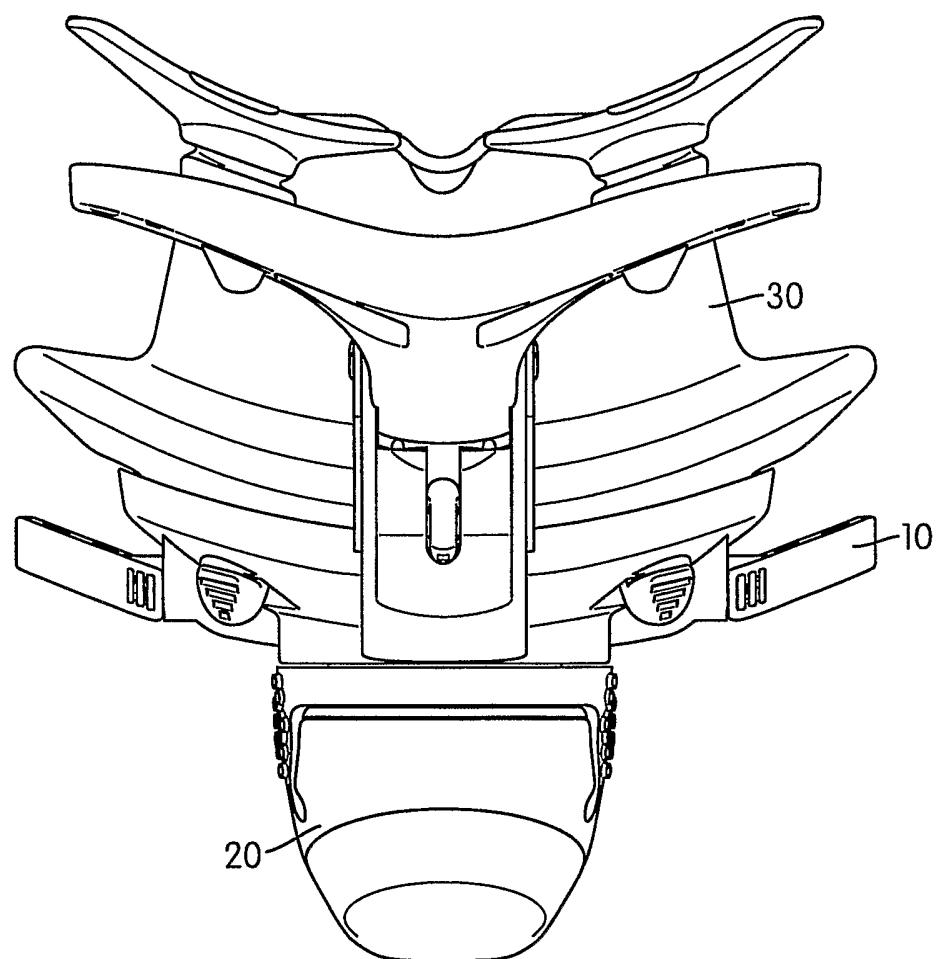
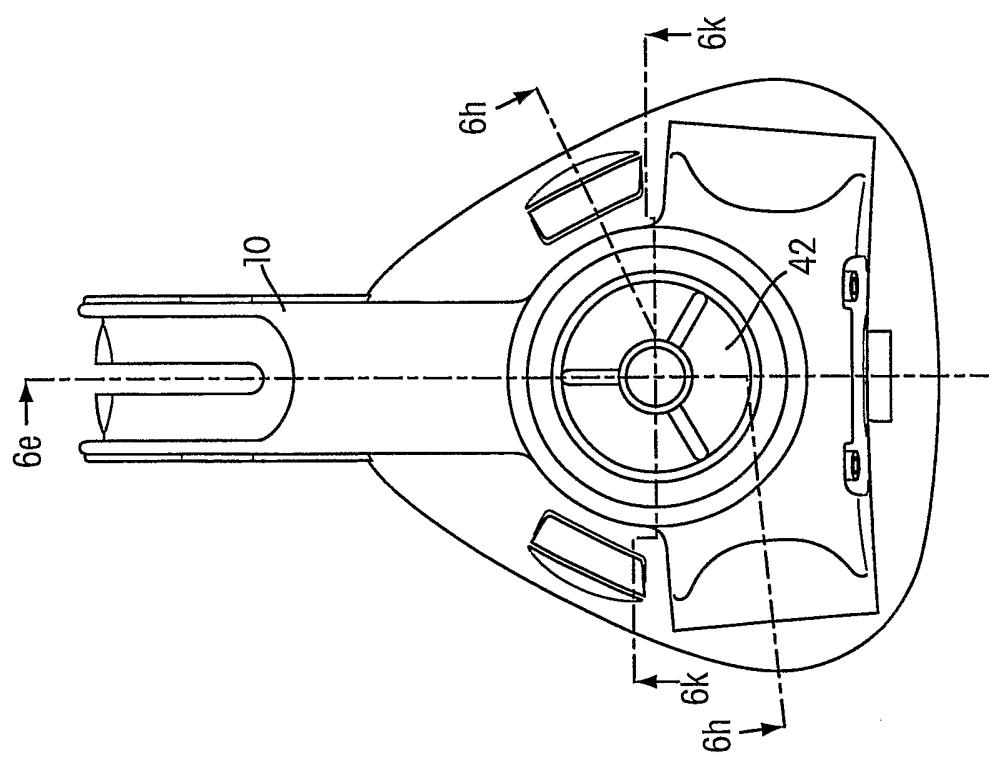
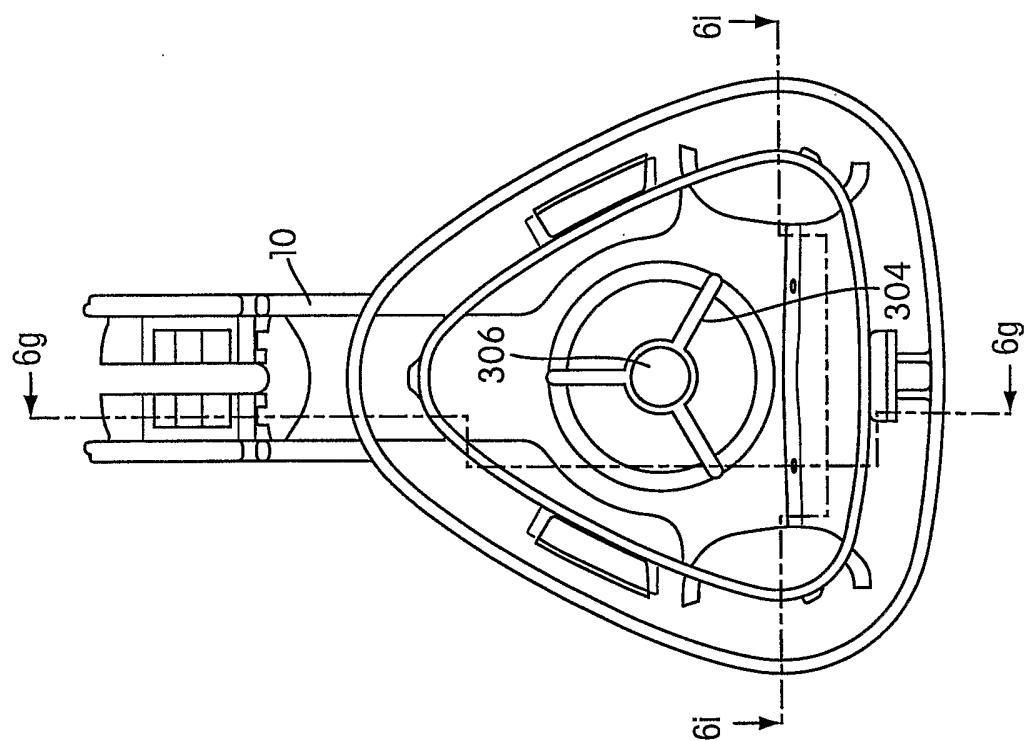


FIG. 5d

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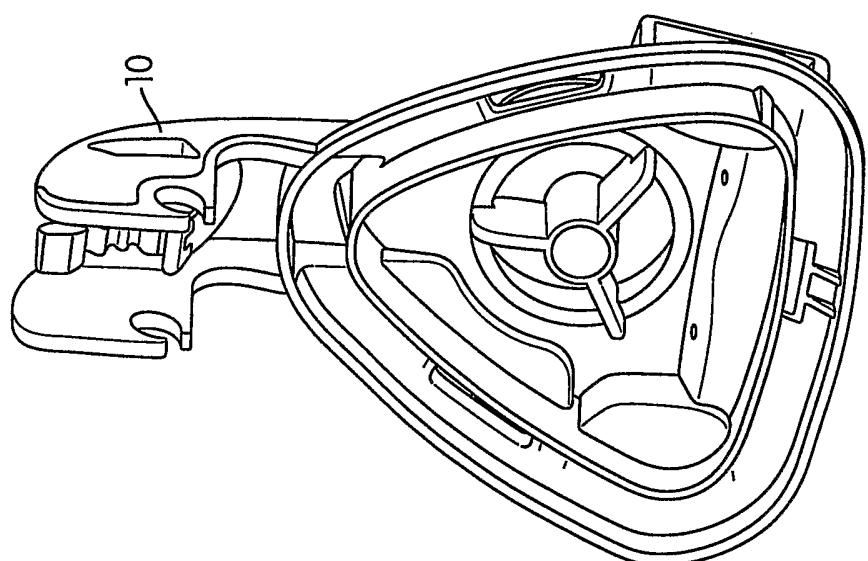


FIG. 6d

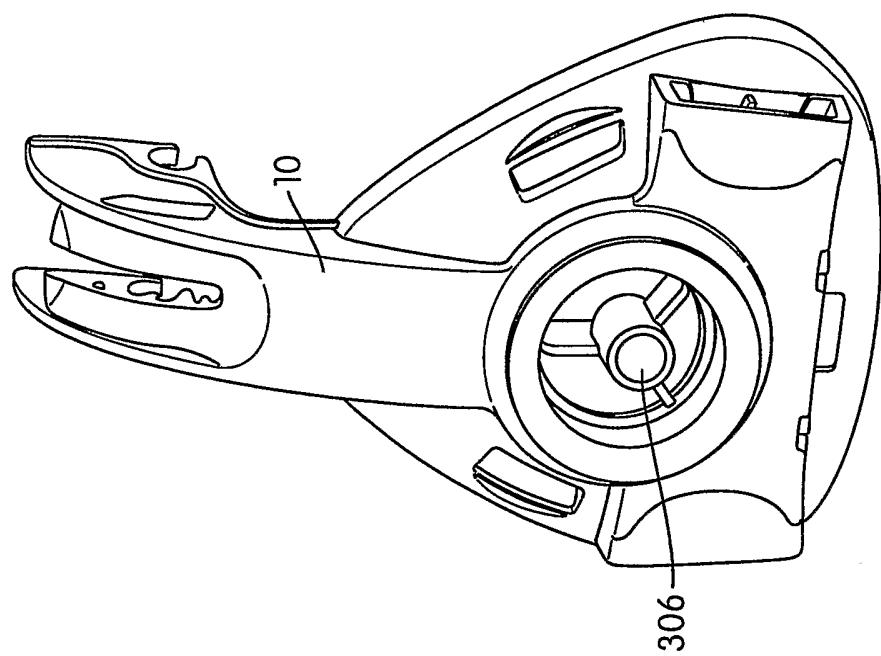
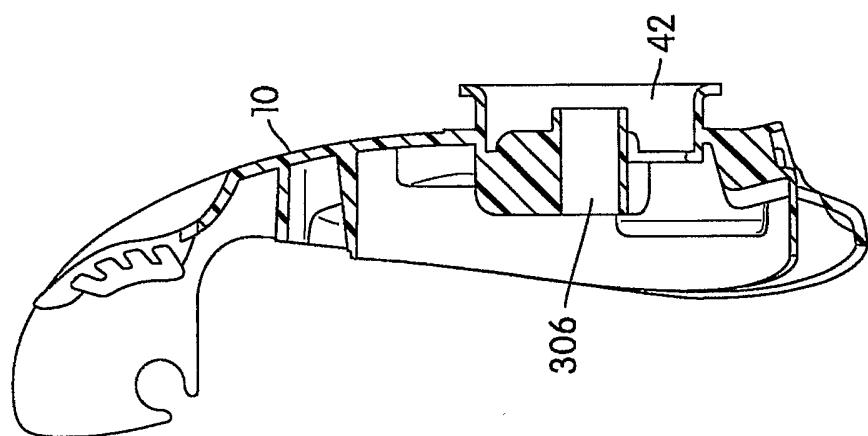
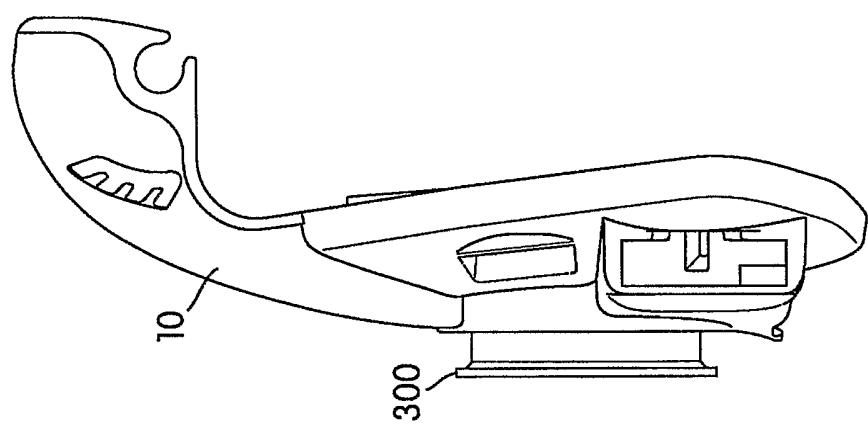
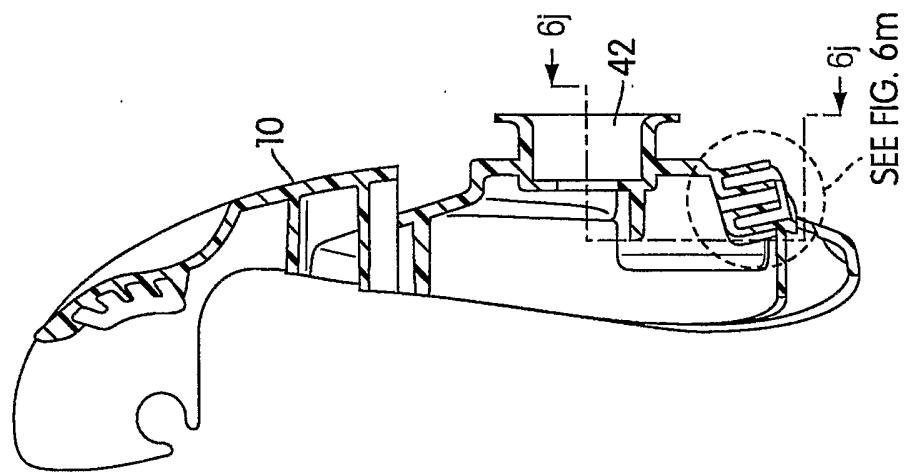


FIG. 6c

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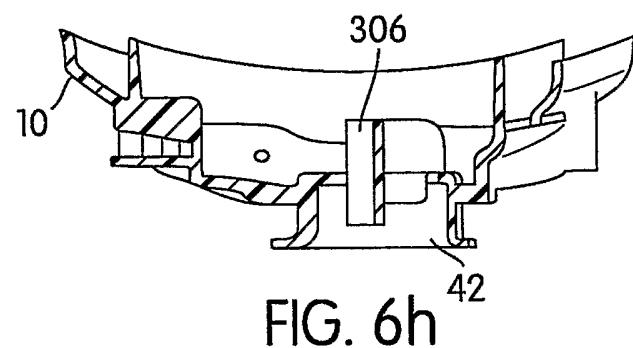


FIG. 6h

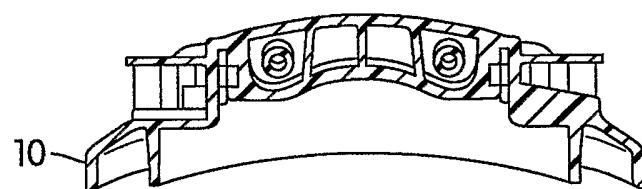


FIG. 6i

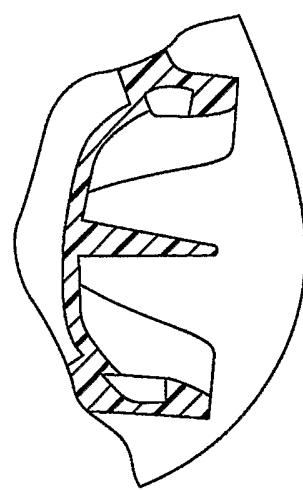


FIG. 6j

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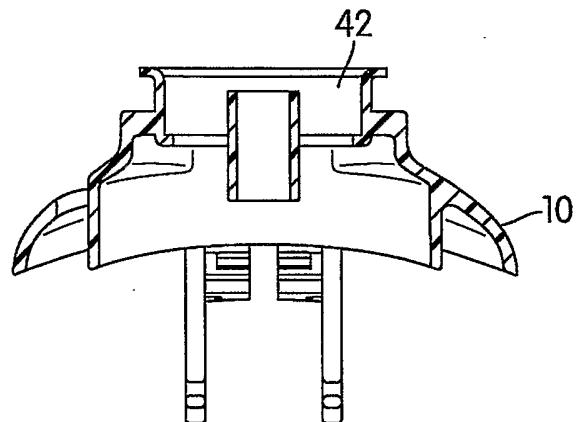


FIG. 6k

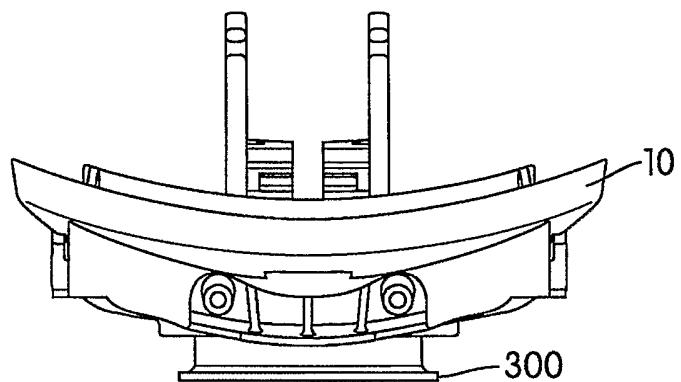


FIG. 6l

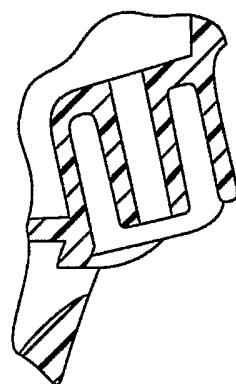


FIG. 6m

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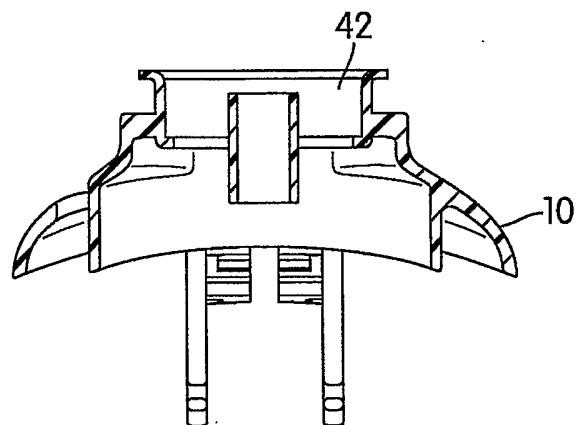


FIG. 6k

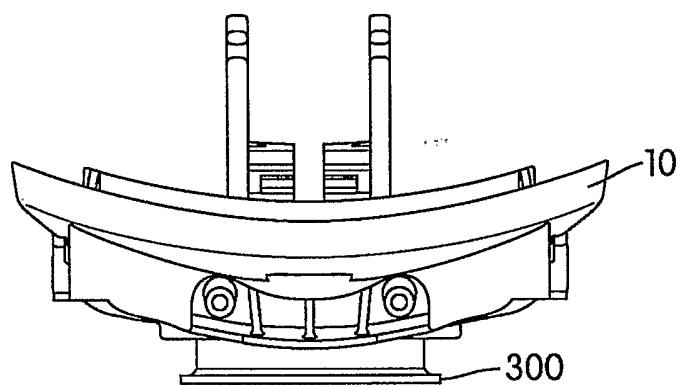


FIG. 6l

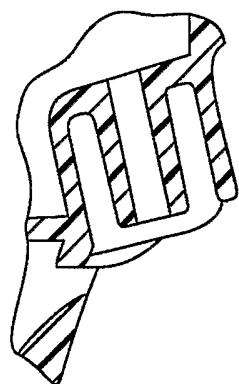


FIG. 6m

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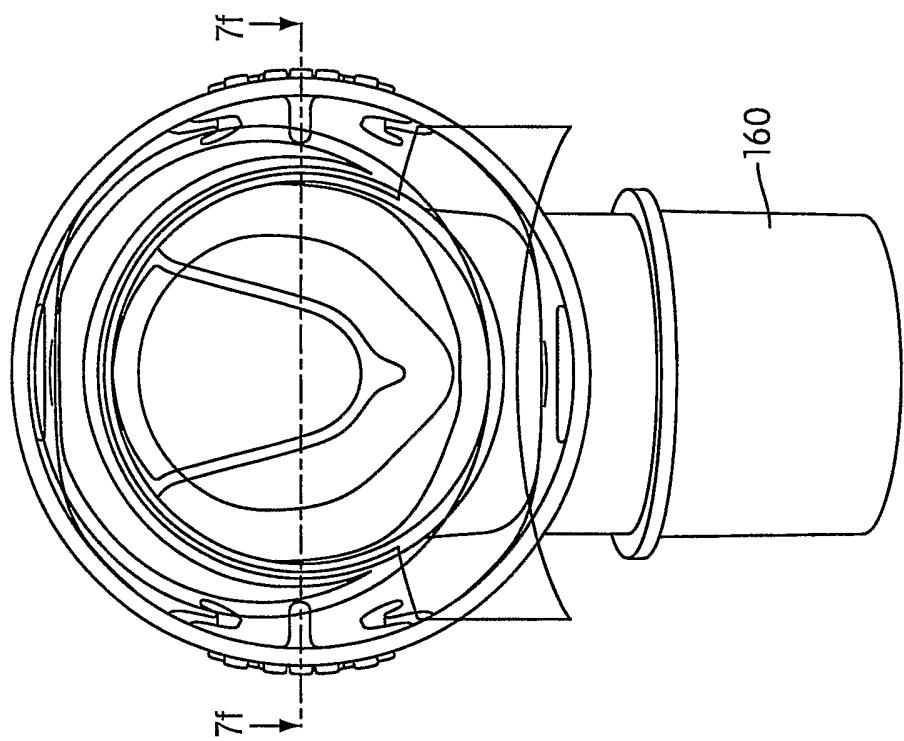


FIG. 7b

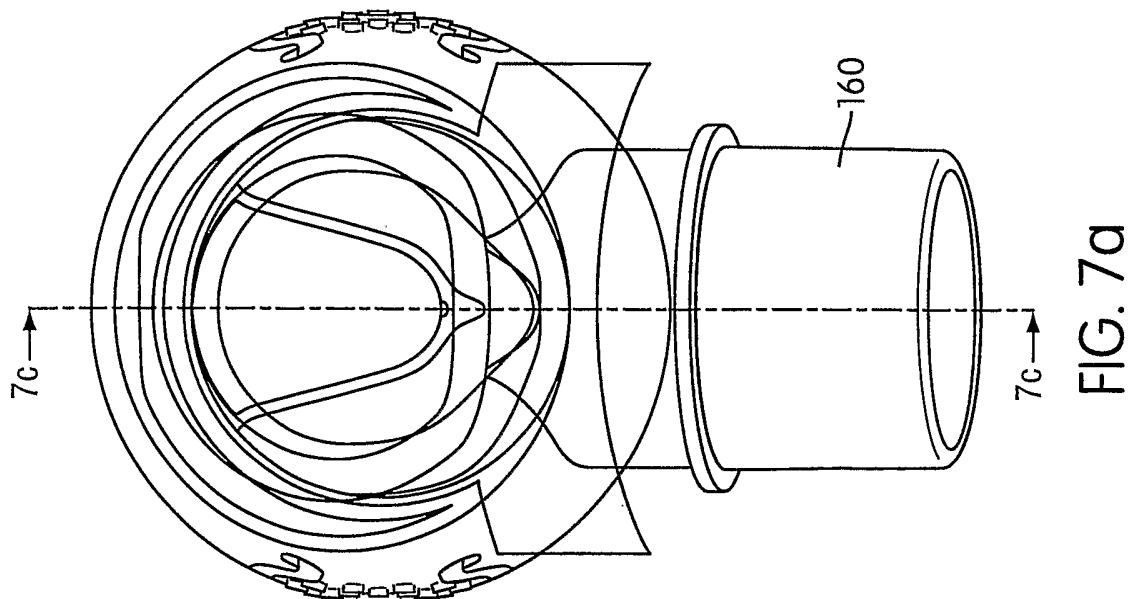


FIG. 7c

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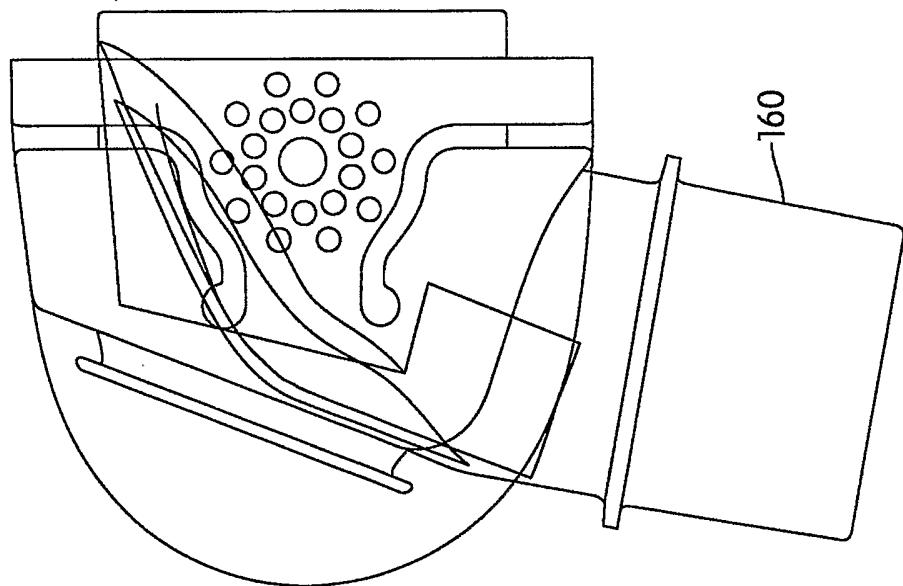


FIG. 7d

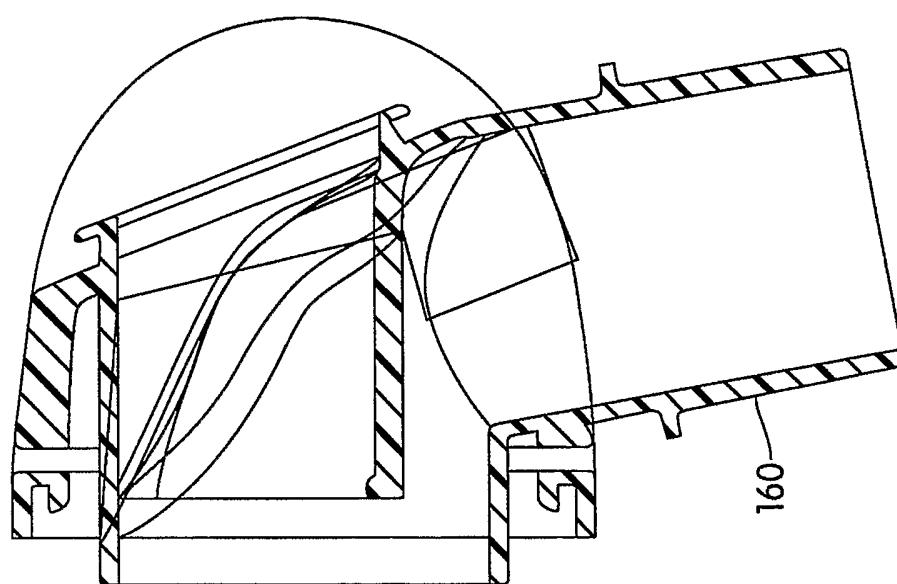


FIG. 7c

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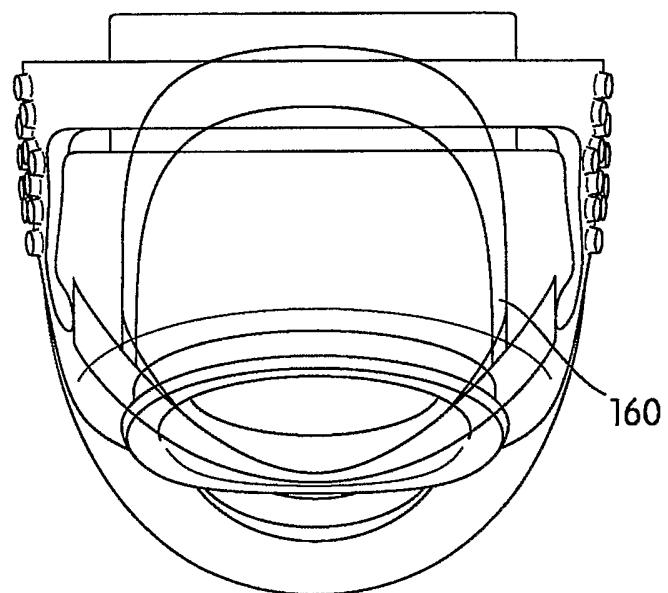


FIG. 7e

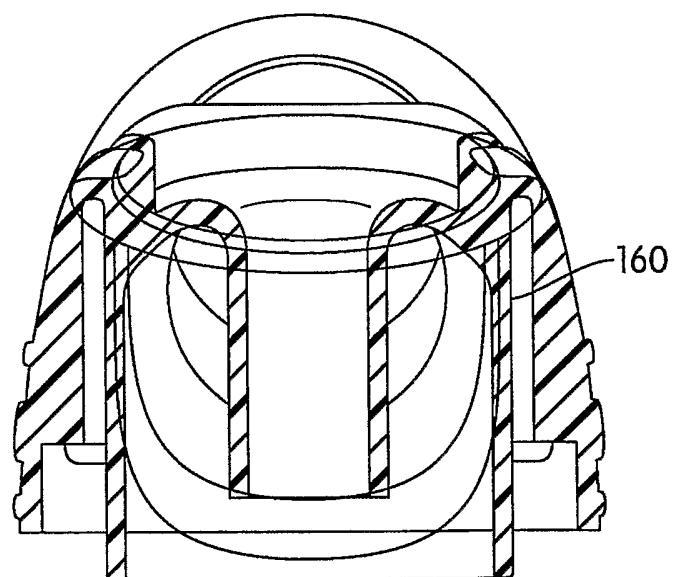


FIG. 7f

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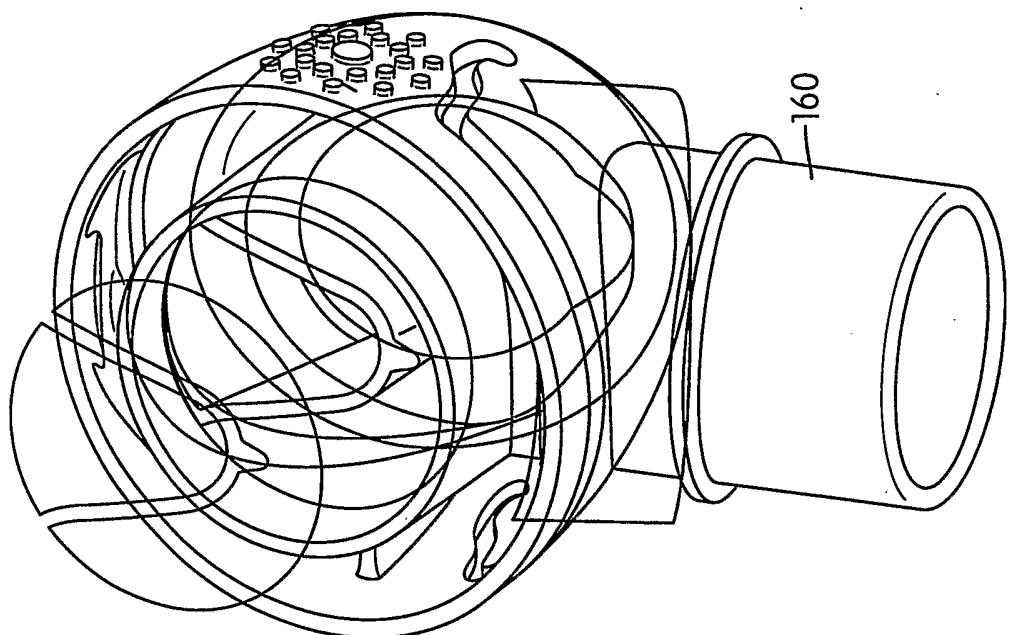


FIG. 7h

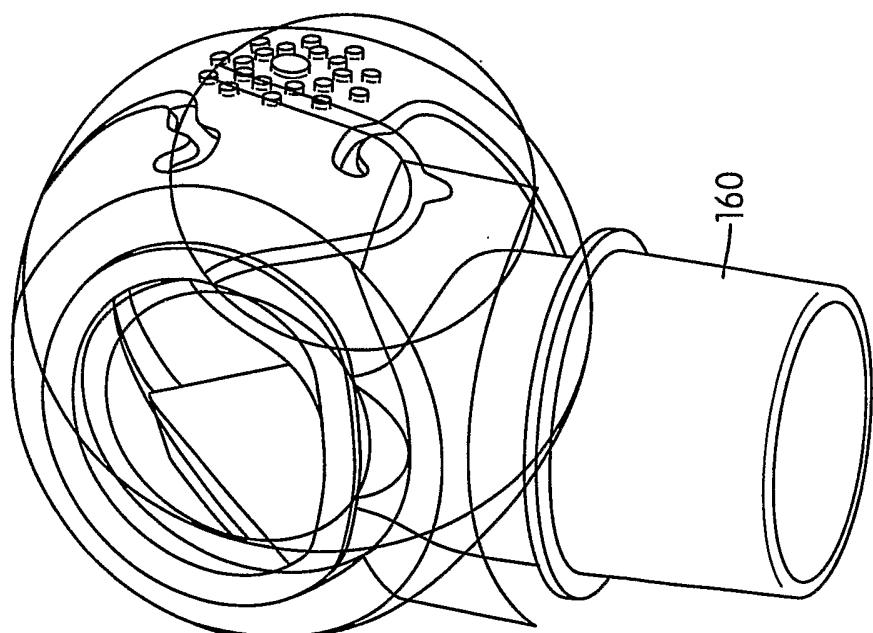


FIG. 7g

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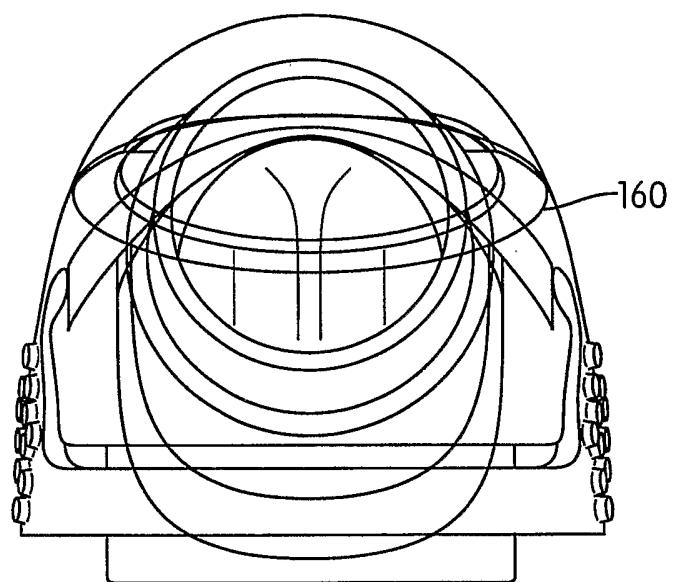


FIG. 7i

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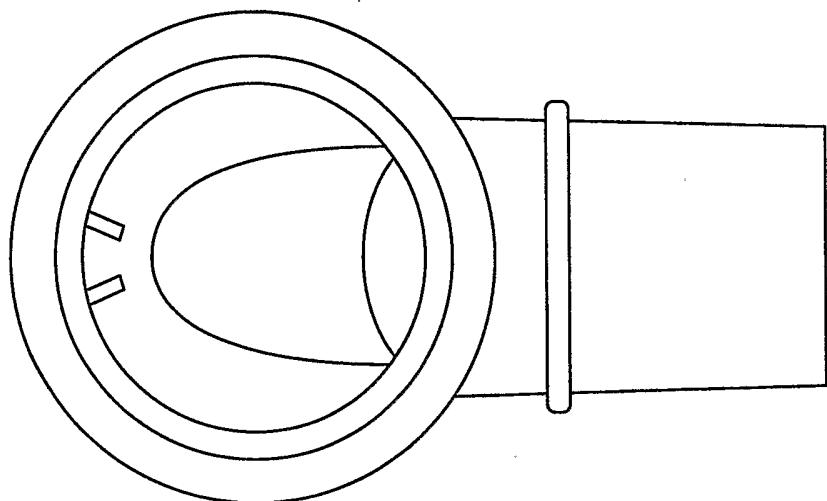


FIG. 8b  
PRIOR ART

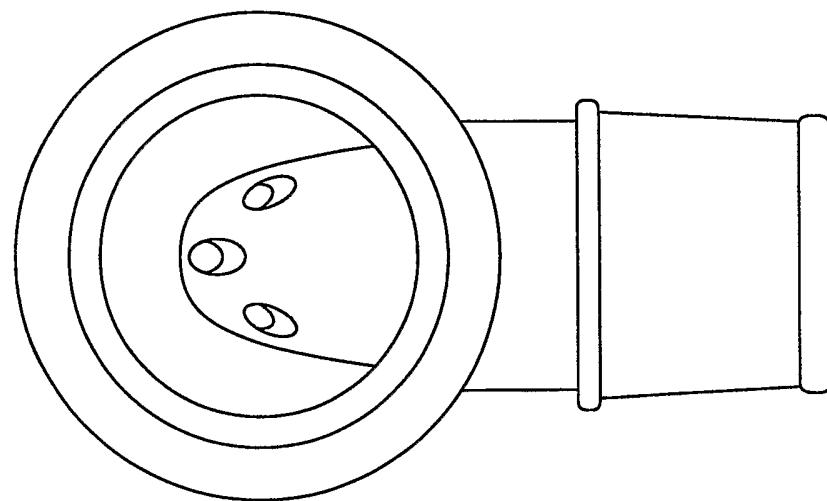


FIG. 8a  
PRIOR ART

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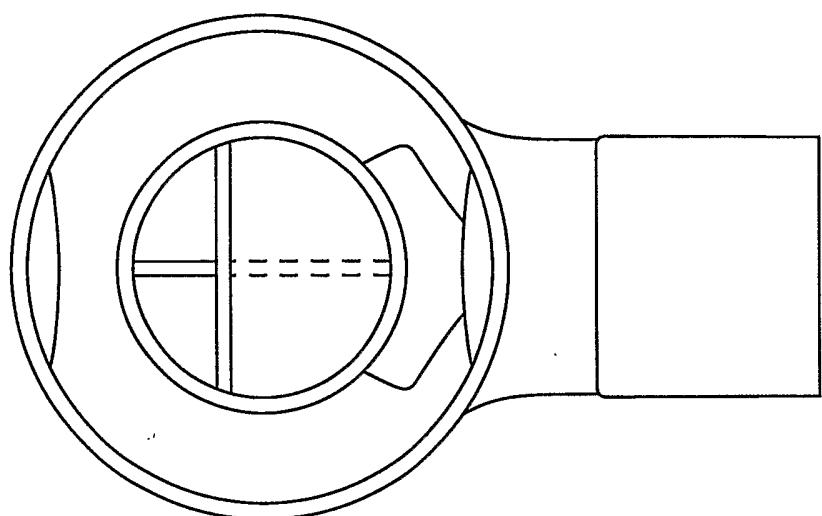


FIG. 8d  
RELATED ART

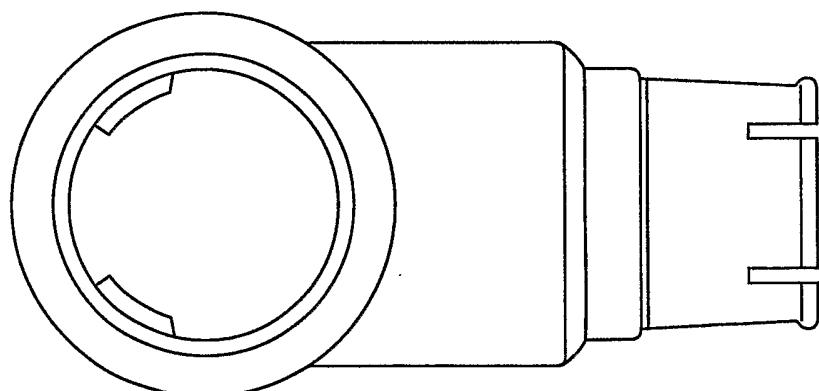


FIG. 8c

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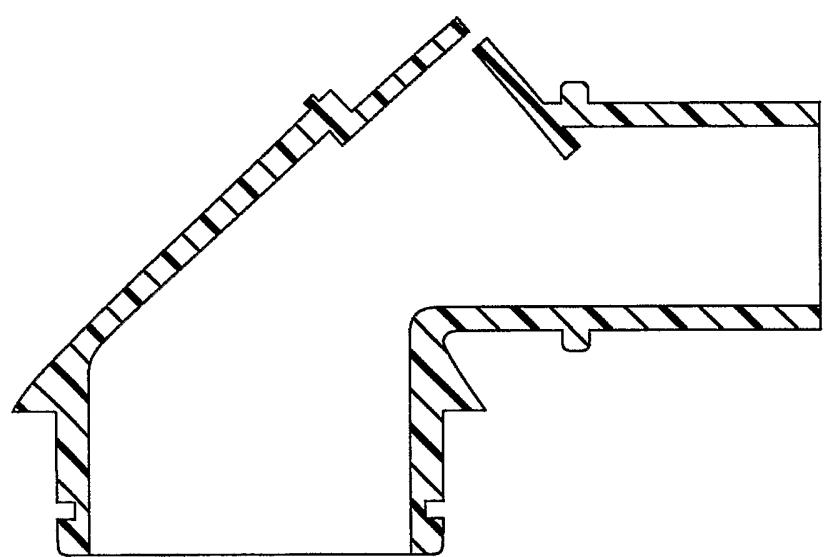


FIG. 9b  
PRIOR ART

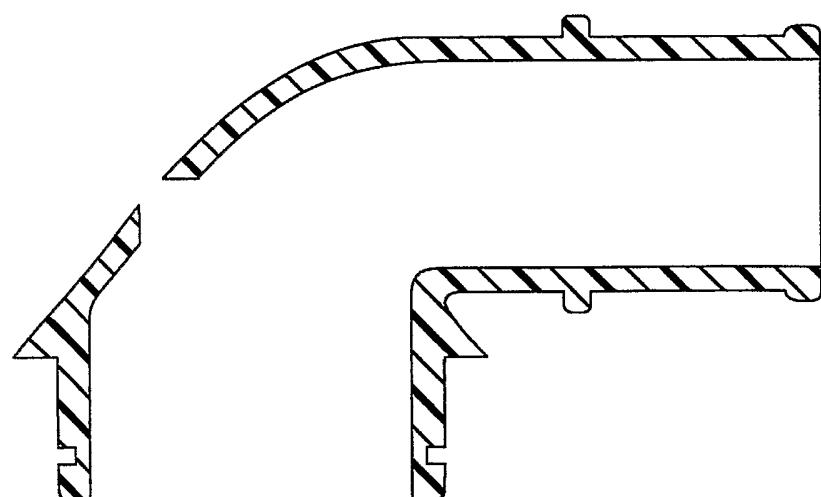


FIG. 9a  
PRIOR ART

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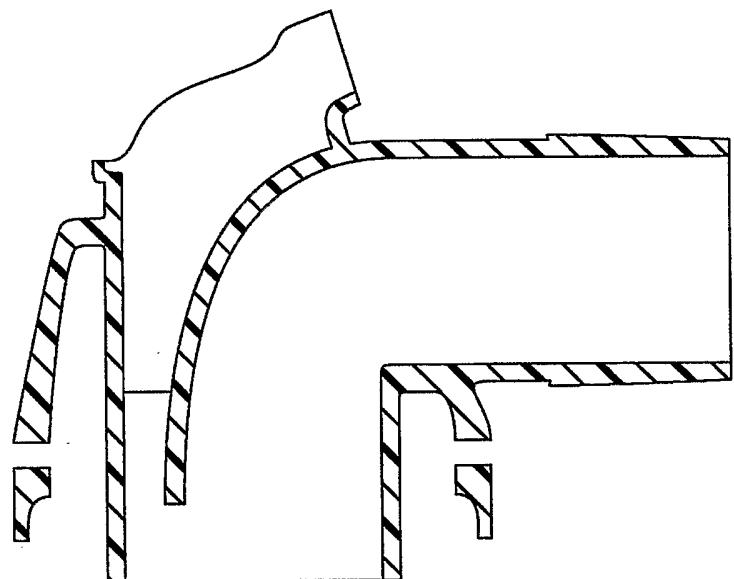


FIG. 9d  
RELATED ART

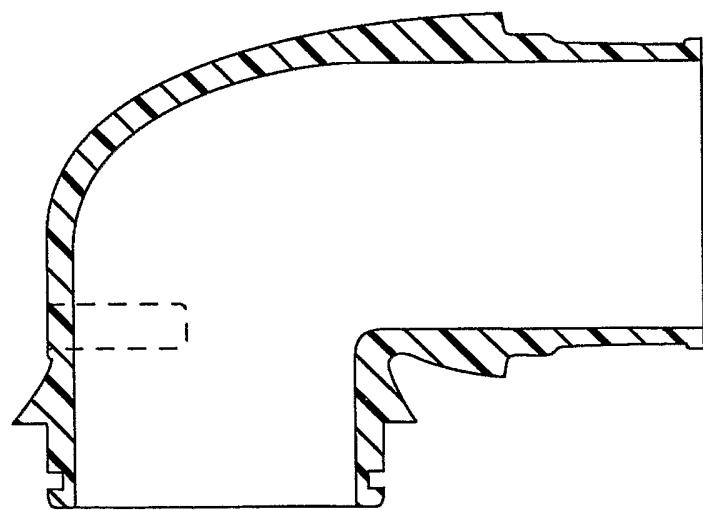


FIG. 9c

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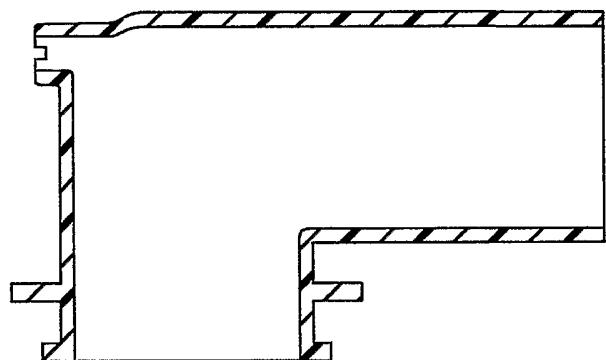


FIG. 10c  
PRIOR ART

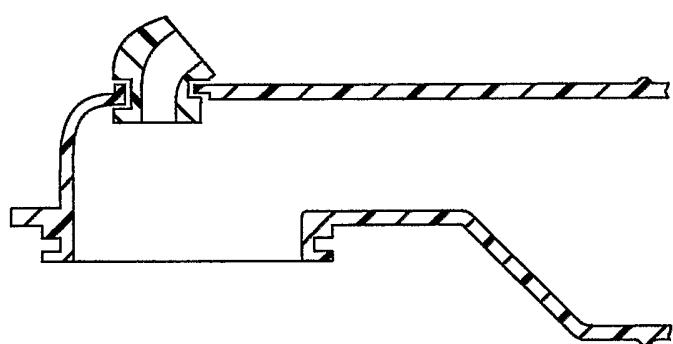


FIG. 10b  
PRIOR ART

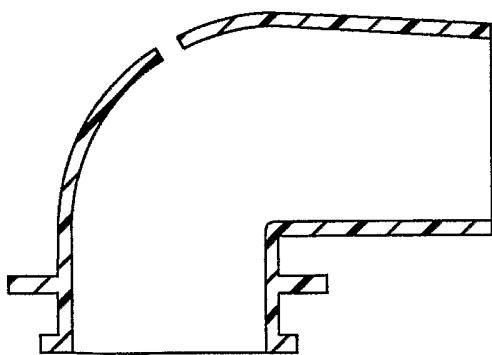
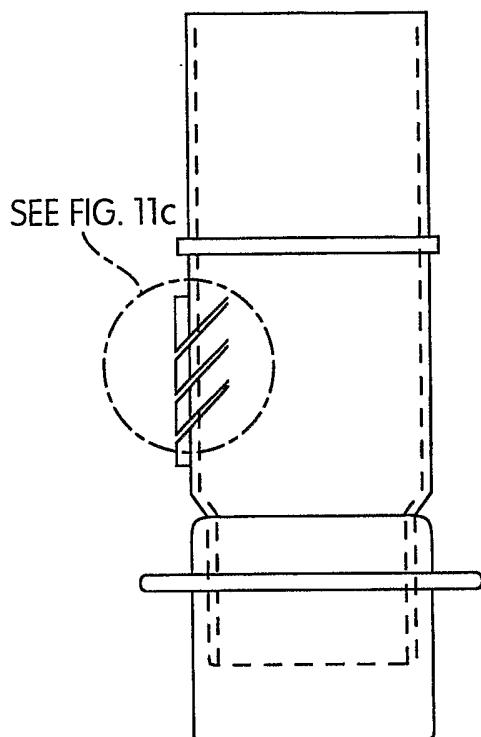
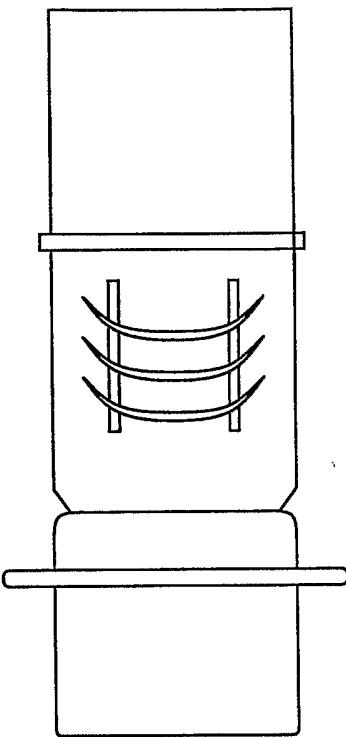


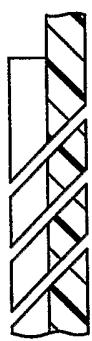
FIG. 10a  
PRIOR ART



**FIG. 11a**  
PRIOR ART

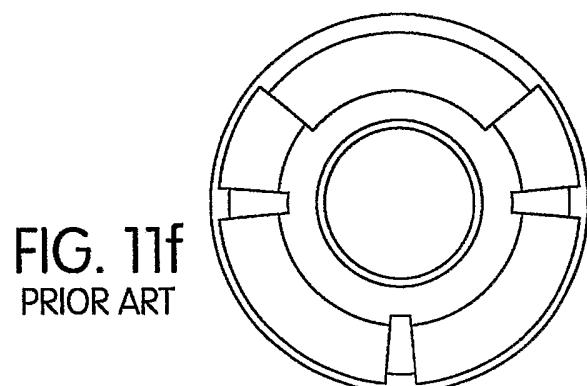
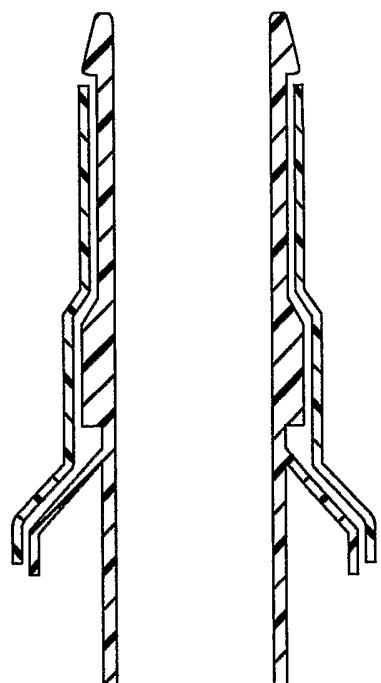
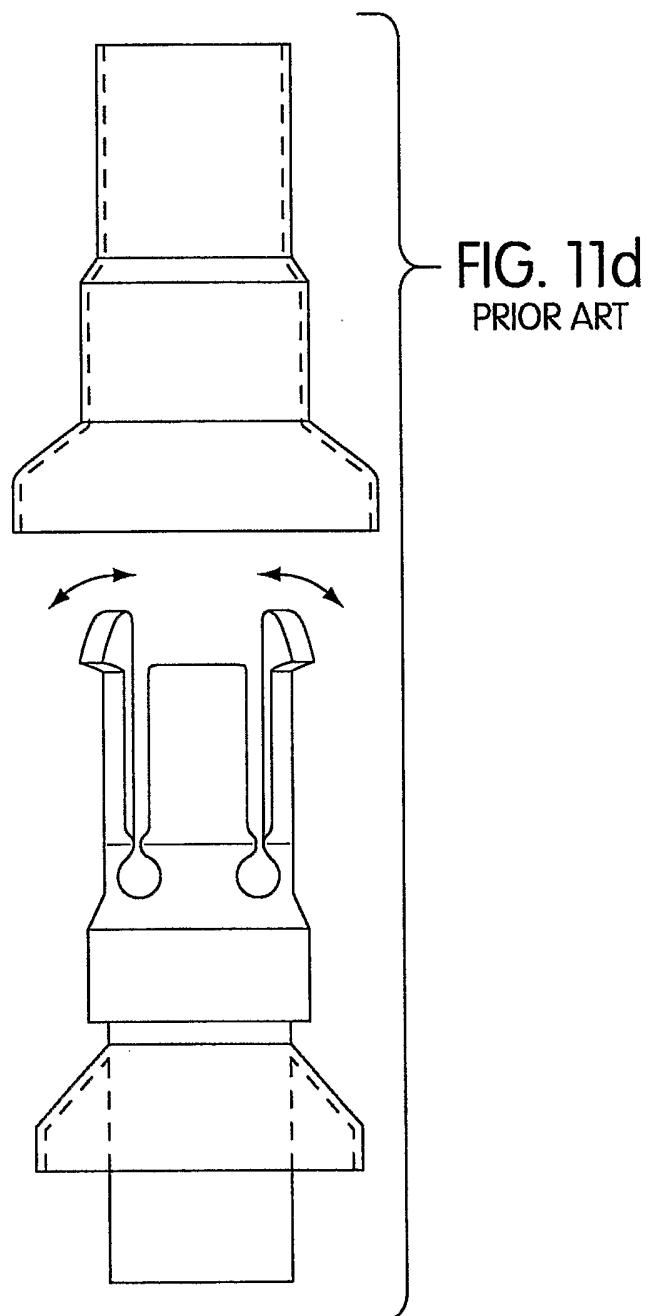


**FIG. 11b**  
PRIOR ART



**FIG. 11c**  
PRIOR ART

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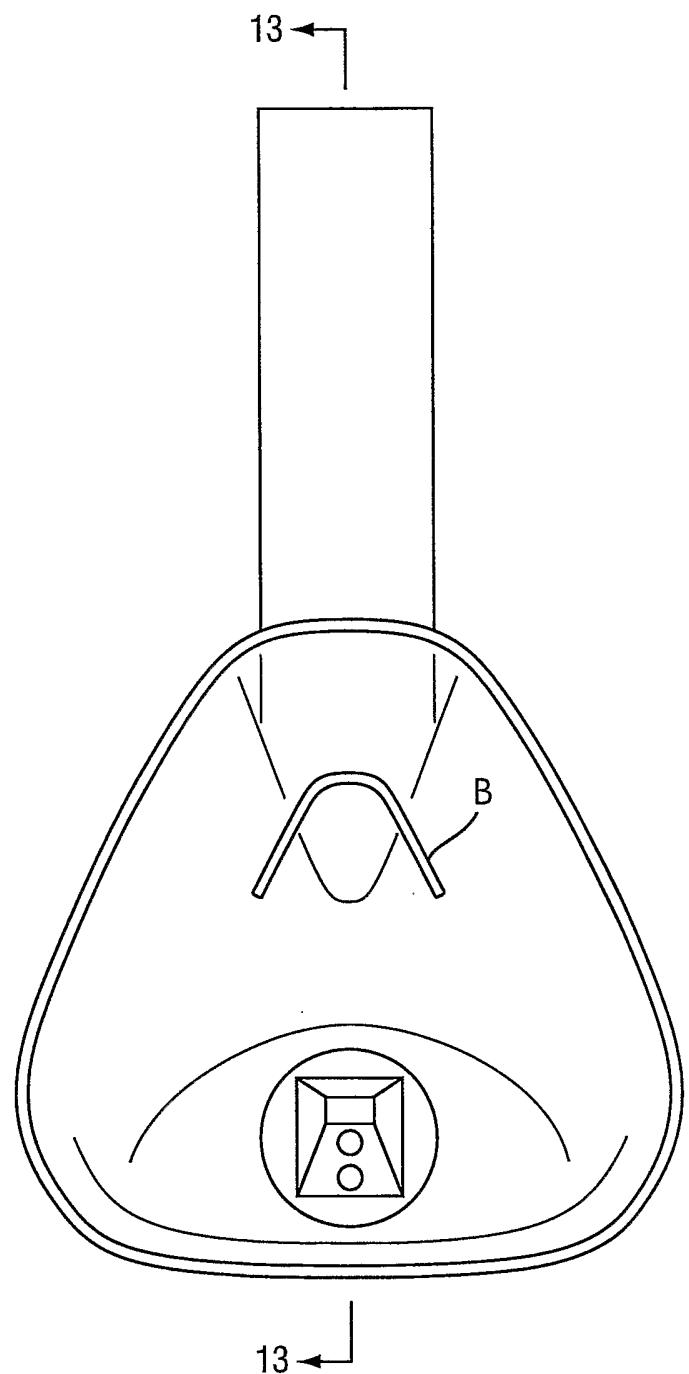
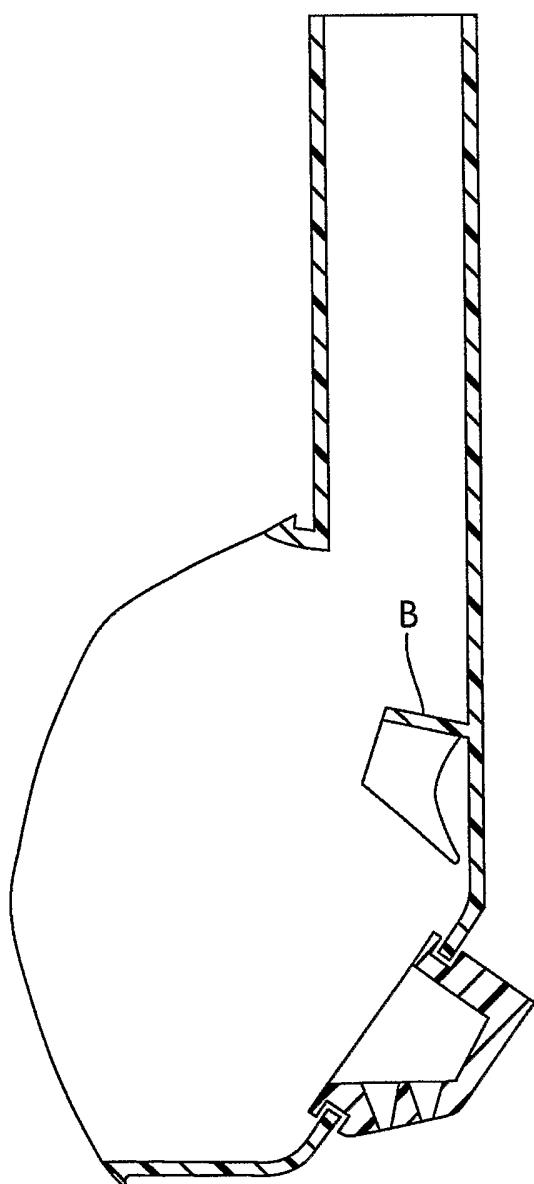


FIG. 12  
PRIOR ART

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**FIG. 13**  
PRIOR ART

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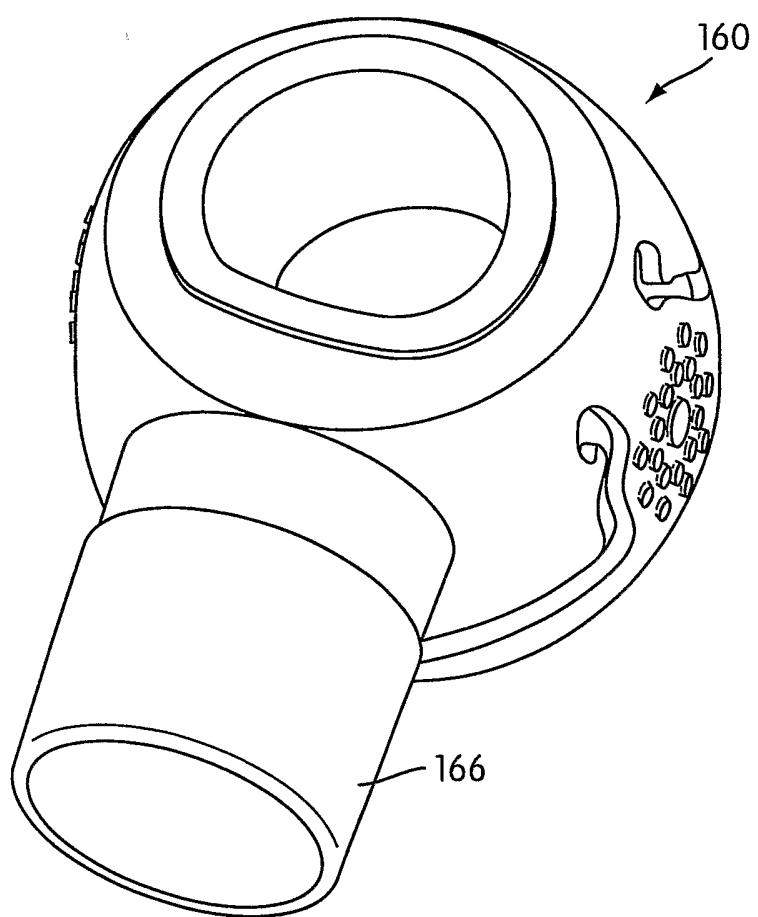


FIG. 14

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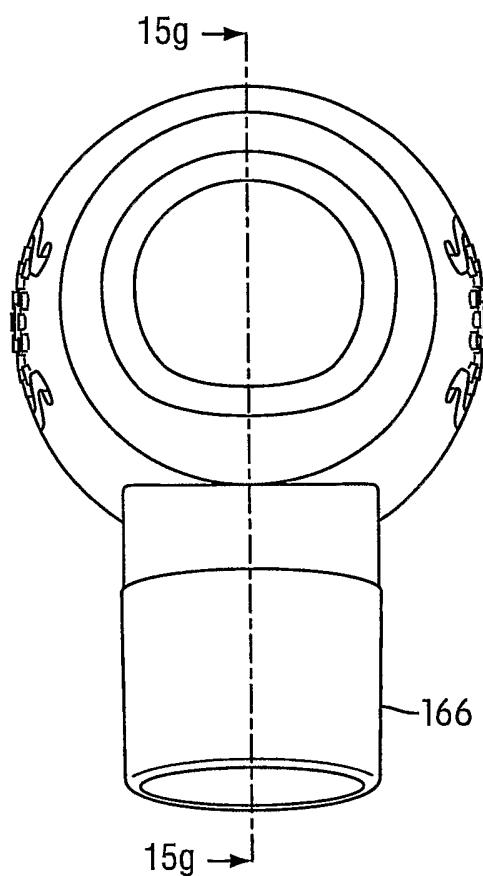


FIG. 15a

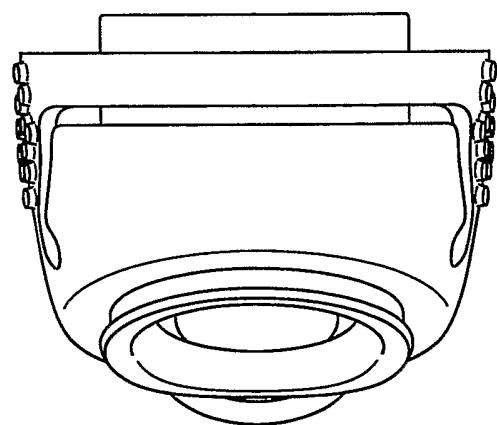


FIG. 15b

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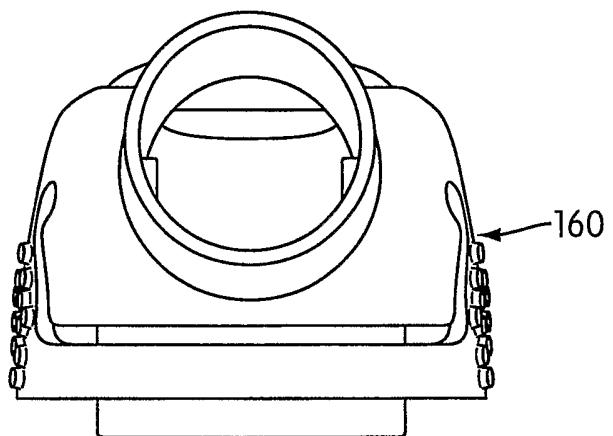


FIG. 15c

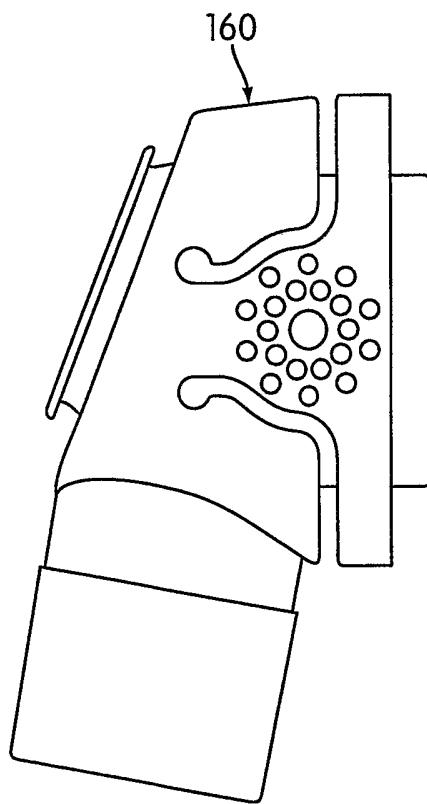


FIG. 15d

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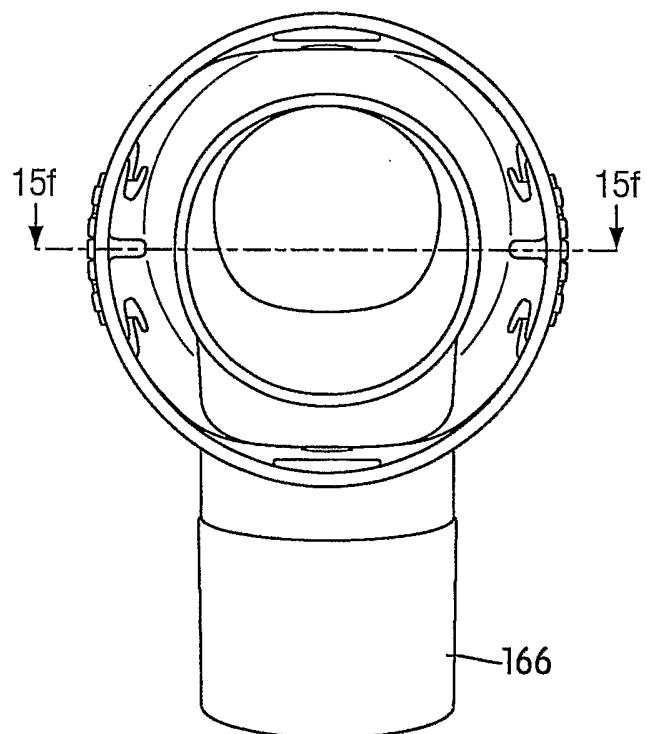


FIG. 15e

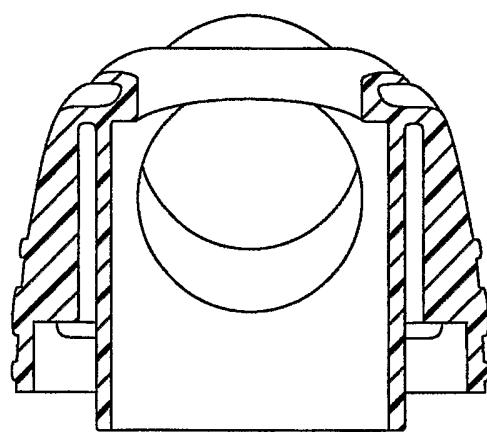


FIG. 15f

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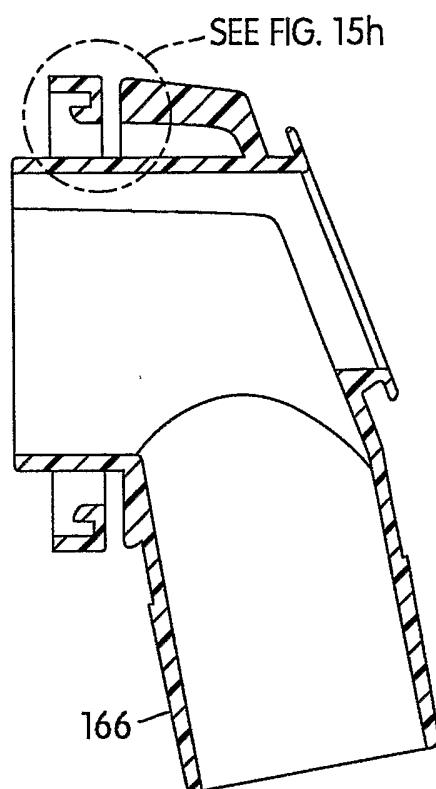


FIG. 15g

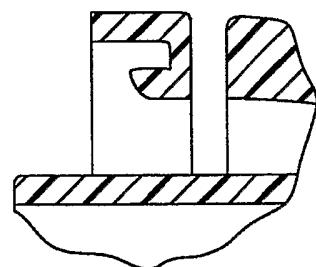
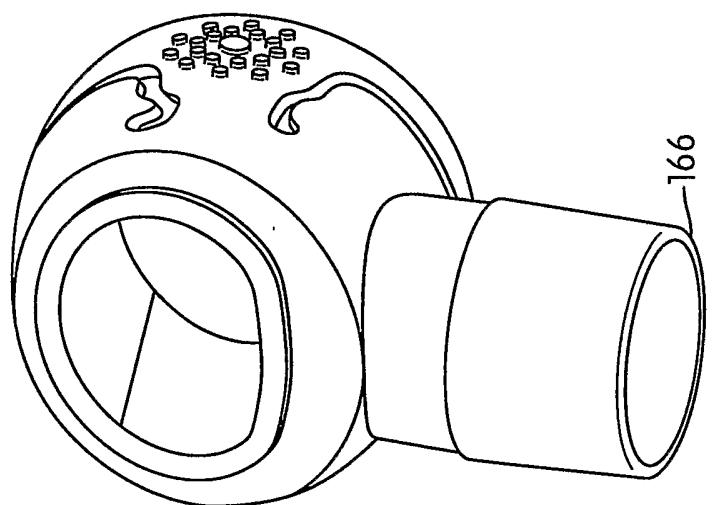
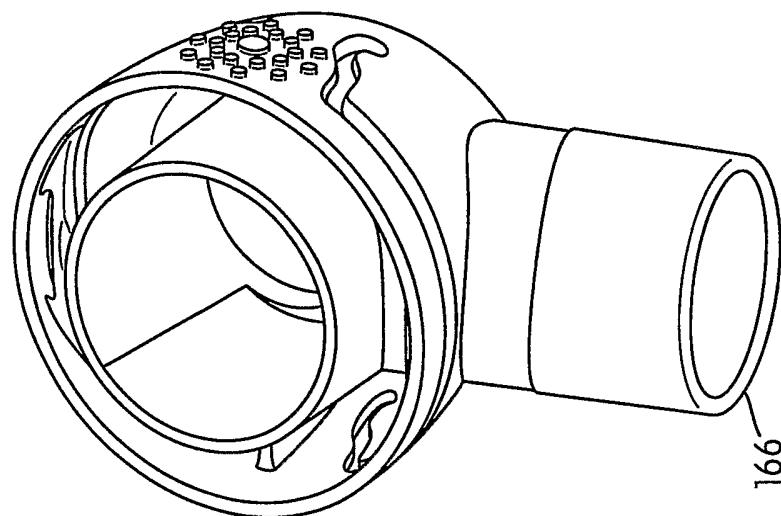
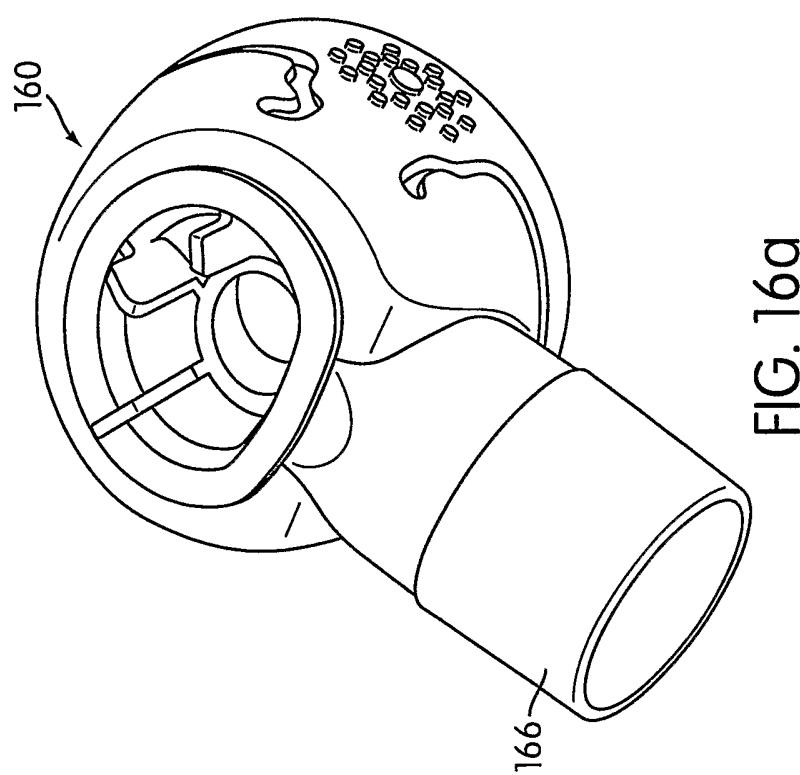
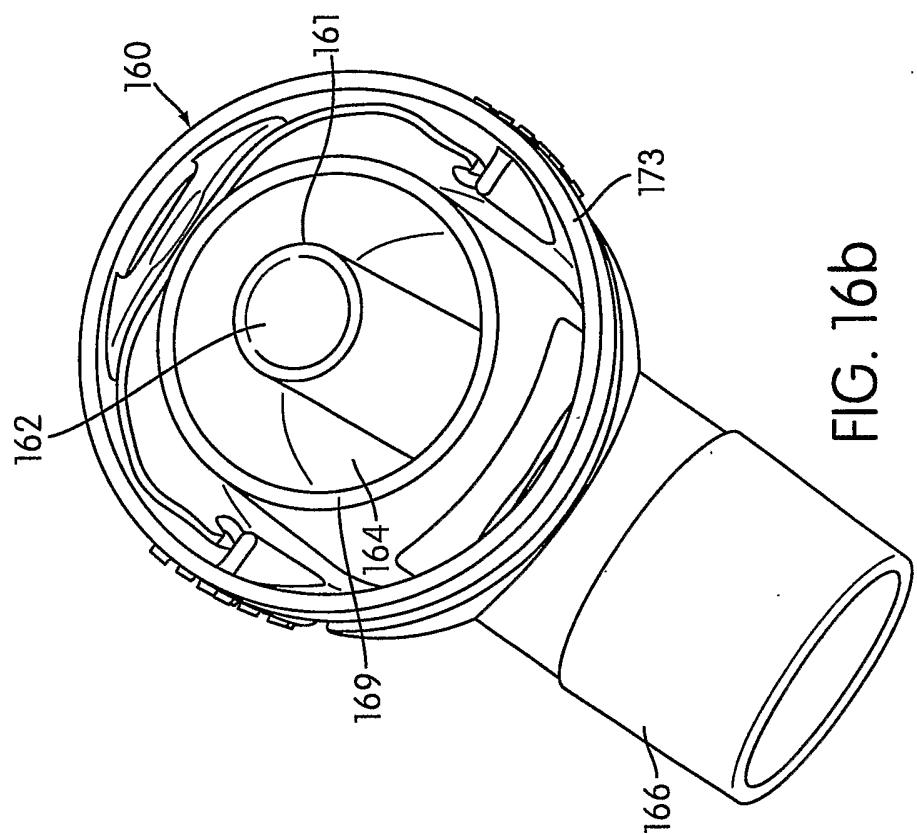


FIG. 15h

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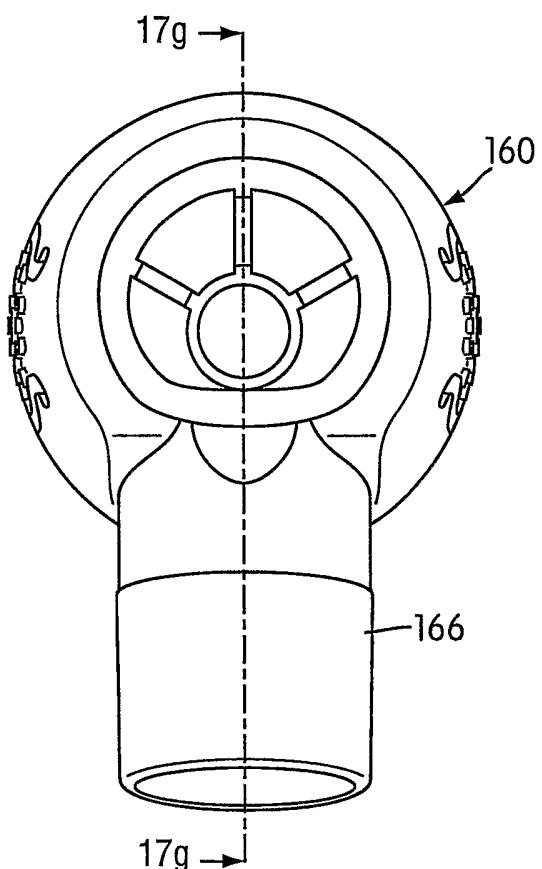


FIG. 17a

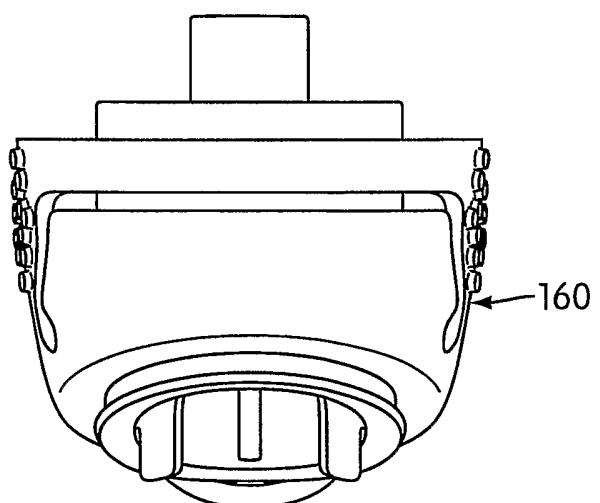
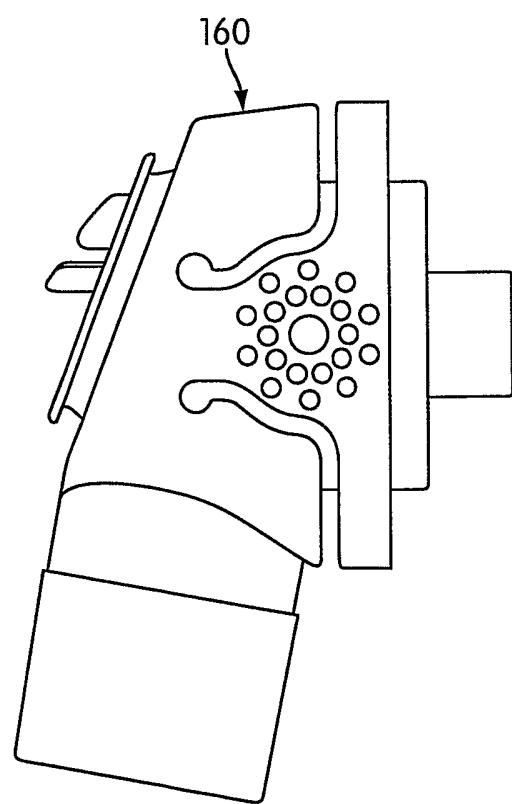
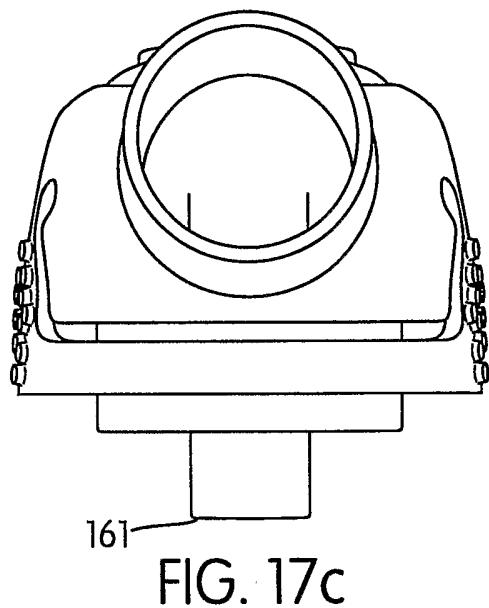


FIG. 17b

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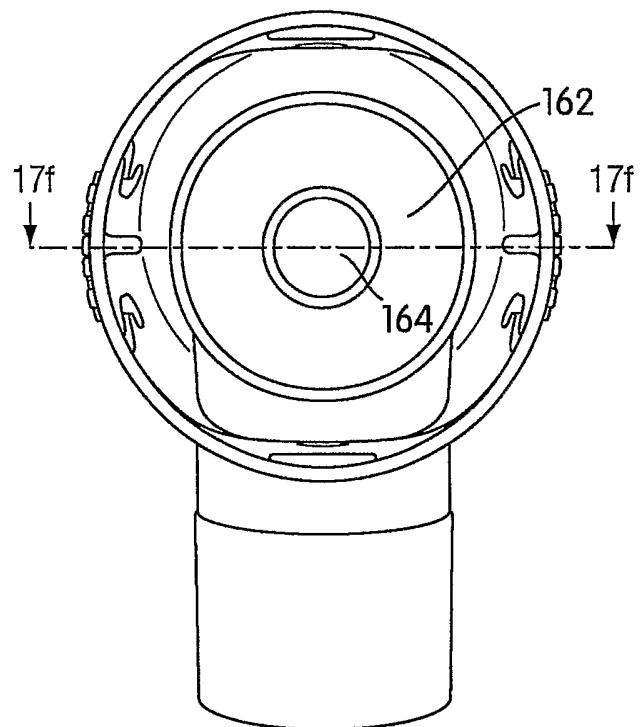


FIG. 17e

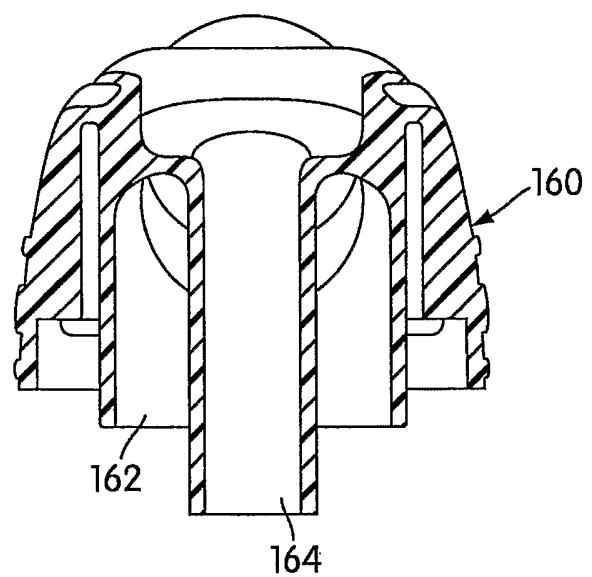


FIG. 17f

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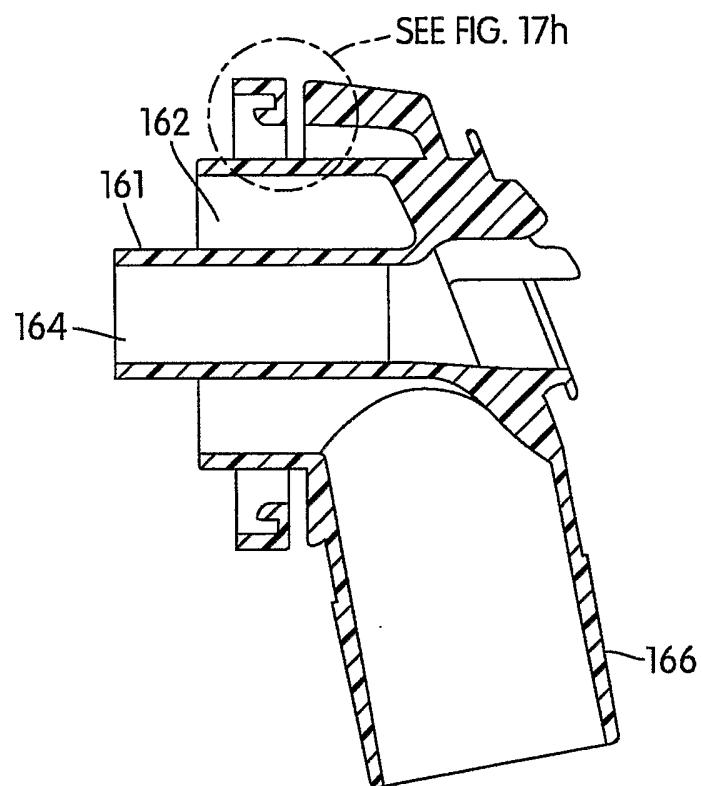


FIG. 17g

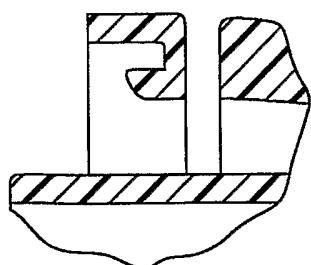


FIG. 17h

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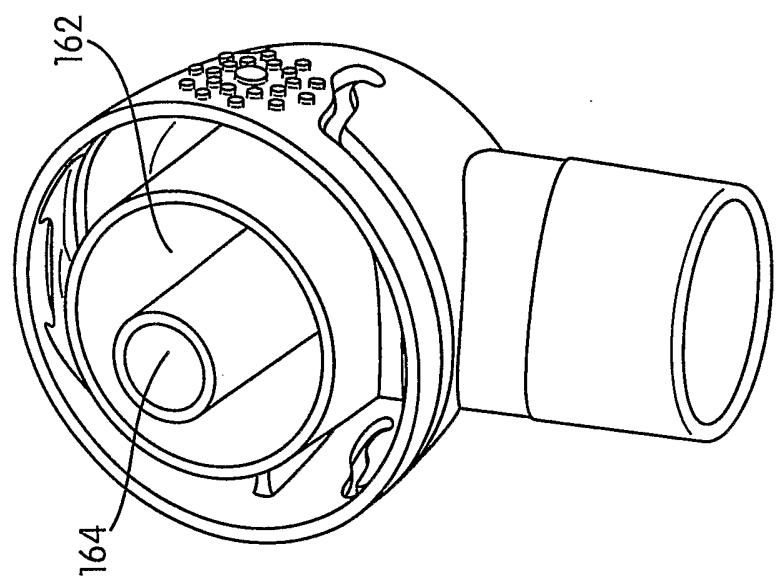


FIG. 17j

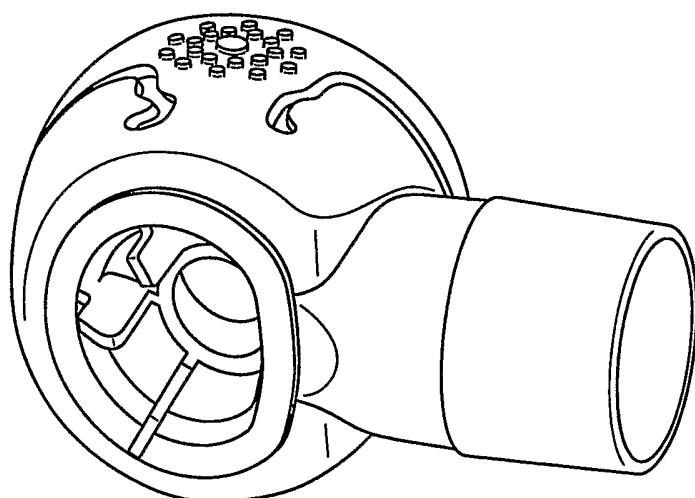
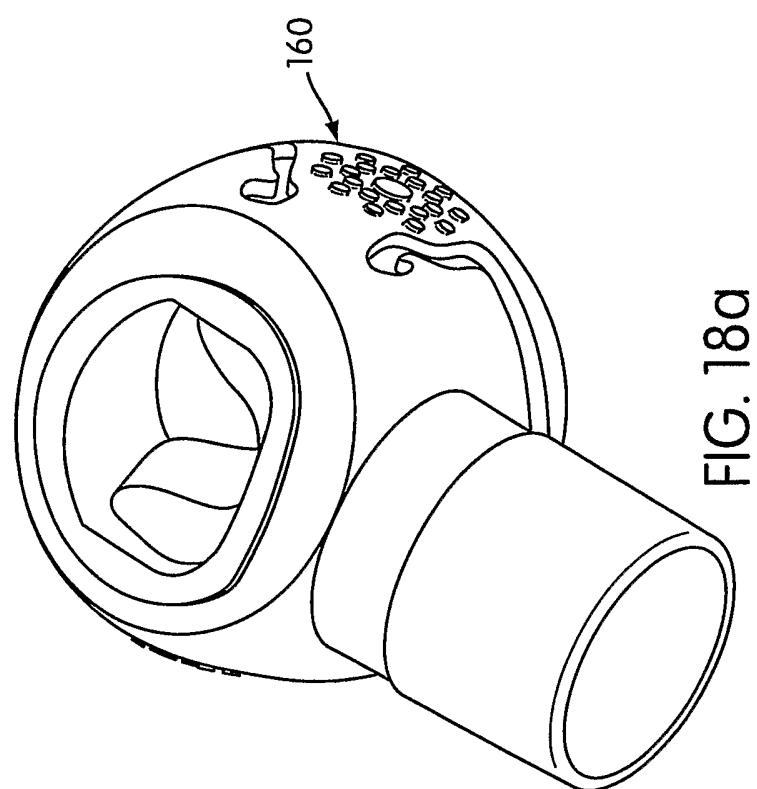
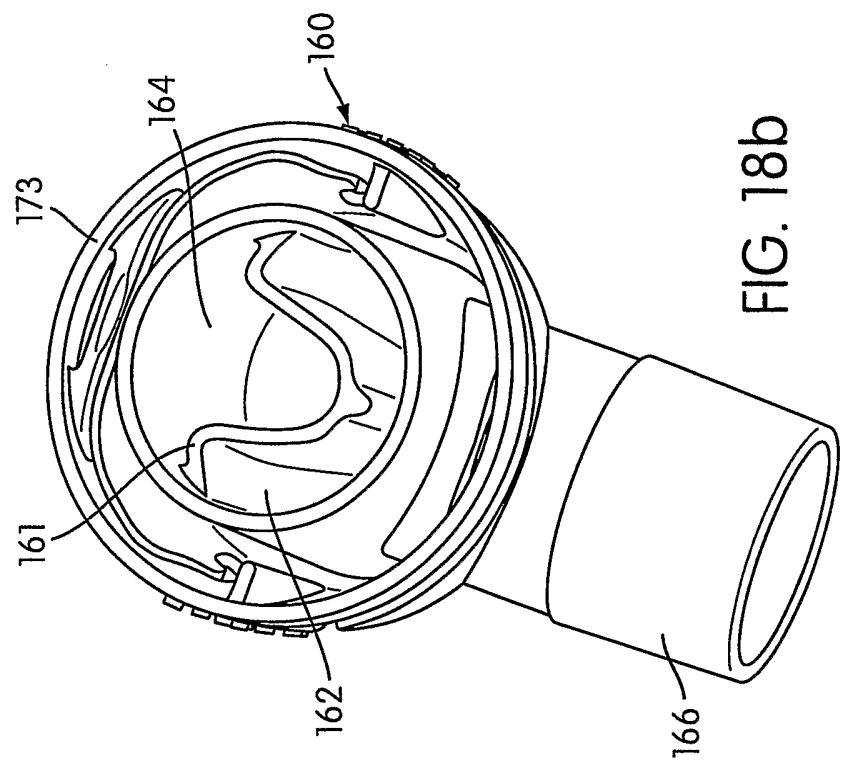


FIG. 17i

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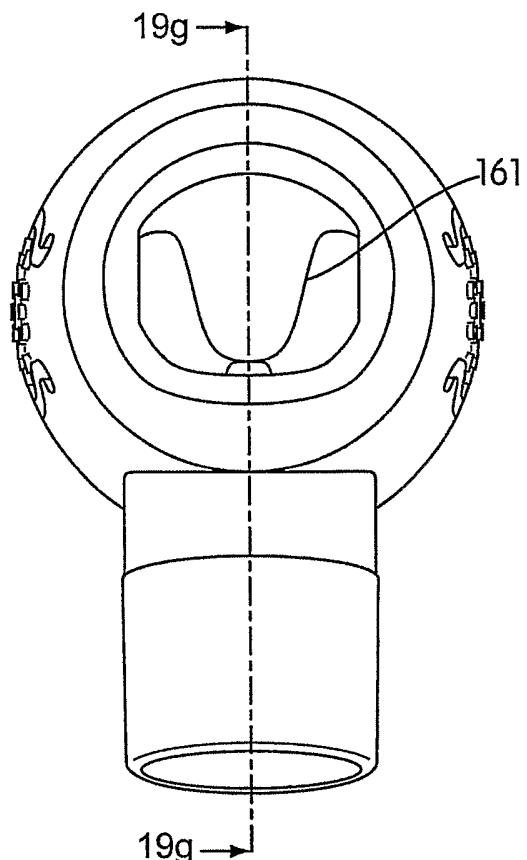


FIG. 19a

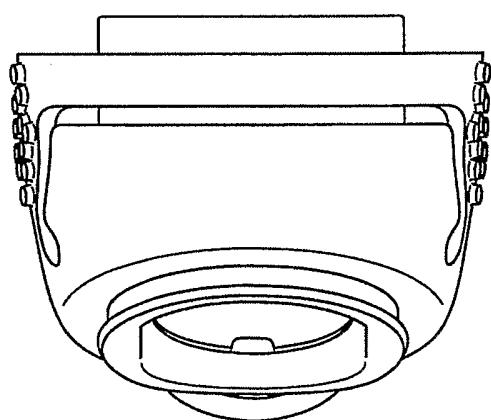


FIG. 19b

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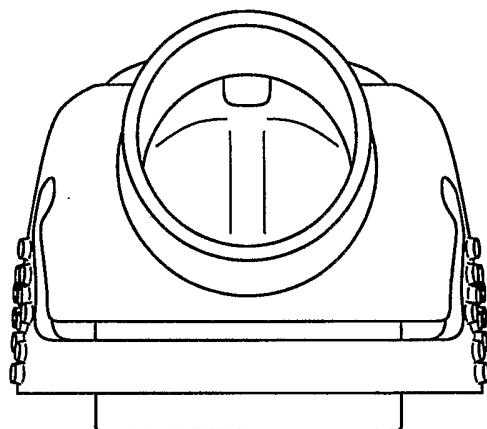


FIG. 19c

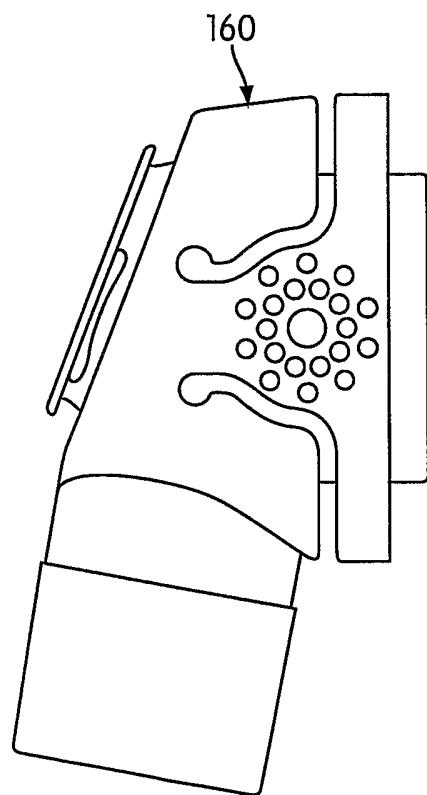


FIG. 19d

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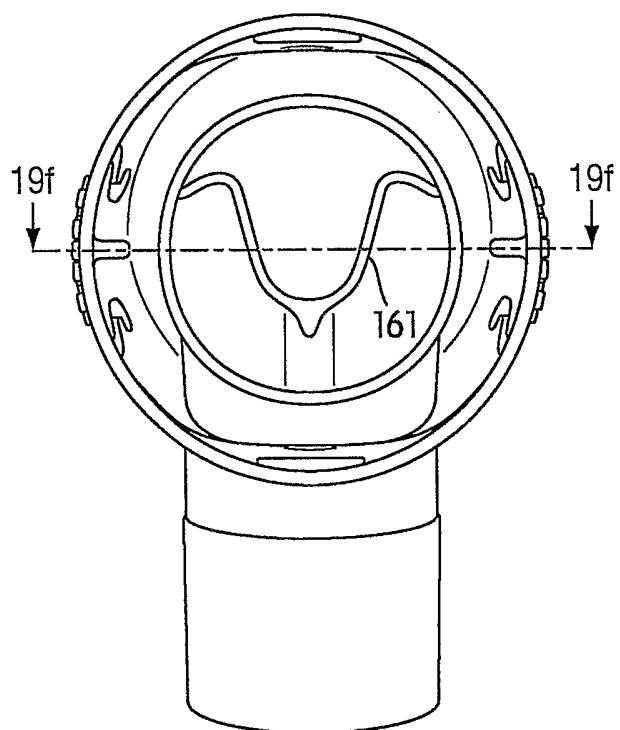


FIG. 19e

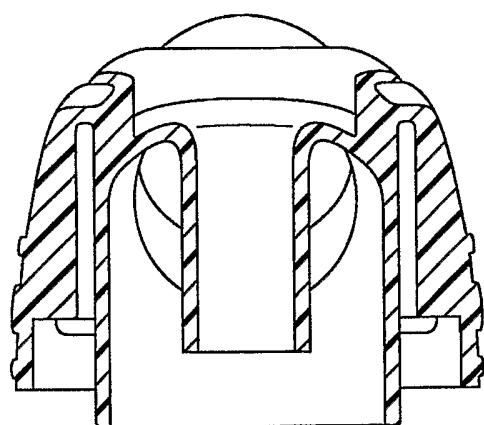


FIG. 19f

D

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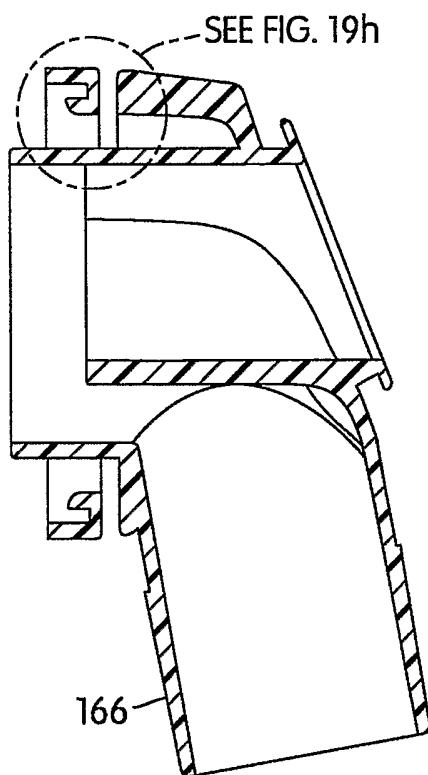


FIG. 19g

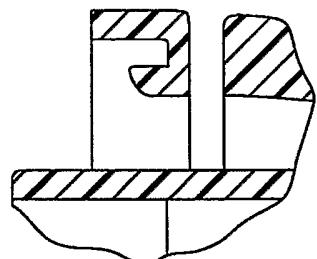
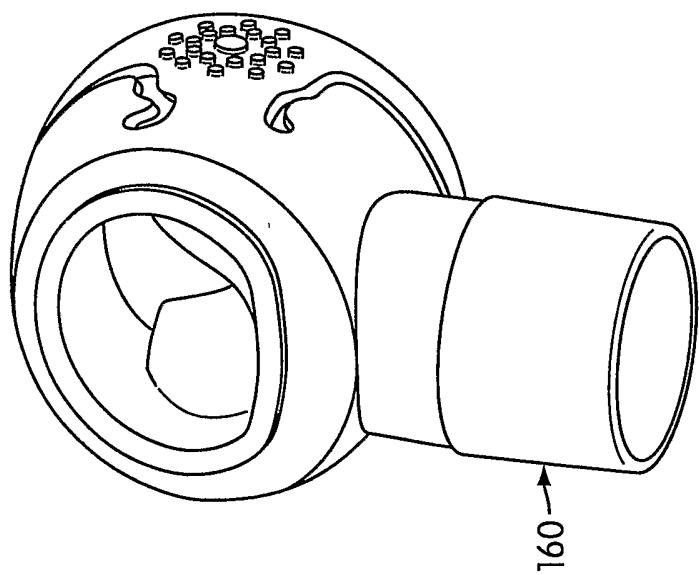
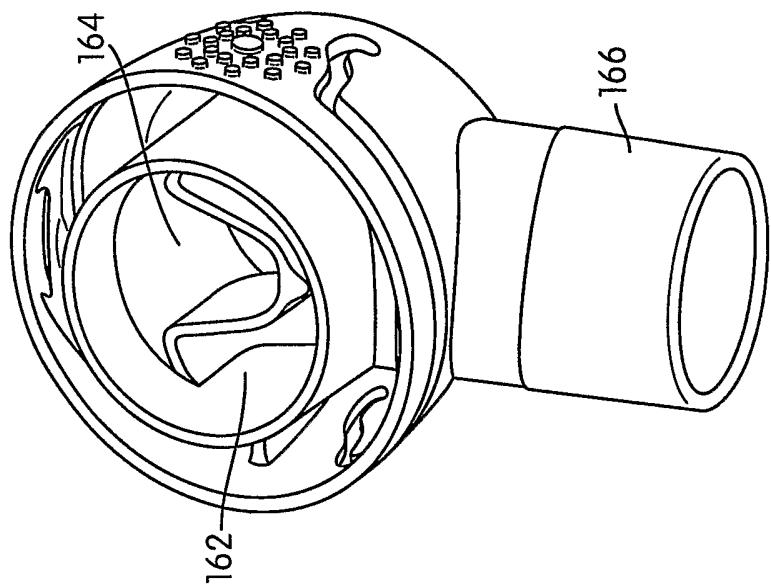
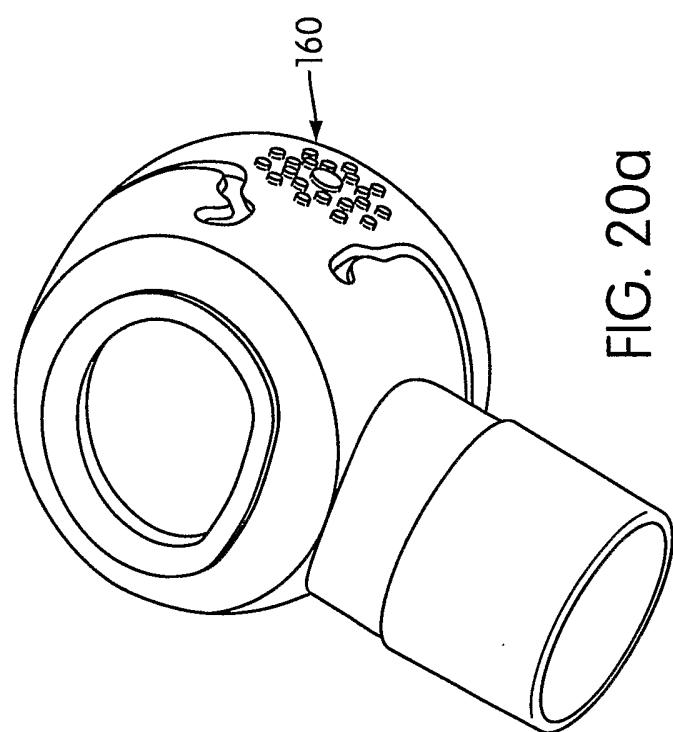
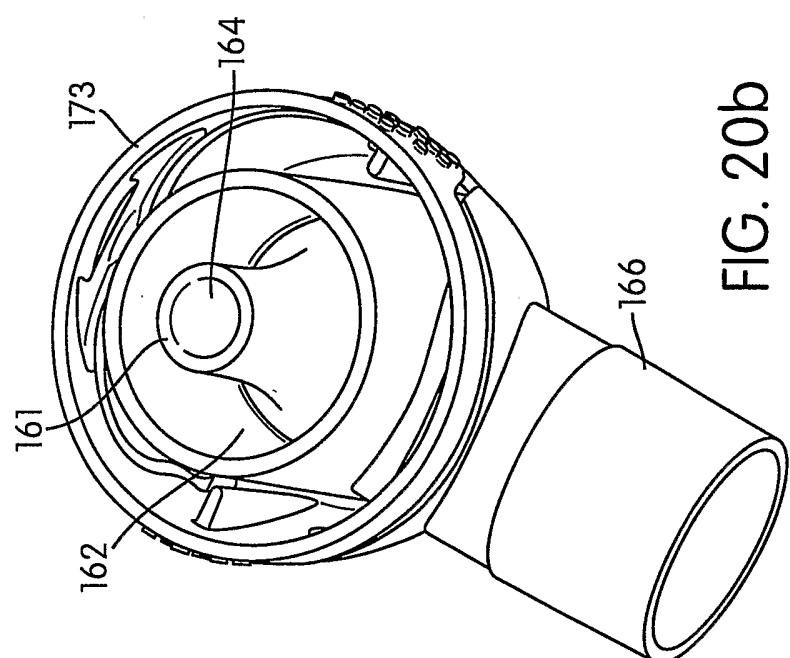


FIG. 19h

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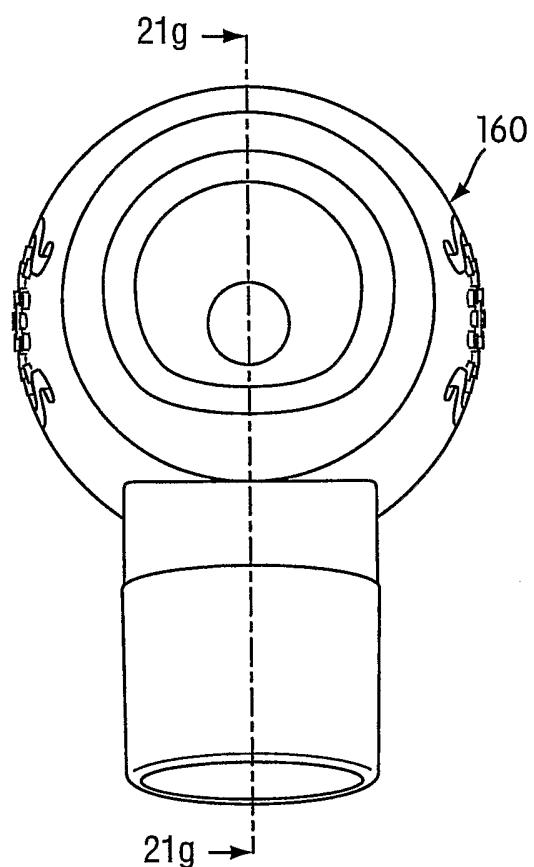


FIG. 21a

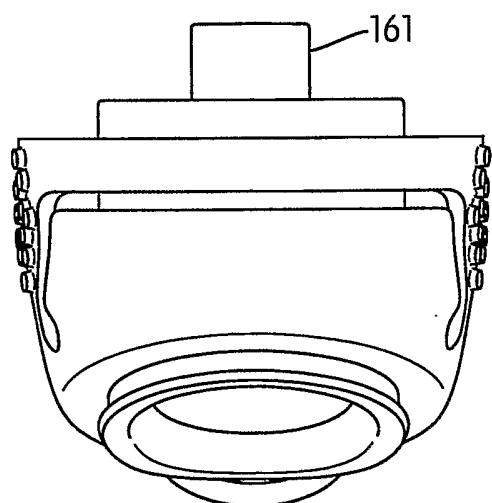


FIG. 21b

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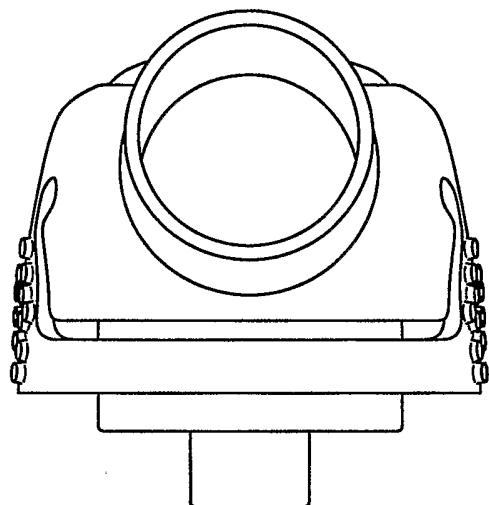


FIG. 21c

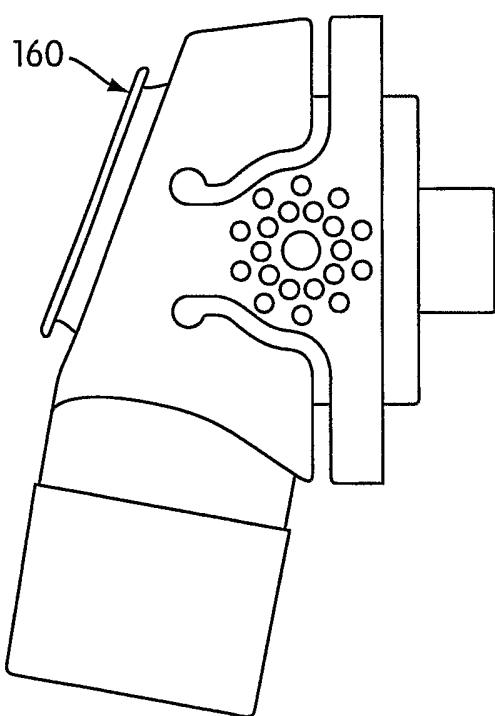


FIG. 21d

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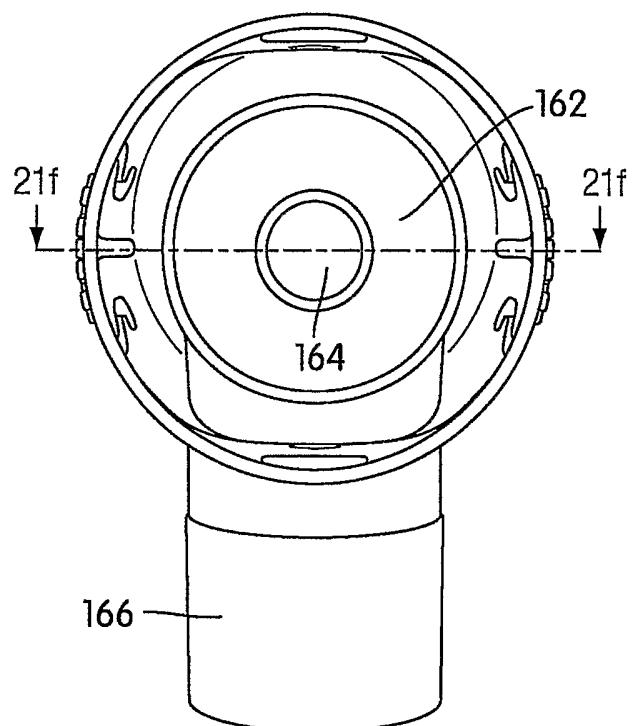


FIG. 21e

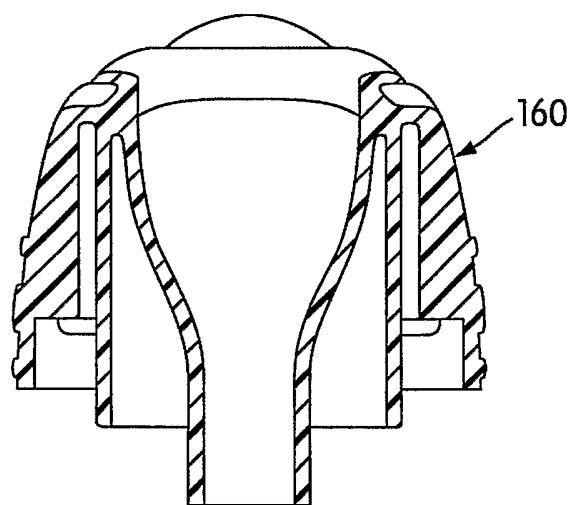


FIG. 21f

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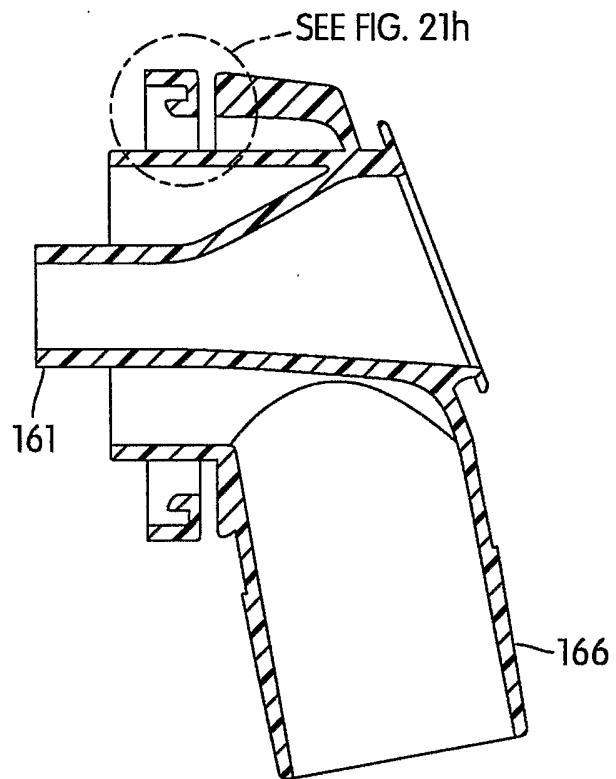


FIG. 21g

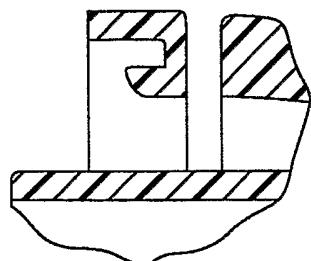


FIG. 21h

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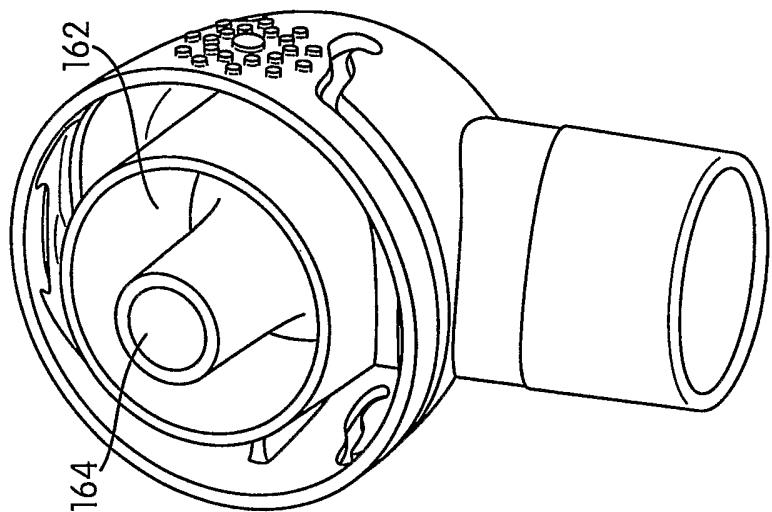


FIG. 21j

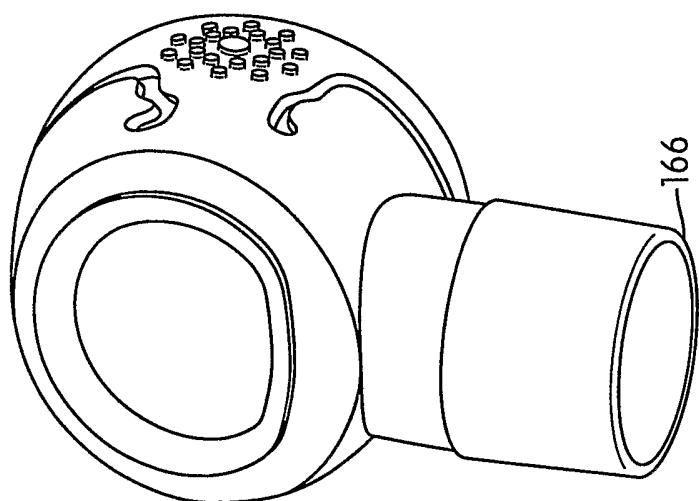
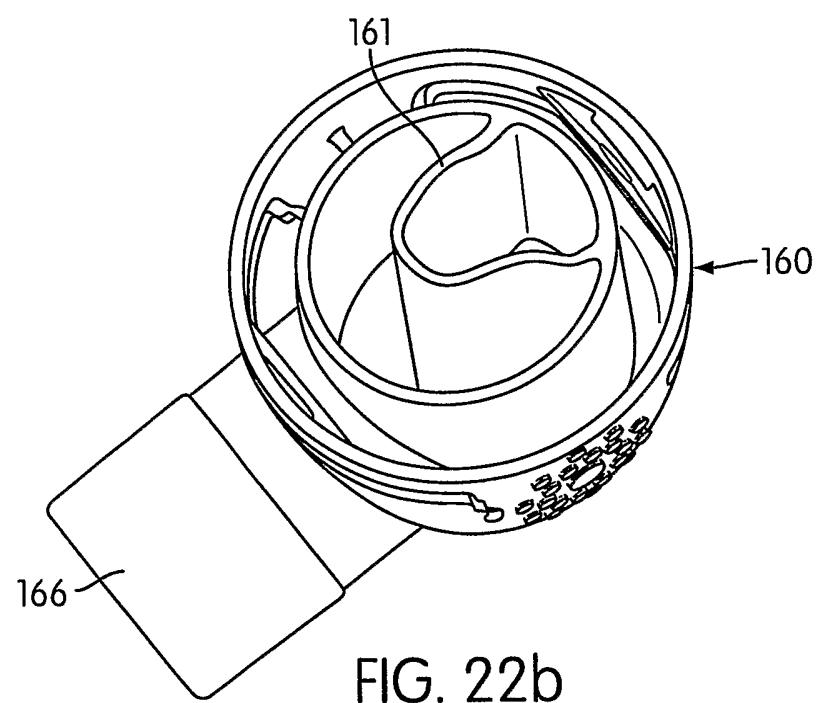
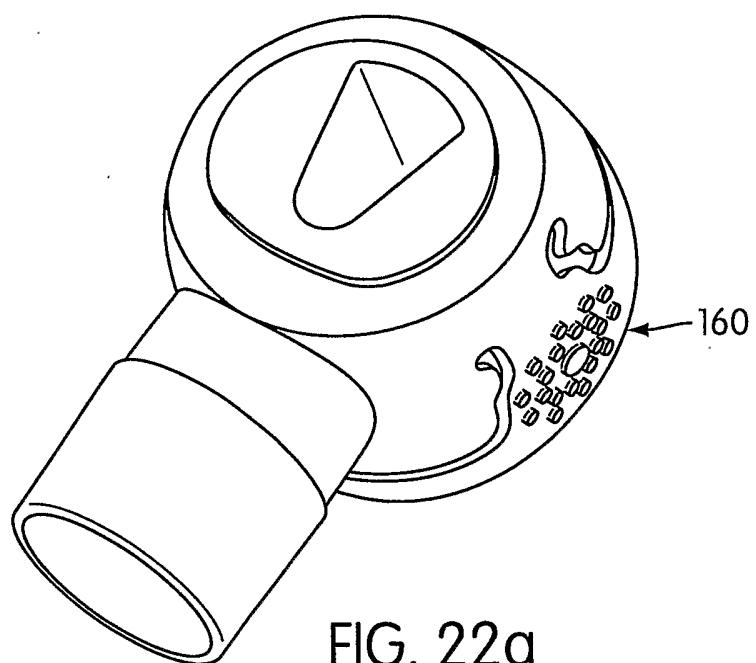


FIG. 21i

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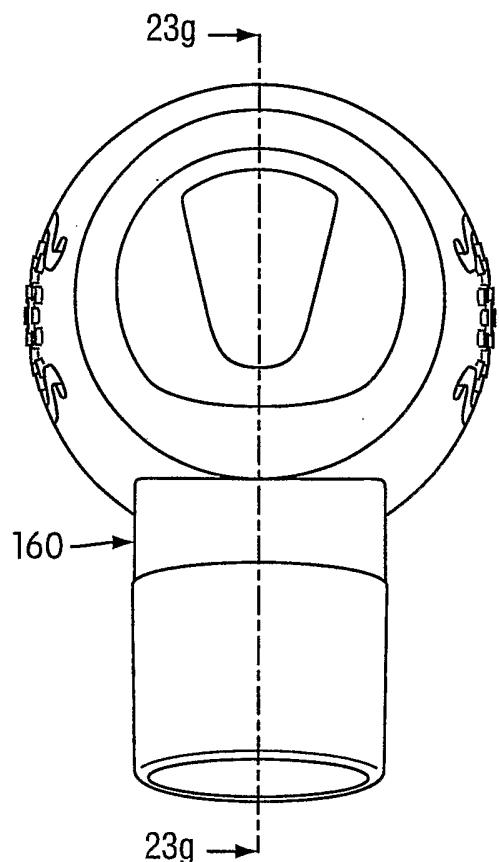


FIG. 23a

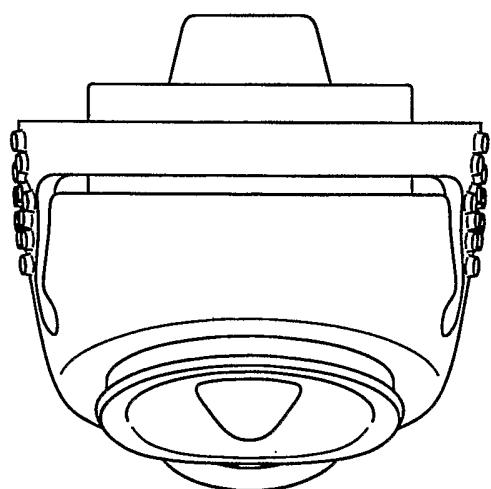


FIG. 23b

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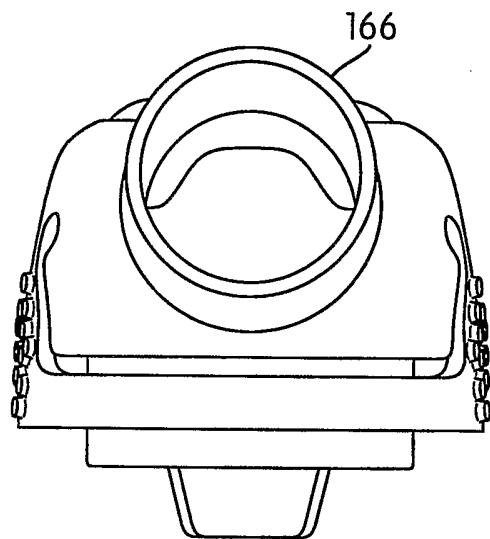
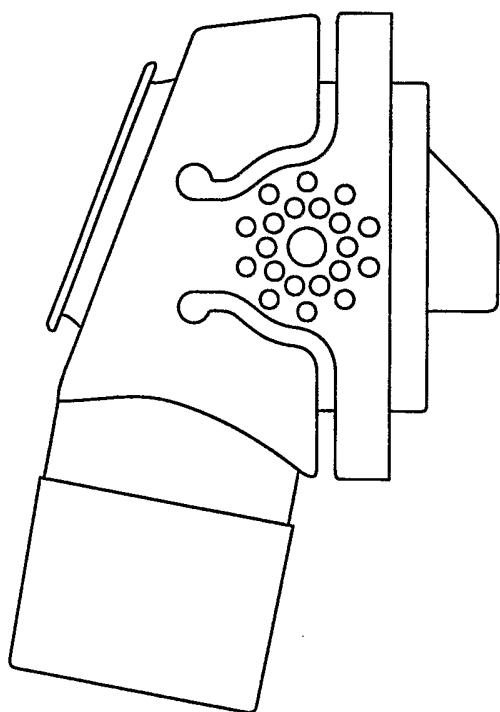


FIG. 23c



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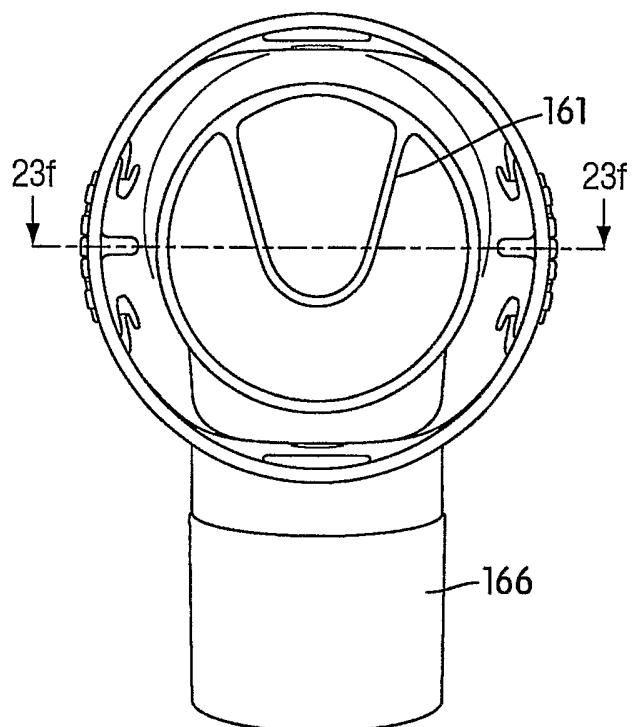


FIG. 23e

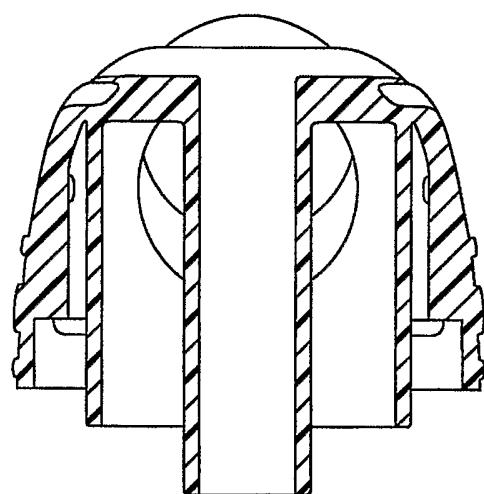


FIG. 23f

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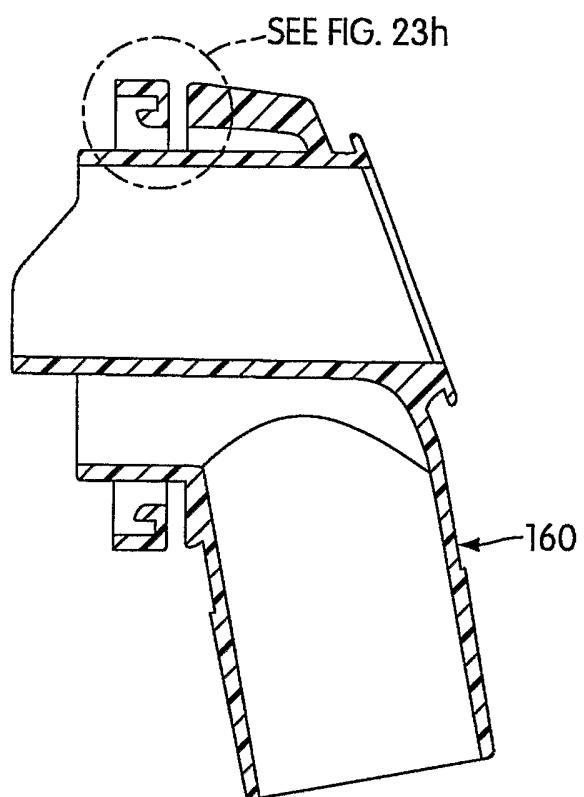


FIG. 23g

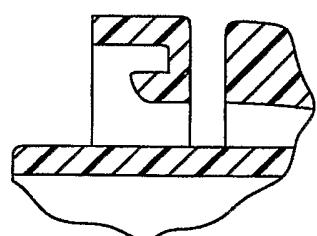


FIG. 23h

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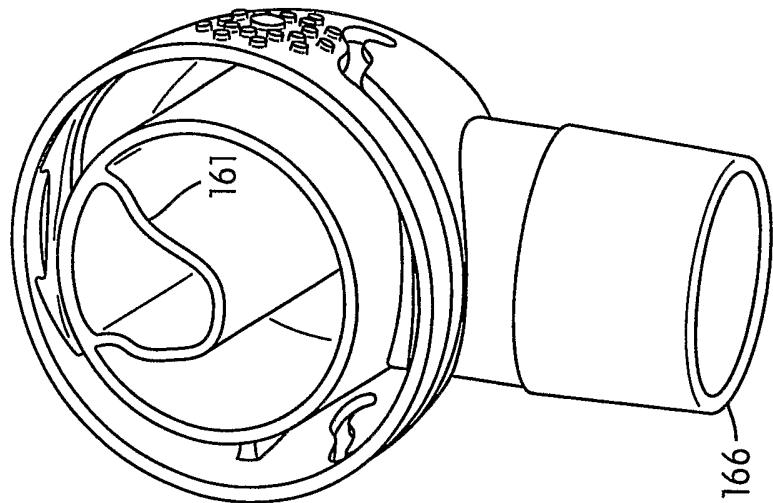


FIG. 23j

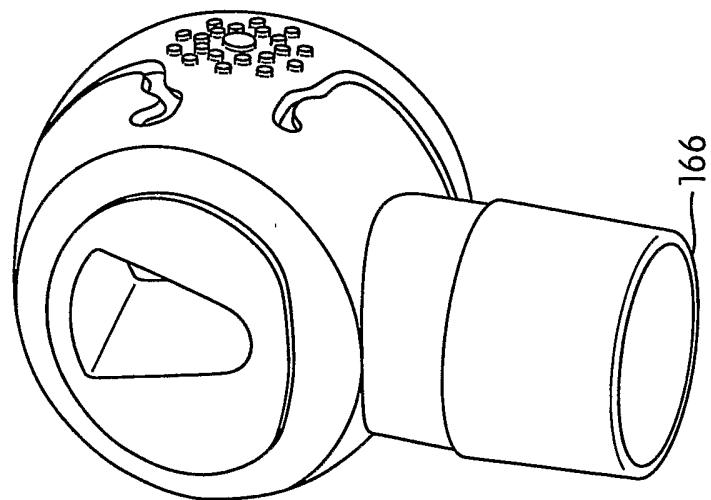


FIG. 23i

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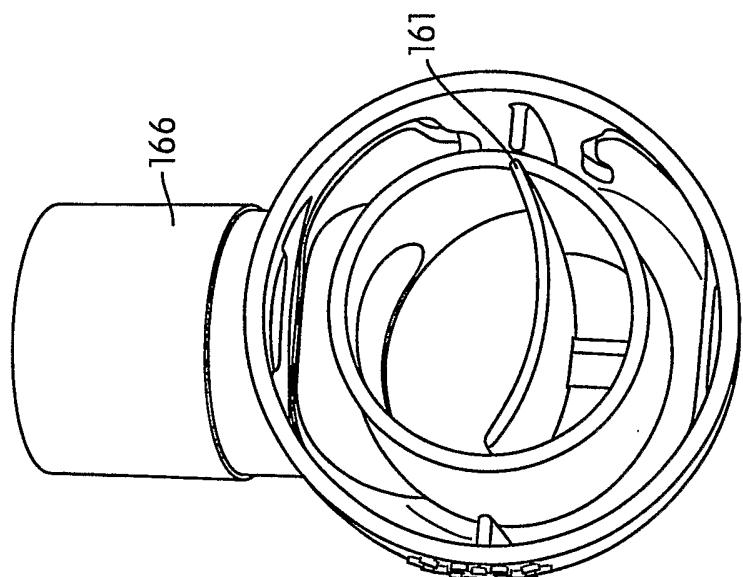


FIG. 24b

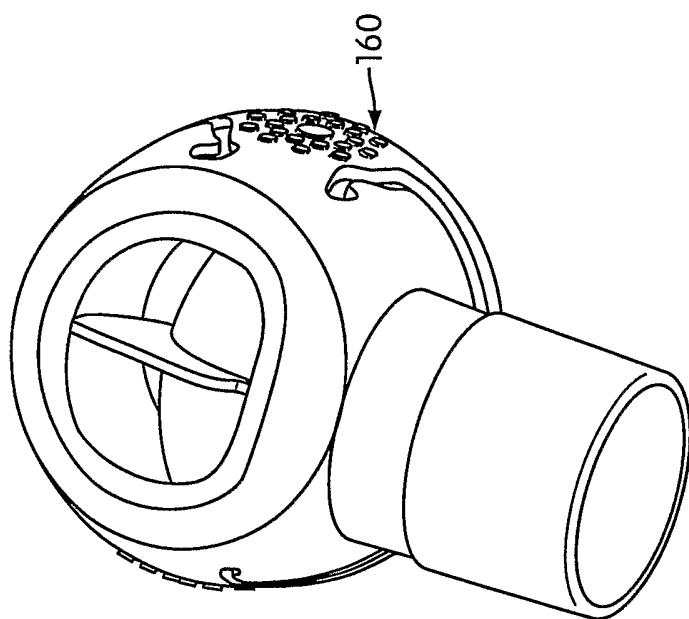


FIG. 24a

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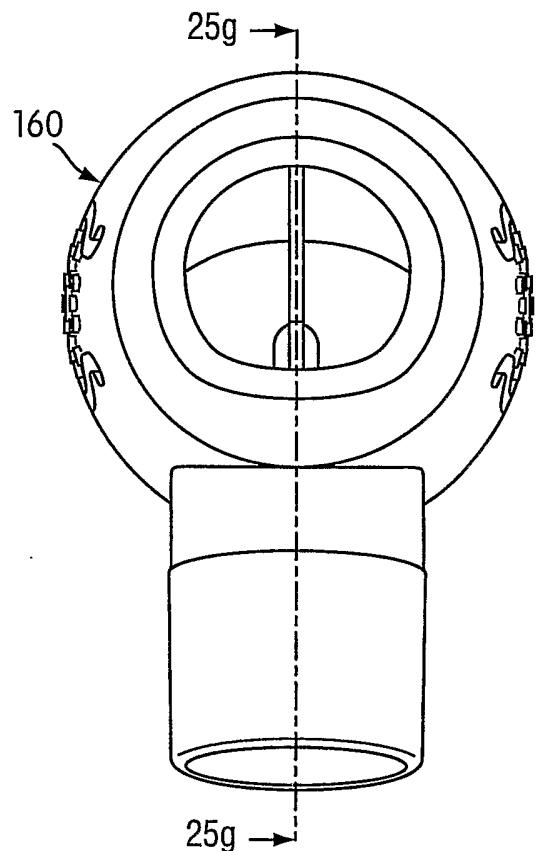


FIG. 25a

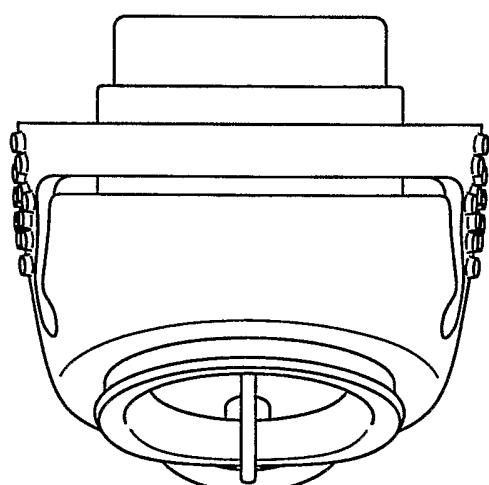


FIG. 25b

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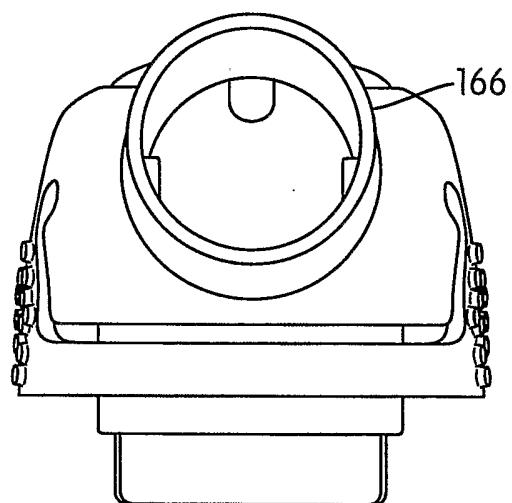


FIG. 25c

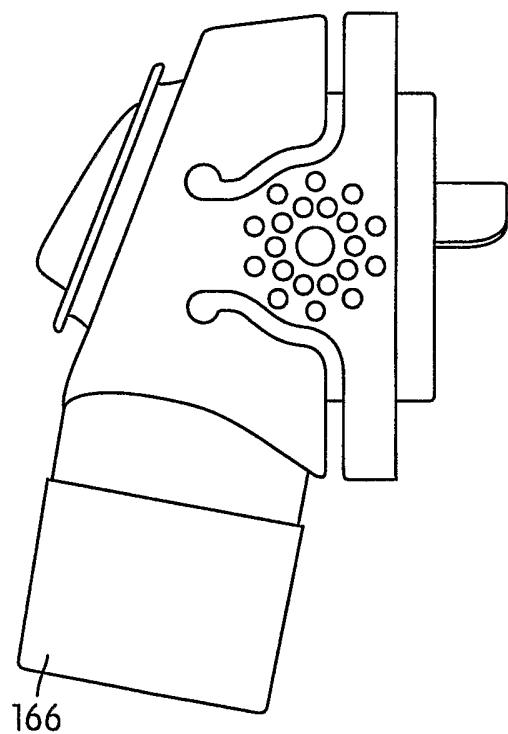


FIG. 25d

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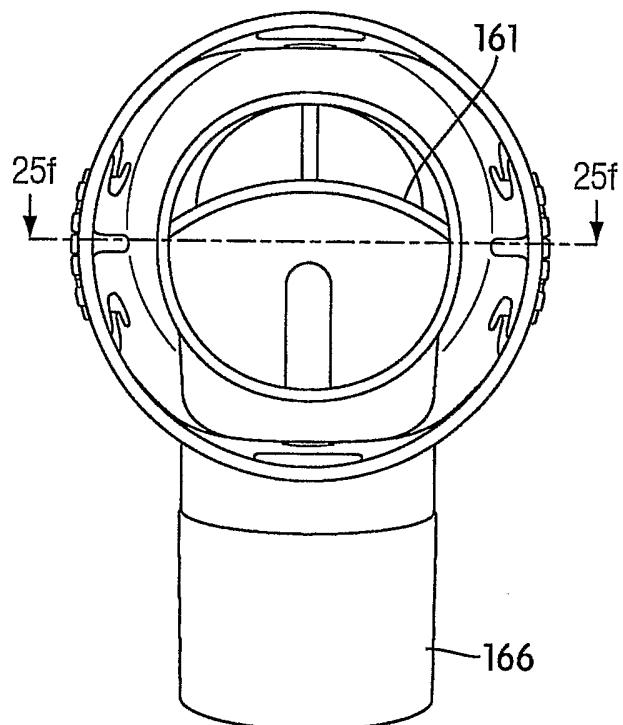


FIG. 25e

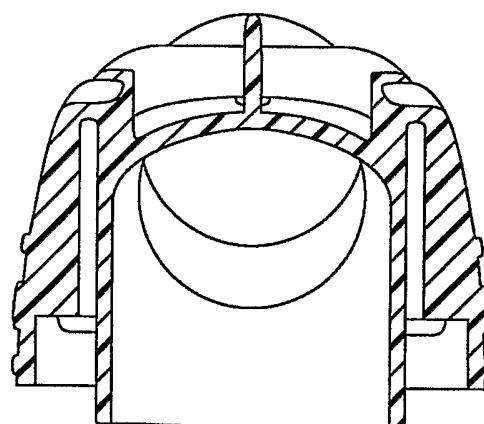


FIG. 25f

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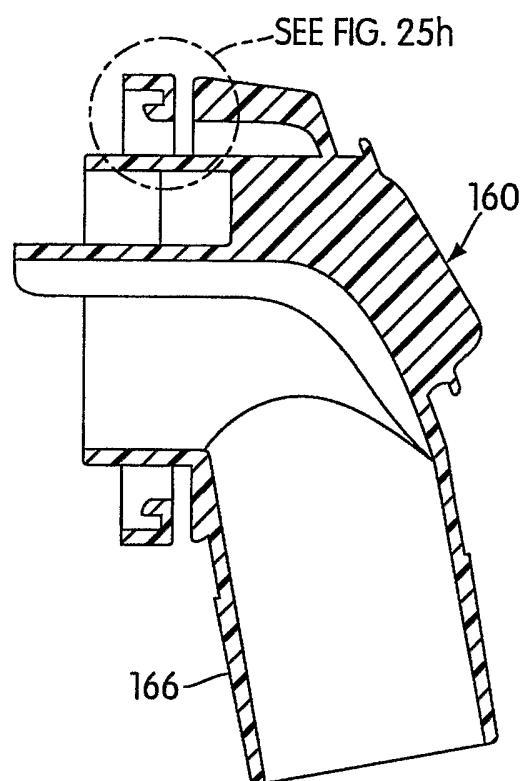


FIG. 25g

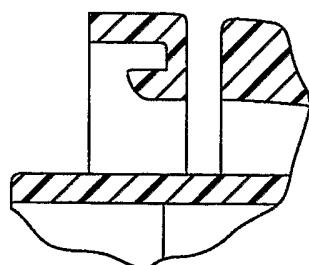


FIG. 25h

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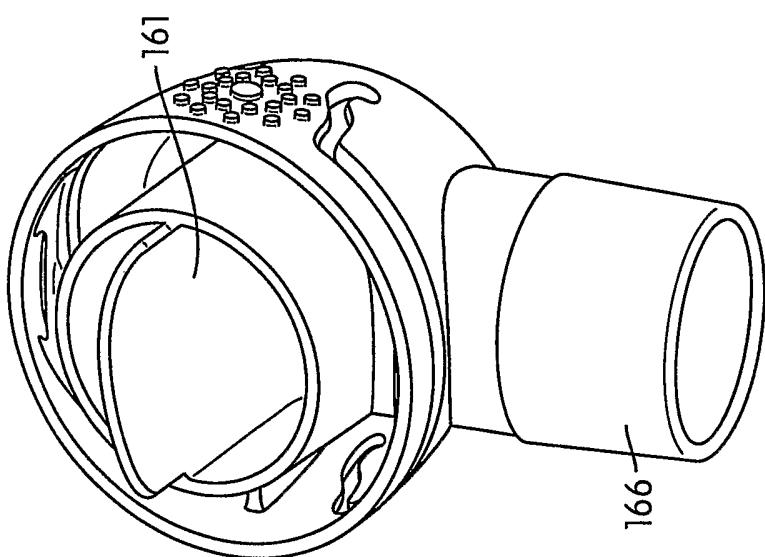


FIG. 25j

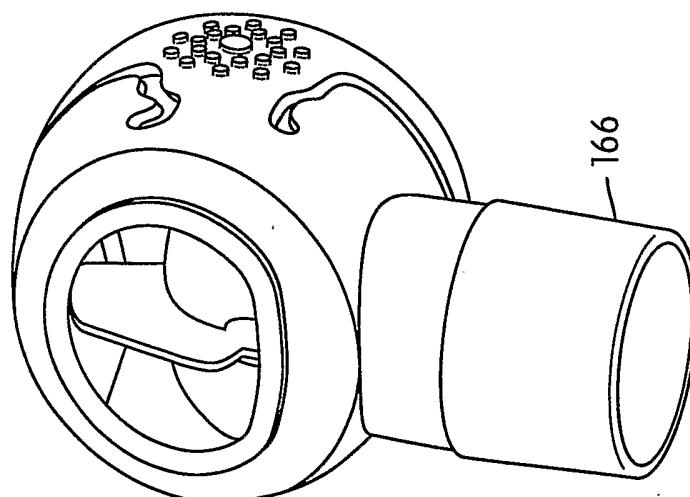
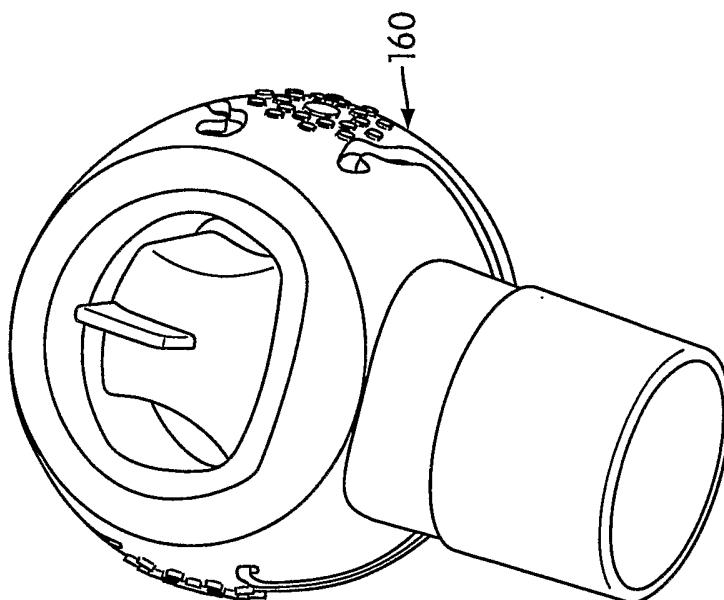
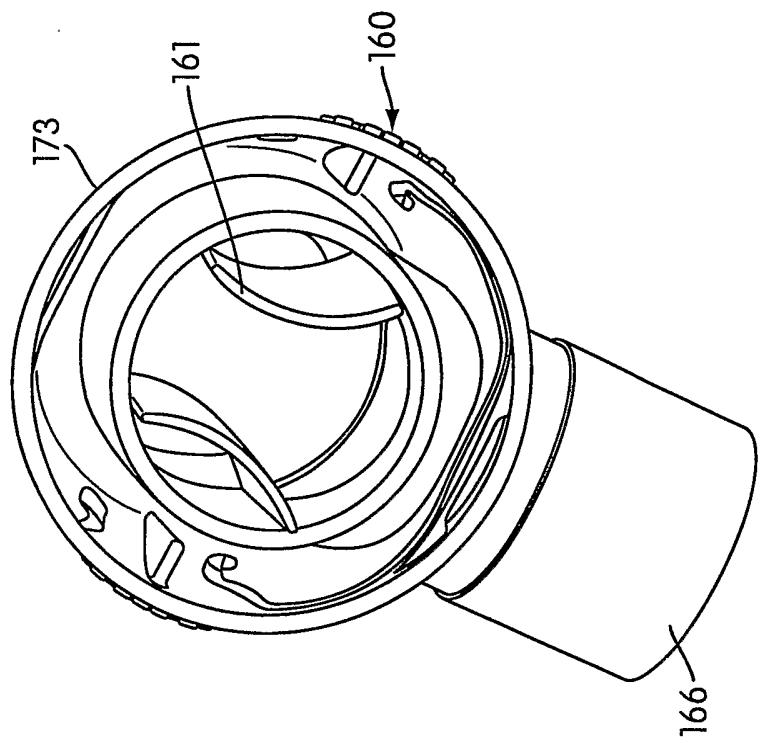


FIG. 25i

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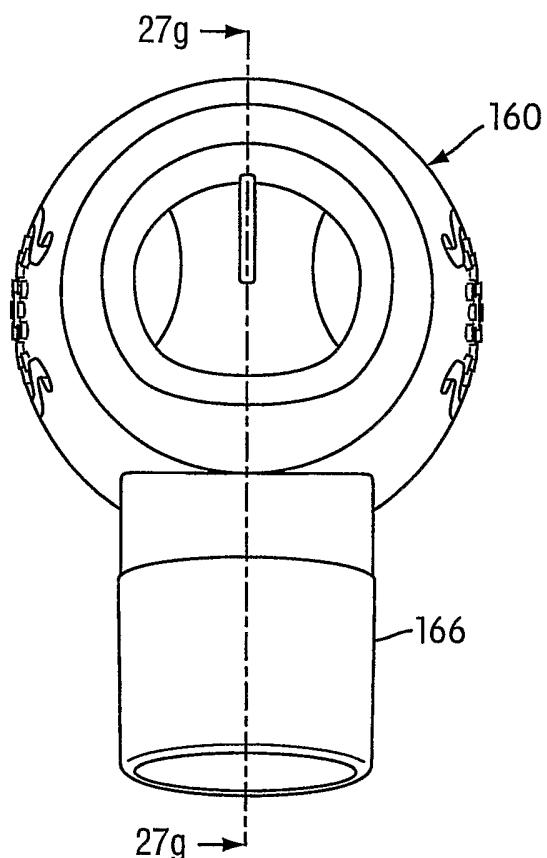


FIG. 27a

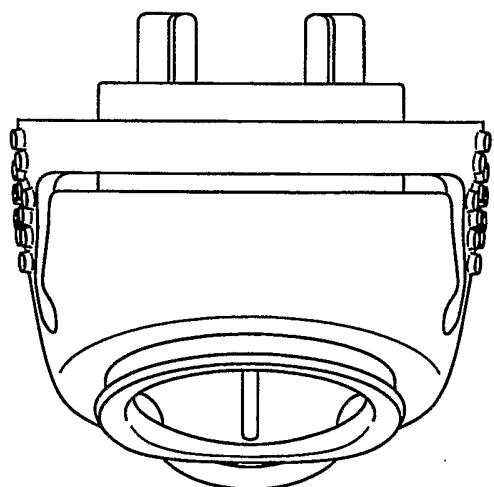


FIG. 27b

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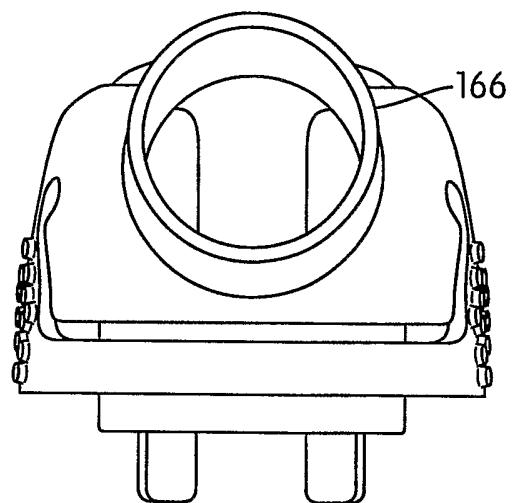


FIG. 27c

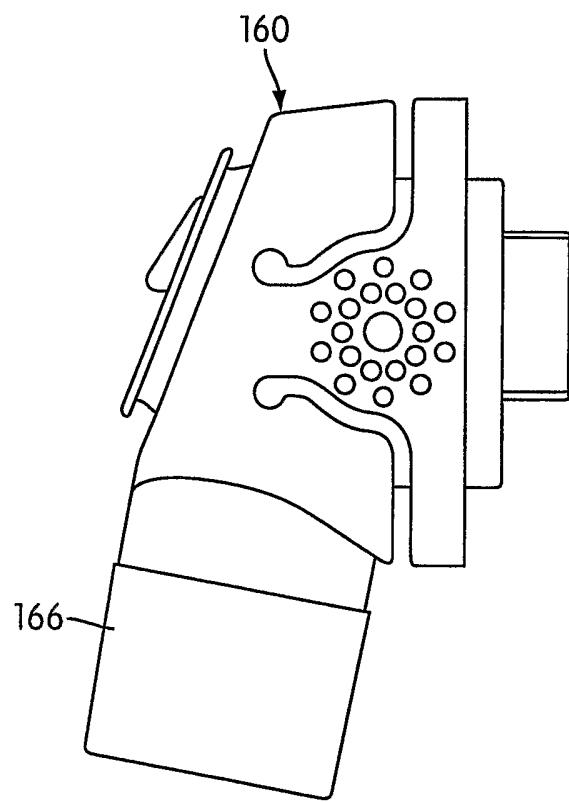
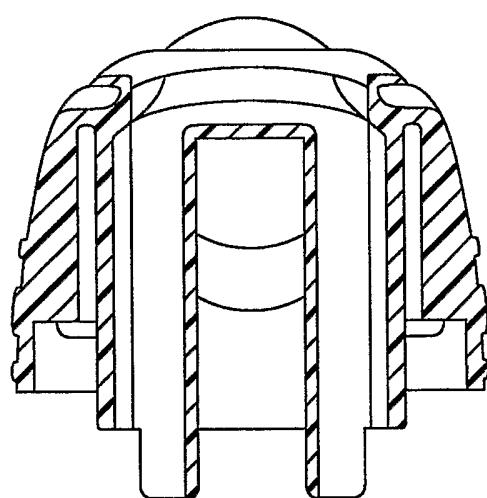
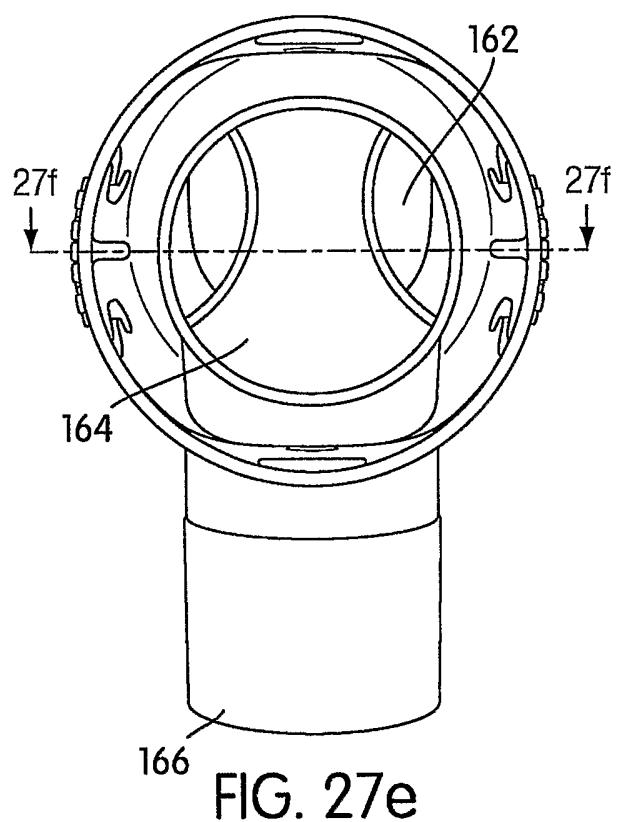


FIG. 27d

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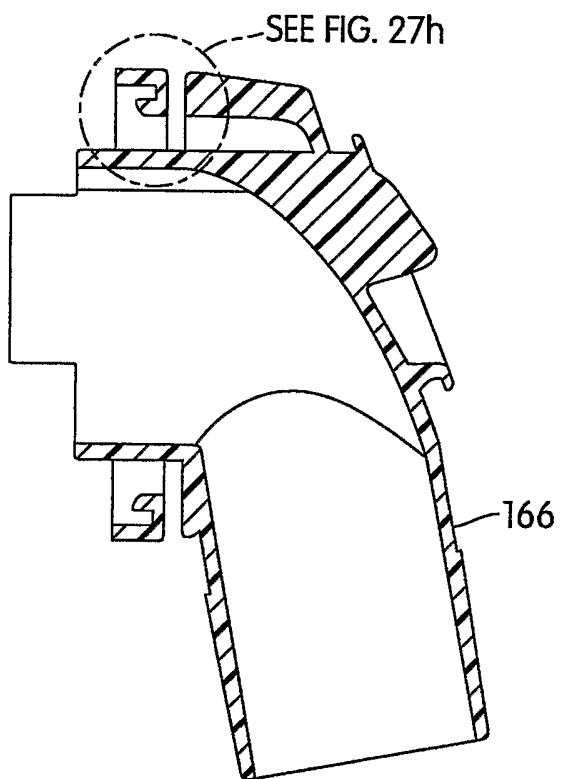


FIG. 27g

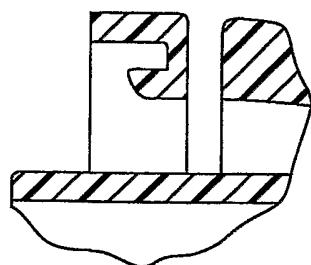


FIG. 27h

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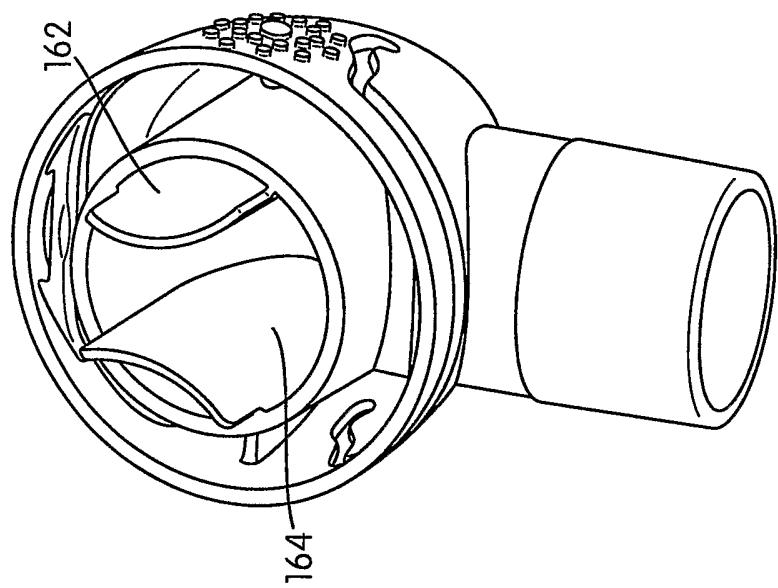


FIG. 27j

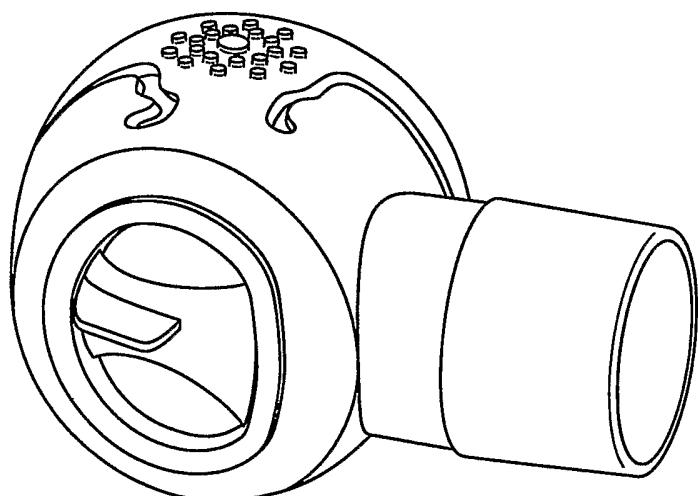


FIG. 27i

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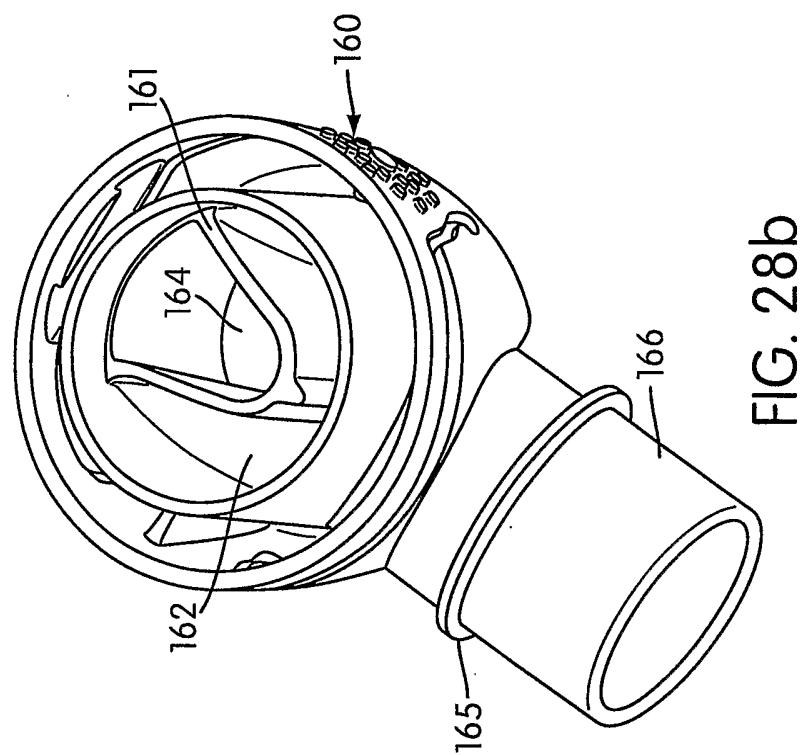


FIG. 28b

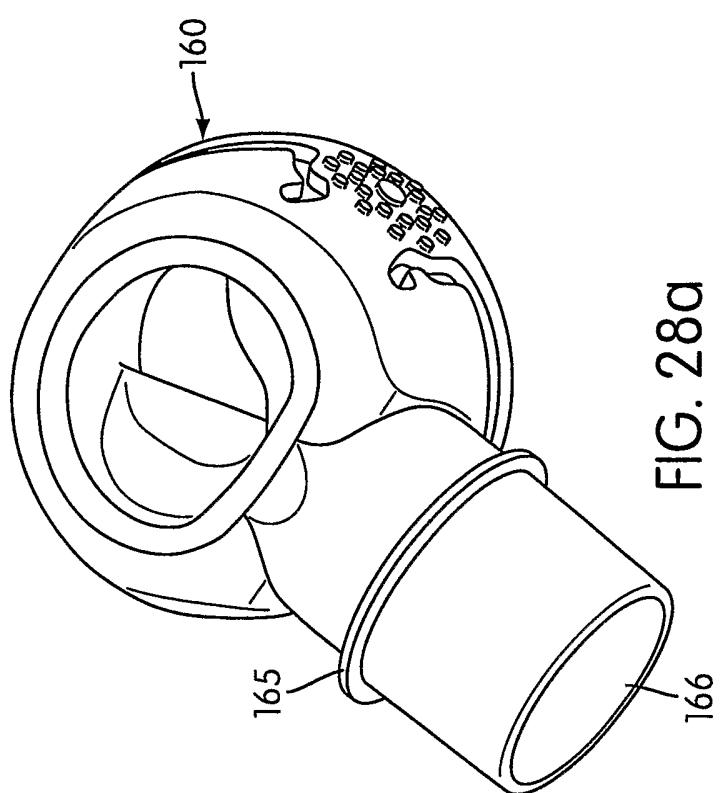


FIG. 28a

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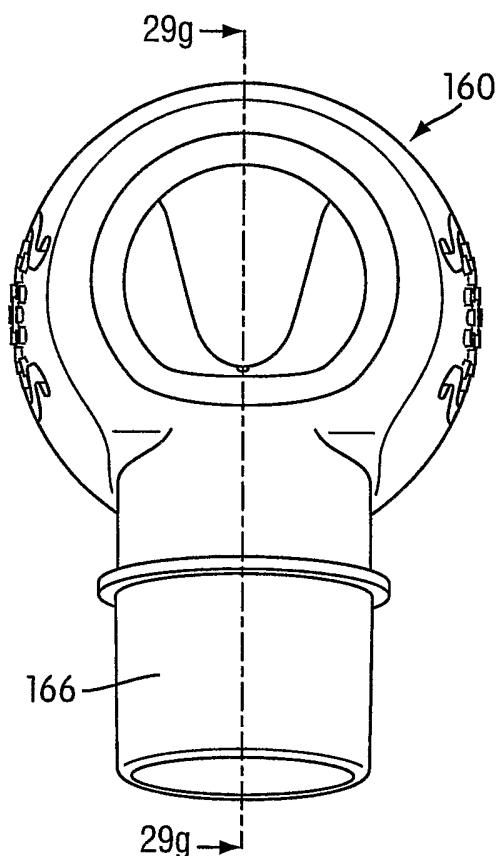


FIG. 29a

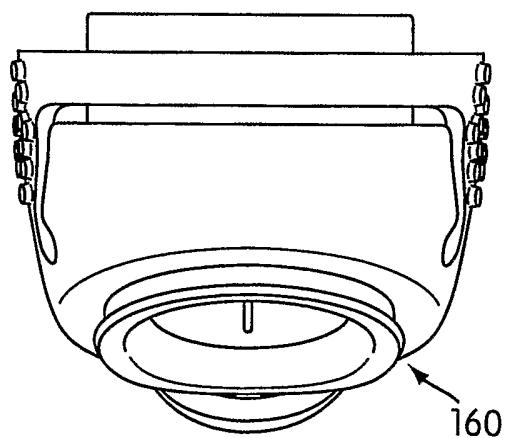


FIG. 29b

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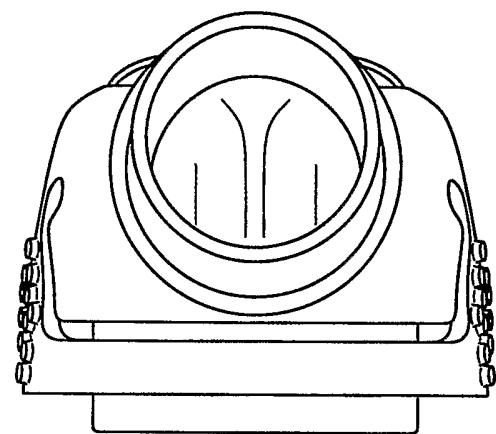


FIG. 29c

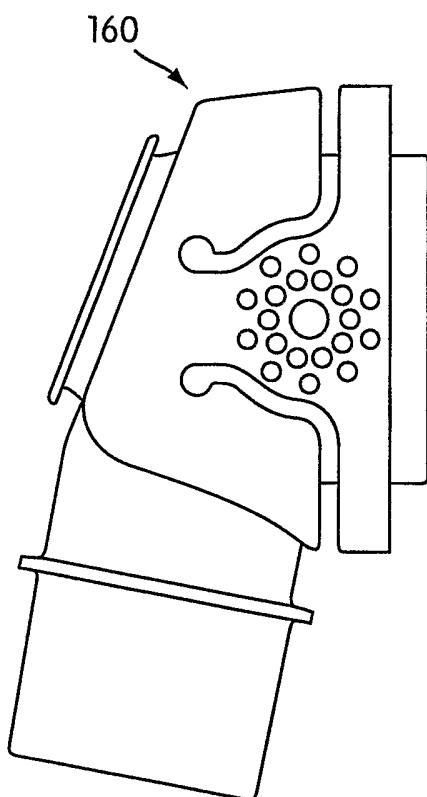


FIG. 29d

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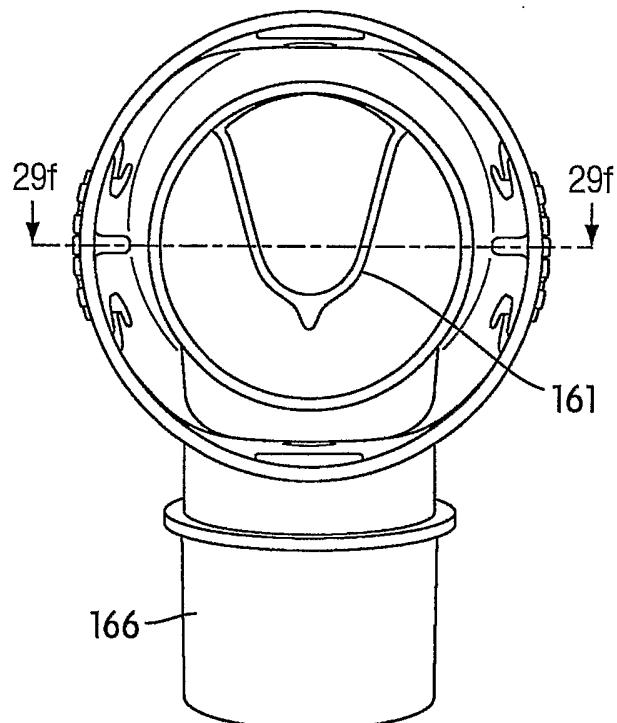


FIG. 29e

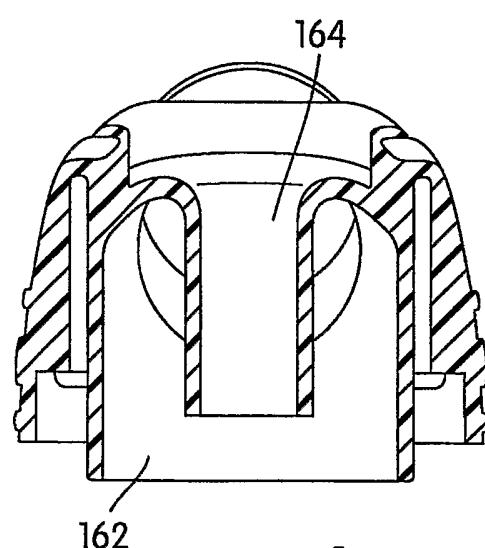


FIG. 29f

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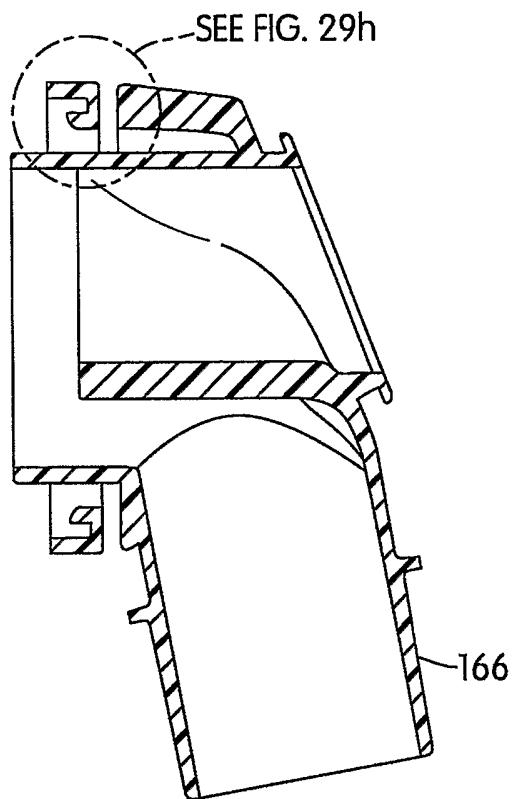


FIG. 29g

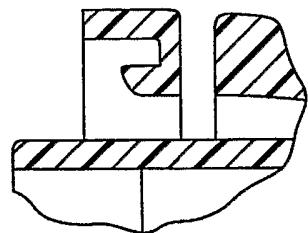


FIG. 29h

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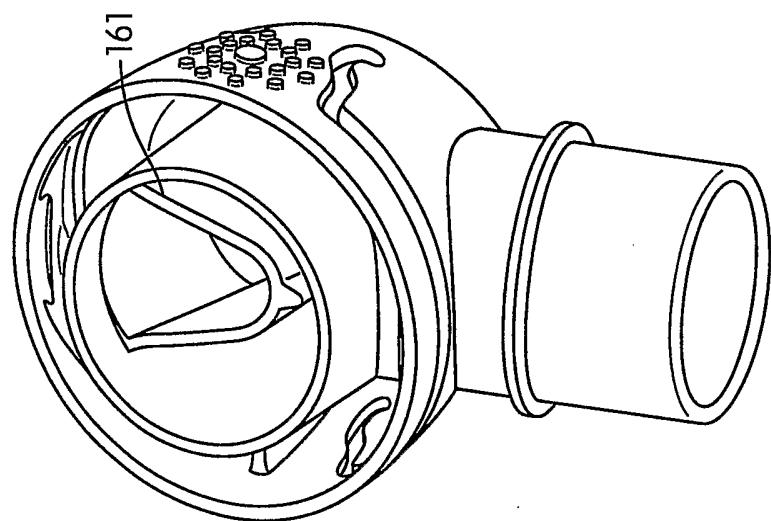


FIG. 29j

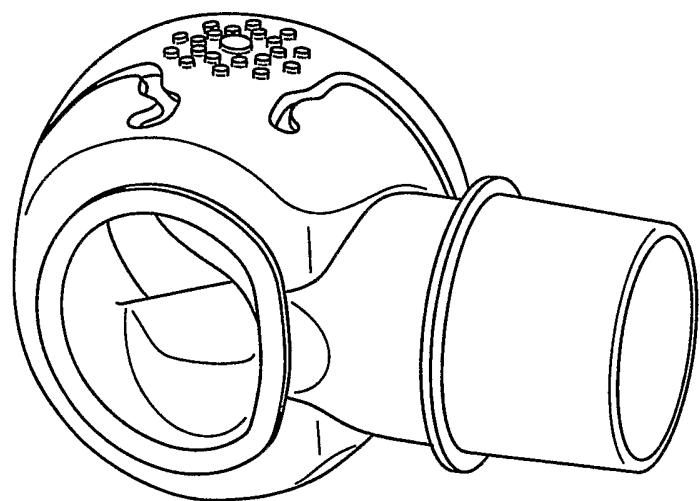


FIG. 29i

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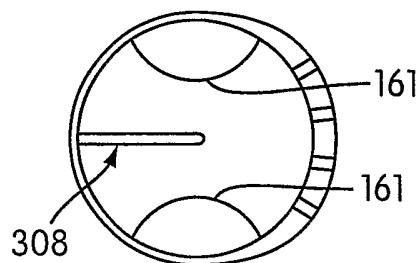
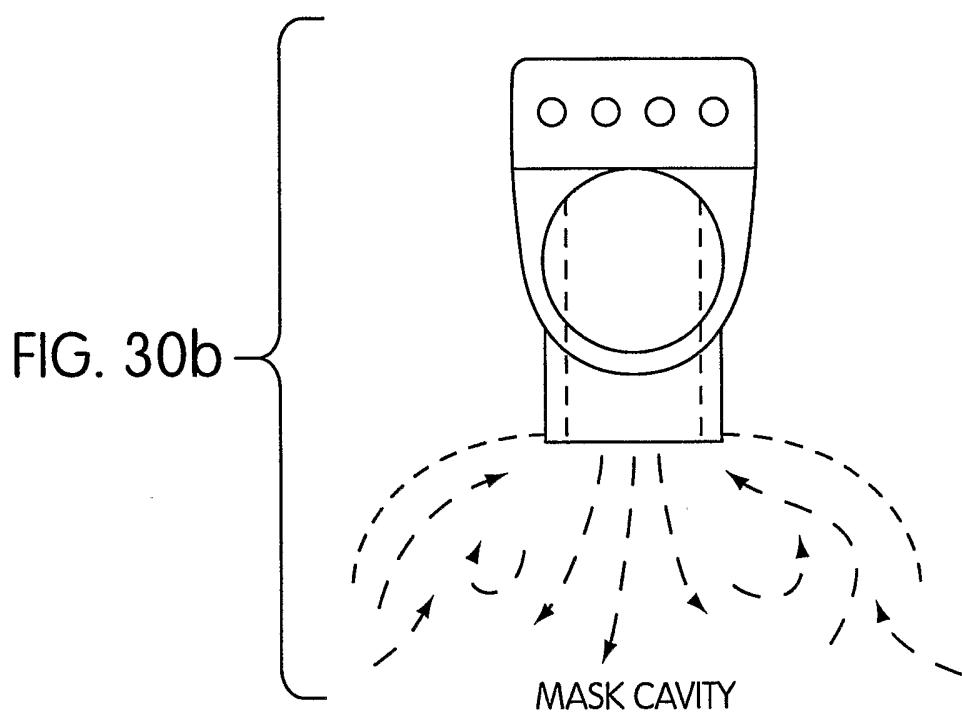
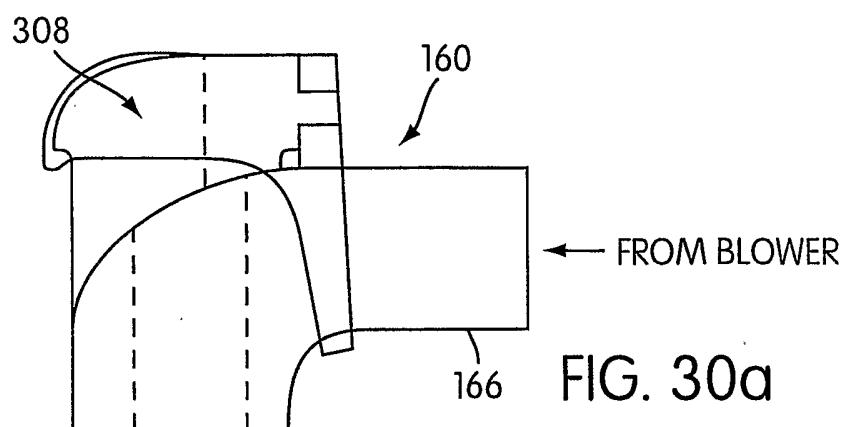


FIG. 30c

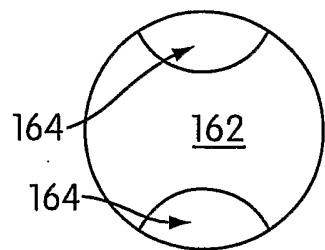


FIG. 30d

# INTERNATIONAL SEARCH REPORT

International application No.  
PCT/AU03/01162

|   |  |   |
|---|--|---|
| <b>A. CLASSIFICATION OF SUBJECT MATTER</b>  |  |   |
| Int. Cl. ?: A61M 16/08 A62B 9/00  |  |   |
| According to International Patent Classification (IPC) or to both national classification and IPC   |  |   |
| <b>B. FIELDS SEARCHED</b>   |  |   |
| Minimum documentation searched (classification system followed by classification symbols)   |  |   |
| Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched   |  |   |
| Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)<br>DWPI + keywords: A61M/IC A62B/IC mask elbow bend connector curve arc baffle direct divert deflect and similar terms   |  |   |
| <b>C. DOCUMENTS CONSIDERED TO BE RELEVANT</b>   |  |   |
| Category*   | Citation of document, with indication, where appropriate, of the relevant passages | Relevant to claim No.                                       |
| X   | WO 00/78381 A1 (RESMED LTD) 28 December 2000<br>Whole document                     | 1, 3, 8, 9, 11-13, 15-27<br>8, 9, 27                        |
| Y   | Whole document   |   |
| Y   | US 5918598 A (BELFER et al) 6 July 1999<br>Abstract, drawings                      | 8, 9, 27  |
| A   | EP 1057494 A2 (SLEEPNET CORP) 6 December 2000<br>Whole document                    |   |
| <input checked="" type="checkbox"/> Further documents are listed in the continuation of Box C   |  | <input checked="" type="checkbox"/> See patent family annex |
| <p>* Special categories of cited documents:</p> <p>"A" document defining the general state of the art which is not considered to be of particular relevance</p> <p>"E" earlier application or patent but published on or after the international filing date</p> <p>"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)</p> <p>"O" document referring to an oral disclosure, use, exhibition or other means</p> <p>"P" document published prior to the international filing date but later than the priority date claimed</p> <p>"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention</p> <p>"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone</p> <p>"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art</p> <p>"&amp;" document member of the same patent family</p> |  |   |
| Date of the actual completion of the international search<br>10 October 2003  | Date of mailing of the international search report<br>15 OCT 2003                  |   |
| Name and mailing address of the ISA/AU<br>AUSTRALIAN PATENT OFFICE<br>PO BOX 200, WODEN ACT 2606, AUSTRALIA<br>E-mail address: pct@ipaaustralia.gov.au<br>Facsimile No. (02) 6285 3929  | Authorized officer<br><b>Sue Thomas</b><br>Telephone No : (02) 6283 2454           |   |

**INTERNATIONAL SEARCH REPORT**

|  |
|--|
| International application No.<br><b>PCT/AU03/01162</b> |
|--|

**C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT**

| Category* | Citation of document, with indication, where appropriate, of the relevant passages | Relevant to claim No. |
|-----------|--|-----------------------|
| P,X       | US 6467483 B1 (KOPACKO et al ) 22 October 2002<br>Whole document                   | 1-4, 7-10, 14-18      |

**INTERNATIONAL SEARCH REPORT**

Information on patent family members

International application No.

**PCT/AU03/01162**

This Annex lists the known "A" publication level patent family members relating to the patent documents cited in the above-mentioned international search report. The Australian Patent Office is in no way liable for these particulars which are merely given for the purpose of information.

| Patent Document Cited in<br>Search Report |         |    |            | Patent Family Member |         |    |            |
|---|---------|----|------------|----------------------|---------|----|------------|
| US  | 6467483 | US | 2003019496 |                      |         |    |            |
| US  | 5918598 | US | 6196223    |                      |         |    |            |
| EP  | 1057494 | AU | 51653/00   | CA                   | 2310919 | CA | 2375928    |
|   |         | EP | 1189650    | WO                   | 0074758 |    |            |
| WO  | 0078381 | AU | 12454/97   | EP                   | 0956069 | JP | 2000279520 |
|   |         | US | 6112746    |                      |         |    |            |
| END OF ANNEX                              |         |    |            |                      |         |    |            |