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Attorneys for Plaintiffs

BY
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UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA

RESMED INC., a Delaware Corporation,
RESMED CORP, a Minnesota
Corporation, and RESMED LTD, an
Australian Corporation,

Plaintiffs,

v.

APEX MEDICAL CORPORATION, a
Taiwanese Corporation, APEX
MEDICAL CORP USA, a California
Corporation, and MEDICAL DEPOT
INC., d/b/a DRIVE MEDICAL DESIGN
& MANUFACTURING, a Delaware
Corporation,

Defendants.

Case No. SACV 13 - 00498 CJC (RNBx)

**RESMED'S COMPLAINT FOR
PATENT INFRINGEMENT**

JURY TRIAL DEMANDED

ORIGINAL

Case No.

1 Plaintiffs ResMed Inc., ResMed Corp, and ResMed Ltd (collectively
2 “Plaintiffs” or “ResMed”) hereby file this complaint against Defendants APEX
3 Medical Corporation and APEX Medical USA Corp. (collectively “APEX”) and
4 Medical Depot Inc., d/b/a Drive Medical Design & Manufacturing (“Drive”) and
5 allege as follows:

6 **PARTIES**

7 1. Plaintiff ResMed Inc. is a corporation organized under the laws of the
8 state of Delaware with its principal place of business in San Diego, California.

9 2. Plaintiff ResMed Corp is a corporation organized under the laws of the
10 state of Minnesota with its principal place of business in San Diego, California.

11 3. Plaintiff ResMed Ltd is a corporation organized under the laws of
12 Australia, having its principal place of business in Bella Vista, New South Wales,
13 Australia.

14 4. ResMed Corp and ResMed Ltd are, respectively, direct and indirect
15 subsidiaries of ResMed Inc.

16 5. As used herein, the term “Plaintiffs” or “ResMed” means individually
17 and/or collectively ResMed Inc., ResMed Corp, and ResMed Ltd.

18 6. On information and belief, Defendant APEX Medical Corp. (“APEX
19 Medical”) is a corporation organized under the laws of the country of Taiwan with
20 its principal place of business at No. 9, Min Sheng St., Tu-Cheng, New Taipei City,
21 23679, Taiwan.

22 7. On information and belief, Defendant APEX Medical USA Corp.
23 (“APEX Medical USA”) is the U.S. subsidiary of APEX Medical Corp., and APEX
24 Medical USA is a corporation organized under the laws of the state of California
25 with its principal place of business at 615 North Berry St, Suite D, Brea, CA 92821.

26 8. As used herein, the term “APEX” means individually and/or
27 collectively APEX Medical Corporation and APEX Medical USA Corp.

1 continue to supply services and things in this district, have caused and continue to
2 cause injury and damages in this district by acts and omissions in this district, and
3 have caused and continue to cause injury and damages in this district by acts or
4 omissions outside of this district while deriving substantial revenue from services or
5 things used or consumed within this district, and will continue to do so unless
6 enjoined by this Court.

7 THE PATENTS

8 15. ResMed Ltd is the owner by assignment of all right, title, and interest
9 in and to United States Patent No. 7,159,587 entitled “Respiratory Mask Having Gas
10 Washout Vent And Gas Washout Vent Assembly For Respiratory Mask,”
11 (hereinafter “the ’587 patent”), which was duly and legally issued on January 9,
12 2007. The ’587 patent is valid, enforceable, and currently in full force and effect. A
13 copy of the ’587 patent is attached as Exhibit A.

14 16. ResMed Inc. is the exclusive licensee of the ’587 patent and has
15 exclusively sublicensed the patent to ResMed Corp., the U.S. sales subsidiary.

16 17. ResMed Ltd is the owner by assignment of all right, title, and interest
17 in and to United States Patent No. 7,487,772 entitled “Ergonomic And Adjustable
18 Respiratory Mask Assembly With Elbow Assembly,” (hereinafter “the ’772
19 patent”), which was duly and legally issued on February 10, 2009. The ’772 patent
20 is valid, enforceable, and currently in full force and effect. A copy of the ’772
21 patent is attached as Exhibit B.

22 18. ResMed Inc. is the exclusive licensee of the ’772 patent and has
23 exclusively sublicensed the patent to ResMed Corp., the U.S. sales subsidiary.

24 19. ResMed Ltd is the owner by assignment of all right, title, and interest
25 in and to United States Patent No. 7,997,267 entitled “Ergonomic And Adjustable
26 Respiratory Mask Assembly With Elbow Assembly,” (hereinafter “the ’267
27 patent”), which was duly and legally issued on August 16, 2011. The ’267 patent is
28

1 valid, enforceable, and currently in full force and effect. A copy of the '267 patent
2 is attached as Exhibit C.

3 20. ResMed Inc. is the exclusive licensee of the '267 patent and has
4 exclusively sublicensed the patent to ResMed Corp., the U.S. sales subsidiary.

5 21. ResMed Ltd is the owner by assignment of all right, title, and interest
6 in and to United States Patent No. 7,743,767 entitled "Ergonomic And Adjustable
7 Respiratory Mask Assembly With Frame," (hereinafter "the '767 patent"), which
8 was duly and legally issued on June 29, 2010. The '767 patent is valid, enforceable,
9 and currently in full force and effect. A copy of the '767 patent is attached as
10 Exhibit D.

11 22. ResMed Inc. is the exclusive licensee of the '767 patent and has
12 exclusively sublicensed the patent to ResMed Corp., the U.S. sales subsidiary

13 23. ResMed Ltd is the owner by assignment of all right, title, and interest
14 in and to United States Patent No. 6,216,691 entitled "Mounting Body," (hereinafter
15 "the '691 patent"), which was duly and legally issued on April 17, 2001. The '691
16 patent is valid, enforceable, and currently in full force and effect. A copy of the
17 '691 patent is attached as Exhibit E.

18 24. ResMed Inc. is the exclusive licensee of the '691 patent and has
19 exclusively sublicensed the patent to ResMed Corp., the U.S. sales subsidiary.

20 25. ResMed Ltd is the owner by assignment of all right, title, and interest
21 in and to United States Patent No. 6,935,337 entitled "Humidifier With Structure To
22 Prevent Backflow Of Liquid Through The Humidifier Inlet," (hereinafter "the '337
23 patent"), which was duly and legally issued on August 30, 2005. The '337 patent is
24 valid, enforceable, and currently in full force and effect. A copy of the '337 patent
25 is attached as Exhibit F.

26 26. ResMed Inc. is the exclusive licensee of the '337 patent and has
27 exclusively sublicensed the patent to ResMed Corp., the U.S. sales subsidiary.
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1 pending worldwide, and its product line incorporates technology that is a highly
2 effective and proven way to treat OSA.

3 33. ResMed’s portfolio of SDB products includes flow generators,
4 humidifiers, diagnostic products, mask systems, headgear and other accessories,
5 including, for example, certain sleep-disordered breathing treatment full face masks,
6 including the Quattro FX, Quattro FX for Her, and Mirage Quattro. ResMed’s SDB
7 products also include certain sleep-disordered breathing treatment nasal masks,
8 including the Mirage FX, Mirage FX for Her, Mirage Liberty, Mirage Micro,
9 Mirage Activa LT and Mirage Vista. In addition, ResMed’s SDB products include
10 certain sleep-disordered breathing treatment systems that consist in part of a flow
11 generator, such as the multiple variations of ResMed’s S9 flow generator, and a
12 humidifier, such as the H5i, which works in conjunction with each of ResMed’s
13 various S9 flow generator units.

14 34. ResMed marks its patents on some products and marks all of its
15 products on its website at: www.resmed.com/ip.

16 35. On information and belief, APEX, on its own and/or through its
17 subsidiaries, is in the business of manufacturing, packaging, importing, selling,
18 offering to sell, and/or distributing a variety of sleep-disordered breathing treatment
19 systems and components thereof including (a) flow generators and humidifiers,
20 including, but not limited to, APEX’s XT Fit and iCH Auto (“the Accused APEX
21 Devices”), and (b) masks, including, but not limited to, APEX’s “WiZARD”
22 branded masks, including the WiZARD 210 which is intended to cover just the nose
23 and the WiZARD 220 which is intended to cover the nose and mouth (“the Accused
24 APEX Masks”). As used hereinafter, the phrase “Accused APEX Products” shall
25 mean individually and collectively the Accused APEX Devices and the Accused
26 APEX Masks.

1 sell, and/or selling within the United States, and/or importing into the United States,
2 the Accused Drive Masks.

3 75. As a result of Drive's infringement of the '267 patent, ResMed has
4 suffered and will continue to suffer damage. ResMed is entitled to recover from
5 Drive the damages adequate to compensate for such infringement, which have yet to
6 be determined.

7 76. Drive's acts of infringement have caused and will continue to cause
8 irreparable harm to ResMed unless and until enjoined by this Court.

9 **EIGHTH CLAIM FOR RELIEF**

10 **DRIVE'S INFRINGEMENT OF U.S. PATENT NO. 7,743,767**

11 77. The allegations of Paragraphs 1-40 are incorporated herein by
12 reference.

13 78. Drive has and continues to directly infringe the claims of the '767
14 patent, literally and/or under the doctrine of equivalents, by using, offering to sell,
15 and/or selling within the United States, and/or importing into the United States, the
16 Accused Drive Masks.

17 79. As a result of Drive's infringement of the '767 patent, ResMed has
18 suffered and will continue to suffer damage. ResMed is entitled to recover from
19 Drive the damages adequate to compensate for such infringement, which have yet to
20 be determined.

21 80. Drive's acts of infringement have caused and will continue to cause
22 irreparable harm to ResMed unless and until enjoined by this Court.

23 **NINTH CLAIM FOR RELIEF**

24 **APEX'S INFRINGEMENT OF U.S. PATENT NO. 6,216,691**

25 81. The allegations of Paragraphs 1-40 are incorporated herein by
26 reference.

1 88. APEX has directly infringed the claims of the '337 patent, literally
2 and/or under the doctrine of equivalents, by using, offering to sell, and/or selling
3 within the United States, and/or importing into the United States, at least APEX's
4 iCH Auto device.

5 89. ResMed is well-known in the industry for making and selling SDB
6 products and ResMed is well-known in the industry to be an innovator. ResMed
7 also marks its products with its patents. Therefore, on information and belief,
8 APEX either must have known about the '337 patent or must have been willfully
9 blind to it at the time they engaged in their infringing activities and, in any event,
10 was aware of the '337 patent at least as early as the service date of this complaint.

11 90. On information and belief, APEX has induced and continues to induce
12 infringement of the '337 patent by actively encouraging customers and others to
13 import, sell and/or use APEX's iCH Auto device in the United States with
14 knowledge that such import, sale or use would infringe the '337 patent. On
15 information and belief, those customers and others in fact infringed the '337 patent
16 by importing, selling and/or using APEX's iCH Auto device in the United States.

17 91. As a result of APEX's infringement of the '337 patent, ResMed has
18 suffered and will continue to suffer damage. ResMed is entitled to recover from
19 APEX the damages adequate to compensate for such infringement, which have yet
20 to be determined.

21 92. APEX's acts of infringement have caused and will continue to cause
22 irreparable harm to ResMed unless and until enjoined by this Court.

23 **ELEVENTH CLAIM FOR RELIEF**

24 **APEX's INFRINGEMENT OF U.S. PATENT NO. 7,614,398**

25 93. The allegations of Paragraphs 1-40 are incorporated herein by
26 reference.

- 1 (b) That APEX has induced infringement of the Patents-in-Suit;
- 2 (c) That APEX, and its officers, agents, servants, employees, and those in
3 active concert or participation with them directly or indirectly, be enjoined from
4 infringing the Patents-in-Suit;
- 5 (d) That APEX pay to ResMed the damages resulting from APEX's
6 infringement of the Patents-in-Suit, together with interest and costs, and all other
7 damages permitted by 35 U.S.C. § 284;
- 8 (e) That APEX be ordered to account for additional damages for any and
9 all periods of infringement not included in the damages awarded by the Court or
10 jury, including specifically any time periods between any order or verdict awarding
11 damages and entry of final judgment;
- 12 (f) That Drive has directly infringed the ResMed Mask Patents;
- 13 (g) That Drive, and their officers, agents, servants, employees, and those in
14 active concert or participation with them directly or indirectly, be enjoined from
15 infringing the Patents-in-Suit;
- 16 (h) That Drive pay to ResMed the damages resulting from Drive's
17 infringement of the Patents-in-Suit, together with interest and costs, and all other
18 damages permitted by 35 U.S.C. § 284;
- 19 (i) That Drive be ordered to account for additional damages for any and all
20 periods of infringement not included in the damages awarded by the Court or jury,
21 including specifically any time periods between any order or verdict awarding
22 damages and entry of final judgment; and
- 23 (j) That ResMed be awarded such other equitable or legal relief as this
24 Court deems just and proper under the circumstances.

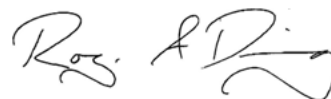
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1 **DEMAND FOR JURY TRIAL**

2 99. Pursuant to Federal Rule of Civil Procedure 38, ResMed demands a
3 jury trial on all issues so triable.

4
5 Dated: March 28, 2013

FISH & RICHARDSON P.C.

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7 By: _____

Roger A. Denning

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9 Attorneys for Plaintiffs ResMed Inc.,
10 ResMed Corp, and ResMed Ltd.
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EXHIBIT A



US007159587B2

(12) **United States Patent**
Drew et al.

(10) **Patent No.:** **US 7,159,587 B2**
(45) **Date of Patent:** ***Jan. 9, 2007**

(54) **RESPIRATORY MASK HAVING GAS WASHOUT VENT AND GAS WASHOUT VENT ASSEMBLY FOR RESPIRATORY MASK**

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5,657,752 A *	8/1997	Landis et al. 128/207.13
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(75) Inventors: **Joanne Drew**, Balgowlah (AU);
Alexander Virr, Balmain (AU);
Geoffrey Crumblin, Baulkham Hills (AU)

(73) Assignee: **ResMed Limited**, North Ryde (AU)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 12 days.

This patent is subject to a terminal disclaimer.

(21) Appl. No.: **10/976,874**

(22) Filed: **Nov. 1, 2004**

(65) **Prior Publication Data**

US 2005/0092326 A1 May 5, 2005

Related U.S. Application Data

(63) Continuation of application No. 10/377,110, filed on Mar. 3, 2003, now Pat. No. 6,823,865, which is a continuation of application No. 09/570,907, filed on May 15, 2000, now Pat. No. 6,581,594.

(51) **Int. Cl.**
A61M 16/00 (2006.01)

(52) **U.S. Cl.** **128/204.18**; 128/205.11;
128/207.12; 128/207.13

(58) **Field of Classification Search** 128/200.29,
128/201.29, 204.18, 205.11, 207.12, 207.13
See application file for complete search history.

(56) **References Cited**

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Instruction Brochure for "E-vent-N" Aug. 1997, © Dräger Medizintechnik GmbH, 2 pages.

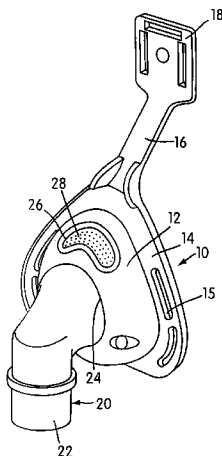
Primary Examiner—Aaron J. Lewis

(74) *Attorney, Agent, or Firm*—Nixon & Vanderhye P.C.

(57) **ABSTRACT**

The present invention provides a vent assembly suitable for use with a respiratory mask of the type used in CPAP treatment. In one embodiment the vent is made of a thin air permeable membrane. Generally, the membrane is thinner than 0.5 mm. The membrane can be made of a hydrophobic material such as polytetrafluoroethylene (PTFE). The membrane can also be fabricated from expanded PTFE. The expanded PTFE membrane is mounted on a polypropylene scrim. The pores of the membrane have a reference pore size of 10 to 15 microns. In an alternative embodiment, the vent assembly includes a vent constructed from stainless steel. In another embodiment the membrane has a superficial cross-sectional area of approximately 500 mm². In another embodiment the vent assembly comprises a membrane attached to a vent frame, the vent assembly forming an insert which can be removably attached to a mask frame.

40 Claims, 4 Drawing Sheets



US 7,159,587 B2

Page 2

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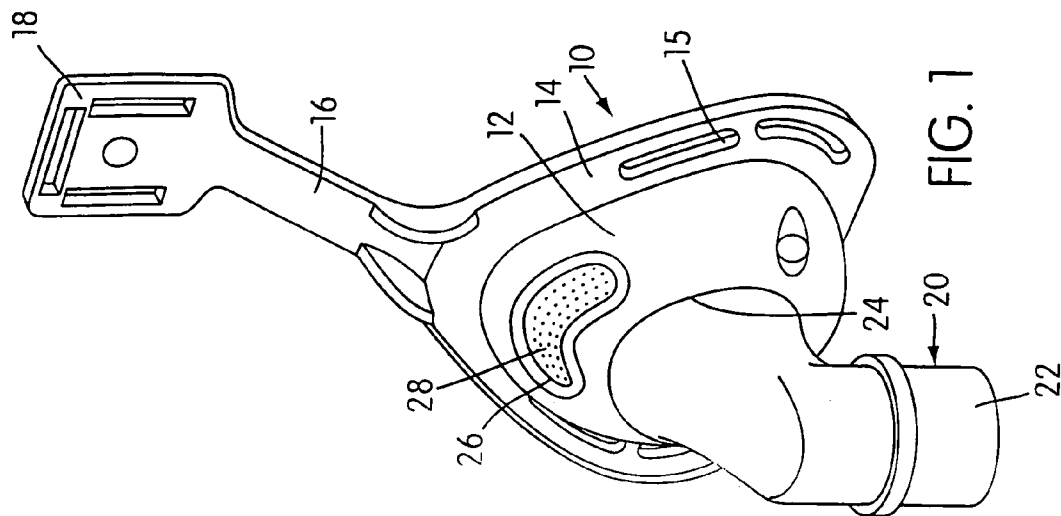
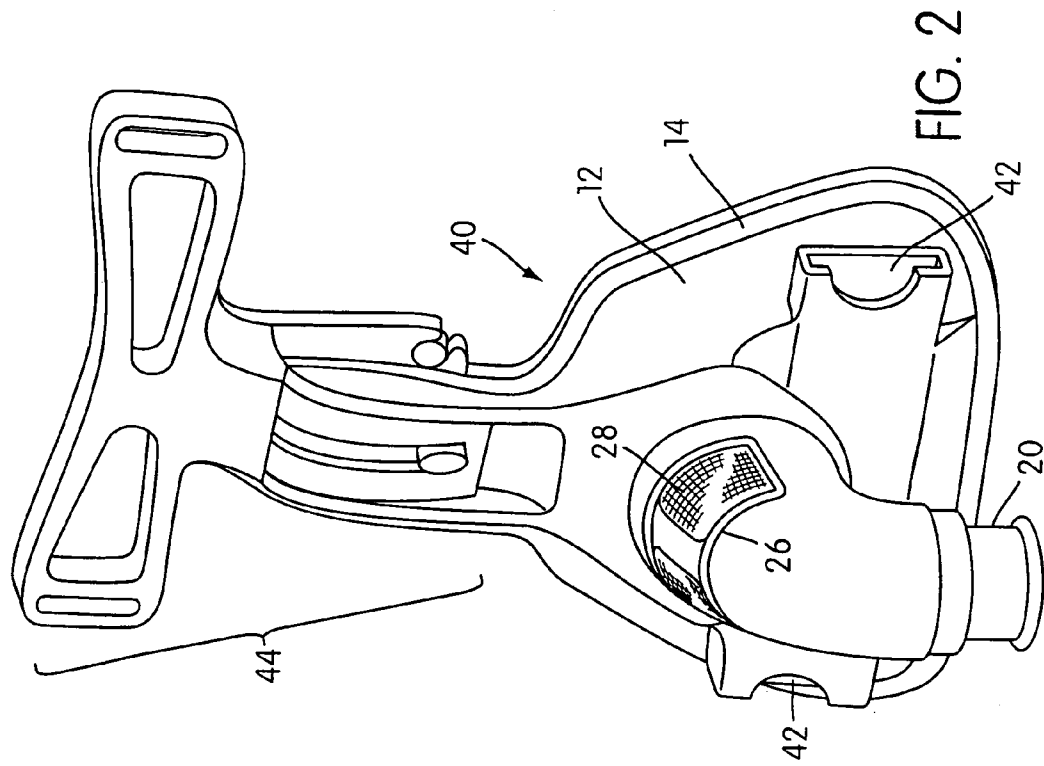
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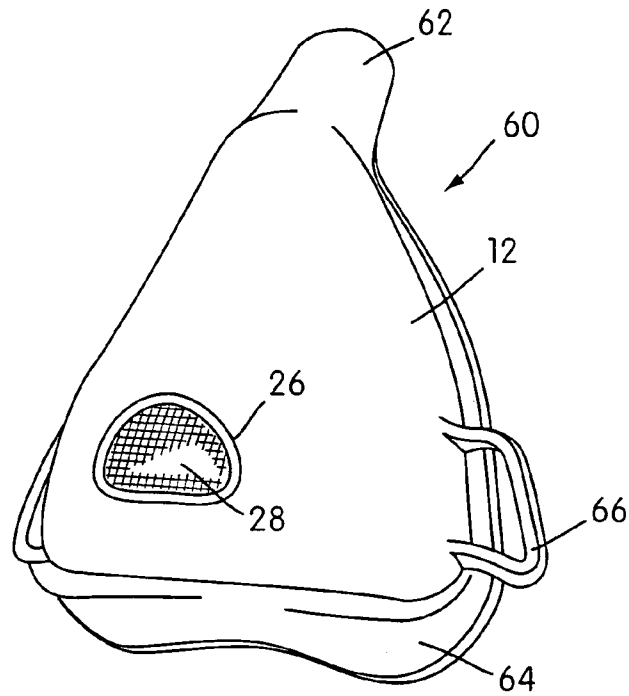


FIG. 3

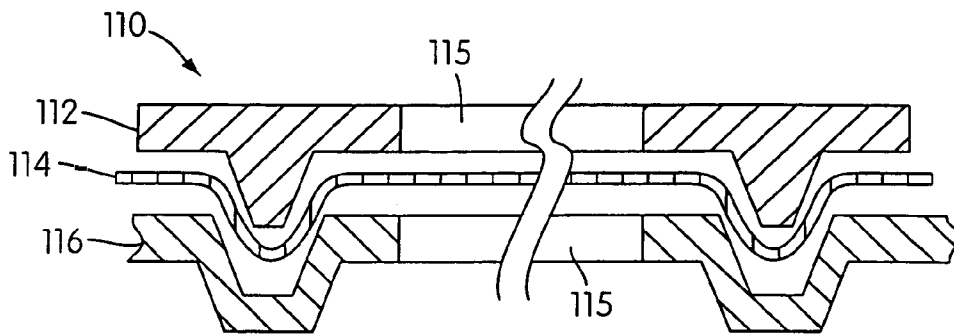


FIG. 4

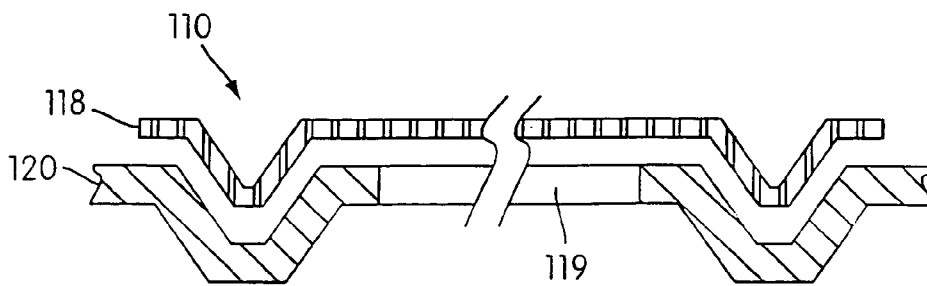
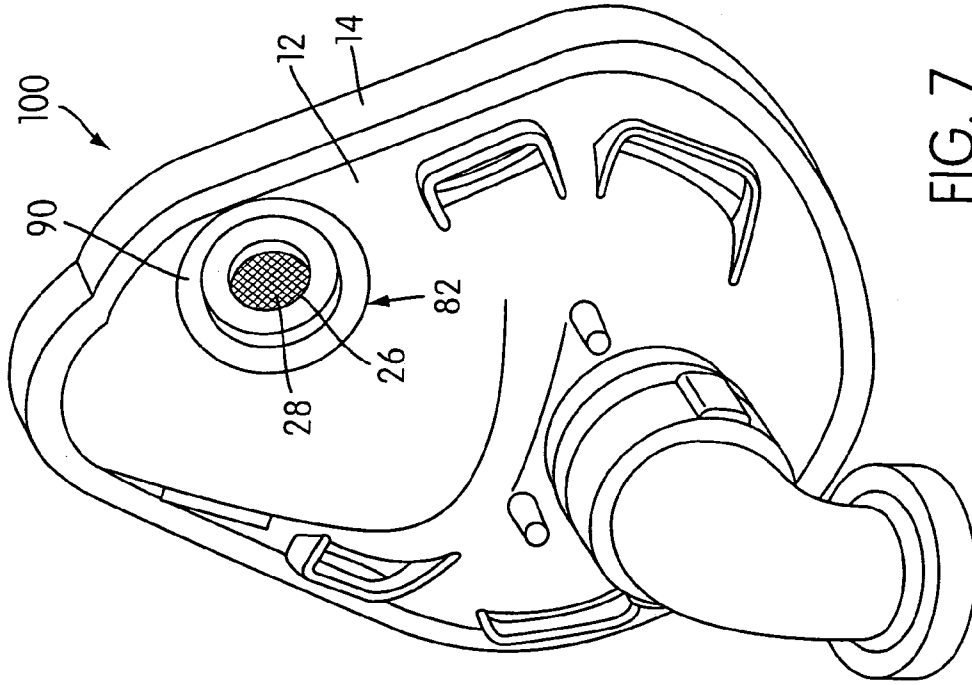
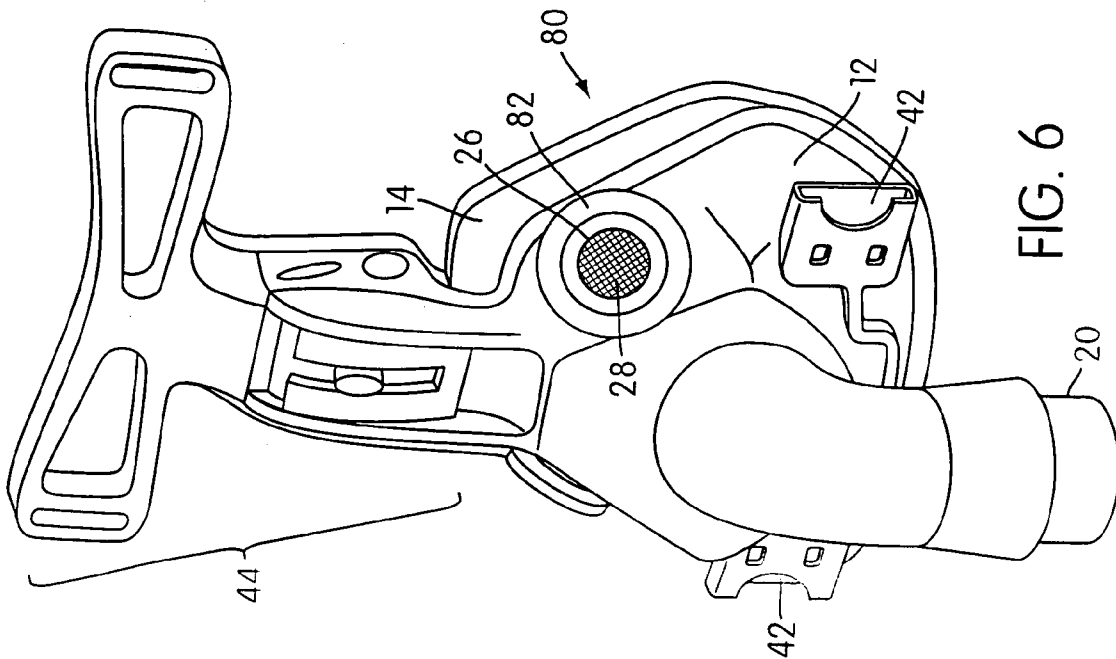
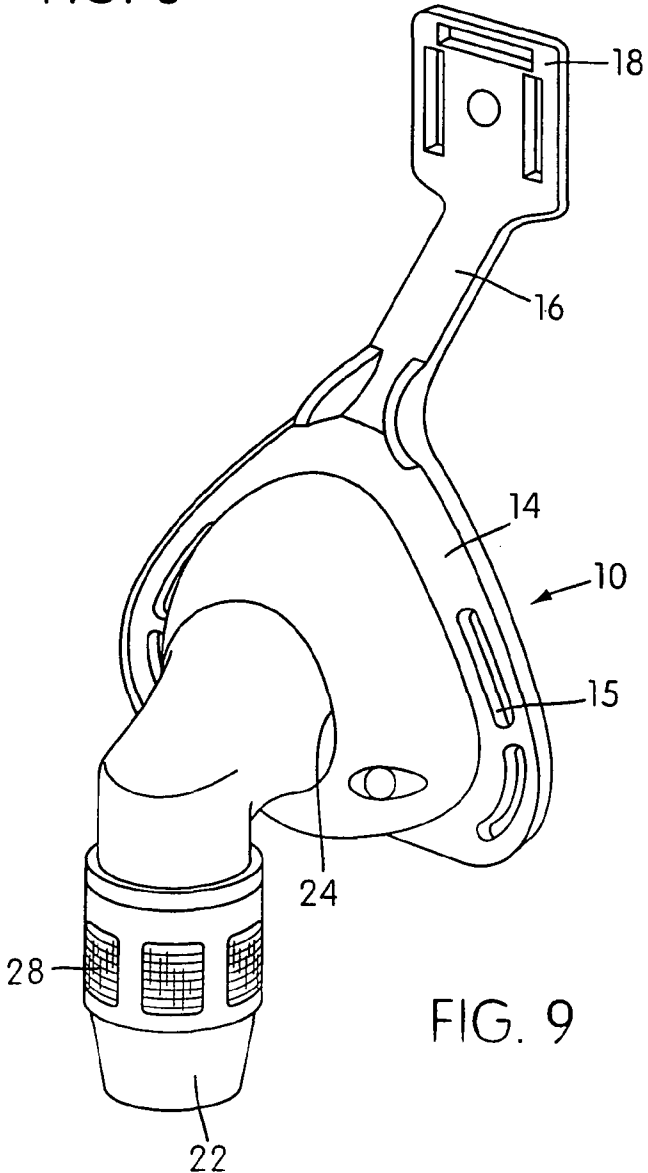
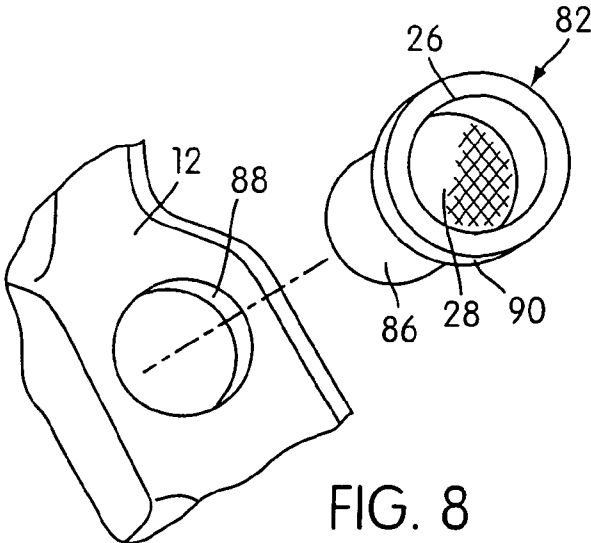


FIG. 5





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**RESPIRATORY MASK HAVING GAS
WASHOUT VENT AND GAS WASHOUT
VENT ASSEMBLY FOR RESPIRATORY
MASK**

CROSS REFERENCE TO RELATED
APPLICATIONS

This application is a continuation of U.S. application Ser. No. 10/377,110, filed Mar. 3, 2003, now U.S. Pat. No. 6,823,865, which is a continuation of U.S. application Ser. No. 09/570,907, filed May 15, 2000, now U.S. Pat. No. 6,581,594, each incorporated by reference in its entirety.

BACKGROUND OF INVENTION

1. Field of the Invention

The present invention relates to a respiratory mask and a vent for a respiratory mask.

2. General Background and Related Art

The application of Continuous Positive Airway Pressure (CPAP) via a nasal mask is a common ameliorative treatment for sleep disordered breathing (SDB) including obstructive sleep apnea (OSA) as described in commonly-assigned U.S. Pat. No. 4,944,310. In CPAP treatment for OSA, air or other breathable gas is supplied to the entrance of a patient's airways at a pressure elevated above atmospheric pressure, typically in the range 3–20 cm H₂O as measured in the patient interface. It is also known for the level of treatment pressure to vary during a period of treatment in accordance with patient need, that form of CPAP being known as automatically adjusting nasal CPAP treatment, as described in commonly-assigned U.S. Pat. No. 5,245,995.

Non-invasive positive pressure ventilation (NIPPV) is another form of treatment for breathing disorders including sleep disordered breathing. In a basic form, NIPPV involves a relatively high pressure of gas being provided in the patient interface during the inspiratory phase of respiration and a relatively low pressure or atmospheric pressure being provided in the patient interface during the expiratory phase of respiration. In other NIPPV modes the pressure can be made to vary in a complex manner throughout the respiratory cycle. For example, the pressure at the patient interface during inspiration or expiration can be varied through the period of treatment as disclosed in commonly-assigned International PCT Patent Application No. WO 98/12965 and International PCT Patent Application No. WO 99/61088.

In this specification any reference to CPAP treatment is to be understood as embracing all of the above-described forms of ventilatory treatment or assistance.

Typically, the patient interface for CPAP treatment consists of a nasal mask. The nasal mask is generally defined by a mask shell which forms an inner cavity defined by its interior surface, mask cushion and the user's face, a gas inlet which may or may not include a separate component such as a swivel elbow. Alternatively, a nose-mouth mask or full-face mask or nasal prongs or nasal pillows can be used. In this specification any reference to a mask is to be understood as incorporating a reference to a nasal mask, nose-mouth mask, full face mask, nasal prongs or nasal pillows unless otherwise specifically indicated. The mask incorporates, or has in close proximity, a gas washout vent for venting exhaled gases to atmosphere. The gas washout vent (the vent) is sometimes referred to as a CO₂ washout vent.

It is important that the apparatus is quiet and comfortable to encourage patient compliance with therapy. The exhaust-

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ing to atmosphere of exhaled gas through the vent creates noise. As CPAP and NIPPV treatments are normally administered while the patient is sleeping, minimization of such noise is desirable for both the comfort of the patient and any bed partner.

From a clinical perspective it is desirable for a mask and vent combination to maximize both the elimination of exhaled CO₂ through the vent and also the inhalation of the supplied breathable gas. In this way, retention of exhaled CO₂ within the mask, which is "re-breathed" by the wearer, is minimized. Generally by locating the vent in the mask shell CO₂ washout will be superior to locating the same vent between the mask shell and the breathable gas supply conduit. It is desirable to minimize the weight of the vent assembly for greater patient comfort.

Systems for the delivery of nasal CPAP treatment often incorporate in-line humidifiers to minimize drying of the nasal mucosa and increase patient comfort. Accordingly, it is also desirable that a vent not block when used with humidified gas. It is also desirable that a vent be easily cleaned or economically disposable.

A number of vent configurations are known. One approach to vent configuration is to create within the mask shell one or more openings that allow for the flow of exhaust gas from the inner cavity to atmosphere. The exhaust flow may be directed through the incorporation of an additional pipe extending out from the opening located on the mask shell outer surface.

The assignee's nasal mask system known by the name ResMed Modular Mask System incorporates an outlet vent located in the swivel elbow connected to the mask shell. The ports defining the vent have the same cross-sectional thickness and are formed from the same polycarbonate material that is used to form the swivel elbow and mask shell frame.

The whisper swivel, manufactured by Respirationics, Inc provides three slots on the circumference of a generally cylindrical attachment piece. In use, the attachment piece is to be interposed between the mask shell and the gas conduit. The attachment piece is made of the same material and thickness as is used to make the mask shell.

European Patent No. 0 697 225 discloses a vent formed from a porous sintered material.

A known vent, manufactured by Gottlieb Weinmann Gerate Fur Medizin Und Arbeitsschutz GmbH and Co. comprises a generally cylindrical insert to be interposed in use, between the mask shell and the gas conduit. The insert includes a window which is covered with a porous sintered material of approximately 3–4 mm thickness.

Another type of vent intended to be inserted between the mask shell and the breathable gas supply conduit is the E-Vent N by Draeger medizintechnik GmbH (the Draeger vent). The Draeger vent comprises a stack of 21 annular disks, which have slots in their adjacent surfaces for gas to flow therethrough. Each slot has a length of 5 to 7 mm as measured along the path from the interior of the vent to atmosphere.

The assignee produces a respiratory mask known as the MIRAGE® nasal mask system and the MIRAGE® full-face mask (the MIRAGE® mask). The MIRAGE® mask has a crescent shaped opening in the mask shell in which is located a complementary shaped crescent elastomeric insert with six holes therein which constitutes the vent. The elastomeric inset has a cross-sectional thickness of 3 to 4 mm. The vent of the type used in the MIRAGE® is described in International Patent Application No. WO 98/34665 and Australian Patent No 712236.

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It is an object of the present invention to provide an alternative form of vent that is suitable for use in a respiratory mask.

SUMMARY OF THE INVENTION

The present invention provides a vent assembly suitable for use with a mask used in CPAP treatment wherein the vent assembly is a thin air permeable membrane.

In one form of the invention, the membrane is thinner than the mask frame.

In another form of the invention, the membrane is thinner than 0.5 mm.

In another form of the invention the membrane has an approximate thickness of 0.05 mm.

In another form of the invention the membrane is constructed from a hydrophobic material such as polytetrafluoroethylene (PTFE).

In another form of the invention the membrane is constructed from expanded PTFE.

In another form of the invention the expanded PTFE membrane is mounted on a polypropylene scrim.

In another form, the pores of the membrane have a reference pore size of 10 to 15 microns.

In another form of the invention the membrane is constructed from stainless steel.

In another form of the invention the membrane of the vent has a superficial cross-sectional area of approximately 500 mm².

In another form of the invention the vent assembly comprises a membrane attached to a vent frame, the vent assembly forming an insert which can be removeably attached to a mask frame.

In another form of the invention there is provided a respiratory mask for communicating breathable gas to the entrance of a wearer's airways, the mask including (i) mask shell, (ii) a gas inlet and (iii) an opening into which an insert constructed from a thin air permeable membrane with a corresponding shape may be placed. The opening may be positioned in the mask shell or in the gas inlet.

In one form, the mask includes a mask shell with an integrally formed gas inlet and the opening is provided in the mask shell remote the inlet. In another form, the mask includes a mask shell with an integrally formed gas inlet and the opening is provided in the gas inlet. In yet another form, the mask includes a mask shell with a separately formed gas inlet attached thereto and the opening is provided in the mask shell remote the inlet. In still yet another form, the mask includes a mask shell with a separately formed gas inlet attached thereto and the opening is provided in the gas inlet.

The present invention also provides a respiratory mask arrangement for communicating breathable gas to the entrance of a wearer's airways, the mask arrangement including a vent assembly comprising an opening with a thin air permeable membrane extending across an opening.

The present invention also provides an apparatus for delivering CPAP which apparatus includes a mask arrangement for communicating breathable gas to the entrance of a wearer's airways, the mask arrangement including a gas washout vent assembly comprising an opening with a thin air permeable membrane extending across said opening.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is a perspective view of a respiratory mask according to a first embodiment of the invention;

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FIG. 2 is a perspective view of a respiratory mask according to a second embodiment of the invention;

FIG. 3 is a perspective view of a respiratory mask according to a third embodiment of the invention;

FIG. 4 is a partial cross-sectional view of a vent assembly according to a fourth embodiment of the invention;

FIG. 5 is a partial cross-sectional view of a vent assembly according to a fifth embodiment the invention;

FIG. 6 is a perspective view of a respiratory mask according to sixth embodiment of the invention;

FIG. 7 is a perspective view of a full-face mask according to a seventh embodiment of the invention;

FIG. 8 is an enlarged detailed view of an insert suitable for use with the masks shown in FIG. 6 and FIG. 7; and

FIG. 9 is a perspective view of a vent assembly according to an eighth embodiment of the invention where the thin air permeable membrane is located in a cylindrical position on a tube suitable for attachment to the mask elbow.

DETAILED DESCRIPTION

FIG. 1 shows a nasal respiratory mask 10 according to a first embodiment of the invention. The mask 10 includes a rigid plastic mask shell 12, which has a peripheral flange 14 for mounting of a cushion (not shown) to the shell 12. The cushion abuts the wearer's face in use and is well known in the art. The flange 14 includes slots 15 for the connection of mask restraining straps (not shown) that extend around the head of the wearer to maintain the mask 10 adjacent to the wearer's face. The straps are also known in the art. The shell 12 also includes an arm 16, which terminates in a fitting 18 that is adapted to connect to a forehead support (not shown), which is also known in the art.

The mask shell 12 includes a breathable gas inlet 20 which is rotatably mounted to the shell 12. The inlet 20 has a first end 22 which is adapted for connection with a breathable gas supply conduit (not shown) and a second end 24 which is adapted to connect to, and communicate the supplied gas to the interior of the shell 12 for subsequent communication with the wearer's airways.

The mask 10 includes a gas washout vent constituted by an opening 26 in the shell 12 across which extends a thin air permeable membrane 28.

In the FIG. 1 embodiment, the thin air permeable membrane 28 is a stainless steel sheet approximately 0.45 mm thick having holes with a diameter approximately 0.1 mm in diameter. The total open area is approximately 5% of the total superficial surface area of the sheet. The dimensions of the sheet are approximately 322 mm². The holes are laser cut into the stainless steel. The holes are desirably laser cut or flame cut through the stainless steel.

Preferably the holes have a diameter of less than 0.2 mm, and preferably provide a total open area of approximately 1% to 25% of the superficial surface area of the steel. The holes may be tapered (in a gradual or stepped manner) through their internal bore. In use, if the smaller end of the vent's openings are located on the atmosphere side the opportunity for blockage occurring by the insertion of particulate matter will be minimized. Alternatively, the larger end of the vent's openings may be located on the atmosphere side which may make the vent quieter.

FIG. 2 shows a nasal respiratory mask 40 according to a second embodiment of the invention. Like reference numerals to those used in describing the first embodiment will be used to denote like features in respect of the second embodiment. Accordingly, the mask 40 has a shell 12 with a gas inlet 20. Instead of the slots 15 of the first embodiment the

mask shell includes openings 42 which are adapted to snap engage with connection fittings (not shown) provided on the end of mask restraining straps (not shown). Further, instead of the arm 16 and fitting 18, the mask 40 includes an adjustable forehead support mechanism indicated generally by the reference numeral 44.

The mask 40 also includes a vent constituted by an opening 26 formed in the gas inlet 20 across which extends a thin air permeable membrane 28.

FIG. 3 shows a mask 60 according to a third embodiment of the present invention. Although this particular embodiment is directed to a nasal mask, it should be noted that various vent arrangements can be used with various mask arrangements. Once again like reference numerals to those used in describing features of the first embodiment shall be used to denote like features in respect of the third embodiment. The mask 60 includes a mask shell 12 with an integrally formed fixed gas inlet 62. A cushion 64 is attached to the peripheral flange 14 of the shell 12. The shell 12 also includes slotted extensions 66 for connecting headgear (not shown) to the mask. The mask 60 includes an opening 26 across which is extended a thin air permeable membrane 28 of identical construction to the ePTFE membrane discussed below in relation to the mask 40 shown in FIG. 6.

FIG. 4 shows a cross-section of vent assembly 110. There is provided a membrane 114 interposed between an outer element 112 and an inner element 116. This arrangement provides for a simple assembly. There is a corresponding opening 115 in the outer element 112 and inner element 116 to allow for the passage of air through the membrane. The inner element 116 may form part of the mask frame or of a separate insert to be positioned in an opening in the mask frame.

FIG. 5 shows an alternative cross-section of a vent assembly 110. There is provided a stainless steel membrane insert 118 positioned over the inner element 120. There is an opening 119 in the inner element 120 to allow for the passage of air through the membrane. The inner element 119 may form part of the mask frame or of a separate insert to be positioned in an opening in the mask frame.

FIG. 6 shows a nasal respiratory mask 80 according to a sixth embodiment of the invention. The mask 80 is similar to the second embodiment of the mask 40 shown in FIG. 2 and like reference numerals have been used to indicate like features with respect to the second embodiment. In the mask 40 of FIG. 2, the vent is provided in the gas inlet 20, whereas in the mask 80 the vent is provided in the shell 12. More particularly, the mask 80 includes two cylindrical inserts 82 which have an inner opening 26 across which extends the thin air permeable material 28. The thin air permeable material is made from GORE-TEX® product attached to a polypropylene scrim having an area of 481 mm². The membrane is constructed from expanded polytetrafluoroethylene (ePTFE). The inventors have identified GORE-TEX® ePTFE product manufactured by W. L. Gore & Associates, Inc. of Maryland USA (GORE-TEX® membrane) as being a suitable material for constructing a membrane. In one preferred form, the GORE-TEX® membrane has the following characteristics:

Membrane material	100% expanded polytetrafluoroethylene
Reference pore size	10–15 micron
Bubble Point	typical minimum individual 0.02 bar
Airflow	0.37 LPM/cm ²

-continued

Thickness	0.05 mm
Substrate	polypropylene scrim

FIG. 7 shows a seventh embodiment of a full-face respiratory mask 100 according to the invention. Once again like reference numerals to those used in denoting like features with previous embodiments have been used to denote like features in respect of this embodiment. The mask 100 is similar to the mask 80 shown in FIG. 6 in that the vent is provided in the inserts 82. However the mask 100 uses slotted extensions 66 to attach mask restraining straps (not shown), not openings 42.

As best seen in FIG. 8, which is a close-up view of the insert shown in FIG. 6, the insert 82 is comprises a cylindrical portion 86 sized to be a snug fit into a circular orifice 88 provided in the mask shell 12. The insert 82 located against the outer surface of the shell 12 by a peripheral flange 90. The inserts may be glued in position.

FIG. 9 shows a further embodiment of the invention in which an in-line vent assembly is provided. Like numerals are used to indicate like features with previous embodiments. In this embodiment, the in-line vent assembly comprises a generally cylindrical shaped vent frame with “windows” or “ports” covered with a membrane as described above.

The thin air permeable membrane of the present invention may be attached to the mask by any suitable means. For examples the stainless steel vent described above may be attached to a polycarbonate mask shell by way of hot glue adhesive (for example) or any other suitable adhesive. The durability sought to be achieved will determine the suitable approach for attachment.

In a further embodiment there is provided a means to indicate the volume of air that has passed through the vent, or alternatively the time that the vent assembly has been used. When a sufficient volume of air has passed through the vent assembly, or the assembly has been used for a sufficient time and may have become blocked, the indicator will signal that the vent assembly should be replaced.

For convenience, the thin air permeable membrane can be provided in an insert which is releasably attachable to the mask shell via a push-fit mechanism, as shown in FIG. 8. Preferably on at least the outer surface of the insert there is provided at least one cross-piece that protects the air permeable membrane from being damaged as it is located into the receiving orifice of the mask shell. This approach will allow for the easy placement, removal and replacement of a vent insert while retaining the other components of the mask. While the insert may be configured to take the form of any requisite shape preferably the insert has a circular circumferential shape defining a cylindrical insert which has a frictional fit within a corresponding circular orifice in the mask shell or gas inlet.

Formation of the vent through use of an insert configuration facilitates the selection and fitting of a vent to suit a user’s requirements. For example where a low treatment pressure is required the associated flow will also be relatively small compared with flow required to achieve a higher treatment pressure. In such circumstances a relatively large vent area may be adopted to facilitate achievement of the clinically desirable mask CO₂ washout rate. Should a higher treatment pressure be required then the previously selected vent may be exchanged for a vent being more restrictive to flow. The more restrictive vent will allow achievement of the

clinically desirable mask CO₂ washout rate while avoiding the intensity of noise and exhaust gas jetting that would occur had the previously selected low pressure vent been used with the higher treatment pressure.

Locating the vent in the mask shell results in an improvement in the minimization of CO₂ retention within the mask compared to locating the vent as an inline mask component.

Although the invention has been described with reference to specific examples, it is to be understood that these examples are merely illustrative of the application of the principles of the invention. Thus it is to be understood that numerous modifications may be made in the illustrative examples of the invention and other arrangements may be devised without departing from the spirit and scope of the invention.

We claim:

1. A respiratory mask comprising:
 - a patient interface structured for communication with a patient's airways in use;
 - a gas inlet to supply pressurized breathable gas in the range of 3–20 cm H₂O to the patient interface; and
 - a gas washout vent portion having a plurality of holes therein, said holes having a diameter selected to allow adequate CO₂ washout at a lowest end of the pressure range, a total open area of a superficial surface area of the vent portion being about 5%, wherein the patient interface includes a mask frame and a cushion provided to the mask frame, the holes in the vent portion have a length of about 0.45 mm.
2. A respiratory mask according to claim 1, wherein a diameter of each of the holes is less than about 0.2 mm.
3. A respiratory mask according to claim 2, wherein the diameter is about 0.1 mm.
4. A respiratory mask according to claim 2, wherein the holes are tapered.
5. A respiratory mask according to claim 2, wherein the total area of the vent portion is about 322 mm².
6. A respiratory mask according to claim 2, wherein the holes are laser cut.
7. A respiratory mask according to claim 1, wherein the vent area is provided to the gas inlet.
8. A respiratory mask according to claim 7, wherein the gas inlet is formed on a swivel elbow.
9. A respiratory mask according to claim 7, wherein the gas inlet includes an in-line vent provided with the vent portion.
10. A respiratory mask according to claim 1, wherein the patient interface includes a nose mask, a nose-mouth mask, a full-face mask, nasal prongs or nasal pillows.
11. A respiratory mask comprising:
 - a patient interface;
 - a breathable gas inlet to provide pressurized gas to the patient interface when the mask is in use; and
 - a gas washout vent including an air permeable portion to allow gas to exit from the patient interface, wherein the portion has a surface area, a thickness, and a plurality of holes each having a length, a diameter, and a total open area due to the presence of the holes that are selected to help eliminate or reduce noise while maintaining sufficient CO₂ washout during patient breathing, wherein the thickness of the portion is less than 3 mm and the total open area is about 5% or greater.
12. The respiratory mask according to claim 11, wherein the thickness is about 0.5 mm or less.
13. The respiratory mask according to claim 11, wherein the total open area is 20% or greater.

14. A respiratory mask according to claim 11, wherein a diameter of each of the holes is about 0.2 mm or less.

15. A respiratory mask comprising:

- a patient interface;
- a breathable gas inlet to provide pressurized gas to a breathing cavity formed at least in part by the patient interface when the mask is in use; and
- a gas washout vent portion having a plurality of holes extending therethrough, each said hole having a diameter selected to allow gas to quietly exit from the breathing cavity, wherein:
 - the vent portion has a thickness of less than about 3 mm, and
 - the vent portion is made of a hydrophobic material.

16. A respiratory mask according to claim 15, wherein the diameter is about 0.2 mm or less.

17. A respiratory mask comprising:

- a patient interface structured for communication with a patient's airways in use, the patient interface including a mask frame and a nasal cushion provided to the mask frame;
- a gas inlet to supply pressurized breathable gas in the range of 3–20 cm H₂O to the patient interface; and
- a gas washout vent portion provided to the mask frame and having a plurality of holes therein, said holes having a diameter selected to allow adequate CO₂ washout at a lowest end of the pressure range, wherein said plurality of holes is arranged in a plurality of rows, each said row having at least 3 of said holes, and wherein each of the holes has a first end positioned on an inside surface of the mask, a second end positioned on an outer surface of the mask, and a tapered portion between the first and second ends, and wherein the first end has a diameter that is smaller than a diameter of the second end.

18. A respiratory mask according to claim 17, wherein plurality of rows includes at least 3 rows.

19. A respiratory mask according to claim 17, wherein the plurality of rows includes at least 2 rows each having at least 5 of said holes.

20. A respiratory mask according to claim 17, wherein the plurality of holes includes at least 10 holes.

21. A respiratory mask according to claim 20, wherein the plurality of holes includes at least 20 holes.

22. A respiratory mask according to claim 21, wherein the plurality of holes includes at least 30 holes.

23. A respiratory mask according to claim 21, wherein said vent portion includes at least two discrete portions.

24. A respiratory mask according to claim 17, wherein the vent portion is structured such that a total open area of a superficial surface area of the vent portion is about 5–25% or larger.

25. A respiratory mask according to claim 24, wherein the open area is about 5%–15%.

26. A respiratory mask according to claim 17, wherein the open area is greater than 1%.

27. A respiratory mask according to claim 17, wherein each said hole has a length of about 0.5 mm.

28. A respiratory mask comprising:

- a patient interface structured for communication with a patient's airways in use, the patient interface, including a mask frame and a nasal cushion provided to the mask frame;
- a gas inlet to supply pressurized breathable gas in the range of 3–20 cm H₂O to the patient interface; and
- a gas washout vent portion provided to the mask frame and having a plurality of holes therein, said holes

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having a diameter selected to allow adequate CO₂ washout at a lowest end of the pressure range, wherein said plurality of holes is arranged in a plurality of rows, each said row having at least 3 of said holes, and wherein each of the holes has a first end positioned on an inside surface of the mask, a second end positioned on an outer surface of the mask, and a tapered portion between the first and second ends, and wherein the first end has a diameter that is larger than a diameter of the second end.

29. A respiratory mask comprising:
a patient interface including a frame portion and a nasal mask;
a breathable gas inlet to provide pressurized gas to the patient interface when the mask is in use; and
a gas washout vent including an air permeable portion to allow gas to exit from the patient interface, wherein the portion has a surface area, a thickness, and a plurality of holes each having a length, a diameter, and a total open area due to the presence of the holes that are selected to help eliminate or reduce noise while maintaining sufficient CO₂ washout during patient breathing, wherein the plurality of holes includes at least 10 holes that extend through the frame portion, and wherein each of the holes has a first end positioned on an inside surface of the mask, a second end positioned on an outer surface of the mask, and a tapered portion between the first and second ends, and wherein the first end has a diameter that is smaller than a diameter of the second end.

30. A respiratory mask according to claim 29, wherein the total open area is about 5% or more.

31. The respiratory mask according to claim 30, wherein the total open area is less than 25%.

32. A respiratory mask according to claim 29, wherein each said hole has a length of about 0.5 mm.

33. A respiratory mask comprising:
a patient interface including a frame portion and a nasal mask;
a breathable gas inlet to provide pressurized gas to the patient interface when the mask is in use; and
a gas washout vent including an air permeable portion to allow gas to exit from the patient interface, wherein the portion has a surface area, a thickness, and a plurality of holes each having a length, a diameter, and a total open area due to the presence of the holes that are selected to help eliminate or reduce noise while maintaining sufficient CO₂ washout during patient breath-

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ing, wherein the plurality of holes includes at least 10 holes that extend through the frame portion, and wherein each of the holes has a first end positioned on an inside surface of the mask, a second end positioned on an outer surface of the mask, and a tapered portion between the first and second ends, and wherein the first end has a diameter that is larger than a diameter of the second end.

34. A respiratory mask comprising:
a patient interface having a frame portion and a nasal cushion;
a breathable gas inlet to provide pressurized gas to a breathing cavity formed at least in part by the patient interface when the mask is in use; and
a gas washout vent portion provided on the frame and having a plurality of holes extending through the frame portion, said holes having a diameter and shape selected to allow gas to quietly exit from the breathing cavity, wherein:
the vent portion has a thickness of less than about 3 mm, and
the vent portion includes at least 20 of said holes, said holes being arranged in a plurality of rows.

35. A respiratory mask according to claim 34, wherein the plurality of rows includes at least 4 rows each including at least 3 of said holes.

36. A respiratory mask according to claim 35, wherein the plurality of rows includes at least 6 rows each including at least 3 of said holes.

37. A respiratory mask according to claim 36, wherein the plurality of rows includes at least 8 rows each including at least 3 of said holes.

38. A respiratory mask according to claim 34, wherein each of the holes has a first end positioned on an inside the mask and a second end positioned on an outer surface of the mask, and wherein the first end has a diameter that is larger than a diameter of the second end.

39. A respiratory mask according to claim 34, wherein each of the holes has a first end positioned on an inside surface of the mask, a second end positioned on an outer surface of the mask, and a tapered portion between the first and second ends, and wherein the first end has a diameter that is smaller than a diameter of the second end.

40. A respiratory mask according to claim 34, wherein each said hole has a length of about 0.5 mm.

* * * * *

EXHIBIT B



US007487772B2

(12) **United States Patent**
Ging et al.

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(45) **Date of Patent:** ***Feb. 10, 2009**

(54) **ERGONOMIC AND ADJUSTABLE
RESPIRATORY MASK ASSEMBLY WITH
ELBOW ASSEMBLY**

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(*) Notice: Subject to any disclaimer, the term of this
patent is extended or adjusted under 35
U.S.C. 154(b) by 1036 days.

This patent is subject to a terminal dis-
claimer.

(21) Appl. No.: **10/390,720**

(22) Filed: **Mar. 19, 2003**

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Related U.S. Application Data

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12, 2002, provisional application No. 60/397,195,
filed on Jul. 22, 2002, provisional application No.
60/377,254, filed on May 3, 2002.

(30) **Foreign Application Priority Data**

Apr. 23, 2002 (AU) PS1926

(51) **Int. Cl.**
A61M 16/00 (2006.01)

(52) **U.S. Cl.** **128/202.27**; 128/204.18;
128/205.25

(58) **Field of Classification Search** 128/202.27,
128/203.29, 204.11, 204.12, 204.18, 205.25,
128/205.27, 206.12, 206.13, 206.14

See application file for complete search history.

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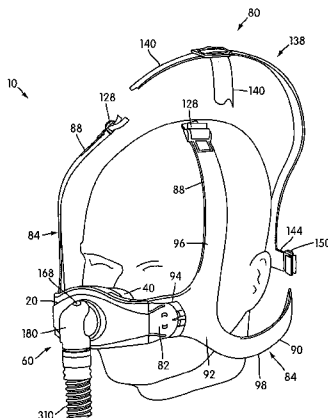
Primary Examiner—Steven O Douglas

(74) *Attorney, Agent, or Firm*—Nixon & Vanderhye P.C.

(57) **ABSTRACT**

A respiratory mask assembly for delivering breathable gas to
a patient includes a frame having a front surface and a rear
surface adapted in use to face the patient. The frame includes
a main body providing an aperture therethrough for the intro-
duction of breathable gas into a nasal breathing cavity. An
elbow assembly is swivelably coupled to the front surface of
the frame. The elbow assembly includes a swivel elbow that
defines an intake port and an exhaust port separated from the
intake port using a baffle. The elbow assembly includes an
end portion that interfaces with the aperture of the frame.

37 Claims, 56 Drawing Sheets



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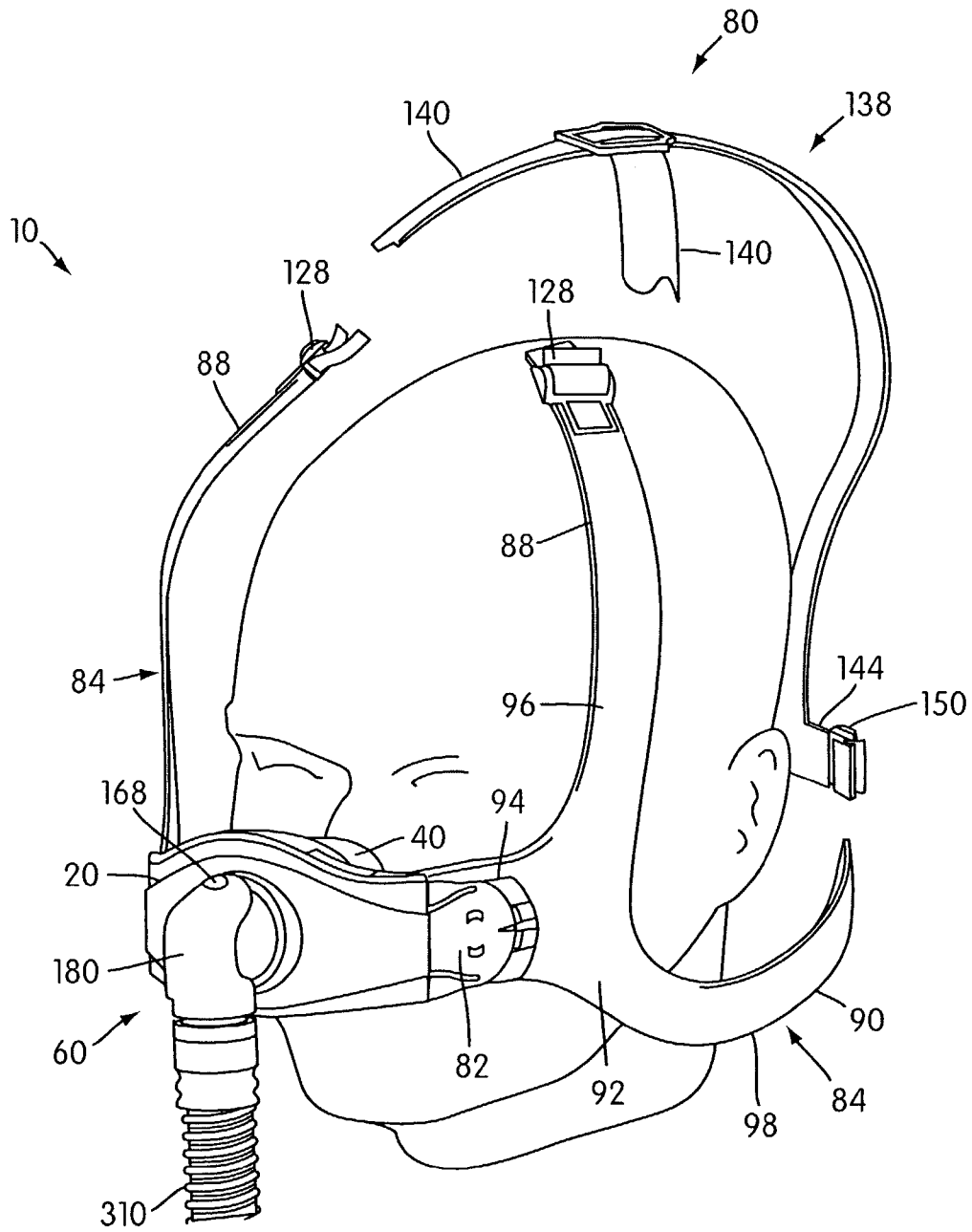


FIG. 1

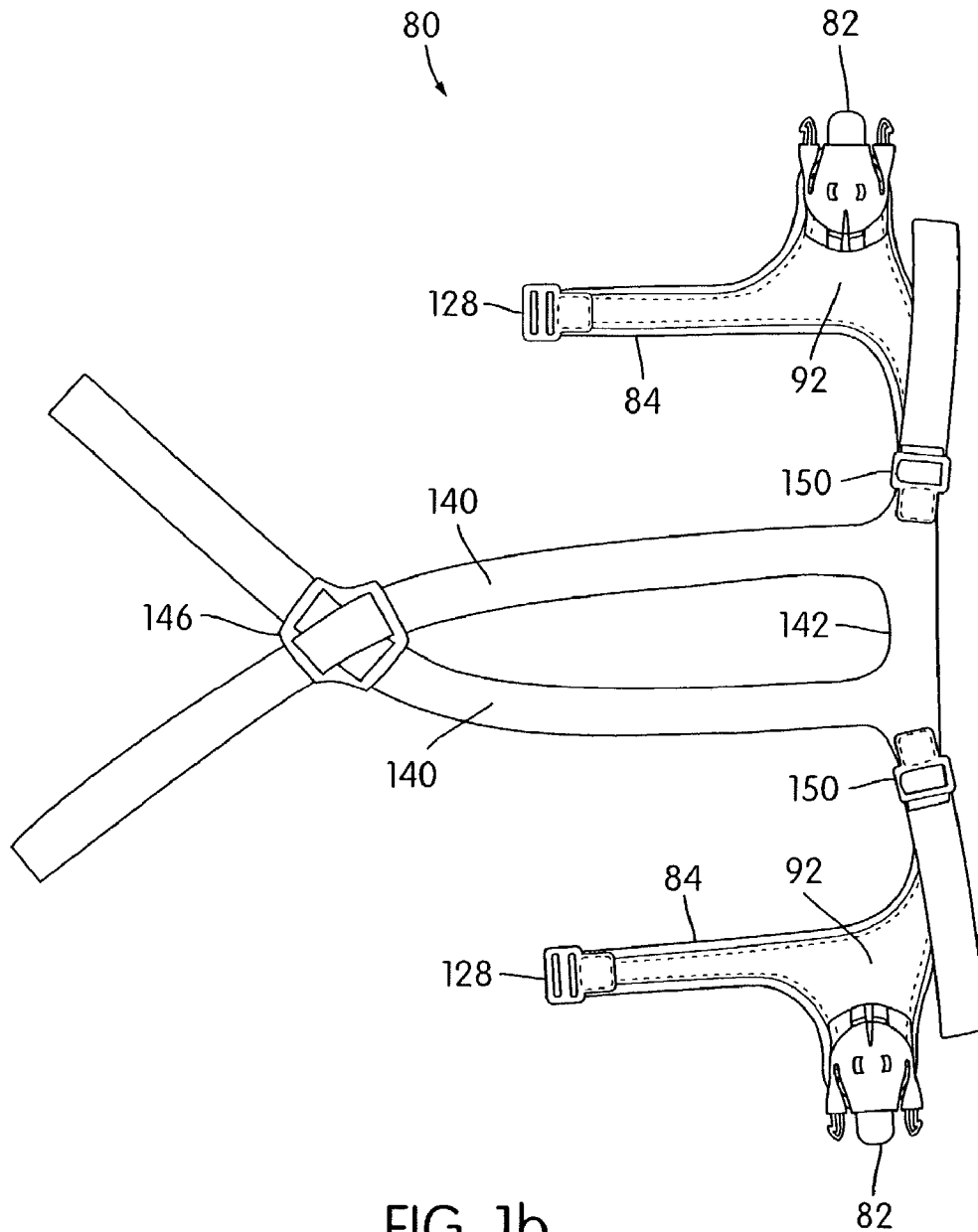


FIG. 1b

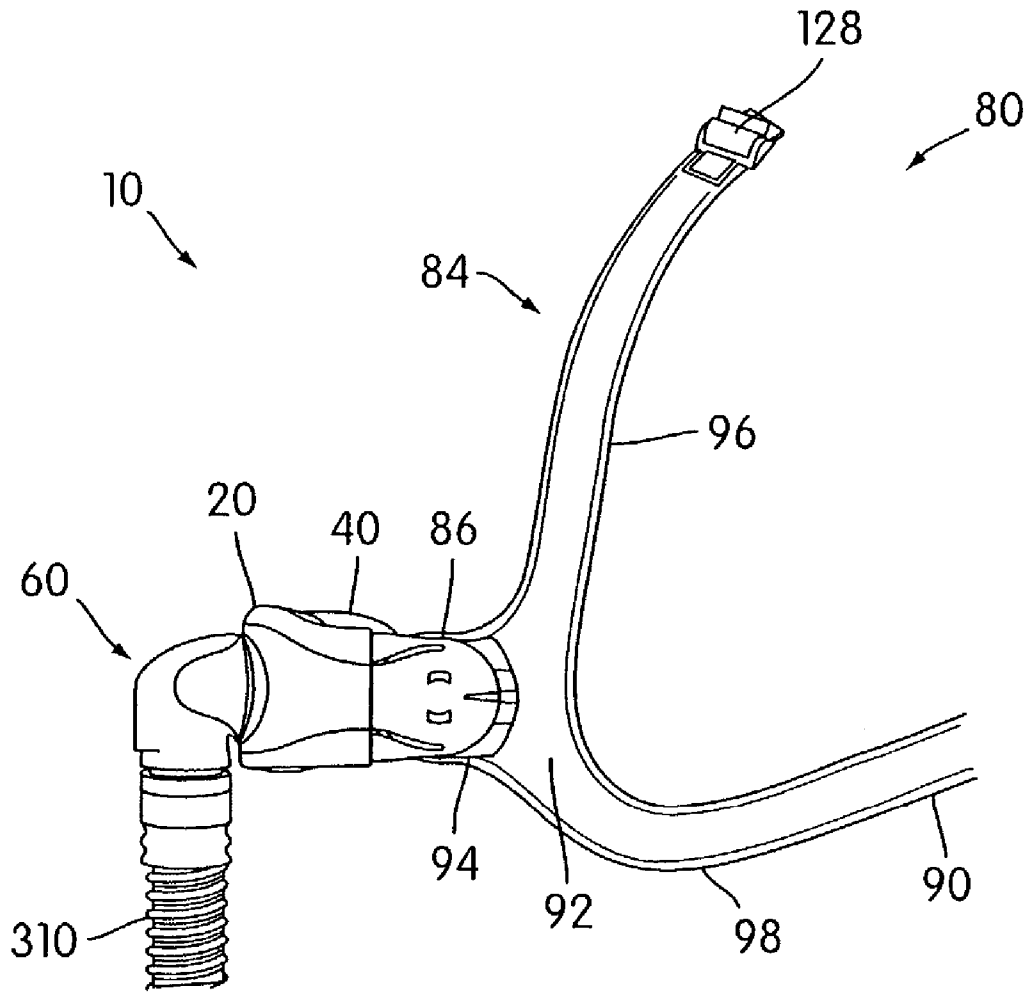


FIG. 2

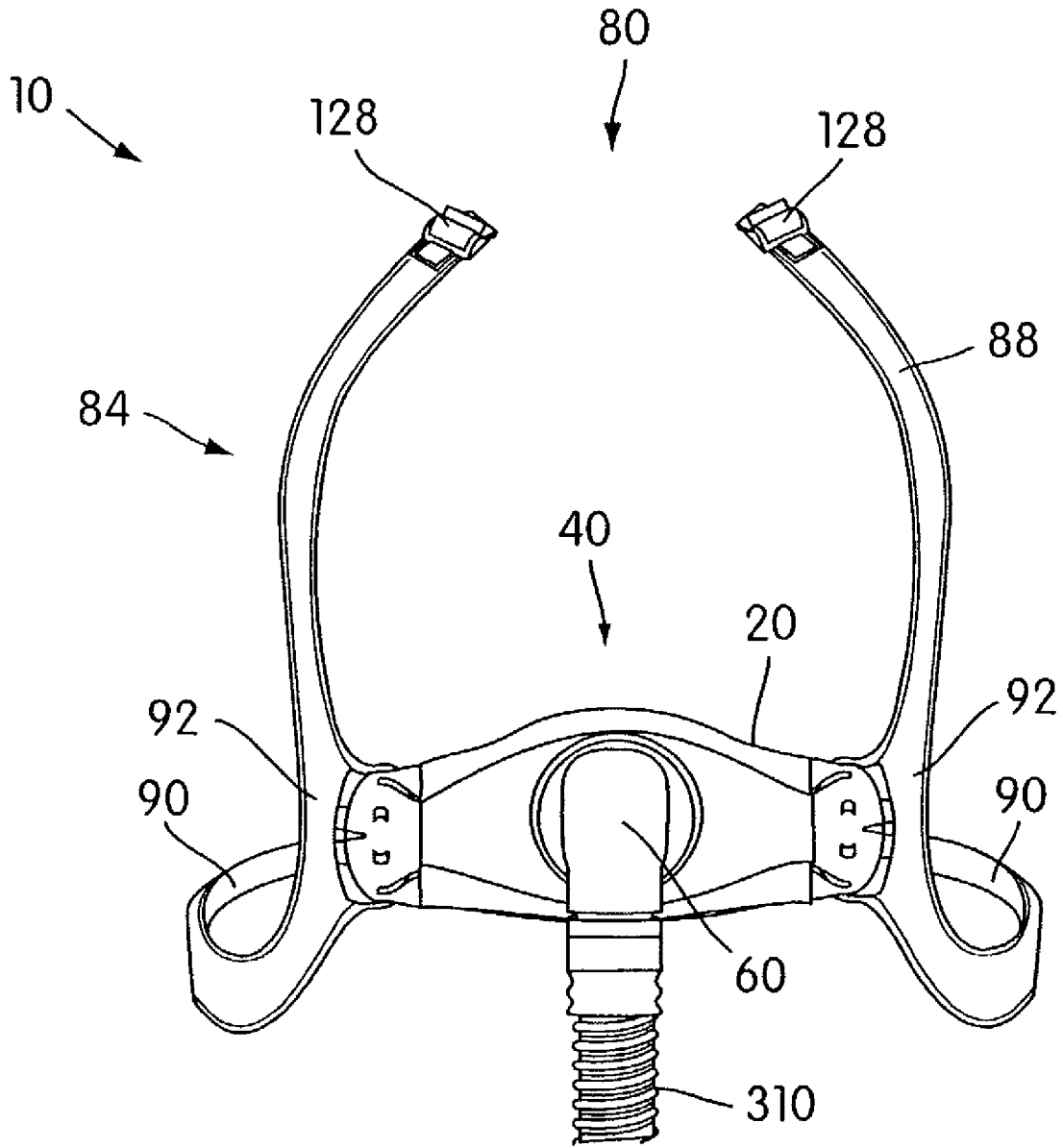


FIG. 3

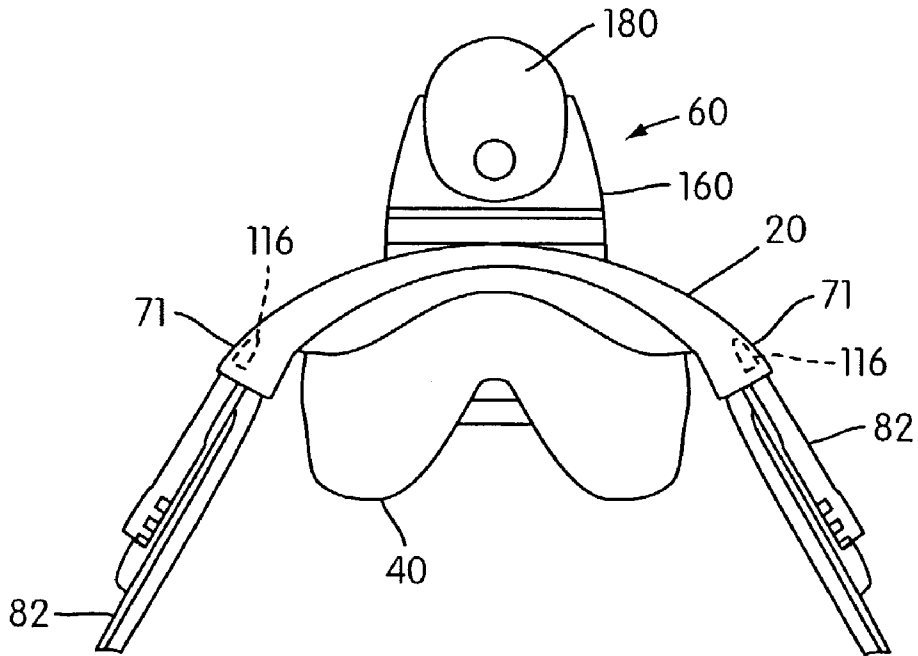


FIG. 4

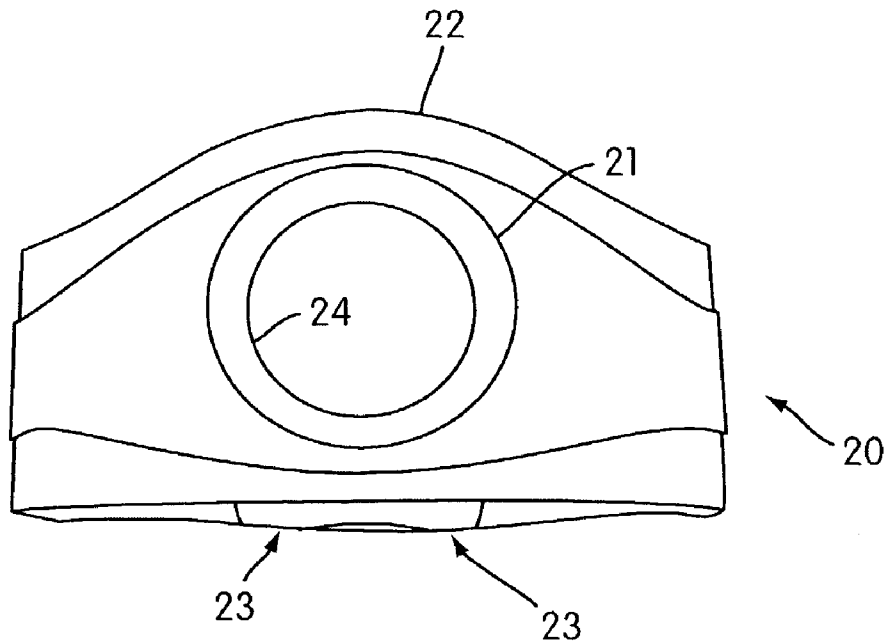


FIG. 5

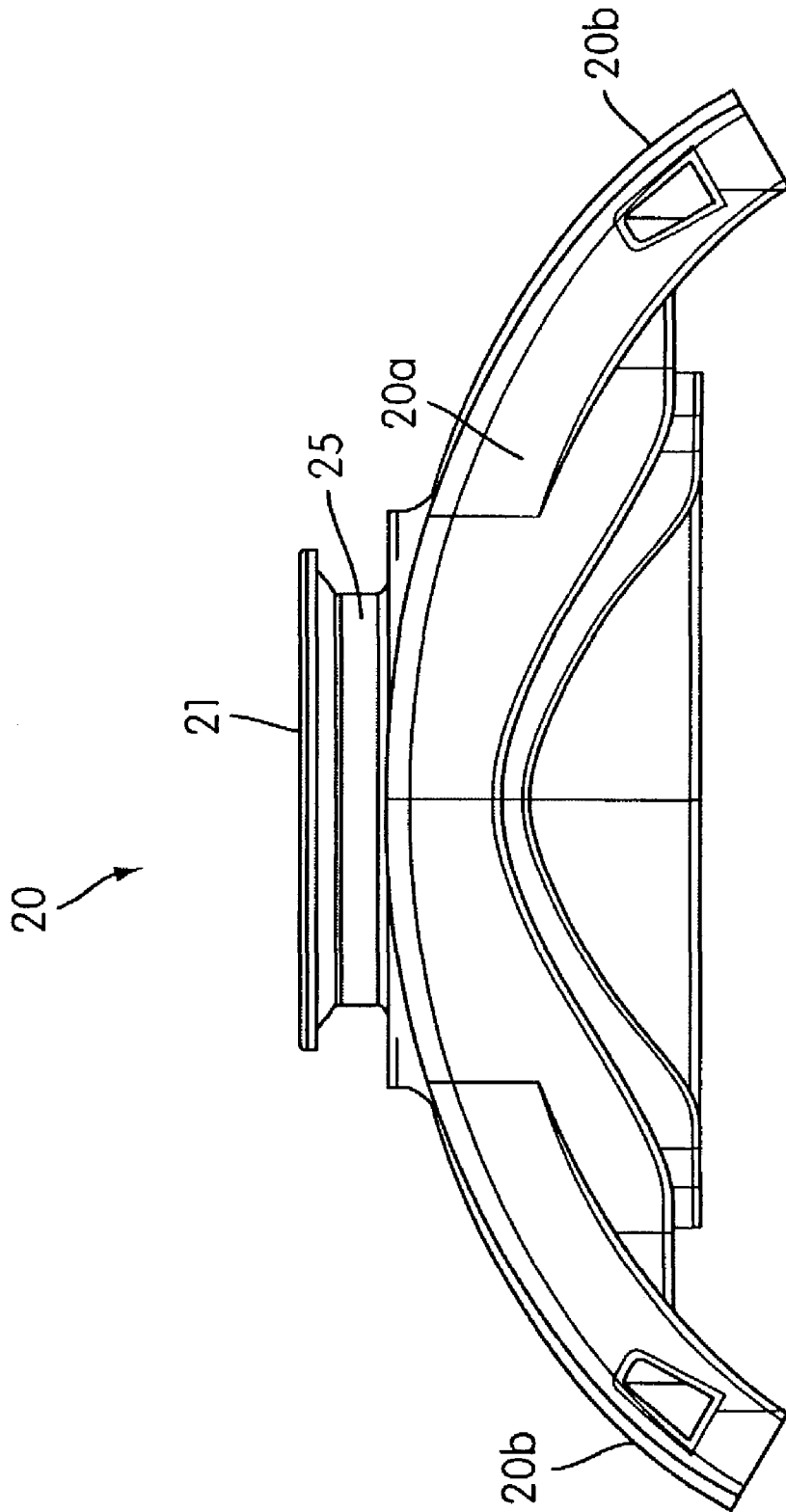


FIG. 5a

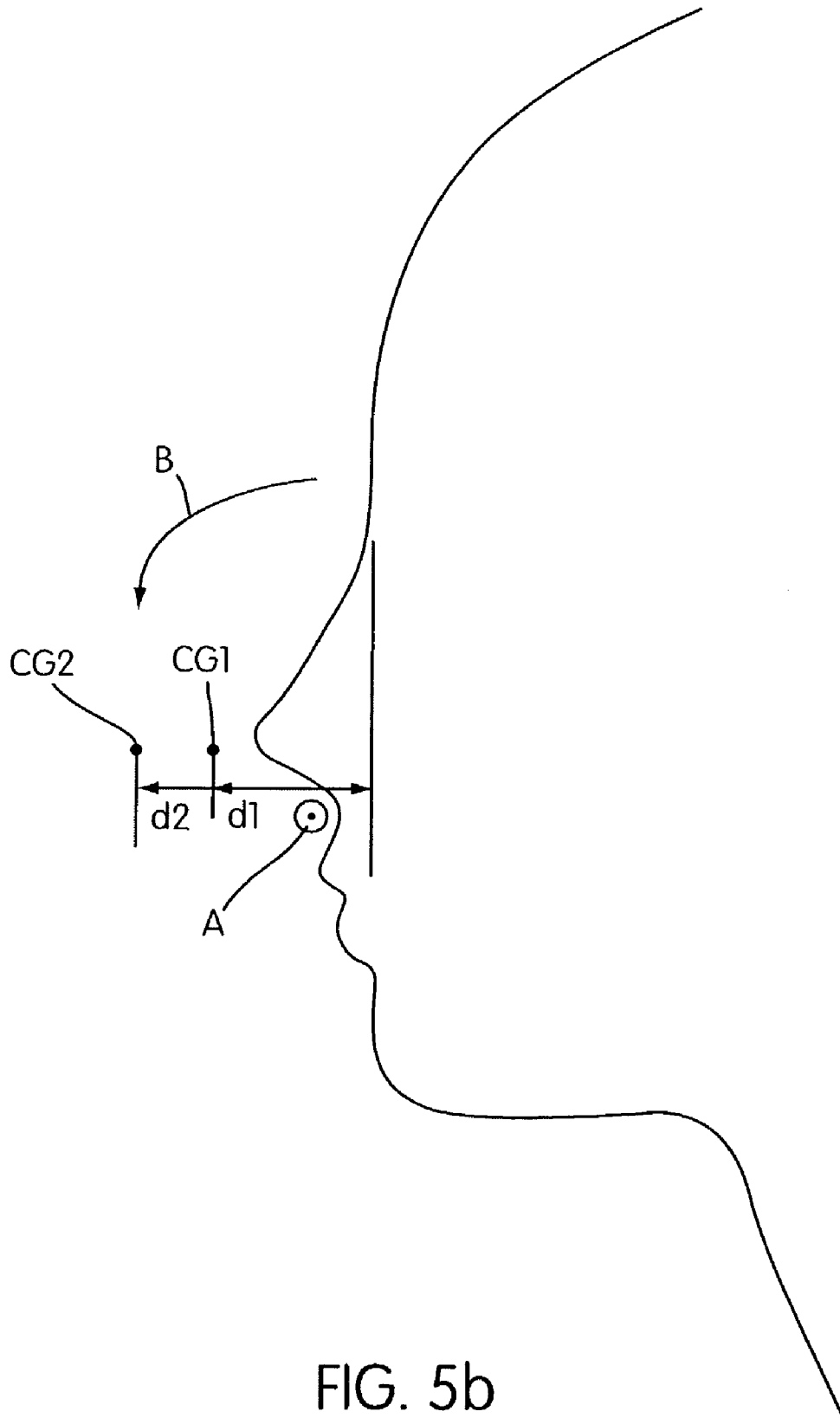


FIG. 5b

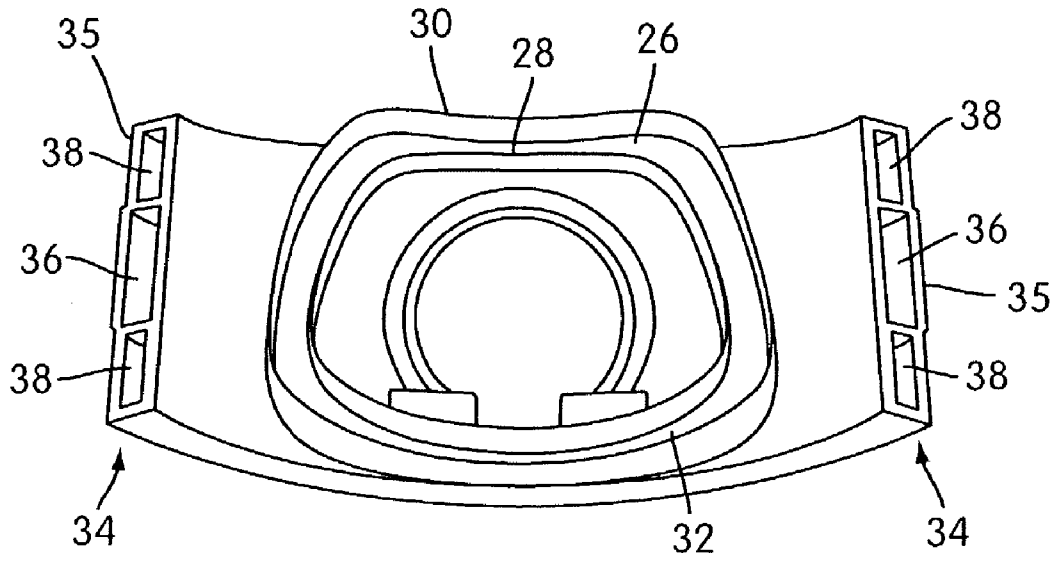


FIG. 5c

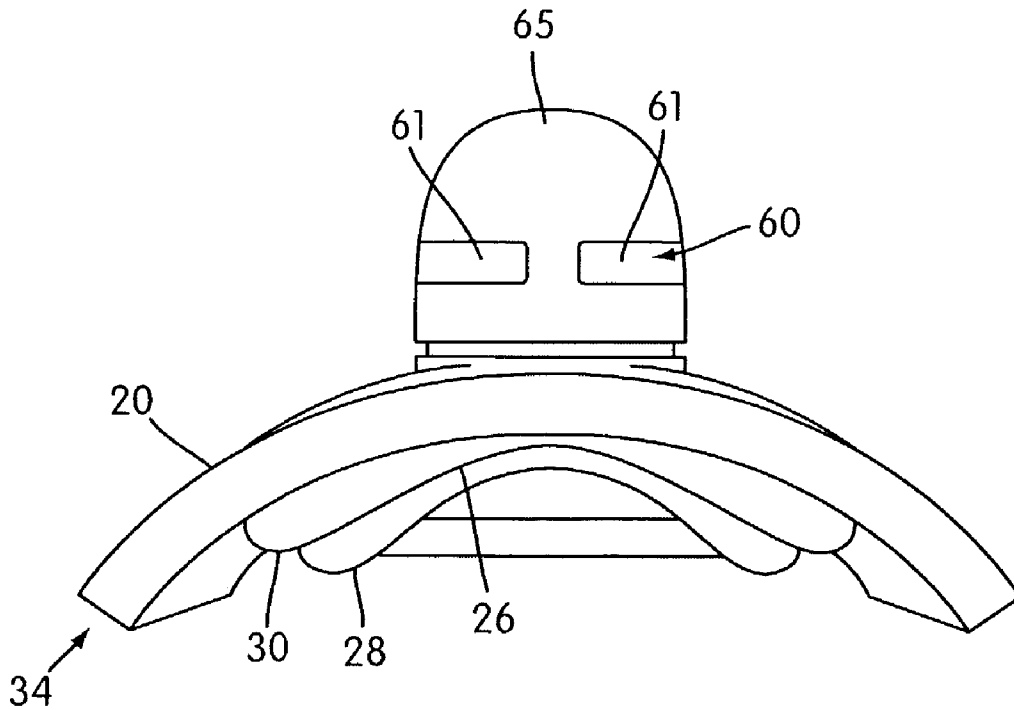


FIG. 6a

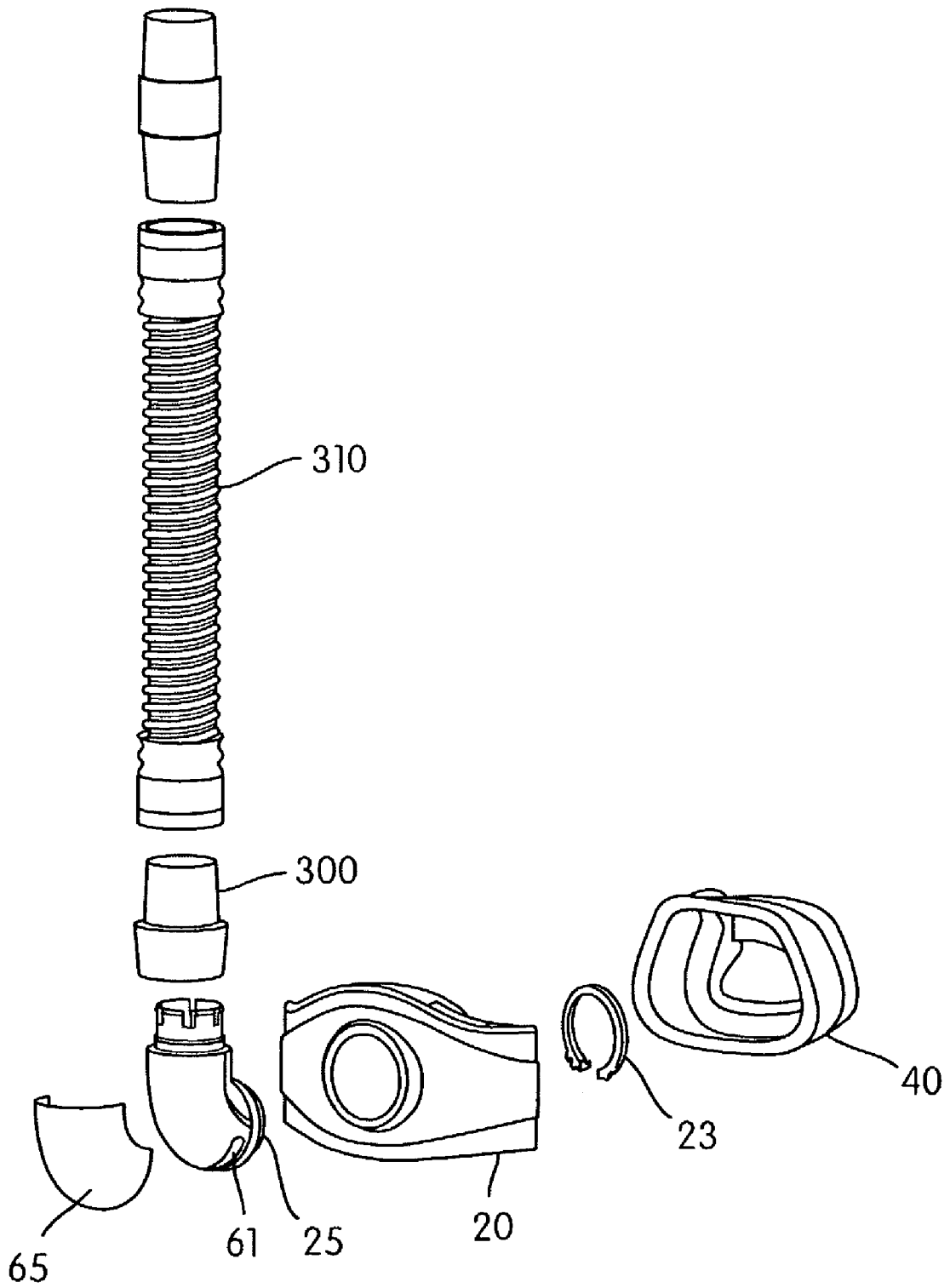


FIG. 6b

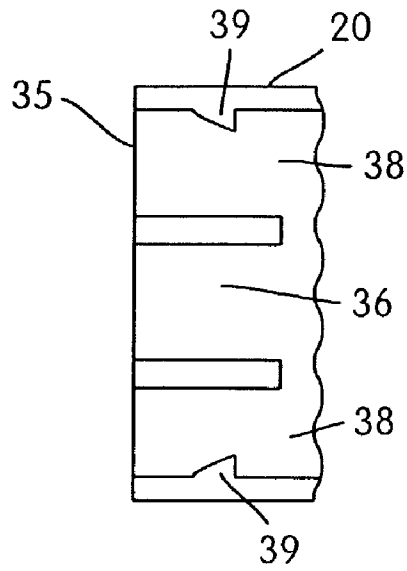


FIG. 7

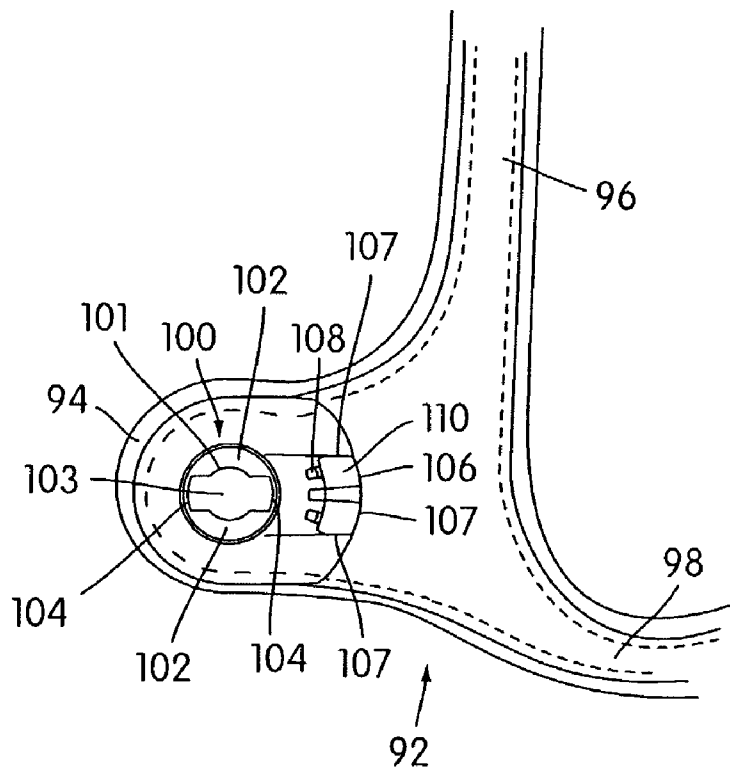


FIG. 8

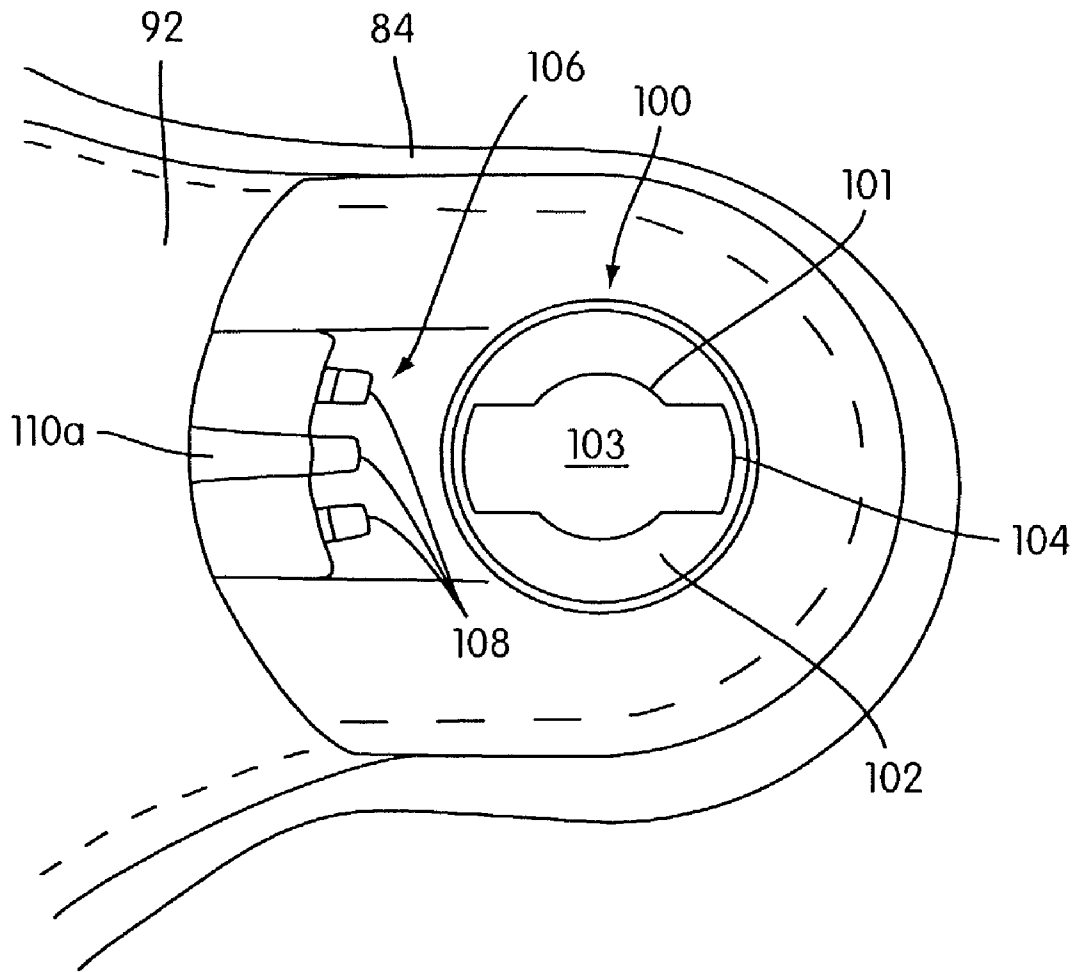


FIG. 8a

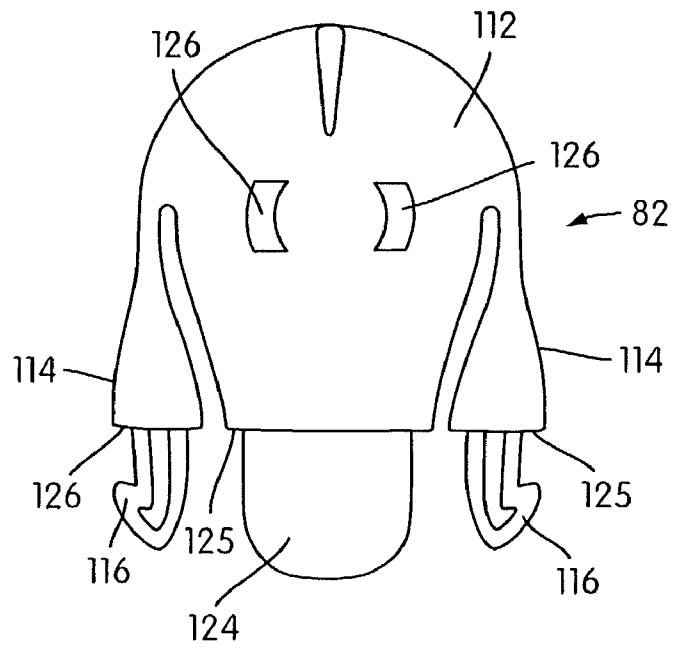


FIG. 9a

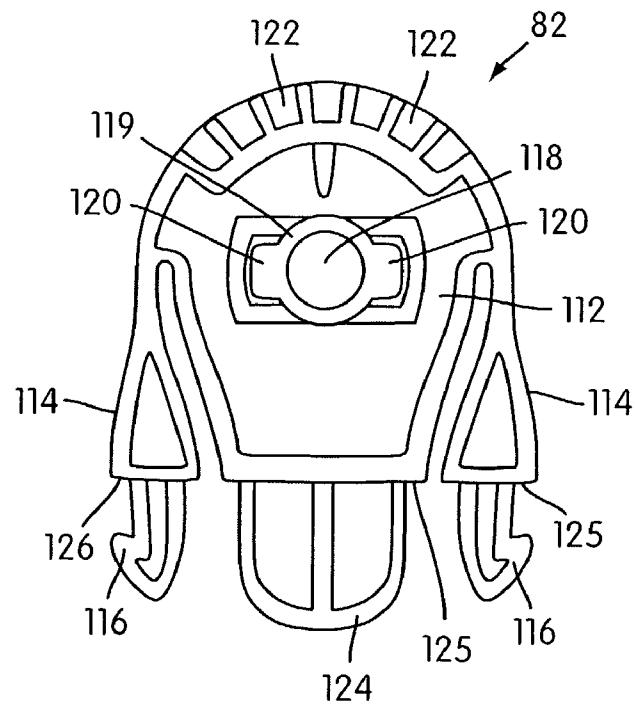


FIG. 9b

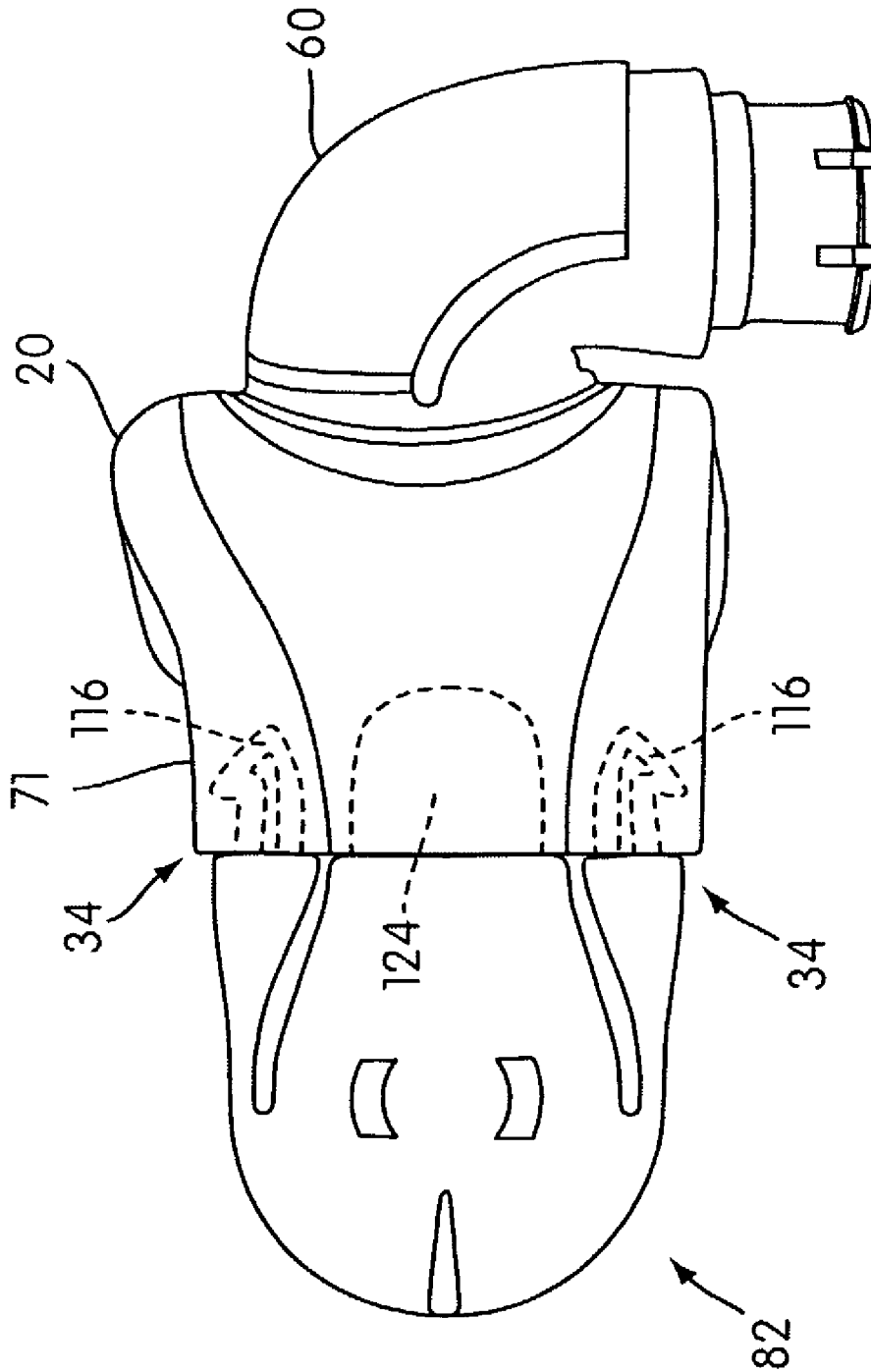


FIG. 10a

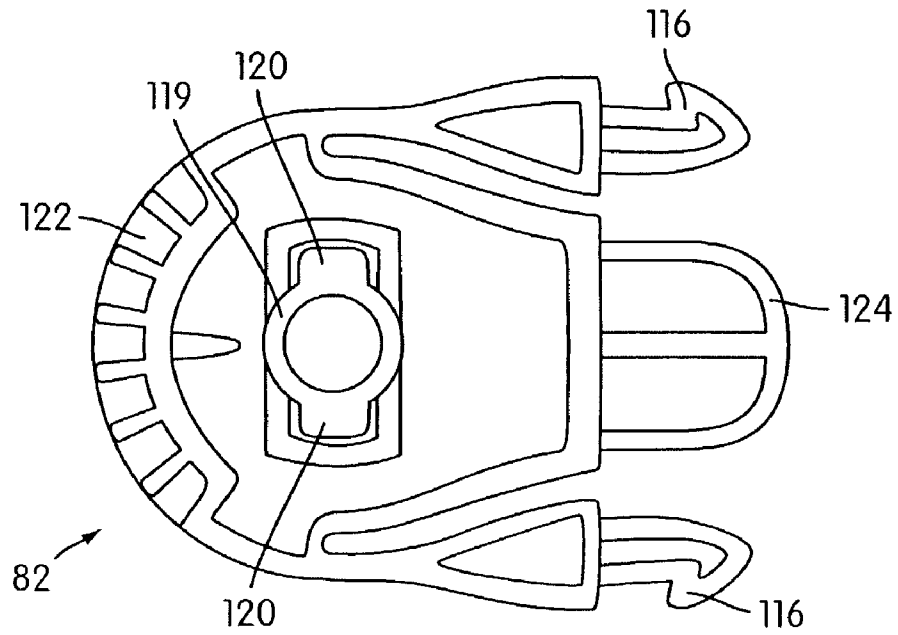


FIG. 10b

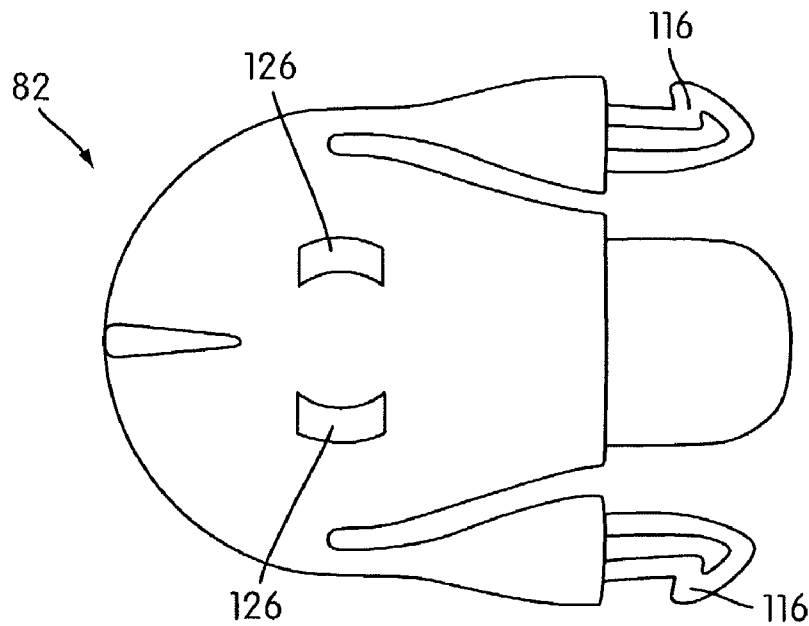
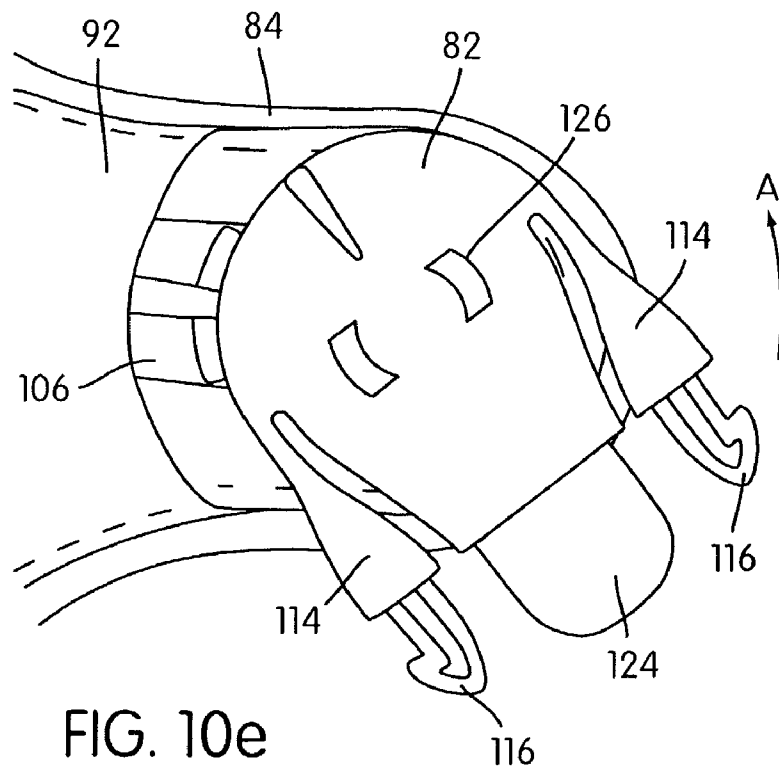
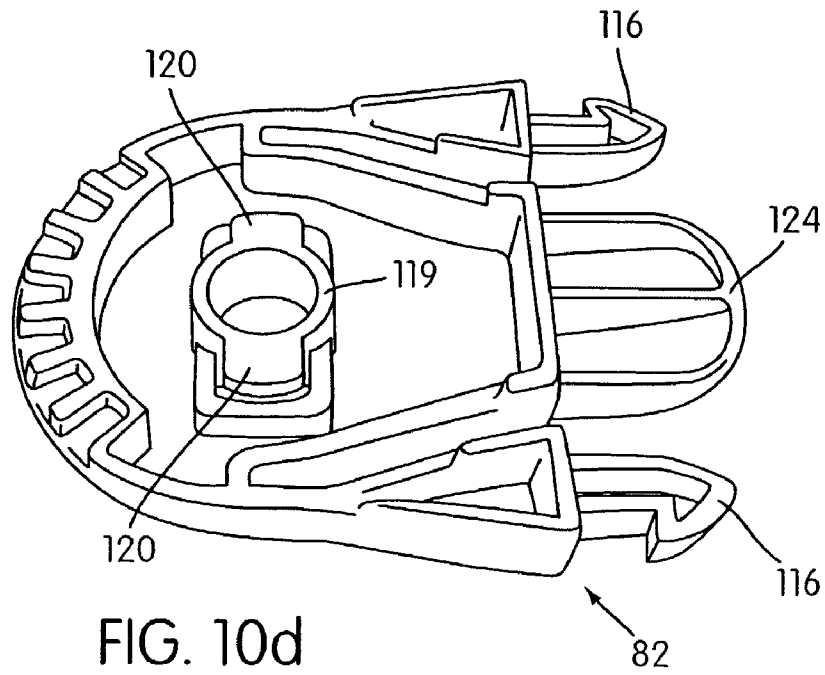


FIG. 10c



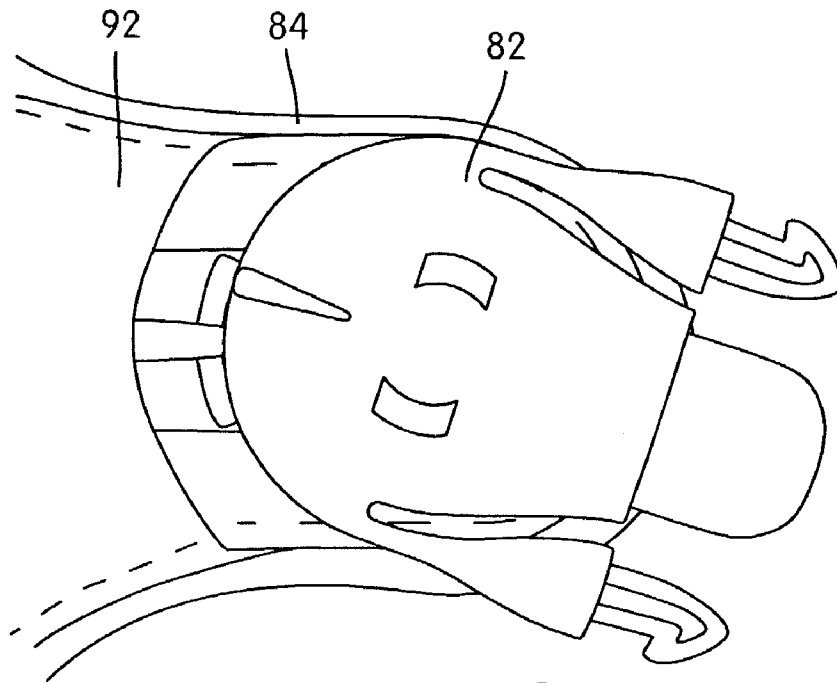


FIG. 10f

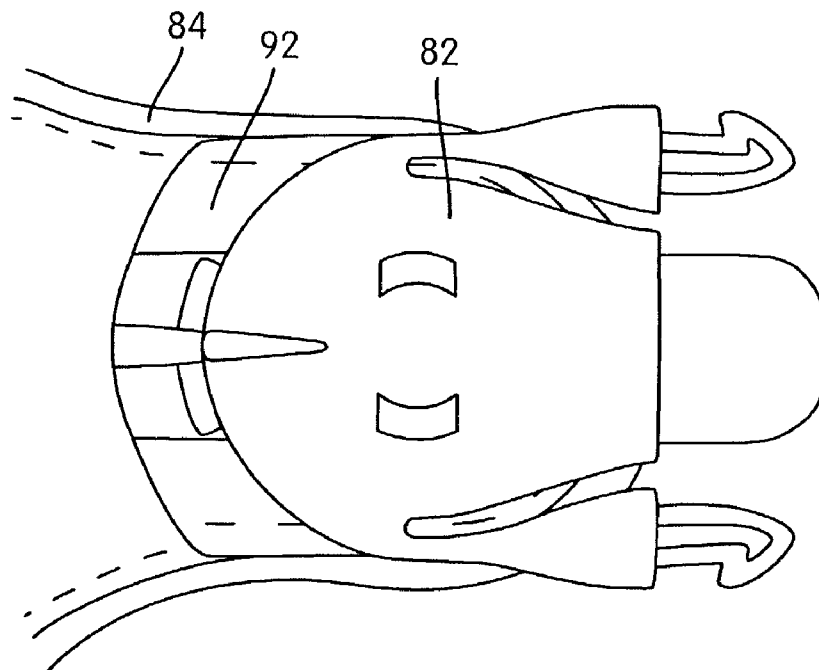


FIG. 10g