PATENT

IN THE UNITED STATES
PATENT AND TRADEMARK OFFICE

Serial No.:	Not yet assigned
Applicant:	McAuley et al.
Filed:	Herewith
For:	BREATHING ASSISTANCE APPARATUS
Examiner:	Not yet assigned
Art Unit:	Not yet assigned
Attorney Docket No.:	1171/48067/202-PCT-US

PRELIMINARY AMENDMENT

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Prior to examination of the above-identified patent application, kindly amend the application as follows:

IN THE SPECIFICATION:

After the title, please add the following paragraph:

This application is a National Phase filing of PCT/NZ2007/000185, having an International filing date of July 13, 2007, which disclosure is herein incorporated by reference.

IN THE CLAIMS:

1. (Original) Headgear for use with a respiratory mask comprising:

a continuous and substantially curved elongate member extending in use below a patient's nose,

at least two headgear straps capable of attachment to the ends of said elongate member, and

a mask attachment on said elongate member disposed to sit below or on one of said user's nose, mouth, upper lip and an inlet to the mask, said attachment capable of receiving said mask.

2. (Original) Headgear according to claim 1 wherein said at least two straps are substantially flexible, soft straps each extending down a user's cheekbones in use and terminating at each of said strap's ends in said user's upper lip area and said a substantial portion of said elongate member is attached to each of said straps.

3. (Original) Headgear according to claim 2 wherein the length of said at least two straps that extends in use along said user's cheekbones is attached to said elongate member, said elongate member providing rigidity to said length of said at least two straps.

4. (Original) Headgear according to claim 1 wherein said elongate member has two ends each of which is attached to one of said at least two straps, said elongate member having at least one pad extending along the inner side of the elongate member in at least the areas where the

elongate member is incident on said patient's cheekbones.

5. (Original) Headgear according to claim 4 wherein said at least one pad are substantially the same width as said elongate member.

6. (Currently Amended) Headgear according to ~~any one of claims~~ claim 1 ~~to 5~~ wherein said continuous elongate member is substantially rigid compared to said straps.

7. (Currently Amended) Headgear according to ~~any one of claims~~ claim 1 ~~or 6~~ wherein said continuous elongate member includes two side arms and a central section.

8. (Original) Headgear according to claim 7 wherein said side arms and said central section are formed as a single item.

9. (Original) Headgear according to claim 7 or 8 wherein said at least one pad is two pads one each extending substantially along the length of each said side arm.

10. (Original) Headgear according to claim 7 wherein said side arms and said central section are formed as two separate items.

11. (Currently Amended) Headgear according to ~~any of claims~~ claim 7 ~~to 10~~ wherein said side arms have at least one weakened or narrow area to allow for manipulation of said side arms.

12. (Currently Amended) Headgear according to ~~any of claims~~ claim 7 ~~to 11~~ wherein a mask base is capable of frictionally fitting to said central section, such that said central section places said mask base near a breathing orifice of a user.

13. (Original) Headgear according to claim 12 wherein said mask base is integrally formed with said central section.

14. (Currently Amended) Headgear according to ~~any of claims~~ claim 1 ~~to 13~~ wherein said curved elongate member is moulded in a three dimensional manner to fit the contours of said patient's cheeks.

15. (Original) A breathing assistance apparatus for use with delivery of respiratory gases to a user comprising:

a mask having a base and body, said body having two flexible nasal pillows that in use rest in a substantially sealed manner against said user's nares,

a continuous and substantially curved elongate member extending in use below a patient's nose,

at least two headgear straps capable of attachment to the ends of said elongate member, and

a mask attachment on said elongate member disposed below said user's nose, said attachment capable of receiving said mask.

16. (Original) A breathing assistance apparatus according to claim 15 wherein said at least two straps are substantially flexible, soft straps each extending down a user's cheekbones in use and terminating at each of said strap's ends in said user's upper lip area and said a substantial portion of said elongate member is attached to each of said straps.

17. (Original) A breathing assistance apparatus according to claim 15 wherein the length of said at least two straps that extends in use along said user's cheekbones is attached to said elongate member, said elongate member providing rigidity to said length of said at least two straps.

18. (Original) A breathing assistance apparatus according to claim 15 wherein said elongate member has two ends each of which is attached to one of said at least two straps, said elongate member having at least one pad extending along the inner side of the elongate member in at least the areas where the elongate member is incident on said patient's cheekbones.

19. (Original) A breathing assistance apparatus according to claim 18 wherein said at least one pad are substantially the same width as said elongate member.

20. (Currently Amended) A breathing assistance apparatus according to ~~any one of claims~~ claim 15 ~~to 19~~ wherein said continuous elongate member is substantially rigid compared to said straps.

21. (Currently Amended) A breathing assistance apparatus according to ~~any one of claims~~ claim 15 ~~or 20~~ wherein said nasal pillows are substantially elliptical and have gases outlets that are offset from the centre of said elliptical pillows.

22. (Currently Amended) A breathing assistance apparatus according to ~~one of claims~~ claim 15 ~~to 22~~ wherein said breathing assistance apparatus includes humidification means adapted to, in use, be in fluid communication with said source of gases and said transportation means and adapted to in use humidify said gases.

23. (Currently Amended) A breathing assistance apparatus according to ~~any one of claims~~ claim 15 ~~to 22~~ wherein said continuous elongate member includes two side arms and a central section.

24. (Original) A breathing assistance apparatus according to claim 23 wherein said side arms and said central section are formed as a single item.

25. (Original) A breathing assistance apparatus according to claim 23 wherein said side arms and said central section are formed as two separate items.

26. (Original) A breathing assistance apparatus according to claim 18 wherein said at least one pad is two pads one each extending substantially along the length of each said side arm.

27. (Currently Amended) A breathing assistance apparatus according to ~~any of claims~~ claim 23 ~~to 26~~ wherein said side arms have at least one weakened or narrow area to allow for manipulation of said side arms.

28. (Currently Amended) A breathing assistance apparatus according to ~~any of claims~~ claim 23 ~~to 27~~ wherein said base frictionally fits to said central section, and said body to said base, such that said central section suspends said base below said user's nares, and when said body is attached to said base, said nasal pillows rest against said user's nares.

29. (Currently Amended) A breathing assistance apparatus according to ~~any of claims~~ claim 23 ~~to 28~~ wherein said base is integrally formed with said central section.

30. (Currently Amended) A breathing assistance apparatus according to ~~any of claims~~ claim 23 ~~to 29~~ wherein said side arms attach one to each side of said base.

31. (Currently Amended) A breathing assistance apparatus according to ~~any of claims~~ claim 15 ~~to 30~~ wherein said curved elongate member is moulded in a three dimensional manner to fit the contours of said user's cheeks.

32 - 37. (Cancelled)

REMARKS

Applicant has amended the specification to reference the International application and has amended the claims to provide proper dependencies in accordance with United States practice. Entry is requested.

If the Examiner has any questions regarding this Amendment, the Examiner is invited to contact one of the undersigned at 312/704-1890.

Respectfully submitted,

Dated: Jan. 8, 2008

By: _____

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A82914.WPD

DECLARATION AND POWER OF ATTORNEY FOR PATENT APPLICATION

My residence, post office address and citizenship are as stated below next to my name,

I believe I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention entitled: BREATHING ASSISTANCE APPARATUS the specification of which

(check one) [ ] is attached hereto.
[X] was filed on July 13, 2007 as Application Serial No. PCT/NZ2007/000185 and was amended on January 8, 2009.

I hereby state that I have reviewed and understand the contents of the above identified specification, including the claims, as amended by any amendment referred to above.

I acknowledge the duty to disclose information which is material to patentability as defined in Title 37, Code of Federal Regulations, §1.56.

I hereby claim foreign priority benefits under Title 35, United States Code, §119(a)-(d) of any foreign application(s) for patent or inventor's certificate listed below and have also identified below any foreign application for patent or inventor's certificate having a filing date before that of the application on which priority is claimed:

Prior Foreign Application(s)

			Priority Claimed	
548575 (Number)	New Zealand (Country)	14 July 2006 (Day/Month/Year Filed)	[X] Yes	[ ] No
551103 (Number)	New Zealand (Country)	06 November 2006 (Day/Month/Year Filed)	[X] Yes	[ ] No

Prior Provisional Application(s)

I hereby claim the benefit under Title 35, United States Code, §119(e) of any United States provisional application(s) listed below.

(Application Number) (Filing Date)

(Application Number) (Filing Date)

I hereby claim the benefit under Title 35, United States Code, §120 of any United States application(s) listed below; insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States application in the manner provided by the first paragraph of Title 35, United States Code, §112, I acknowledge the duty to disclose material information as defined in Title 37, Code of Federal Regulations, §1.56(a) which occurred between the filing date of the prior application and the national or PCT international filing date of this application:

(Application Serial No.) (Filing Date) (Status: patented, pending, abandoned)

POWER OF ATTORNEY: As a named inventor, I hereby appoint the following attorney(s) and/or agent(s) to prosecute this application and transact all business in the Patent and Trademark Office connected therewith: Richard A. Giangiorgi, Reg. 24,284; Raiford A. Blackstone, Jr., Reg. 25,156; David J. Marr, Reg. 32,915; Linda L. Palomar, Reg. 37,903; James R. Foley, Reg. 39,979; James A. O'Malley, Reg. 45,952; Timothy M. McCarthy, Reg. 42,855; and Paige A. Kitzinger, Reg. 45,219.

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DIRECT TELEPHONE CALLS TO: (312) 704-1890 Raiford A. Blackstone, Esq.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

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I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Full name of second inventor OLIVER GLEESON
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I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

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I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

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I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

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I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

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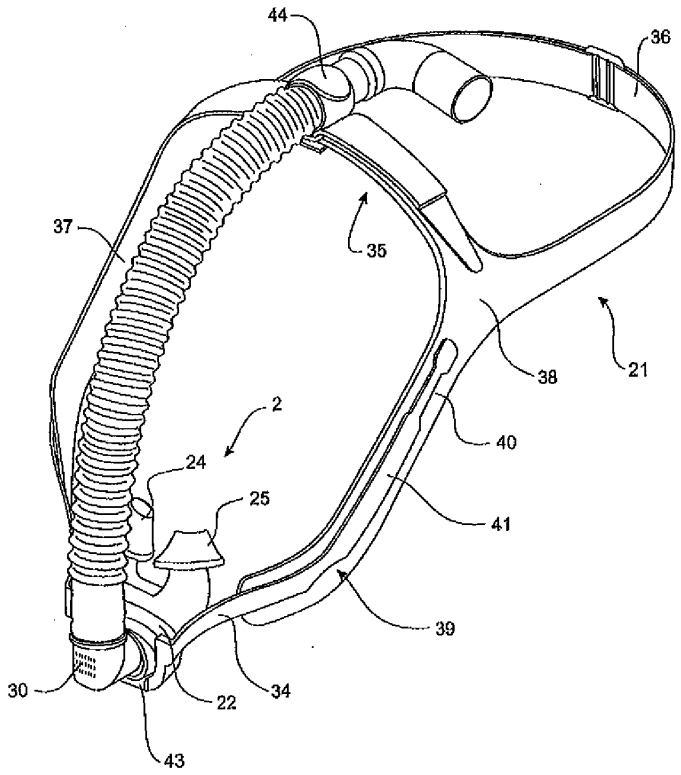
[Continued on next page]

(54) Title: BREATHING ASSISTANCE APPARATUS



(57) Abstract: Headgear for use with a respiratory mask is described. The headgear comprises a continuous and substantially curved elongate member extending in use below a user's nose and at least two headgear straps capable of attachment to the ends of the elongate member. A mask attachment on the elongate member is disposed to sit below or on one of said user's nose, mouth, upper lip and an inlet to the mask. The attachment is capable of receiving the mask.

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For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

BREATHING ASSISTANCE APPARATUS

BACKGROUND OF THE INVENTION

Technical Field

The present invention relates to apparatus for treating sleep apnoea. More specifically, the present invention provides a nasal interface for the supply of respiratory gases, but most particularly positive pressure gases.

Summary of the Prior Art

In the art of respiration devices, a variety of respiratory masks which cover the nose and/or mouth of a human user in order to provide a continuous seal around the nasal and/or oral areas of the face are well known. Masks that provide gas at positive pressure within the mask for consumption by the user are also well known. The uses for such masks range from high altitude breathing (i.e., aviation applications) to mining and fire fighting applications, to various medical diagnostic and therapeutic applications.

Obstructive Sleep Apnoea (OSA) is a sleep disorder that affects up to at least 5% of the population in which muscles that normally hold the airway open relax and ultimately collapse, sealing the airway. The sleep pattern of an OSA sufferer is characterised by repeated sequences of snoring, breathing difficulty, lack of breathing, waking with a start and then returning to sleep. Often the sufferer is unaware of this pattern occurring. Sufferers of OSA usually experience daytime drowsiness and irritability due to a lack of good continuous sleep.

In an effort to treat OSA sufferers, a technique known as Continuous Positive Airway Pressure (CPAP) was devised. A CPAP device consists of a gases supply (or blower) with a conduit connected to supply pressurised gases to a patient, usually through a nasal mask. The pressurised air supplied to the patient effectively assists the muscles to keep the patient's airway open, eliminating the typical OSA sleep pattern.

The procedure for administering CPAP treatment has been well documented in both the technical and patent literature. Briefly stated, CPAP treatment acts as a pneumatic splint of the airway by the provision of a positive pressure, usually in the range 4 to 20 cm H_2O. The air is supplied to the airway by a motor driven blower whose outlet passes via an air delivery hose to a nose, full face, nose and mouth, or oral mask that is sealingly engaged to a patient's face, preferably by means of a harness or other headgear. An exhaust port is usually also provided in the delivery tube proximate to the mask or on the mask itself. More sophisticated

forms of positive airway pressure devices, such as bi-level devices and auto-titrating devices, are described in US Patent No. 5,148,802 of Respironics, Inc. and US Patent No. 5,245,995 of Rescare Limited, respectively.

One requisite of respiratory masks has been that they provide an effective seal against the user's face to prevent leakage of the gas being supplied. Commonly, in prior mask configurations, a good mask-to-face seal has been attained in many instances only with considerable discomfort for the user. A common complaint of a user of CPAP therapy is pressure sores caused by the mask about the nose and face and in particular in the nasal bridge region of the user. This problem is most crucial in those applications, especially medical applications, which require the user to wear such a mask continuously for hours or perhaps even days. In such situations, the user will not tolerate the mask for long durations and optimum therapeutic or diagnostic objectives thus will not be achieved, or will be achieved with great difficulty and considerable user discomfort.

US Patent No. 5,477,852 of Airways Ltd, Inc. discloses a nasal positive airway pressure device that has a pair of nasal members each having a cannula tip to be inserted into the nares of the patient. Each cannula is tapered from a substantially circular cross section outside the patient's nostril to a substantially oval cross section at the tip inserted into the nostril. An inflatable cuff surrounds each cannula with the interior space of the cuff communicating with the lumen of the cannula through at least one aperture in the sidewall of the cannula. The nasal members are connected to one or more flexible hoses that, in turn, are connected to a source of positive air pressure. In use, positive air pressure is supplied to each cannula tip through the air hoses and nasal members. The positive air pressure inflates the cuffs to hold the nasal members in place and to effect treatment. The nasal device of US Patent No. 5,477,852 is attached to headgear that is located about a patient's head. This headgear could be considered by many patients as cumbersome and uncomfortable.

Conventional nasal masks used for administrating CPAP treatment are also considered uncomfortable and cumbersome, and prior art nasal masks can be noisy due to air leaks. These disadvantages in many cases are a formidable obstacle to patient acceptance of such treatment. Therefore, a substantial number of patients either cannot tolerate treatment or choose to forego treatment. It is believed a number of such patients might benefit from a nasal positive airway pressure apparatus that is more convenient to use and comfortable to wear, thereby resulting in increased treatment compliance.

Innomed Technologies, Inc. manufactures a nasal cannula device called the NASALAIRE™. In this device air or oxygen travels down a wide bore conduit to nasal cannula. The NASALAIRE™ creates a physical seal between the nares and itself, and relies on the absence of leaks around the cannula and the nares to deliver pressure supplied by a continuous positive airway pressure (CPAP) blower to the airway of the wearer.

US6,119,694 of Respironics Georgia, Inc discloses a nasal mask having a nare seal and lateral support members to support the mask.

WO2004/073778 of ResMed Limited discloses a nasal mask including a frame where headgear is provided with rigid sections that extend to the nasal mask.

WO04/041341 of ResMed Limited discloses headgear for a patient mask that includes a sewn on rigid section to the back area of headgear straps to provide rigidity to the straps.

US6,907,882 of ResMed Limited discloses a nasal mask and headgear that is attachable to the frame of the nasal mask. The headgear straps have rigid sections integral with the releasable connectors that attach the headgear to the mask.

DISCLOSURE OF THE INVENTION

It is an object of the present invention to attempt to provide a patient interface that goes some way to overcoming the abovementioned disadvantages in the prior art or which will at least provide the industry with a useful choice.

In a first aspect the present invention consists in headgear for use with a respiratory mask comprising:

a continuous and substantially curved elongate member extending in use below a patient's nose,

at least two headgear straps capable of attachment to the ends of said elongate member, and

a mask attachment on said elongate member disposed to sit below or on one of said user's nose, mouth, upper lip and an inlet to the mask, said attachment capable of receiving said mask.

In a second aspect the present invention consists in a breathing assistance apparatus for use with delivery of respiratory gases to a user comprising:

a mask having a base and body, said body having two flexible nasal pillows that in use rest in a substantially sealed manner against said user's nares,

a continuous and substantially curved elongate member extending in use below a

patient's nose,

at least two headgear straps capable of attachment to the ends of said elongate member, and

a mask attachment on said elongate member disposed below said user's nose, said attachment capable of receiving said mask.

In a third aspect the present invention consists in a breathing assistance apparatus for use with delivery of respiratory gases to a user comprising:

a mask comprising a body and a cushion, said cushion substantially forming a seal with said patient's airways,

headgear comprising substantially flexible, soft straps and a substantially continuous curved elongate member to which said mask is attached, said elongate member extending over said user's cheeks, and

wherein said mask has an inlet extension tube and said curved elongate member is attached or rests beneath said inlet extension tube, anchoring said mask to said user's face in use.

To those skilled in the art to which the invention relates, many changes in construction and widely differing embodiments and applications of the invention will suggest themselves without departing from the scope of the invention as defined in the appended claims. The disclosures and the descriptions herein are purely illustrative and are not intended to be in any sense limiting.

In this specification where reference has been made to patent specifications, other external documents, or other sources of information, this is generally for the purpose of providing a context for discussing the features of the invention. Unless specifically stated otherwise, reference to such external documents is not to be construed as an admission that such documents, or such sources of information, in any jurisdiction, are prior art, or form part of the common general knowledge in the art.

The invention consists in the foregoing and also envisages constructions of which the following gives examples.

BRIEF DESCRIPTION OF THE FIGURES

Preferred forms of the present invention will now be described with reference to the accompanying drawings.

Figure 1 is a block diagram of a humidified continuous positive airway pressure system as might be used in conjunction with the nasal mask of the present invention.

Figure 2 is a perspective view of a first form of a patient interface that is nasal mask and headgear of the present invention.

Figure 3 is an exploded view of the nasal mask and headgear of Figure 2.

Figure 4 is a side view of a mask base of the nasal mask and headgear of Figure 2.

Figure 5 is a perspective end view of the mask base of Figure 4.

Figure 6 is an end view of a body of the nasal mask and headgear of Figure 2, particularly showing two nasal pillows.

Figure 7 is a perspective view of the body of Figure 6.

Figure 8 is a perspective view of a nasal mask of the first form of the present invention but having alternative headgear that includes additional rigid extensions.

Figure 9 is perspective view of a second form of a patient interface and headgear of the present invention.

Figure 10 is an exploded view of the patient interface and headgear of Figure 9.

Figure 11 is an exploded view of a third form of a patient interface and headgear of the present invention.

Figure 12 is an exploded view of a fourth form of a patient interface and headgear of the present invention.

Figure 13 is a perspective view of a fifth form of a patient interface and headgear of the present invention.

Figure 14 is an exploded view of the patient interface and headgear of Figure 13.

Figure 15 is a perspective view of a sixth form of a patient interface and headgear of the present invention.

Figure 16 is a perspective view of a seventh form of a patient interface and headgear of the present invention.

Figure 17 is a cross-sectional view of the patient interface of Figure 16.

Figure 18 is a front view of a nasal pillow of Figure 6.

Figures 19a is a front view of the nasal pillows of Figure 6.

Figures 19b to 19d are graphs of the gradients of various nasal pillow connecting surfaces.

Figure 20 is a perspective view of an eighth form of a patient interface and headgear of the present invention.

Figure 21 is a perspective view of the interface and headgear of Figure 20 showing inner pads on the arms of the headgear.

Figure 22 is an exploded view of the interface and headgear of Figure 20.

Figure 23 is a perspective view of a ninth form of a patient interface and headgear the present invention.

DESCRIPTION OF THE PREFERRED EMBODIMENTS OF THE INVENTION

The breathing assistance apparatus of the present invention including masks and headgear as described in the preferred embodiments of this invention can be used in respiratory care generally or with a ventilator. It is described below with reference to use in a humidified CPAP system.

A humidified Continuous Positive Airway Pressure (CPAP) system is shown in Figure 1. A patient 1 is receiving humidified and pressurised gases through a patient interface 2 connected to a humidified gases transportation pathway or inspiratory conduit 3. Alternative delivery systems may also be used such as, VPAP (Variable Positive Airway Pressure) and BiPAP (Bi-level Positive Airway Pressure) or numerous other forms of respiratory therapy. A nasal mask 2 is illustrated in Figure 7 but other masks such as oral, full face or nasal cannula may be used.

An inspiratory conduit 3 is connected to an outlet 4 of a humidification chamber 5 that contains a volume of water 6. The inspiratory conduit 3 may contain heating means or heater wires (not shown) that heat the walls of the conduit to reduce condensation of humidified gases within the conduit 3.

The humidification chamber 5 is preferably formed from a plastics material and preferably has a highly heat conductive base (for example an aluminium base) that is in direct contact with a heater plate 7 of humidifier 8. The humidifier 8 is provided with control means or an electronic controller 9 that may comprise a microprocessor based controller executing computer software commands stored in associated memory.

The controller 9 preferably receives input from sources such as user input means or a dial 10 through which a user of the device may, for example, set a predetermined required value (preset value) of humidity or temperature of the gases supplied to patient 1. The controller 9 may also receive input from other sources, for example temperature and/or flow

velocity sensors 11, 12, through a connector 13 and a heater plate temperature sensor 14. In response to the user set humidity or temperature value input via the dial 10 and the other inputs, the controller 9 determines when (or to what level) to energise the heater plate 7 to heat the water 6 within the humidification chamber 5. As the volume of the water 6 within the humidification chamber 5 is heated, water vapour begins to fill the volume of the chamber above the water's surface and is passed out of the humidification chamber 5 outlet 4 with the flow of gases (for example air) provided from a gases supply means or blower 15 that enters the chamber 5 through an inlet 16. Exhaled gases from the patient's mouth are passed directly to the ambient surroundings in Figure 1.

The blower 15 is provided with variable pressure regulating means or variable speed fan 21 that draws air or other gases through a blower inlet 17. The speed of the variable speed fan 21 is controlled by an electronic controller 18 (or alternatively the function of the controller 18 may be carried out by the controller 9) in response to inputs from the controller 9 and a user set predetermined required value (preset value) of pressure or the fan speed via dial 19.

Figures 2 and 3 show a first embodiment of a patient interface of the present invention. This patient interface is a nasal mask 2. The nasal mask 2 is comprised of a mask base 22 and body 23. The body 23 is substantially tubular with two nasal pillows 24, 25 extending from it. The nasal pillows 24, 25 are preferably frustoconical in shape and in use rest against a patient's nares, to substantially seal the patient's nares. The body 23 has an external lip 28 that frictionally fits in a channel in the mask base 22.

The body 23 and nasal pillows 24, 25 of the nasal mask of the present invention are shown in further detail in Figures 6 and 7. The body and pillows are preferably integrally moulded in a substantially flexible plastics material. In the preferred form this material is silicone, but other appropriate materials, such as, rubber, thermoset elastomer or thermoplastic elastomer, such as Kraton™ may be used.

The nasal pillows 24, 25 are preferably an elliptical cone and as such are tubular and allow for a passage of gases to flow from the tubing 3 and through the mask body 23. The pillows 24, 25 are preferably angled toward one another and each have a preferably elliptical outlet 26, 27 that may be slightly offset from the centre of each pillow 24, 25, as shown in Figure 6.

Figures 18 and 19a show a nasal pillow 24 with an offset outlet in more detail. The

pillow 24 has an outer profile 200 and inner profile 201 with respective centre points 202, 203. The inner profile 201 (outlet of the nasal pillow 24) is offset inward, by a horizontal spacing 204 and vertical spacing 205. Meaning the outlet 201 of the nasal pillow is offset horizontally 204 towards the middle of the nose and vertically 205 towards the user's upper lip. Offsetting the outlet 201 downwards in this manner allows the outlet to be inserted into a user's nostril without the outer profile 200 pushing the user's upper lip. Offsetting the outlet 201 inwards allows the pillow to better seal on the septum of the user's nose in use.

The outlet 201 may also be angled compared to the outer profile 200. For example in Figure 18, there is a horizontal angle difference between the outer profile 200 and outlet 201 shown as 206. A similar vertical angle difference between the outer profile 200 and outlet 201 is shown as 207.

With the outer profile and inner profile having different sections or offsets allows the gradient of the connecting surface between the profiles to be changeable. This is shown in the graphs of Figures 19b, 19c and 19d. The connecting surface between the inner 201 and outer 200 profiles can have differing gradients, 208, 209, 210. The different gradients 208, 209, 210 of the connecting surface are possible due to the difference in offset difference 211, 212 (horizontal, vertical or angled) between the inner 201 and outer 200 profiles.

There may also be a difference in the rate of change of the gradient (as illustrated in the difference between 208 and 210). This allows easier insertion of the pillow 24 into a user's nostrils due to more lead in and better sealing that may be achieved due to more ergonomic contouring of the connecting surface that contacts the user's nostril.

Referring back to Figure 7, the external lip 28 on the mask body 23 is an area of reduced circumference around the tubular part of the body 23. A projection 47 may be provided on the lip 28 that fits with a corresponding recess or channel (discussed below) on the mask base 22 to ensure correct assembly of the nasal mask.

The mask base 22 is shown in further detail in Figures 4 and 5. The mask base 22 is a ring or sleeve type attachment. The base 22 is preferably made from a substantially hard (rigid) plastics material, such as polypropylene, polycarbonate or acetyl. However, other appropriate materials may be used. The base 22 has an internal circumferential recessed area or channel 45 on one side and a semi-tubular projection 29 on its other side. When assembling the mask body 23 to the mask base 22 the channel 45 receives the lip 28. These parts are maintained together by friction fit, however other types of fitting may be provided for, such as

a snap or bump fitted part or the body may be over moulded to a clip that causes the fitting to the mask body 23. In this form the friction fitting of the lip 28 to the recessed area 45 is assisted by elongate projections 49 extending along the central part 50 of the mask base 22. The projection 47 on the mask body 23 allows for correct fitting or keying of the mask base to the mask body, such that when the lip 28 is fitted into the recessed area 45, the projection 47 enters the recess 48 formed in the mask base 22.

The semi-tubular projection 29 is curved in this embodiment such that a ball jointed connector end 46 such that a connector 30 can be fitted into it. The projection 29 forms a socket for the connector end 46 and the connector end can swivel within the socket. The connector 30 is attached to a tube 31 to allow for gases to be passed to the nasal mask 2. The tubing 31 may be attached to inspiratory conduit 3 or the tubing 31 may simply be the inspiratory conduit 3.

In alternative embodiments the projection 29 may not be semi-circular but the inner surface of the base 22 may be curved and form a socket for receiving the connector end 46.

The base 22 has an extension or partial lip 32 extending beneath the semi-tubular projection (socket) 29. A slot 33 is created between the socket 29 and extension 32. The extension and slot is used to fit the mask base 22 to the headgear 21. In this embodiment the extension 32 is substantially curved to follow the shaped of the projection 29. However, in other forms the extension may be substantially straight or otherwise shaped.

In use, the nasal mask is assembled with headgear 21. The headgear 21 in the preferred form is comprised of headgear straps 35, 36, 37, 38 and a substantially curved and elongate member 34. The member 34 is curved and substantially rigid, or at least more rigid than the headgear straps.

The headgear straps 35, 36, 37, 38 are preferably made from a composite foam layered material, such as Breathoprene™. The headgear 21 preferably includes a first strap 35 and a second strap 36. The first strap 35 extends in use over the forehead or top front area of a patient's head. The second strap 36 extends around the back of the patient's head. The headgear 21 also has side straps 37, 38 that in use extend down the cheeks of a patient and the ends of the straps terminate in the upper lip area of the patient in use.

Referring to Figure 2, the curved and elongate member 34 is comprised of a central section 42 and contoured side arms 41, 54. A substantial length of each of the side arms 41, 54 overlaps and is attached to the side straps 37, 38. However, the side straps 37, 38 only

extend partially along the length of the side arms 41, 54 so as to terminate beneath the cheek or near the upper lip region. As the side straps 37, 38 are made from a soft foam type material they provide a comfortable fitting of the headgear and curved member 34, while the substantially rigid side arms 41, 54 provide rigidity and stability to the headgear 21 and nasal mask 2. The attachment between the side straps and rigid extension side arms may be made by gluing, sewing or other appropriate fastening.

Preferably the side arms of the curved member 34 are integrally moulded with the central section 42. The curved member 34 is preferably three dimensionally moulded to a shape to substantially match the cheek contours of a human. The side arms 41, 54 are preferably of thinner width (cross-section) than the central section 42. As the side arms 41, 54 are moulded of a plastics material to be substantially thin they are capable of being bent or adjusted to allow for better and more comfortable fit to a patient. The side arms 41, 54 may also include weakened or narrow areas 39 to allow for additional bending, moulding or twisting of the arms 41, 54 to better fit the headgear to individual patients. For example, in the embodiment shown in Figures 2 and 3, the narrowed area 39 corresponds to the cheek bone area of a patient and allows for the side arms 41, 54 to easier bend or twist to fit the contours of the patient's face.

In alternative embodiments the side arms may have weakened areas that are narrower in cross-section to that of the remainder of the side arms. A narrower cross-section area would also provide a weakened area that may be easily manipulated.

In alternative embodiments of the present invention the side straps of the headgear may not extend under and along the length of the curved member but be attached to the distal ends of the straps. This attachment may be by hook and loop material, as is known in the art, or by other attachment methods as known in the art. In this form, the arms of the curved member may have padding underneath them or no padding at all.

Referring to Figure 3, the curved elongate member has a central section 42 that in an assembled form supports the mask base and body such that the pillows 24, 25 rest against the patient's nares. The central section 42 is a half circle that is integrally moulded with the side arms 41, 54. The central section 42 has a raised area 43 on its exterior, at the apex of the half circle. The raised area 43 is shaped to receive the mask base 22. To assemble, a patient merely needs to slide the mask base 22 into the central section 42 such that the raised area 43 fits into the slot 33 on the mask base 22.

The side arms 41, 54 of the curved member 34 preferably have varying cross-sectional thickness. The ends of the arms 41, 54 attached to the central section 42 are thicker over the most curved parts 55, 56 of the arms, whereas the straighter parts of the arms 57, 58 have a narrow cross-section. Therefore, the thicker ends 55, 56 hold their shape better.

In alternative embodiments, the mask base 22 may be formed integrally with the curved member 34. Therefore, the central section and base would be one and would not be able to be separated from one another.

An example of this is shown in Figures 20 to 22, the eighth embodiment of the patient interface and headgear 300. Here, the mask base 301 and the curved elongate member 302 are integrally formed, for example, by moulding or the like. The elongate member comprises arms 303, 304 similar to that described above. Also the mask body 305 has integral nasal pillows 306, 307 similar to that described above in relation to Figure 2.

As can be seen in Figures 21 and 22 in this eighth embodiment the headgear straps 308, 309 do not extend down the arms 303, 304 as with other embodiments. In this embodiment the headgear straps 308, 309 attach through recesses 310, 313 at the end of the arms 303, 304 extending along the arms are inner pads 311,312 that rest against the patient's cheekbones in use and provide comfort to the patient's face. The pads 311, 312 only extend up to near the attachment recesses 309, 310. The pads are preferably made from a foam type material, such as the laminated material that the headgear straps are made from. The pads 311, 312 preferably do not extend beyond the edges of the arms 303,304.

Referring back to Figures 2 and 3, alternatively, the curved member 34 may be formed as two separate pieces. That is, the central section 42 may be formed as two parts with a central split seam, the two left and right halves joined in use. The two left and right parts could either be joined along a seam as described above, with the base 22 slotting into the slot 33 as described above, or alternatively, each of the two left and right arms may be attached one to each side of the base 22.

Where a "substantially continuous elongate member" or "curved member" is referred to in this specification, it refers to any of the options for the curved member 34 outlined above.

The side arms 41, 54 may also include a loop 40 or detached section. This is where a section of the side arms 41 is not attached to the strap 38, 37 lying underneath. Thus the detached section 40 of the side arms forms a loop to which a tubing attachment 44 (such as that shown attached to another strap in Figures 2 and 3) may be looped to the side arms 41, 54

and the tubing 31 attached to either of the side arms.

The connector 30 in the preferred form is a ball and socket jointed connector to allow for the tubing 31 to swivel in the mask base 22. The tubing 31 may be attached to any of the headgear straps. However, a tube attachment 44 is shown where the tubing is attached by fasteners, such as hook and loop fastener, to the first strap 35. In other embodiments the tubing 31 may be attached to either the side straps 37, 38 or merely allowed to fall freely from the nasal mask 2.

Although a ball and socket joint, as described above, between the mask base 22 and tubing 31 is preferred other connections may be utilised, such as a flexible piece of silicone, or other appropriate connection. The connection between the base and tubing must be able to be flexed or rotated to allow for the tubing to be moved without causing the dislodgement of the nasal mask 2 from the user's nares.

The mask body 23 may be provided with nasal pillows of various different sizes, such that user's may remove an existing mask body and simply attach a different sized body to the mask base 22.

Alternative headgear may be used with the patient interface of the present invention. In particular, alternative headgear is shown in use with the first form of the patient interface (of Figure 2) in Figure 8. Here the headgear may include an additional strap 53 extending from the cheek region of the side straps 41 and extending behind the user's head. This lower additional strap 53 may also include substantially rigid arms 51 similar to the arms 41 described above. Any number of connecting straps 52 may also be provided between the upper strap 36 and lower strap 53. Again, the arms 51 would provide stability and rigidity to the additional strap 53.

In the embodiment described above, when the patient interface of the first form is in use, the user's face causes the mask base 22 and body 23 to clip with the curved member 34. This is due to the angle of the curved member 34 and fixing of the mask base 22 and body 23 to the curved member 34.

Further, in all forms, the curved member 34 transfers the load of the patient interface away from the user's nose and to the cheek regions of the user.

A second form of the patient interface and headgear of the present invention is shown in Figures 9 and 10. In this embodiment a mouthpiece 100 is attached to the substantially tubular mask body 23 substantially below the nasal pillows 24, 25. The mouthpiece 100 is

preferably a flap that is fittable within the patient's mouth. A gases pathway extends through the mask body 23 and through the centre of the mouthpiece 100, such that in use a patient or user is supplied with gases via the nasal pillows 24, 25 and the mouthpiece 100. The flap 100 is preferably made from a silicone plastics material but other appropriate materials such as rubber, thermoset elastomer or thermoplastic elastomer, such as Kraton™ may be used. The flap 100 is preferably integrally moulded with the mask body 23 and nasal pillows 24, 25. In use the flap 100 sits within the user's mouth between the user's teeth and lips.

In this second form the headgear and particularly the curved member 34 is substantially the same as that described in relation to the first embodiment.

A third form of the patient interface and headgear of the present invention is shown in Figure 11. In this embodiment a mouthpiece as well as a nose blocking device is attachable to the mask base 22. The mouthpiece 110 and nose blocking device 111 are preferably integrally formed. The mouthpiece 110 has an inner vestibular shield 112 that is similar to the flap 100 described above. Therefore the vestibular shield 112 in use sits within the patient's mouth between the patient's teeth and lips and provides an at least partial seal between the user and the shield 112.

A tubular extension 113 extends through the mouthpiece 110 to the mask base 22 from the vestibular shield 112. The extension allows for gases to be passed to the patient from the conduit 31.

The nose blocking device 111 in use rests under the user's nose and blocks the user's nares.

In this third form the headgear and particularly the curved member 34 is substantially the same as that described in relation to the first embodiment.

A fourth embodiment of the patient interface and headgear of the present invention is shown in Figure 12. In this embodiment a mouthpiece 120, 121 is attachable via a tubular extension 122 to the mask base 22. The mouthpiece is made up of an outer mouthpiece flap 120 and an inner vestibular shield 121. The shield 121 is substantially the same as that described in reference to the third embodiment. The outer mouthpiece flap 120 rests in use outside the user's mouth and substantially seals about the user's mouth. The outer mouthpiece flap 120 and an inner vestibular shield 121 are described in further detail in United States patent number 6679257, the entire contents of which is herein incorporated by reference.

In the fourth form of the headgear and particularly the curved member 34 is

substantially the same as that described in relation to the first embodiment.

A fifth form of the patient interface and headgear of the present invention is shown in Figures 13 and 14. This embodiment is very similar to the fourth embodiment except the mouthpiece is simply an outer mouthpiece flap 130. This flap 130 is fittable to the mask base 22 by way of the tubular extension 131. Again, as above, the headgear and particularly the curved member 34 are substantially the same as that described in relation to the first embodiment.

A sixth form of the patient interface and headgear of the present invention is shown in Figure 15. In this embodiment the patient interface is a full face mask 140 that extends over a user's nose and mouth and under the user's chin in use. The mask 140 has a body 142 made from a substantially rigid plastics material and a cushion 144 made from a substantially soft plastics material. The mask and cushion are preferably similar to that described in more detail in United States patent application number 11/368004, the entire contents of which is incorporated herein by reference.

A tubular inlet port 143 is formed in the mask body 142. The tubing 31 is attachable to the port 143 to provide gases to the user wearing the mask.

The headgear is substantially similar to that described in relation to Figure 2 (the second form); however, the curved member 141 differs. The curved member 141 does not have a mask base similar to that described in the second form in which to attach to. Therefore, the curved member 141 has a central section 145 that curves under the inlet port 143, effectively anchoring on the inlet port. The curved member 141 is moulded in substantially the same manner as described with reference to the second form.

A seventh form of the patient interface and headgear of the present invention is shown in Figures 16 and 17. Here, the headgear and curved member is similar to that described above in the sixth embodiment, where the curved member 141 has a central section that curves under and anchors onto an inlet port 151 on a patient interface 150. The patient interface 150 is an integral mouth mask 152 and nasal pillows 153. The mouth mask 152 preferably extends under the user's 155 chin, as shown in Figure 17.

The interface 150 has a substantially rigid body 154 that has substantially soft cushion 156 attached to it. The cushion 156 is preferably of the type disclosed in United States patent number 6951218 (the entire contents of which is incorporated herein by reference) having an inner 157 and outer 158 cushions.

Integrally formed in the outer cushion 158 are nasal pillows 153. Preferably two nasal pillows 159, 160 are formed in the cushion 158. These are substantially tubular and carry gases in use from the inside of the interface 150 to the user's 155 nares. The outer cushion 158 and nasal pillows 159, 160 are preferably made from a soft pliable plastics material such as silicone but other appropriate materials such as rubber or KRATON™ may be used.

A similar but slightly different embodiment to that of Figure 16 is a ninth embodiment of the present invention, as shown in Figure 23. Here the interface 400 is substantially the same as the interface 150 of Figure 16 and 17. The interface 400 has a body 401 with integral nasal pillows 402, 403. The nasal pillows may be integrally formed with the body or separately formed and simply assembled to the body before use. The nasal pillows 402, 403, as above, are substantially tubular and carry gases in use from the inside of the interface 400 to the user's nares. Again, nasal pillows are preferably made from a soft pliable plastics material such as silicone but other appropriate materials such as rubber or KRATON™ may be used.

In this embodiment the body 401 may be made of a more rigid material than the nasal pillows or simply be made from a soft pliable plastics material as are the nasal pillows.

Attached to an inlet 404 of the body 401 is an elongate member 405 similar to that described in any of the embodiments detailed above, but particularly that of Figures 20 to 22. The elongate member 405 has arms 406, 407 that extend along a user's cheekbones then up towards the user's ears when in use. The arms 406, 407 are preferably made from a substantially rigid material, preferably a plastics material. For the users comfort each of the arms 406, 407 have inner pads (only one pad 408 is shown in Figure 23) extending along their inner sides, particularly where the arms are incident on the user's face.

The arms 406, 407 have recesses 409, 410 at there ends to which headgear straps 411, 412 are attached. The arms 406, 407 may also each have optional side hooks (of which only one side hook 413 is shown), again made out of a substantially rigid material, to which additional side headgear straps 414, 415 may be attached.

At the centre of the elongate member 405 is formed an integral inlet 416 that matches and attaches to the inlet 404 on the body. This integral inlet 416 receives a conduit or tube 417 that is connected in use to a supply of gases. Preferably the tube 417 has a swivelable elbow 418 (for example, a ball joint socket similar to the one described above). Preferably on the elbow 418 are a number of holes 419 that provide an exhaust vent for gases exhaled by the patient in use.

In this ninth embodiment of the patient interface and headgear the interface is a mouth mask and nasal pillows. In alternative forms the patient interface may be a full face mask that is attached to an elongate member and headgear similar in form to those described above and particularly in relation to Figure 23.

CLAIMS:

1. Headgear for use with a respiratory mask comprising:

a continuous and substantially curved elongate member extending in use below a patient's nose,

at least two headgear straps capable of attachment to the ends of said elongate member, and

a mask attachment on said elongate member disposed to sit below or on one of said user's nose, mouth, upper lip and an inlet to the mask, said attachment capable of receiving said mask.

2. Headgear according to claim 1 wherein said at least two straps are substantially flexible, soft straps each extending down a user's cheekbones in use and terminating at each of said strap's ends in said user's upper lip area and said a substantial portion of said elongate member is attached to each of said straps.

3. Headgear according to claim 2 wherein the length of said at least two straps that extends in use along said user's cheekbones is attached to said elongate member, said elongate member providing rigidity to said length of said at least two straps.

4. Headgear according to claim 1 wherein said elongate member has two ends each of which is attached to one of said at least two straps, said elongate member having at least one pad extending along the inner side of the elongate member in at least the areas where the elongate member is incident on said patient's cheekbones.

5. Headgear according to claim 4 wherein said at least one pad are substantially the same width as said elongate member.

6. Headgear according to any one of claims 1 to 5 wherein said continuous elongate member is substantially rigid compared to said straps.

7. Headgear according to any one of claims 1 or 6 wherein said continuous elongate

member includes two side arms and a central section.

8. Headgear according to claim 7 wherein said side arms and said central section are formed as a single item.

9. Headgear according to claim 7 or 8 wherein said at least one pad is two pads one each extending substantially along the length of each said side arm.

10. Headgear according to claim 7 wherein said side arms and said central section are formed as two separate items.

11. Headgear according to any of claims 7 to 10 wherein said side arms have at least one weakened or narrow area to allow for manipulation of said side arms.

12. Headgear according to any of claims 7 to 11 wherein a mask base is capable of frictionally fitting to said central section, such that said central section places said mask base near a breathing orifice of a user.

13. Headgear according to claim 12 wherein said mask base is integrally formed with said central section.

14. Headgear according to any of claims 1 to 13 wherein said curved elongate member is moulded in a three dimensional manner to fit the contours of said patient's cheeks.

15. A breathing assistance apparatus for use with delivery of respiratory gases to a user comprising:

a mask having a base and body, said body having two flexible nasal pillows that in use rest in a substantially sealed manner against said user's nares,

a continuous and substantially curved elongate member extending in use below a patient's nose,

at least two headgear straps capable of attachment to the ends of said elongate member, and

a mask attachment on said elongate member disposed below said user's nose, said attachment capable of receiving said mask.

16. A breathing assistance apparatus according to claim 15 wherein said at least two straps are substantially flexible, soft straps each extending down a user's cheekbones in use and terminating at each of said strap's ends in said user's upper lip area and said a substantial portion of said elongate member is attached to each of said straps.

17. A breathing assistance apparatus according to claim 15 wherein the length of said at least two straps that extends in use along said user's cheekbones is attached to said elongate member, said elongate member providing rigidity to said length of said at least two straps.

18. A breathing assistance apparatus according to claim 15 wherein said elongate member has two ends each of which is attached to one of said at least two straps, said elongate member having at least one pad extending along the inner side of the elongate member in at least the areas where the elongate member is incident on said patient's cheekbones.

19. A breathing assistance apparatus according to claim 18 wherein said at least one pad are substantially the same width as said elongate member.

20. A breathing assistance apparatus according to any one of claims 15 to 19 wherein said continuous elongate member is substantially rigid compared to said straps.

21. A breathing assistance apparatus according to any one of claims 15 or 20 wherein said nasal pillows are substantially elliptical and have gases outlets that are offset from the centre of said elliptical pillows.

22. A breathing assistance apparatus according to one of claims 15 to 22 wherein said breathing assistance apparatus includes humidification means adapted to, in use, be in fluid communication with said source of gases and said transportation means and adapted to in use humidify said gases.

23. A breathing assistance apparatus according to any one of claims 15 to 22 wherein said continuous elongate member includes two side arms and a central section.

24. A breathing assistance apparatus according to claim 23 wherein said side arms and said central section are formed as a single item.

25. A breathing assistance apparatus according to claim 23 wherein said side arms and said central section are formed as two separate items.

26. A breathing assistance apparatus according to claim 18 wherein said at least one pad is two pads one each extending substantially along the length of each said side arm.

27. A breathing assistance apparatus according to any of claims 23 to 26 wherein said side arms have at least one weakened or narrow area to allow for manipulation of said side arms.

28. A breathing assistance apparatus according to any of claims 23 to 27 wherein said base frictionally fits to said central section, and said body to said base, such that said central section suspends said base below said user's nares, and when said body is attached to said base, said nasal pillows rest against said user's nares.

29. A breathing assistance apparatus according to any of claims 23 to 28 wherein said base is integrally formed with said central section.

30. A breathing assistance apparatus according to any of claims 23 to 29 wherein said side arms attach one to each side of said base.

31. A breathing assistance apparatus according to any of claims 15 to 30 wherein said curved elongate member is moulded in a three dimensional manner to fit the contours of said user's cheeks.

32. A breathing assistance apparatus for use with delivery of respiratory gases to a user comprising:

a mask comprising a body and a cushion, said cushion substantially forming a seal with said patient's airways,

headgear comprising substantially flexible, soft straps and a substantially continuous curved elongate member to which said mask is attached, said elongate member extending over said user's cheeks, and

wherein said mask has an inlet extension tube and said curved elongate member is attached or rests beneath said inlet extension tube, anchoring said mask to said user's face in use.

33. A breathing assistance apparatus according to claim 32 wherein said continuous elongate member is substantially rigid compared to said straps.

34. A breathing assistance apparatus according to claim 32 or 33 wherein said mask is a full face mask where said body extends to cover said patient's mouth and nose.

35. A breathing assistance apparatus according to any one of claims 32 to 34 wherein said curved elongate member is moulded in a three dimensional manner to fit the contours of said user's cheeks.

36. Headgear as described herein with reference to the accompanying figures.

37. A breathing assistance apparatus as described herein with reference to the accompanying figures.

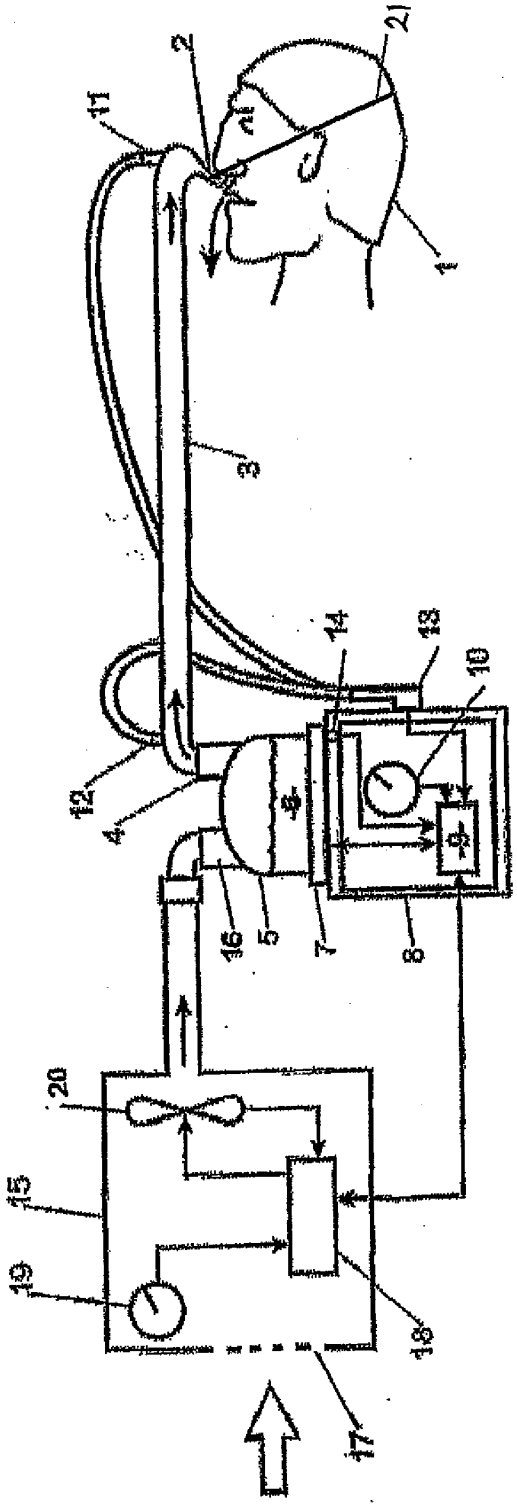

FIGURE 1

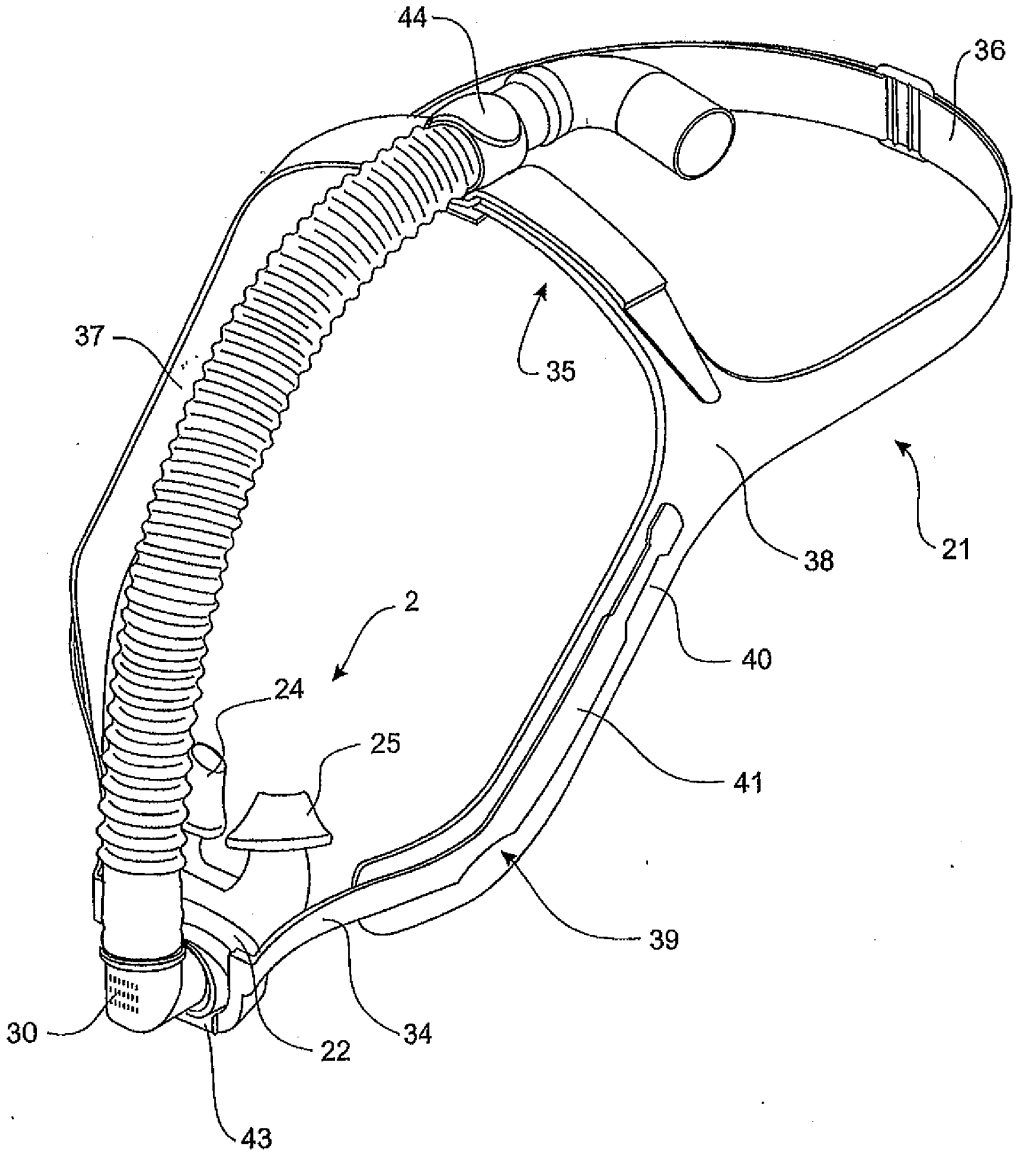

FIGURE 2

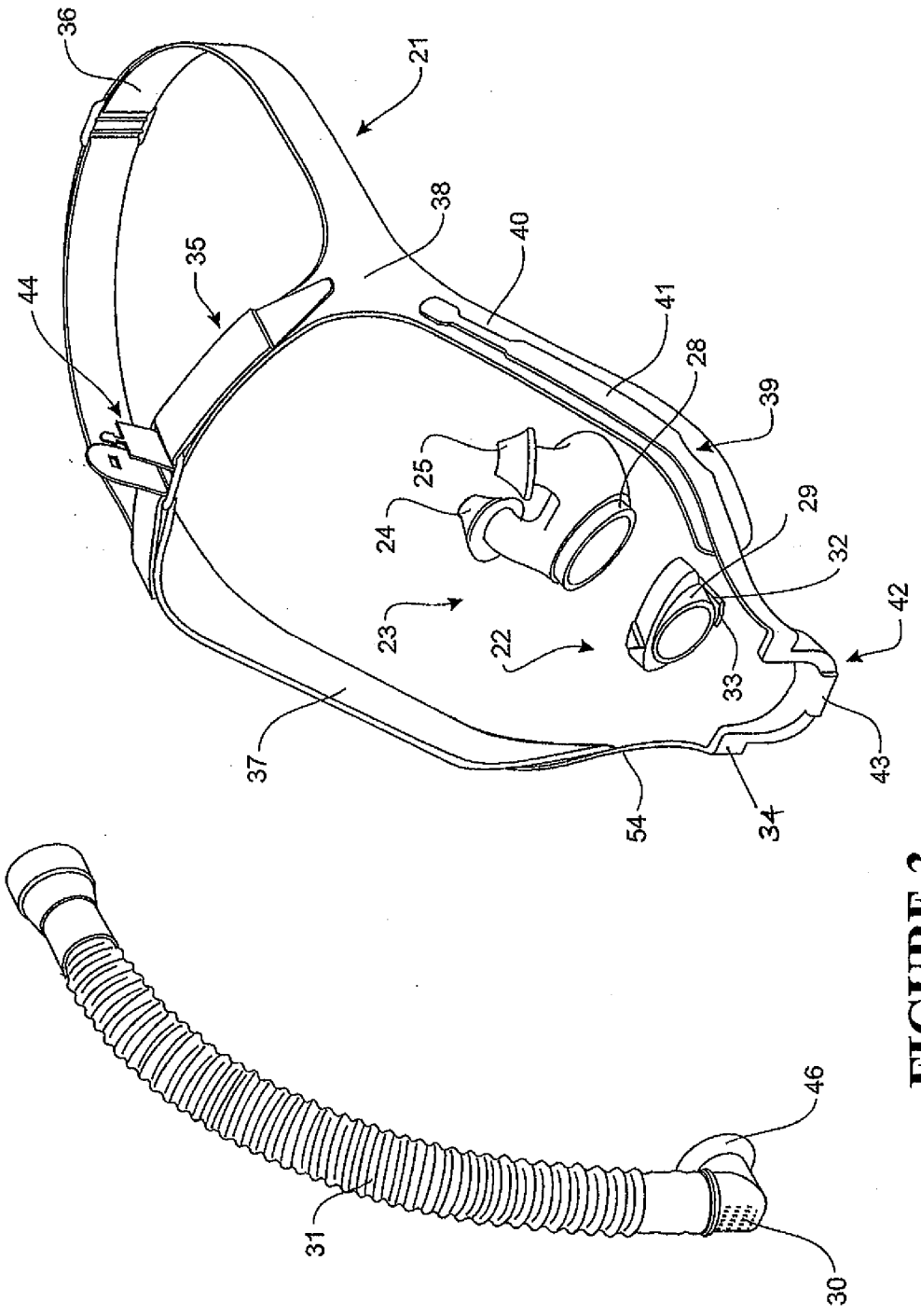

FIGURE 3

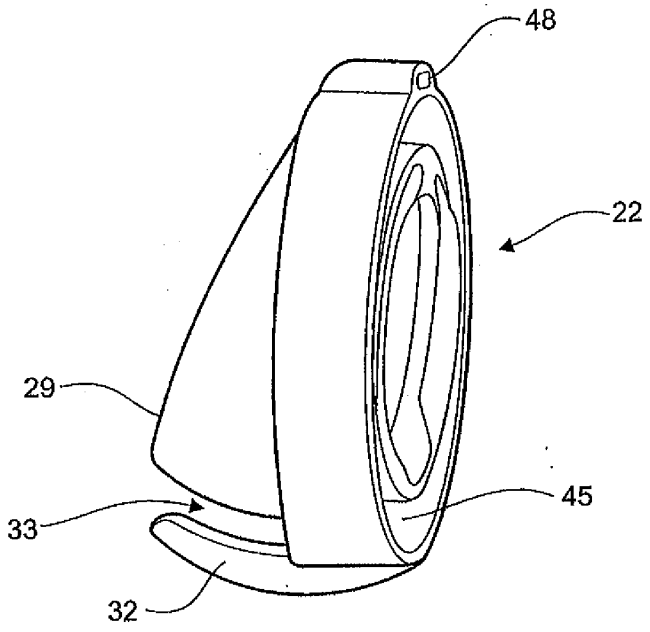

FIGURE 4

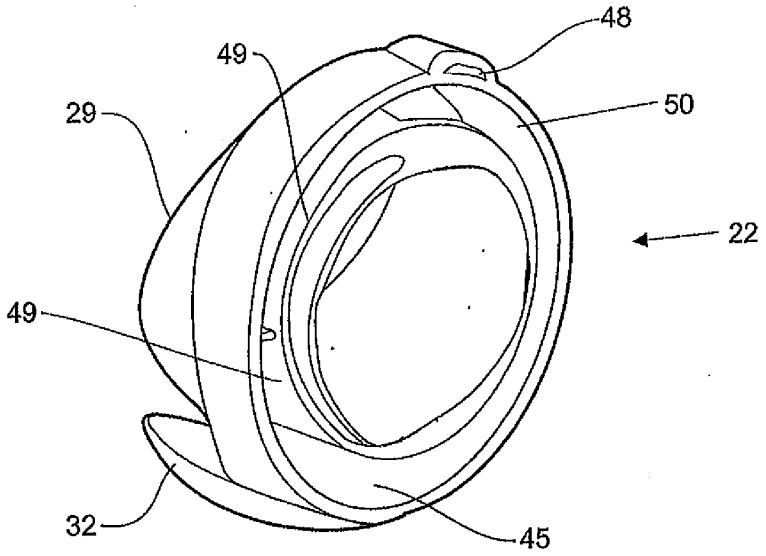

FIGURE 5

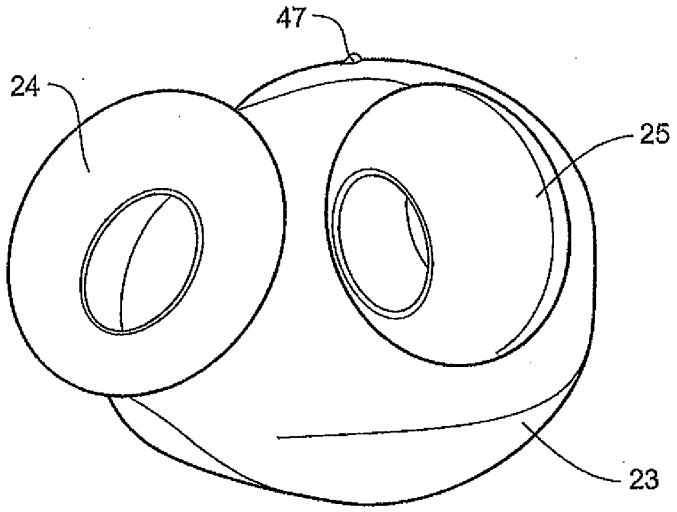

FIGURE 6

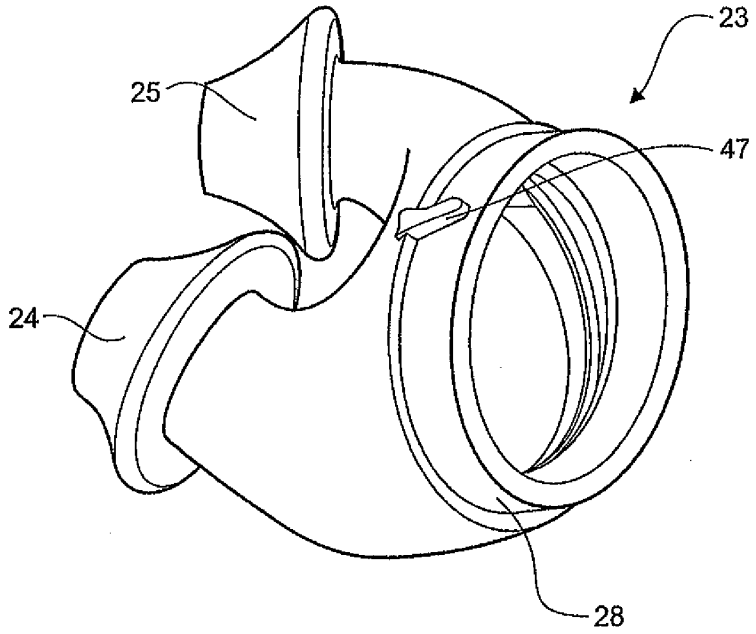

FIGURE 7

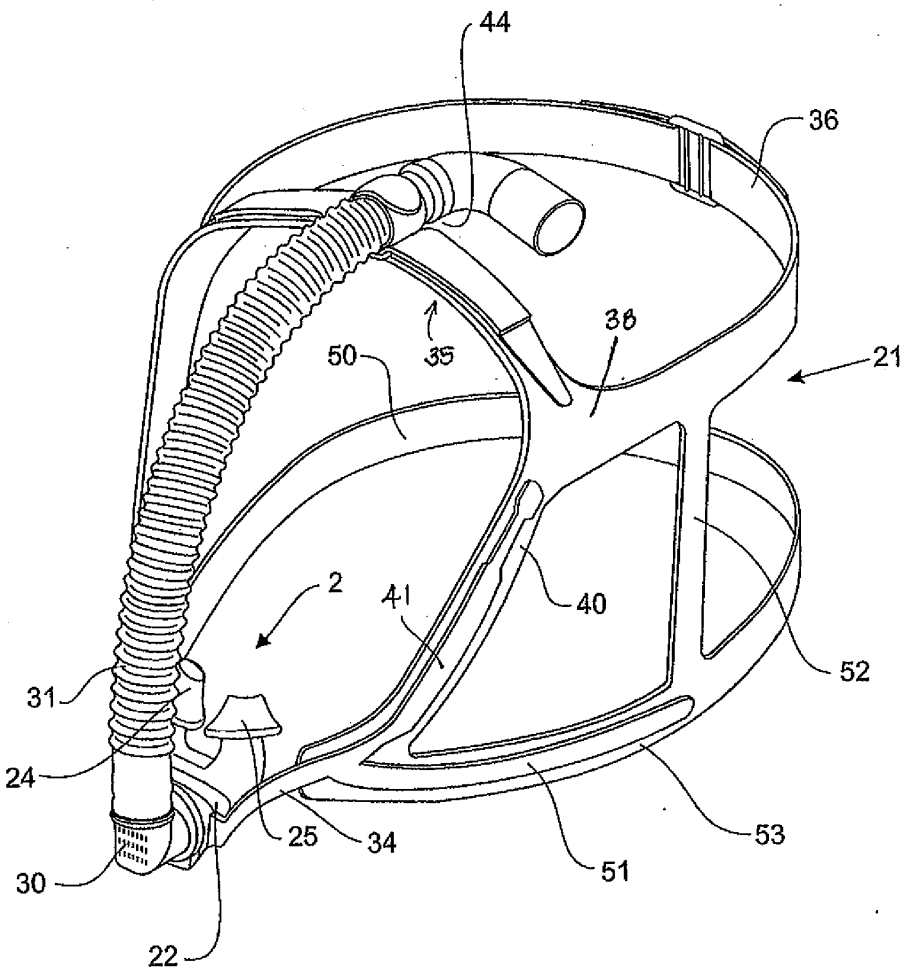

FIGURE 8

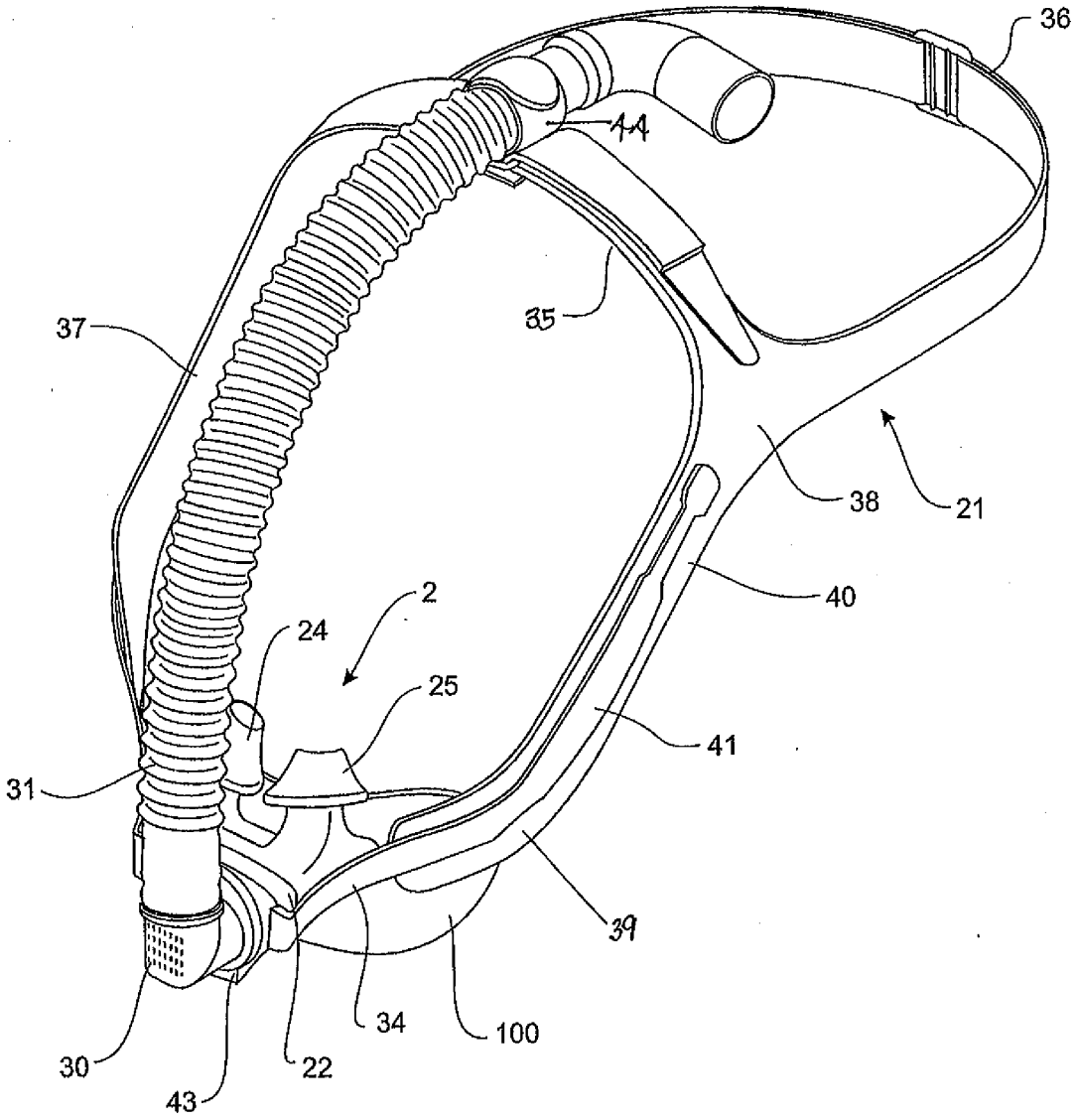

FIGURE 9

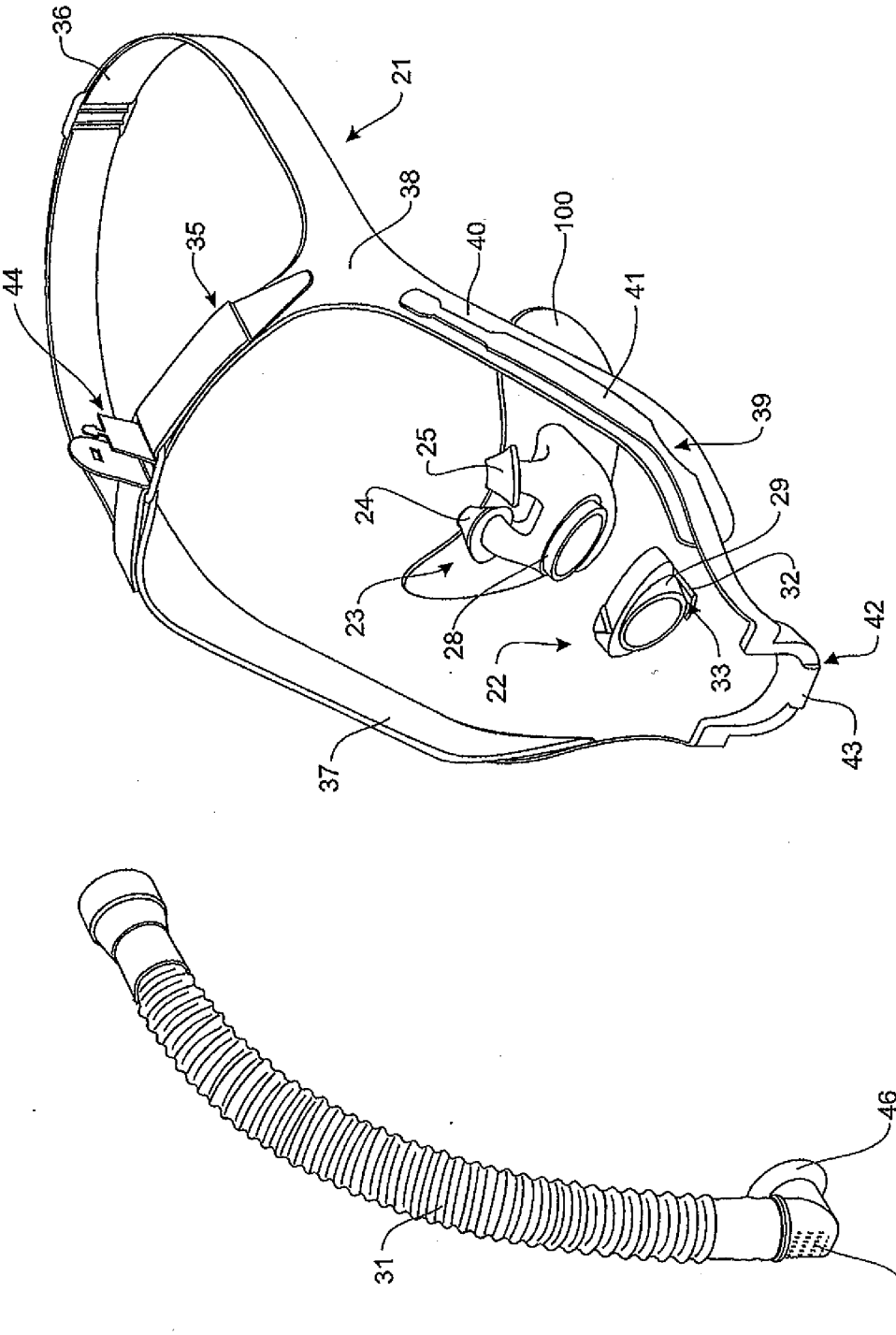

FIGURE 10

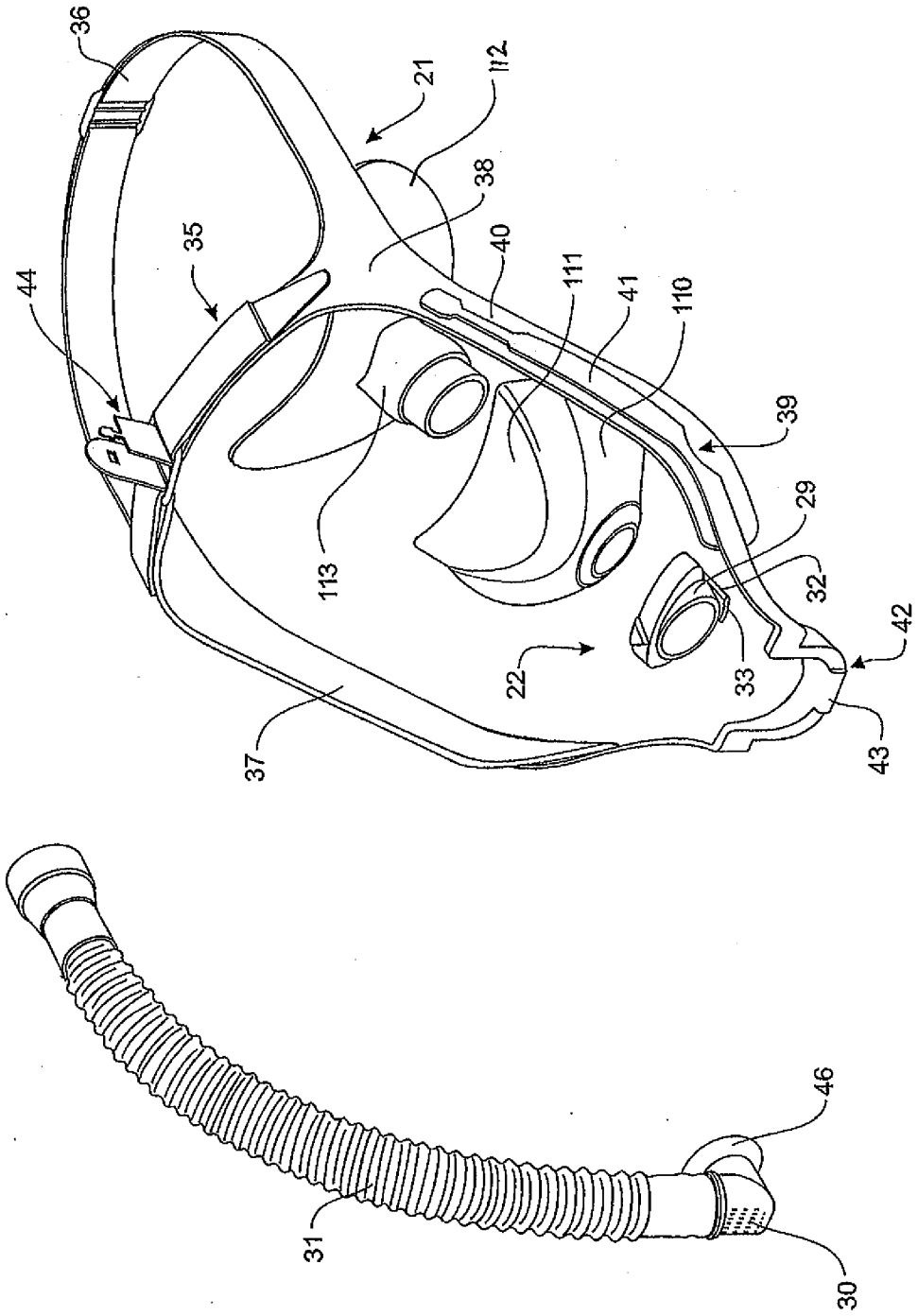

FIGURE 11

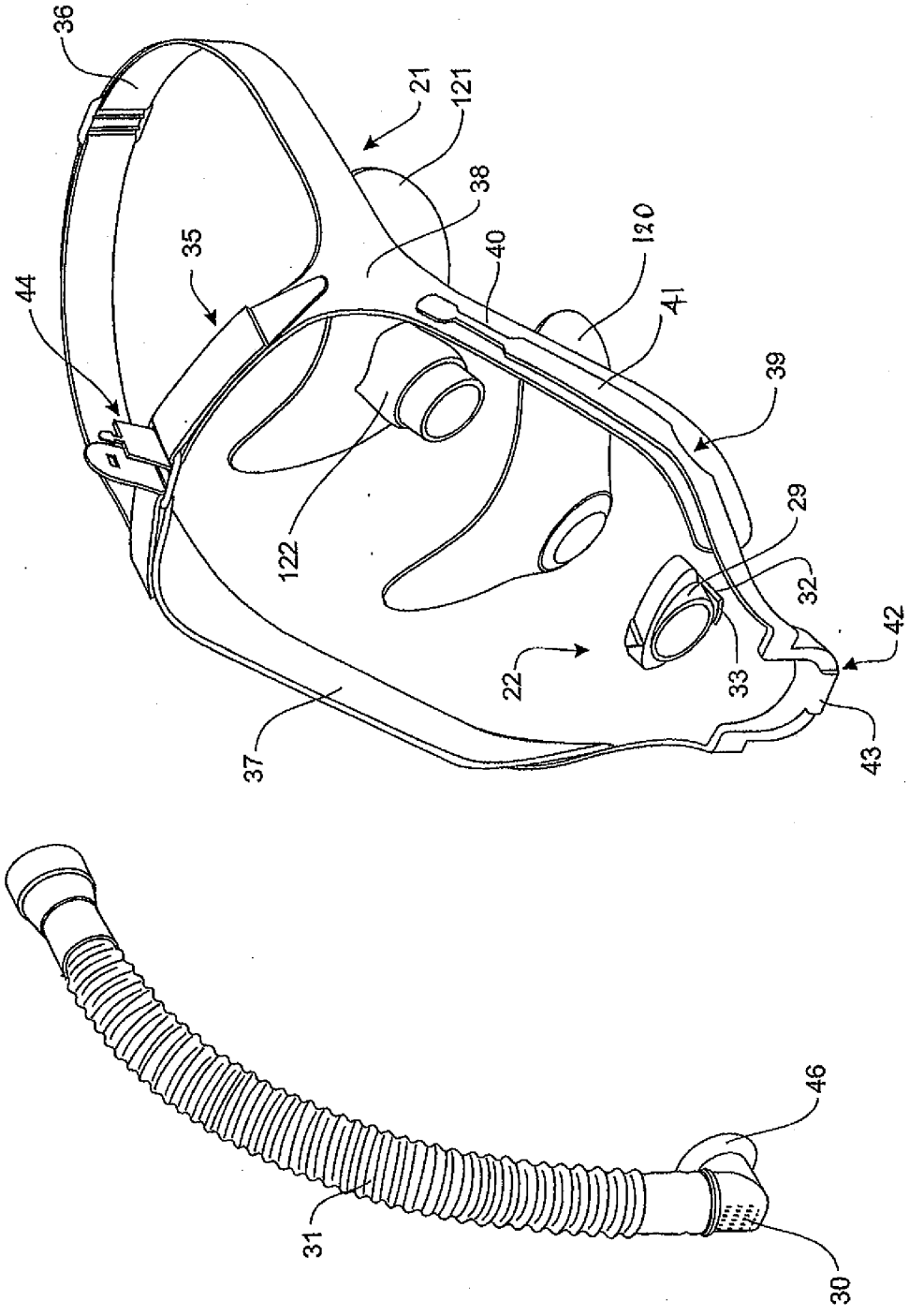

FIGURE 12

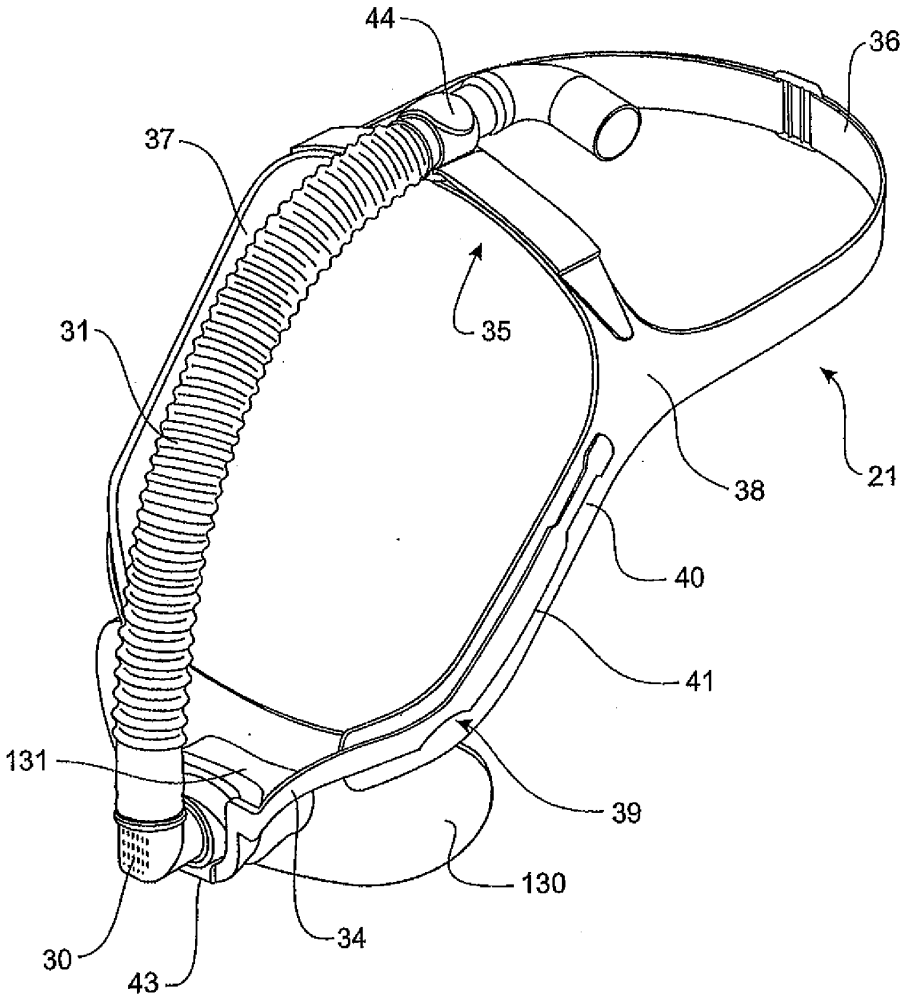

FIGURE 13

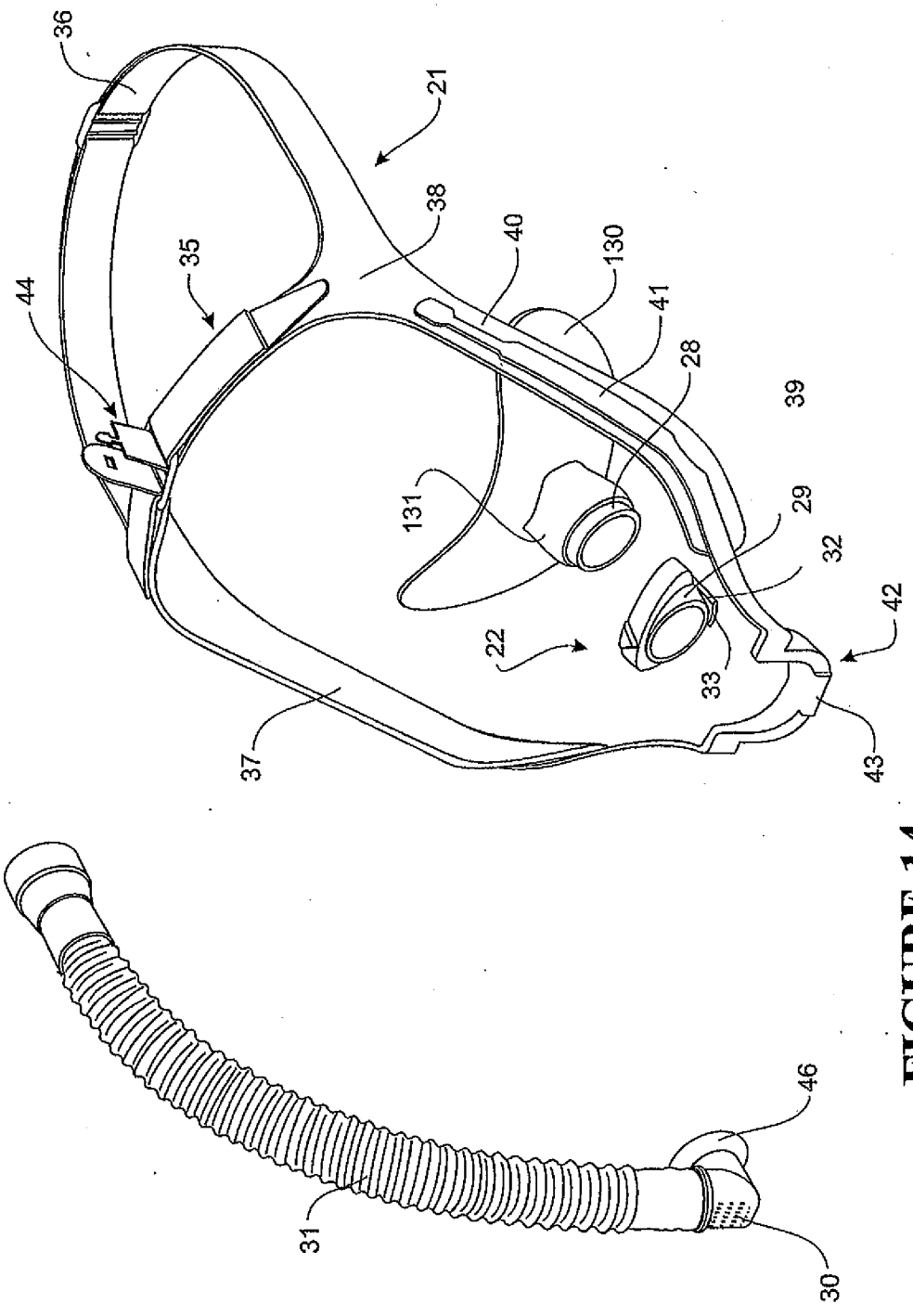

FIGURE 14

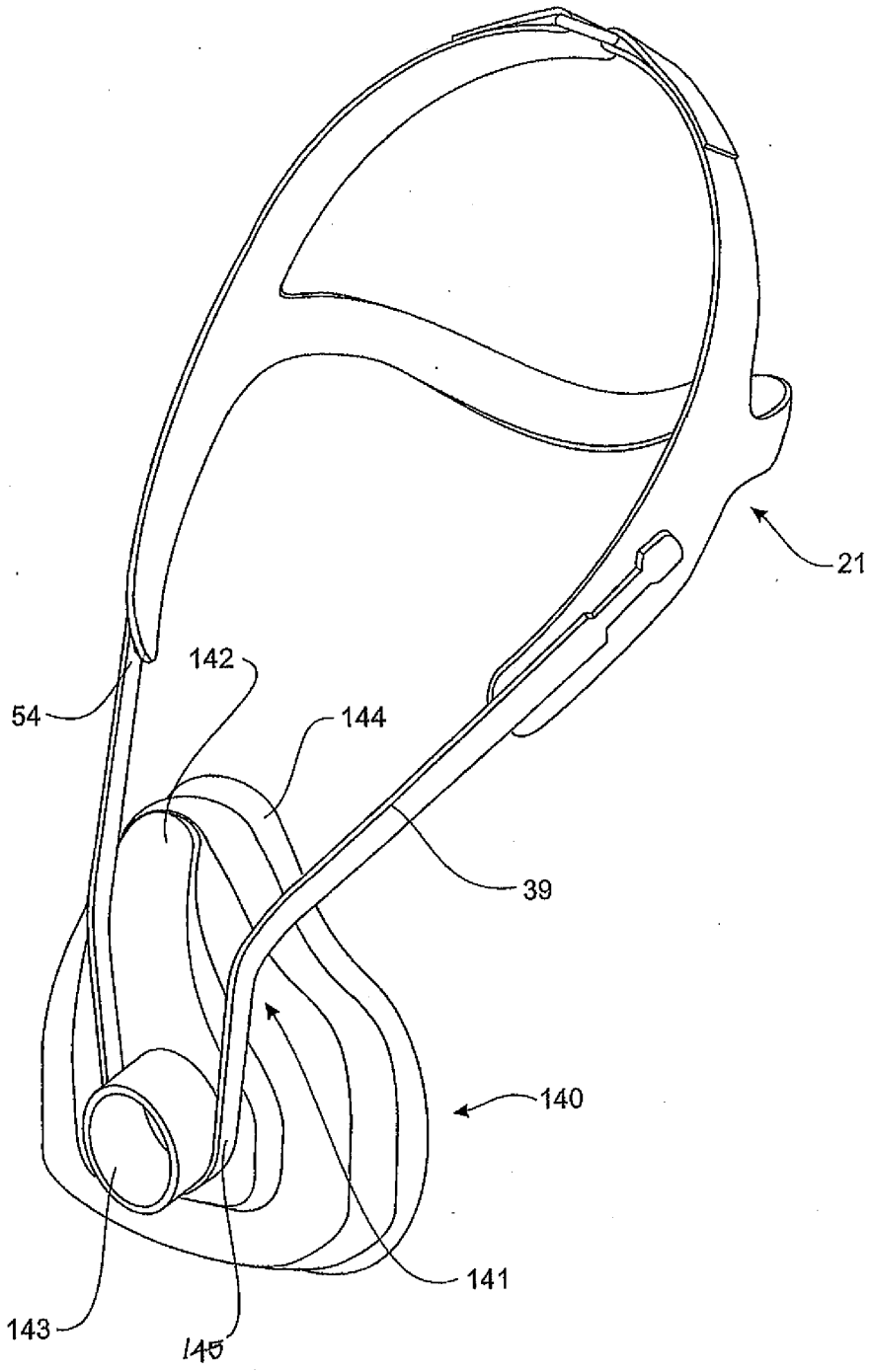

FIGURE 15

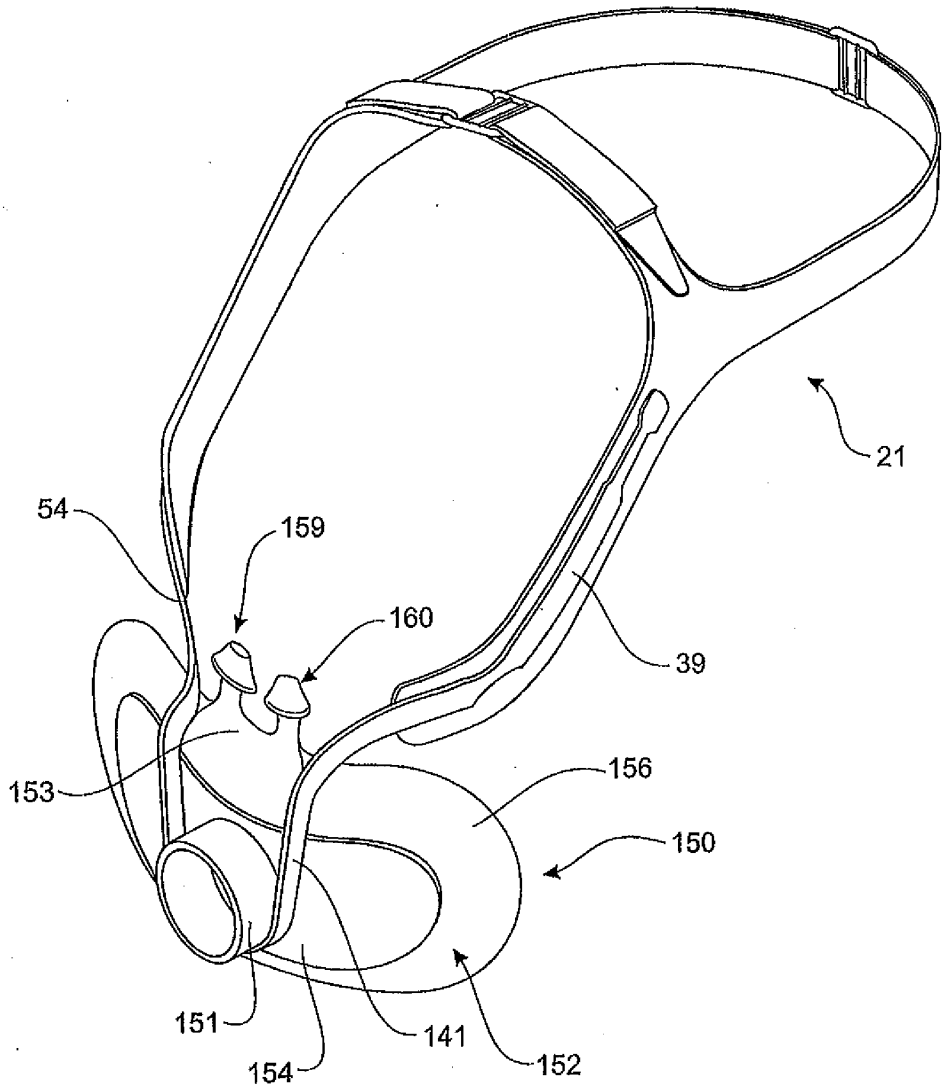

FIGURE 16

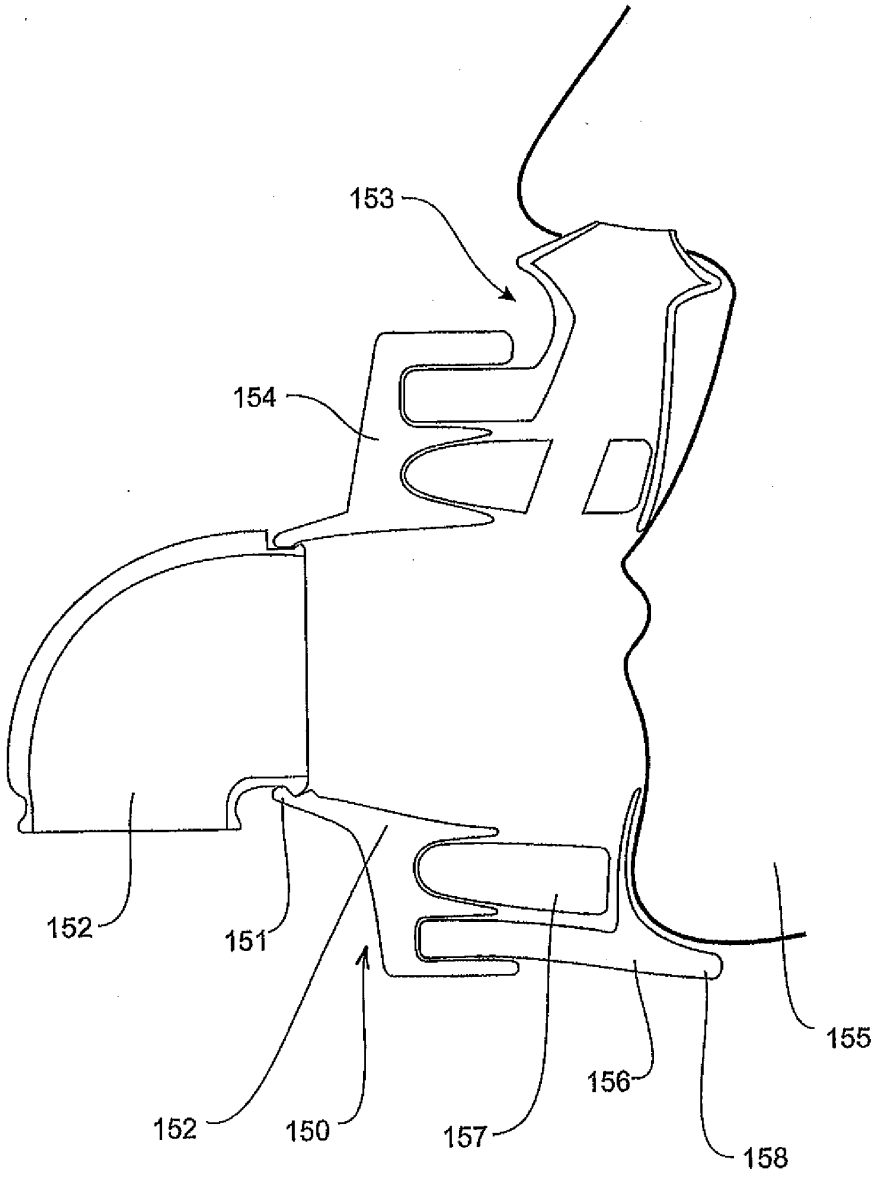

FIGURE 17

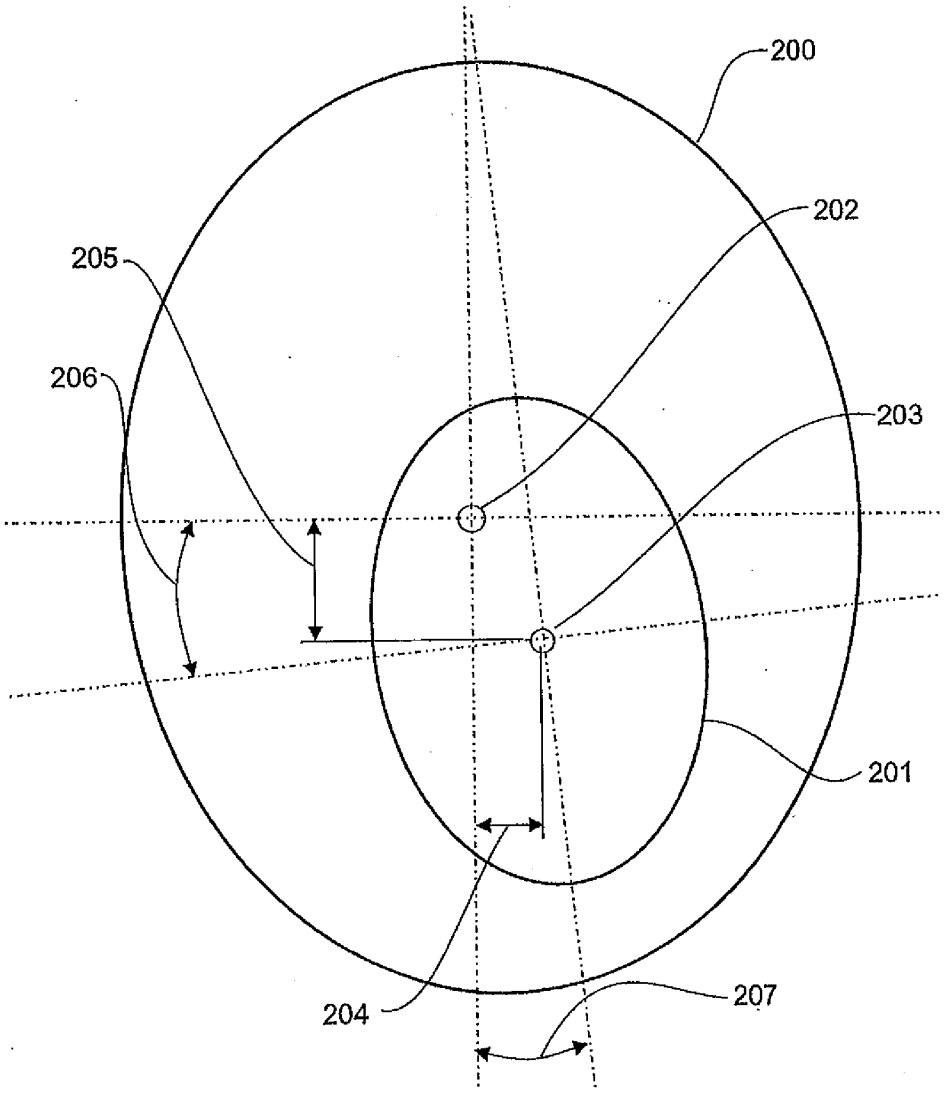

FIGURE 18

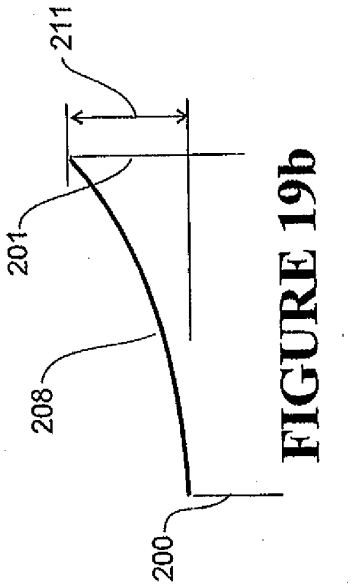

FIGURE 19b

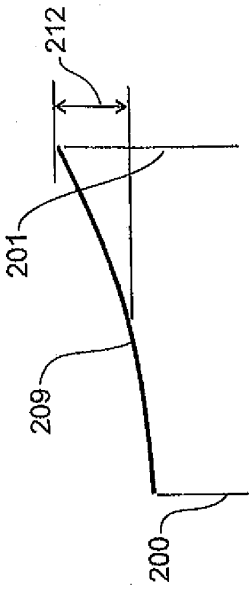

FIGURE 19c

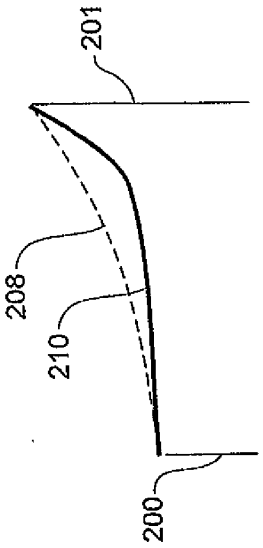

FIGURE 19d

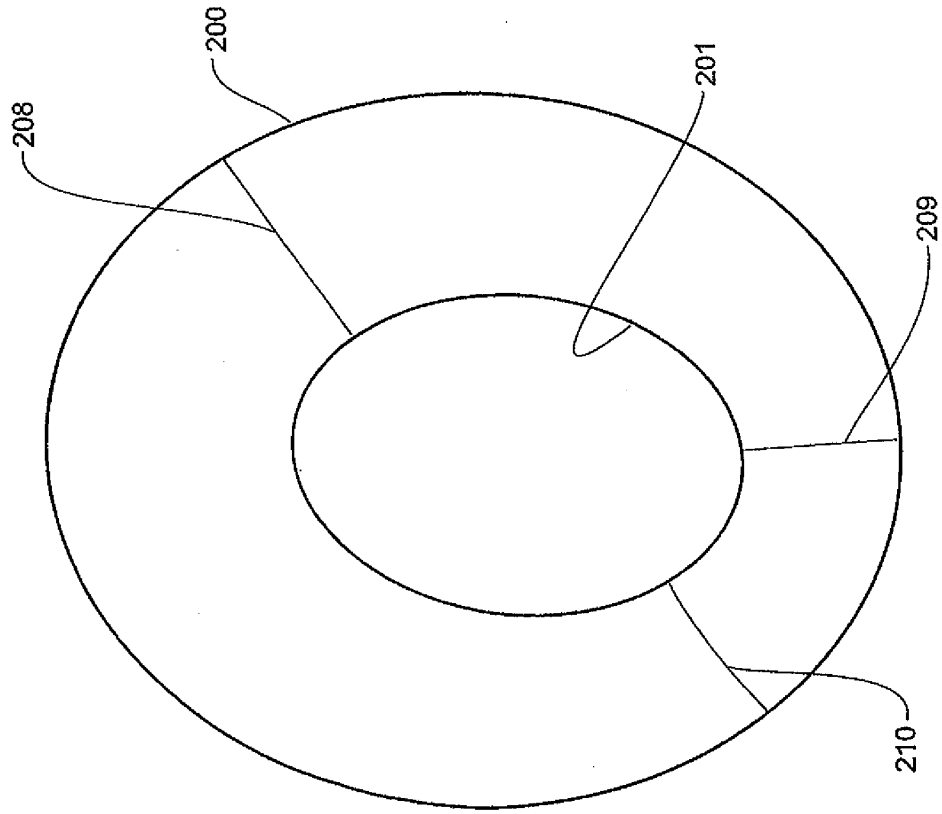

FIGURE 19a

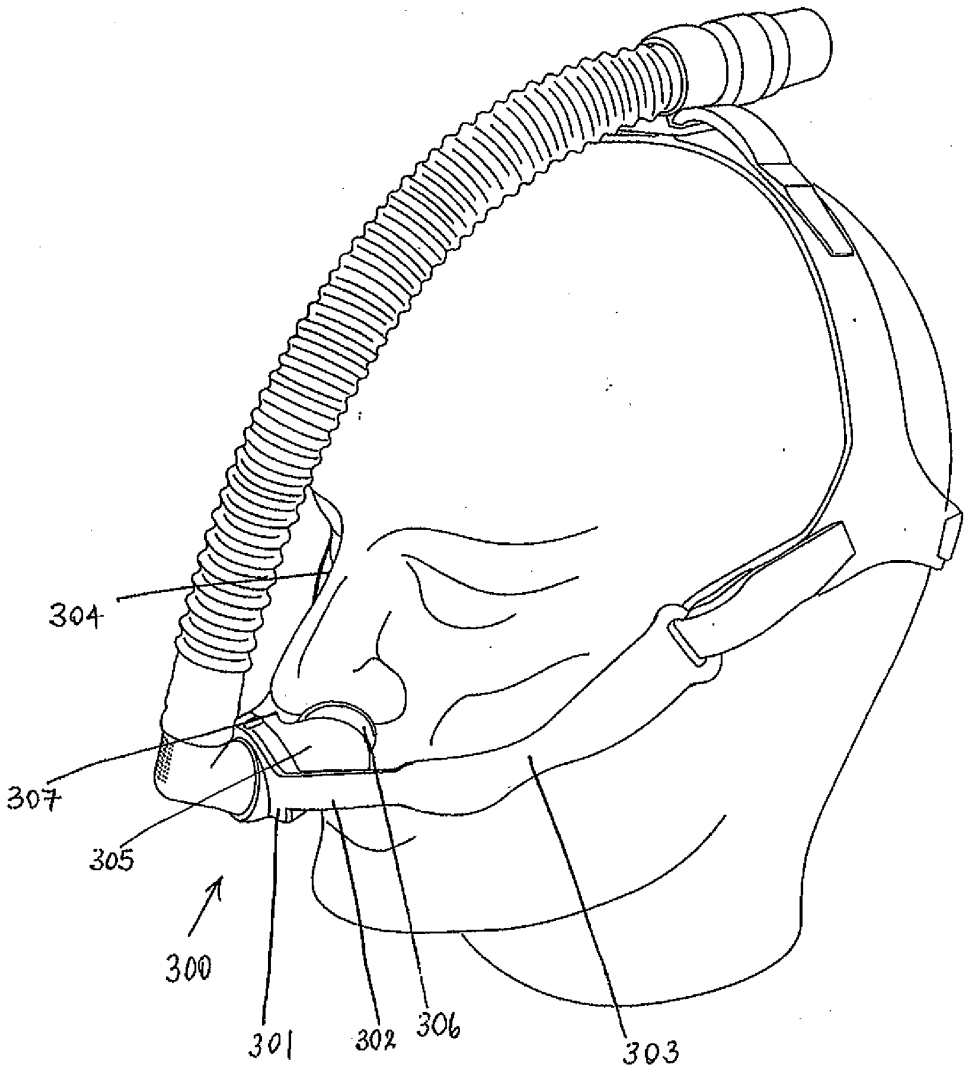

FIGURE 20

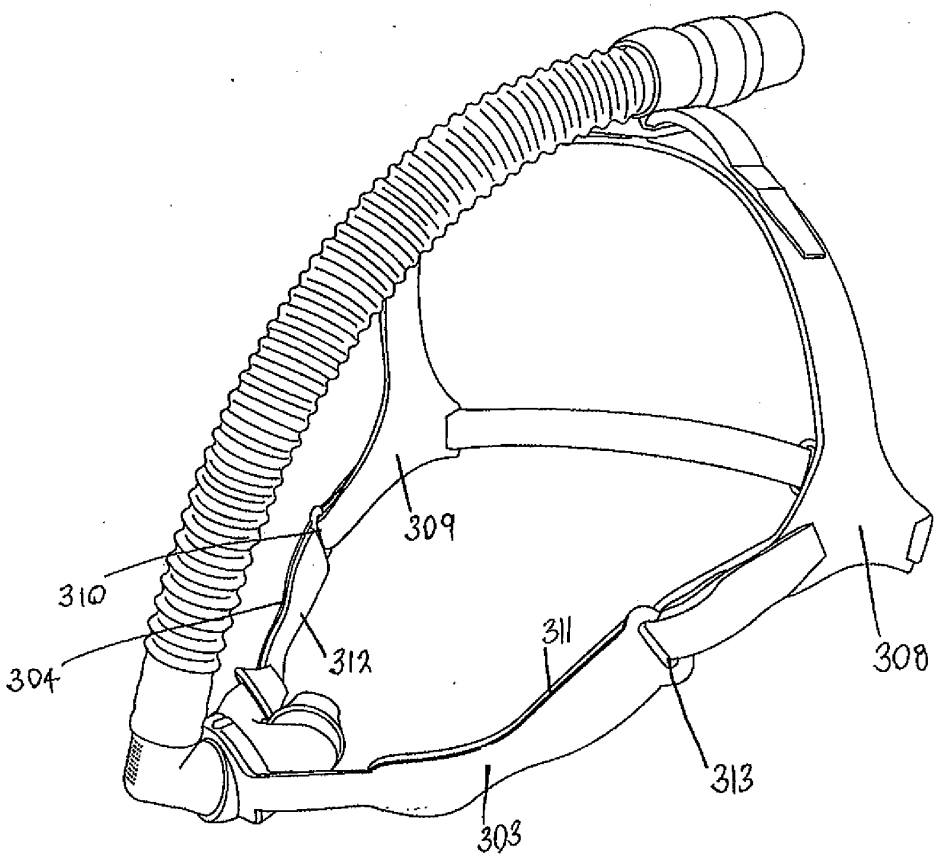

FIGURE 21

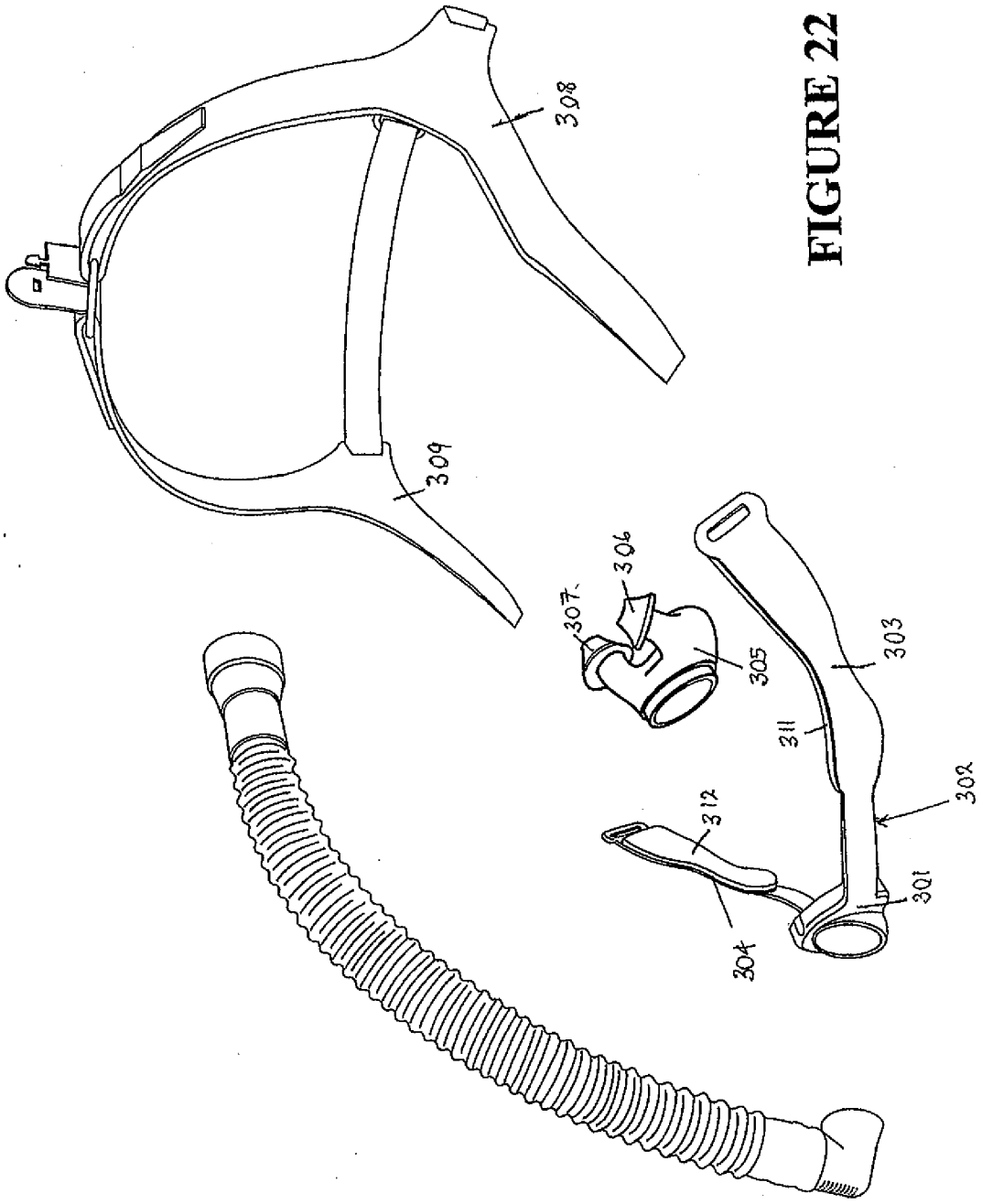

FIGURE 22

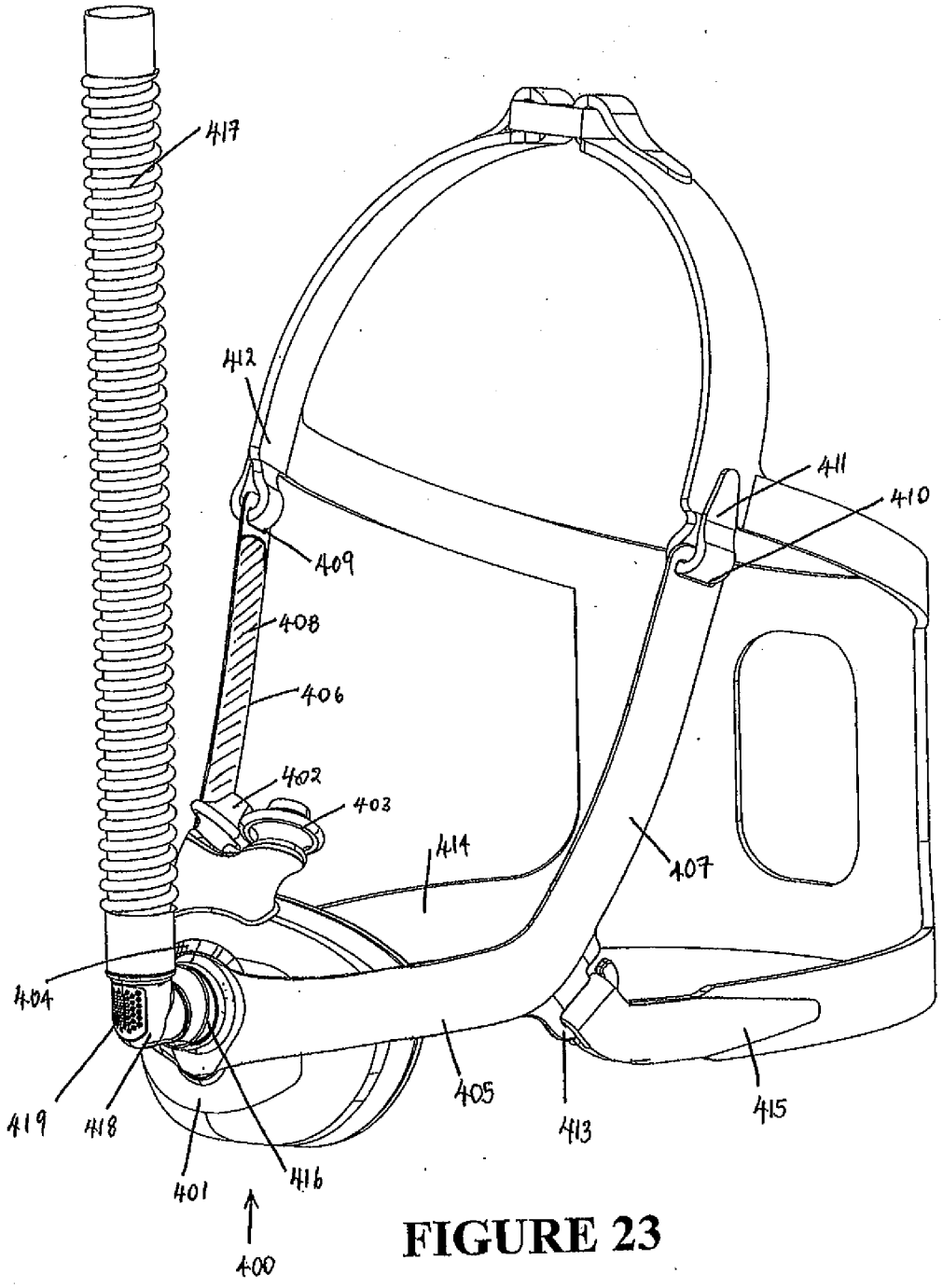
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FIGURE 23

PATENT COOPERATION TREATY

From the:
INTERNATIONAL SEARCHING AUTHORITY

To:

A J Park & Son
PO Box 949
Wellington 6001
NEW ZEALAND

PCT

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43*bis*.1)

Date of mailing *(day/month/year)*	31 OCT 2007
Applicant's or agent's file reference 561956NJC	FOR FURTHER ACTION See paragraph 2 below

International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/NZ2007/000185	13 July 2007	14 July 2006

International Patent Classification (IPC) or both national classification and IPC
Int. Cl.

A61M 16/06 (2006.01)

Applicant

FISHER & PAYKEL HEALTHCARE LIMITED et al

1. This opinion contains indications relating to the following items:

- [X] Box No. I Basis of the opinion
- [ ] Box No. II Priority
- [ ] Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- [ ] Box No. IV Lack of unity of invention
- [X] Box No. V Reasoned statement under Rule 43*bis*.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- [ ] Box No. VI Certain documents cited
- [ ] Box No. VII Certain defects in the international application
- [X] Box No. VIII Certain observations on the international application

2. **FURTHER ACTION**

If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1*bis*(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA	Date of completion of this opinion	Authorized Officer
AUSTRALIAN PATENT OFFICE PO BOX 200, WODEN ACT 2606, AUSTRALIA E-mail address: pct@ipaustralia.gov.au Facsimile No. (02) 6285 3929	26 October 2007	**DAVID MELHUISH** AUSTRALIAN PATENT OFFICE (ISO 9001 Quality Certified Service) Telephone No. (02) 6283 2426

Form PCT/ISA/237 (Cover sheet) (April 2007)

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/NZ2007/000185

Box No. I Basis of this opinion

1. With regard to the **language**, this opinion has been established on the basis of:

   [X] The international application in the language in which it was filed

   [ ] A translation of the international application into, , which is the language of a translation furnished for the purposes of international search (under Rules 12.3(a) and 23.1(b)).

2. [ ] This opinion has been established taking into account **the rectification of an obvious mistake** authorized by or notified to this Authority under Rule 91 (Rule 43*bis*.1(a))

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, this opinion has been established on the basis of:

   a. type of material

      [ ] a sequence listing
      [ ] table(s) related to the sequence listing

   b. format of material

      [ ] on paper
      [ ] in electronic form

   c. time of filing/furnishing

      [ ] contained in the international application as filed.
      [ ] filed together with the international application in electronic form.
      [ ] furnished subsequently to this Authority for the purposes of search.

4. [ ] In addition, in the case that more than one version or copy of a sequence listing and/or table(s) relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

5. Additional comments:

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

International application No.

PCT/NZ2007/000185

Box No. V **Reasoned statement under Rule 43*bis*.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

1. Statement

Novelty (N)	Claims	**11, 18, 19, 22, 26 – 28, 34, 36, 37**	YES
	Claims	**1 – 10, 12 – 17, 20, 21, 23 – 25, 29 – 33, 35**	NO
Inventive step (IS)	Claims	**11, 27, 36, 37**	YES
	Claims	**1 – 10, 12 – 26, 28 – 35**	NO
Industrial applicability (IA)	Claims	**1 – 37**	YES
	Claims		NO

2. Citations and explanations:

NOVELTY (N) Claims 1 – 10, 12 – 17, 20, 21, 23 – 25, 29 – 33, 35:

D1 – US 6119694 A

D2 – US 2003/0172936 A1

D3 – US 2004/0226566 A1

D1 discloses the features of claims 1, 4 to 9, 14, 32, 33 and 35. It discloses in figures 1 and 4 headgear for a respiratory mask comprising a curved elongate member 18 extending below a patient's nose, two headgear straps 30 and 36, and a mask attachment comprising the threaded tubes on the elongate member. The elongate member is rigid compared to the straps, is moulded to fit the patient's cheeks and also has cheek pads 116 and 118.

D2 discloses the features of claims 1, 6 to 10, 13 to 15, 20, 23 to 25, 29 to 33 and 35. Figures 2 and 6 of D2 show headgear comprising a curved elongate member 12a, straps 110 and a mask attachment 18. The elongate member 12a has integral central section and side arms, but if pads 14 are considered the side arms then they are separate items from the central section 12a.

D3 discloses the features of claims 1 to 3, 6, 7, 10, 12 to 17, 20, 21, 23, 25, 29 to 33 and 35. See figures 60, 134 and 135 for example. The elongate member is comprised of two separate side portions 592 that are connected by a central portion 528 (see figure 61). The central portion 528 has formations (eg 567) that are capable of receiving a mask 518 comprising two nasal pillows.

fig 107.

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/NZ2007/000185

Box No. VIII Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

1. Claim 13 lacks clarity because the mask base being integrally formed with the central section conflicts with claim 12, which states that the base and the central section are frictionally fitted together.

2. Claim 17 lacks clarity as it should be appended to claim 16 to give an antecedent for the straps that extend along the user's cheekbones.

3. Claim 22 lacks clarity because it is appended to itself.

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International Application No.
PCT/NZ2007/000185

Supplemental Box

In case the space in any of the preceding boxes is not sufficient.

Continuation of: BOX V

INVENTIVE STEP (IS) Claims1 – 10, 12 – 26, 28 – 35 :

Claims 1 – 10, 12 – 17, 20, 21, 23 – 25, 29 – 33, 35: As these claims lack novelty they also lack an inventive step.

Claims 15, 18 – 26, 28 – 31: D1 discloses all the features of claim 15 except that the mask has one orifice for the nose instead of two nasal pillows. However nasal pillows are known in the art, as shown by both D2 and D3. The combination of D1 with either of D2 or D3, as would be obvious to a person skilled in the art, renders claims 15, 18 to 26 and 28 to 31 non-inventive. The humidification means of claim 22 is a standard feature in breathing assistance devices.

Claim 34: The features added by this claim relates only to features that are typical in devices of this type and therefore cannot contribute to providing a patentable inventive step.

PATENT COOPERATION TREATY

PCT

INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference	FOR FURTHER ACTION	see Form PCT/ISA/220 as well as, where applicable, item 5 below.
561956NJC		
International application No.	International filing date *(day/month/year)*	(Earliest) Priority Date *(day/month/year)*
PCT/NZ2007/000185	13 July 2007	14 July 2006

Applicant

FISHER & PAYKEL HEALTHCARE LIMITED et al

This international search report has been prepared by this International Searching Authority and is transmitted to the applicant according to Article 18. A copy is being transmitted to the International Bureau.

This international search report consists of a total of 4 sheets.

☐ It is also accompanied by a copy of each prior art document cited in this report.

1. **Basis of the report**

a. With regard to the **language**, the international search was carried out on the basis of:

☒ The international application in the language in which it was filed.

☐ A translation of the international application into , which is the language of a translation furnished for the purposes of international search. (Rules 12.3(a) and 23.1(b)).

b. ☐ This international search report has been established taking into account the **rectification of an obvious mistake** authorized by or notified to this Authority under Rule 91 (Rule 43.6*bis*(a)).

c. ☐ With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, see Box No. I.

2. ☐ **Certain claims were found unsearchable** (See Box No. II).

3. ☐ **Unity of invention is lacking** (See Box No. III).

4. With regard to the **title**,

☒ the text is approved as submitted by the applicant.

☐ the text has been established by this Authority to read as follows:

5. With regard to the **abstract**,

☒ the text is approved as submitted by the applicant.

☐ the text has been established, according to Rule 38.2(b), by this Authority as it appears in Box No. IV. The applicant may, within one month from the date of mailing of this international search report, submit comments to this Authority.

6. With regard to the **drawings**,

a. the figure of the **drawings** to be published with the abstract is Figure No. 2

☒ as suggested by the applicant.

☐ as selected by this Authority, because the applicant failed to suggest a figure.

☐ as selected by this Authority, because this figure better characterizes the invention.

b. ☐ none of the figures is to be published with the abstract.

Form PCT/ISA/210 (first sheet) (April 2007)

INTERNATIONAL SEARCH REPORT

International application No.
PCT/NZ2007/000185

A. CLASSIFICATION OF SUBJECT MATTER

Int. Cl. ***A61M 16/06*** (2006.01)

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

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)
DWPI and IPC marks A61M, A62B and keywords: mask and headgear and curved and rigid and similar terms.

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
	US 6119694 A (CORREA et al.) 19 September 2000	
X	Column 4 line 53 to column 5 line 12	1,4-9,14,32, 33,35
Y		15,18-26, 28-31
	US 2003/0172936 A1 (WILKIE et al.) 18 September 2003	
X	Paragraph 68	1,6-10,13-15, 20,23-25, 29-33,35
Y		15,18-26, 28-31
	US 2004/0226566 A1 (GUNARATNAM et al.) 18 November 2004	
X	Paragraph 315	1-3,6,7,10,12-17,20,21,23, 25,29-33,35
Y		15,18-26, 28-31

[X] Further documents are listed in the continuation of Box C [X] See patent family annex

* Special categories of cited documents:

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier application or patent but published on or after the international filing date

"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)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"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

"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

"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

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
26 October 2007	31 OCT 2007

Name and mailing address of the ISA/AU	Authorized officer
AUSTRALIAN PATENT OFFICE PO BOX 200, WODEN ACT 2606, AUSTRALIA E-mail address: pct@ipaustralia.gov.au Facsimile No. (02) 6285 3929	**DAVID MELHUISH** AUSTRALIAN PATENT OFFICE (ISO 9001 Quality Certified Service) Telephone No : (02) 6283 2426

C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
P,A	WO 2007/041786 A1 (RESMED LTD) 19 April 2007 Whole document	
A	US 2006/0060200 A1 (HO et al.) 23 March 2006 Whole document	
P,A	US 2006/0196511 A1 (LAU et al.) 7 September 2006 Whole document	

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 Search Report		Patent Family Member					
US	6119694	AU	85962/98	EP	0998319	EP	1488820
		WO	9904842				
US	2003172936	AU	65690/01	EP	1292350	US	7201169
		WO	0197892				
US	2004226566	AU	2004212633	CN	1750854	EP	1603619
		US	2006137690	US	2007062539	WO	2004073778
WO	2007041786						
US	2006060200	AU	2005332069	WO	2006127031		
US	2006196511	US	7178528				

Due to data integration issues this family listing may not include 10 digit Australian applications filed since May 2001.

END OF ANNEX

(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
19 April 2007 (19.04.2007)

PCT

(10) International Publication Number
WO 2007/041786 A1

(51) International Patent Classification:
A61M 16/06 (2006.01) *A62B 9/00* (2006.01)

(21) International Application Number:
PCT/AU2006/001494

(22) International Filing Date: 12 October 2006 (12.10.2006)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
60/726,182 14 October 2005 (14.10.2005) US

(71) Applicant *(for all designated States except US)*: **RESMED LTD** [AU/AU]; 1 Elizabeth Macarthur Drive, Bella Vista, New South Wales 2153 (AU).

(72) Inventors; and

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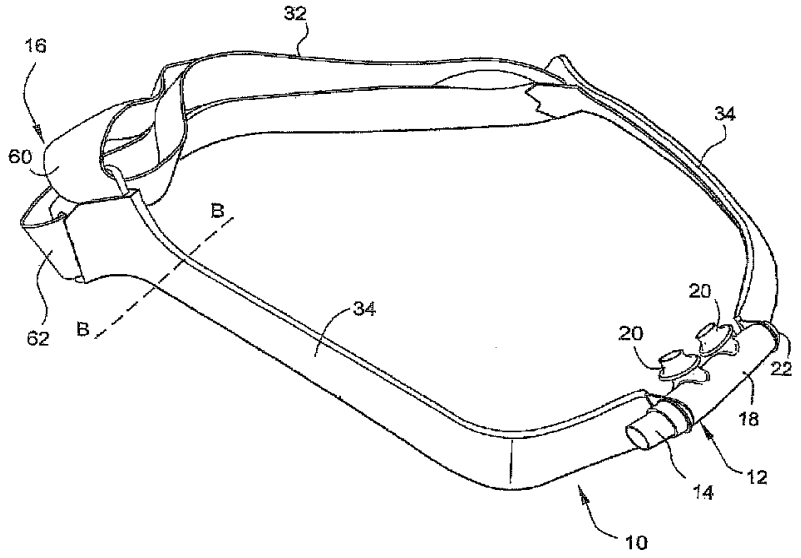
Declaration under Rule 4.17:
— *of inventorship (Rule 4.17(iv))*

[Continued on next page]

(54) Title: NASAL ASSEMBLY



(57) Abstract: A nasal assembly (10) includes a patient interface (12) including a hollow body (18) that defines an air chamber and a pair of nozzles (20) supported by the hollow body (18). Each nozzle (20) includes a conical tip (28) structured to sealingly communicate with a respective nasal passage of a patient's nose in use. Headgear (16) is provided to the patient interface (12) so as to maintain the patient interface (12) in a desired position on the patient's face in use. The hollow body (18) is bendable to adjust a position of the nozzles (20) in use.

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NASAL ASSEMBLY

CROSS REFERENCE TO APPLICATIONS

[0001] This application claims the benefit of U.S. Provisional Application No. 60/726,182, filed October 14, 2005, which is incorporated herein by reference in its entirety.

FIELD OF THE INVENTION

[0002] The present invention relates to a nasal assembly used for treatment, e.g., of Sleep Disordered Breathing (SDB) with Continuous Positive Airway Pressure (CPAP) or Non-Invasive Positive Pressure Ventilation (NPPV).

BACKGROUND OF THE INVENTION

[0003] Some nasal assemblies used in the treatment of SDB are designed for insertion into the nasal passages of the patient. Air or other breathable gas is supplied by a blower and passed along a flexible conduit to the nasal assembly.

[0004] The nasal assembly generally includes a relatively rigid shell, e.g., a frame, and a pair of nozzles (which may be in the form of nasal pillows, nasal prongs, cannula, or nasal puffs) that are mounted on the rigid shell and structured to be inserted into the nasal passages of the patient. The nozzles are usually held in place using a headgear assembly, the relatively rigid shell and headgear assembly being joined using some form of connector.

[0005] A key factor in the efficacy of therapy and compliance of patients with therapy is the comfort and fit of the nasal assembly. While there are a large number of nasal assemblies designed for adults, there are relatively few designed to suit children.

SUMMARY OF THE INVENTION

[0006] One aspect of the present invention relates to a nasal assembly suitable for children or pre-adults.

[0007] Another aspect of the present invention relates to a nasal assembly that provides comfort and softness, stability, and/or unobtrusiveness.

[0008] Another aspect of the present invention relates to a nasal assembly including a patient interface including a hollow body that defines an air chamber and a pair of nozzles supported by the hollow body. Each nozzle includes a conical tip structured to sealingly communicate with a respective nasal passage of a patient's nose in use. Headgear is provided to the patient interface so as to maintain the patient interface in a desired position on the patient's face in use. The hollow body is bendable to adjust a position of the nozzles in use.

[0009] Yet another aspect of the present invention relates to a nasal assembly including a tubular air chamber that provides at least one lateral inlet and a pair of nozzles supported by the tubular air chamber. Each nozzle includes a conical tip structured to sealingly communicate with a respective nasal passage of a patient's nose in use. The conical tip includes an outlet opening. The outlet opening has a circular shape.

[0010] Still another aspect of the present invention relates to a nasal assembly including a patient interface including a hollow body that defines an air chamber and a pair of nozzles supported by the hollow body. Each nozzle includes a conical tip structured to sealingly communicate with a respective nasal passage of a patient's nose in use. Headgear is provided to the patient interface so as to maintain the patient interface in a desired position on the patient's face in use. The patient interface contacts the patient's face only at the nose and below the nose in use.

[0011] Other aspects, features, and advantages of this invention will become apparent from the following detailed description when taken in conjunction with the accompanying drawings, which are a part of this disclosure and which illustrate, by way of example, principles of this invention.

BRIEF DESCRIPTION OF THE DRAWINGS

[0012] The accompanying drawings facilitate an understanding of the various embodiments of this invention. In such drawings:

[0013] Fig. 1 is a perspective view of a nasal assembly according to an embodiment of the present invention;

[0014] Fig. 2 is a front perspective view of the patient interface of the nasal assembly shown in Fig. 1;

[0015] Fig. 3 is a cross-sectional view of the patient interface shown in Fig. 2;

[0016] Fig. 4 is a rear perspective view of the nasal assembly shown in Fig. 1 and showing exemplary dimensions of an embodiment;

[0017] Fig. 5 is an enlarged top view of the patient interface of the nasal assembly shown in Fig. 1;

[0018] Fig. 6 is a front perspective view of the nasal assembly shown in Fig. 1 mounted to a patient's face;

[0019] Fig. 7 is a side view of the nasal assembly shown in Fig. 1 mounted to a patient's face;

[0020] Fig. 8 is a plan view of a yoke of the headgear of the nasal assembly shown in Fig. 1 and showing exemplary dimensions of an embodiment;

[0021] Fig. 9 is a plan view of a yoke ring of the yoke shown in Fig. 8; and

[0022] Fig. 10 is a schematic view of a breathing system including the nasal assembly shown in Fig. 1

DETAILED DESCRIPTION OF ILLUSTRATED EMBODIMENTS

[0023] Fig. 1 illustrates a nasal assembly 10 according to an embodiment of the present invention. As illustrated, the nasal assembly 10 includes a patient interface 12 that provides an effective seal with the patient's nasal passages, an air delivery connecting member 14, e.g., elbow, provided to one end of the patient interface 12 to deliver breathable gas into the patient interface 12 for breathing by the patient, and headgear 16 provided to the patient interface 12 so as to maintain the patient interface 12 in a desired position on the patient's face.

[0024] The overall architecture of the nasal assembly 10 is similar to the nasal assembly disclosed in U.S. Patent Application Nos. 10/781,929, filed February 20, 2004, and 11/101,657, filed April 8, 2005, the entireties of both being incorporated herein by reference. In contrast, the nasal assembly 10 is modified in size and shape for children or pre-adults in the range of 2-3 years old. However, the nasal assembly 10 may be designed for children or pre-adults in the range of 2-12 years old. Also, aspects of the present invention may be applicable to other breathing arrangements and other age groups.

1. Patient Interface

[0025] As best shown in Figs. 2 and 3, the patient interface 12 includes a hollow body or barrel 18 that defines an air chamber and a pair of nozzles 20 supported by the hollow body 18. In an embodiment, the hollow body 18 and nozzles 20 may be formed separately from one another, e.g., by silicone in an injection molding process, and then attached to one another. However, the hollow body 18 and nozzles 20 may formed as a one-piece structure such that the hollow body 18 is integrally formed in one-piece along with the nozzles 20, e.g., by silicone in an injection molding process.

1.1 Hollow Body

[0026] The hollow body or barrel 18 is in the form of a silicone cylindrical tube. In the illustrated embodiment, one end of the hollow body 18 is provided with a plug 22 and the other end is provided with a connector or retainer 24 that supports the air delivery connecting member 14. The positions of the plug 22 and connector 24 may be interchanged, according to preference, e.g., the typical sleeping position of the patient. One or more vents 90, e.g., four vent openings with 2 mm diameters, may be provided in the hollow body 18 for CO_2 washout (see Fig. 3). In the illustrated embodiment, the vents 90 are provided on a side of the hollow body 18 opposite the nozzles 20. However, other vent arrangements are possible.

1.2 Nozzles

[0027] Each nozzle 20 is in the form of a nasal prong and includes a cylindrical tube portion 26 provided to the hollow body 18 and a conical tip 28 structured to sealingly communicate with a respective nasal passage of a patient's nose in use. Each conical tip 28 has a generally cone-like shape with a flange or widened portion 30. However, the nozzles 20 may have other suitable forms to sealingly communicate with the patient's nasal passages, e.g., nasal pillows, cannula, nasal puffs.

[0028] As best shown in Figs. 4 and 5, each conical tip 28 is substantially circular in plan view to conform to a child's nasal passages and ensure substantially even loading into a child's nose. This arrangement dictates that the tube portion 26 is also circular in shape so that the load is transferred evenly to the conical tip 28.

[0029] In the illustrated embodiment, the nozzles 20 extend out from the hollow body 18 in parallel relation (see Figs. 2 and 3). However, the nozzles 20 may be angled with respect to the hollow body 18 to properly position the nozzles with respect to the nasal passages of the patient. Also, a space G is provided between the nozzles 20 to accommodate the patient's septum. As shown in Fig. 3, the spacing G may be in the range of 1-6 mm, e.g, 5.3 mm.

1.3 Hollow Body and Nozzle Flexibility

[0030] The hollow body 18, e.g., formed of silicone, is relatively flexible. This flexibility allows the hollow body 18 to bend or flex which allows adjustment of the nozzles 20 attached thereto, e.g., angle nozzles 20 with respect the patient's nose in use. The nozzles 20, e.g., formed of silicone, are also relatively flexible to properly position the nozzles 20 with the nasal passages of the patient.

[0031] The hollow body 18 may also be rotatable relative to the headgear to adjust a position of the nozzles in use. Rotation of the hollow body 18 may improve seal and comfort of the nozzles in the patient's nose in use.

1.4 Child or Pre-Adult Sizing

[0032] The hollow body 18 and nozzles 20 are suitably shaped and sized to accommodate features of a child or pre-adult, e.g., 2-12 years old, preferably 2-3 years old. For example, Fig. 3 illustrates parameters of an embodiment of the hollow body 18 and nozzles 20. In an embodiment the hollow body 18 has a wall thickness of about 1 mm, a length F of about 35-40 mm, e.g., 38 mm, an inside diameter E of about 6 mm, and an outside diameter D of about 8 mm. Each nozzle 20 has a wall thickness of about 0.5 mm, an inside diameter B at the conical tip outlet opening of about 4 mm, an inside diameter C at the tube portion of about 5 mm, and an outside diameter A at the widened portion of about 10 mm. Although specific dimensions and ranges are provided for an embodiment of the hollow body 18 and nozzles 20, it is to be understood that these dimensions and ranges are merely exemplary and other dimensions and ranges are possible depending on application.

2. Headgear

[0033] As best shown in Figs. 1, 6, and 7, the headgear 16 includes headgear straps 32 and headgear yokes 34 provided between the headgear straps 32 and the patient interface 12.

2.1 Headgear Yokes

[0034] As shown in Figs. 6 and 7, the yokes 34 extend from respective ends of the hollow body 18 to above the patient's ears where they engage the headgear straps 32. The yokes 34 provide a stable connection between the headgear straps 32 and the hollow body 18 in order to secure the patient interface 12 at the correct orientation on the patient's face.

[0035] The yokes 34 are relatively rigid elements that are each constructed from a rigid or semi-rigid material. In the illustrated embodiment, the yokes 34 are manufactured of a relatively rigid or stiff plastic or metal material, e.g., polycarbonate or nylon, having a thickness of 0.8 mm. However, other materials of greater or less rigidity are also possible. Also, the yokes 34 may be constructed from multiple layers, e.g., two or more layers (one of which may be silicone based, for comfort), or may be constructed from a single layer of substantially rigid material. In general, the yokes 34 are constructed of a material that will retain its shape in use.

[0036] The inside surface of each yoke 34, i.e., the surface facing the patient's face in use, may be lined with foam. In an embodiment, the entire yoke 34 may be wrapped in foam. The foam provides a soft contact surface for contacting the patient's face. In an embodiment, the foam may be a nitrogen blow medical grade open celled foam, e.g., PEBA Foam 0.8 mm manufactured by ALVEO.

[0037] In an alternative embodiment, the yokes may be provided by a bendable wire covered with cloth, foam, leather, etc. The bendable wire may be bent or adjusted to correspond with the facial contour of the patient.

2.1.1 Yoke Shape and Sizing

[0038] Each yoke 34 includes upper and lower ladder locks 36, 38 at one end for attachment to the headgear straps 32 (e.g., see Fig. 7), and a yoke ring 40 at the opposite end for attachment to the hollow body 18 (e.g., see Figs. 2-6 and 9).

[0039] As illustrated, each yoke 34 has a bent or curved configuration along its length. Specifically, each yoke 34 has an approximate right angle bend (as indicated by arrow A) from the yoke ring 40 so that a portion 42 of each yoke 34 extends generally parallel with a longitudinal axis of the hollow body 18, as best shown in Fig. 4. Then, each yoke 34 is curved from the bent portion 42 so that it will curve around the patient's cheeks in use. As shown in Fig. 4, each of the yokes 34 makes an angle of about 120° with respect to the longitudinal axis of the hollow body 18. Preferably, the yokes 34 are spaced from the patient's cheeks in use, and only the conical tips 28 and a central portion of the hollow body 18 contact the patient's face in use. That is, the yokes 34 are contoured such that the yokes 34 do not contact the patient's face from the yoke ring 40 to the line B-B adjacent the patient's ears in use (see Fig. 1). However, one or more portions of the yokes 34 could potentially contact the patient's face if extra support were needed.

[0040] The yokes 34 are suitably shaped and sized to accommodate features of a child or pre-adult, e.g., 2-12 years old, preferably 2-3 years old. For example, Fig. 8 illustrates exemplary dimensions of an embodiment of a yoke 34. Although specific dimensions of the yoke 34 are shown in Fig. 8, it is to be understood that these dimensions are merely exemplary and other dimensions are possible depending on application.

2.1.2 Yoke Connection to Patient Interface

[0041] The plug 22 and connector 24 are adapted to connect the yokes 34 to the hollow body 18. As best shown in Fig. 3, the plug 22 includes a tube portion 44 and a head portion 46. The plug 22 is engaged with one yoke 34 by inserting the tube portion 44 through the opening 48 (e.g., see Fig. 9) in the yoke ring 40. The plug 22 is then engaged with an end of the hollow body 18 by inserting the tube portion 44 into an end of the hollow body 18 such that the protrusion 50 provided on the tube portion 44 interacts with a groove 52 provided in the hollow body 18 for sealing and/or locking purposes. Moreover, the head portion 46 of the plug 22 and the end of the hollow body 18 sandwich the yoke ring 40 therebetween to secure the yoke ring 40 to the hollow body 18.

[0042] Similarly, the connector 24 includes a first tube portion 54, a flange 56, and a second tube portion 58. The connector 24 is engaged with the other yoke 34 by inserting the first tube portion 54 through the opening 48 in the yoke ring 40. The connector 24 is then

engaged with the other end of the hollow body 18 by inserting the first tube portion 54 into the other end of the hollow body 18. The first tube portion 54 may be retained to the other end of the hollow body 18, e.g., by friction fit, adhesive, mechanical interlock, etc. Moreover, the flange 56 of the connector 24 and the other end of the hollow body 18 sandwich the yoke ring 40 therebetween to secure the yoke ring 40 to the hollow body 18. The second tube portion 58 is adapted to connect to the air delivery connecting member 14, e.g., by friction fit, adhesive, mechanical interlock, etc.

[0043] In use, the yoke rings 40 may rotate on the respective plug 22/connector 24 to adjust the position of the yokes 34 with respect to the hollow body 18. Also, as noted above, the positions of the plug 22 and connector 24 may be interchanged according to preference.

2.2 Headgear Straps

[0044] As best shown in Figs. 1 and 7, the straps 32 include an upper strap portion 60 provided between the upper ladder locks 36 of the yokes 34, and a lower strap portion 62 provided between the lower ladder locks 38 of the yokes 34. In use, the upper strap portion 60 extends over the top of the patient's head and the lower strap portion 62 extends around the back of the patient's head.

[0045] The strap portions 60, 62 may be connected to respective ladder locks 36, 38 in any suitable manner, e.g., wrapped around respective ladder locks 36, 38 in a known manner. Fastening of the strap portions 60, 62 may be provided by a hook and loop material, e.g., Velcro®. However, other adjustment arrangements are possible.

3.0 Connecting Member and Air Delivery Tubing

[0046] As schematically shown in Fig. 10, a small bore tube 70 is connected to the patient interface 12 via the air delivery connecting member 14. The air delivery connecting member 14 may be an elbow that provides an angle, e.g., in the range of 5-90°. However, the air delivery connecting member 14 may be a straight connecting tube. The small bore tube 70 is communicated, e.g., via a connector 72, with a larger bore tube 74 associated with the flow generator 76. In use, the flow generator 76 provides pressurized air, e.g., in the range of 4-10 cmH_2O, to the patient interface via the tubes 70, 74.

[0047] In the illustrated embodiment, the small bore tube 70 has substantially the same diameter as the hollow body 18 of the patient interface 12, e.g., 6 mm inside diameter. The small bore tube 70 may have a length of 15-25 mm, e.g., 24 mm. The larger bore tube 74, e.g., 22 mm inside diameter, may have a length of 20-30 mm, e.g., 20 mm.

4.0 Children or Pre-Adult Use of Nasal Assembly

[0048] The nasal assembly 10 includes several features that facilitate use for children or pre-adults. For example, the nasal assembly 10 is structured such that only the conical tips 28 and a central portion of the hollow body 18 may contact the patient's face in use. That is, the patient interface 12 contacts the patient's face at the nose and below the nose only. This arrangement makes the nasal assembly 10 non-obtrusive so it doesn't apply pressure to regions of the patient's face that may lead to discomfort.

[0049] Another feature is the circular configuration of the nozzles 20. This arrangement more closely follows the shape of children's nasal passages which are more circular than elliptical for example.

[0050] Yet another feature is the flexibility of the hollow body 18 which facilitates adjustment of the nozzles 20.

[0051] Still another feature is that the parameters of the patient interface 12 and headgear 16 are sized and/or shaped to accommodate features of a child or pre-adult. In addition, the smaller bore air delivery tube 70, e.g., 6 mm vs. larger 15 mm provided in known nasal assemblies, provides air pressure at a level suitable for children or pre-adults, e.g., 4-10 cmH_2O.

[0052] The nasal assembly provides an interface having comfort and softness, stability, and unobtrusiveness. In an embodiment, comfort and softness may be enhanced by including a textile sock or covering around at least a portion of the assembly and/or a yoke constructed of or covered with a silicone material. In an embodiment, stability may be enhanced by including headgear having a bonnet design, e.g., headgear formed with a cupping portion at the back to better grip the occipital region of the child's head. In the illustrated embodiment, the nasal assembly is unobtrusive because it does not cover the eyes of a child or pre-adult. In an embodiment, unobtrusiveness may be enhanced by providing an air delivery connecting member or inlet tube that is integral with the above-noted silicone yoke,

that extends up to a manifold provided at the top/back of a patient's head, that is collapsible (such as collapsible conduit headgear described in PCT Publication No. WO 2005/099801, published October 27, 2005, the entirety of which is incorporated herein by reference), that is not collapsible, that is unattached to the headgear except where it meets the patient interface, and/or that is attached to the headgear at any point along the headgear.

[0053] While the invention has been described in connection with what are presently considered to be the most practical and preferred embodiments, it is to be understood that the invention is not to be limited to the disclosed embodiments, but on the contrary, is intended to cover various modifications and equivalent arrangements included within the spirit and scope of the invention. Also, the various embodiments described above may be implemented in conjunction with other embodiments, e.g., aspects of one embodiment may be combined with aspects of another embodiment to realize yet other embodiments. In addition, while the invention has particular application to patients who suffer from OSA, it is to be appreciated that patients who suffer from other illnesses (e.g., congestive heart failure, diabetes, morbid obesity, stroke, barriatric surgery, etc.) can derive benefit from the above teachings. Moreover, the above teachings have applicability with patients and non-patients alike in non-medical applications.

WHAT IS CLAIMED IS:

1. A nasal assembly, comprising:

a patient interface including a hollow body that defines an air chamber and a pair of nozzles supported by the hollow body, each nozzle including a conical tip structured to sealingly communicate with a respective nasal passage of a patient's nose in use; and

headgear provided to the patient interface so as to maintain the patient interface in a desired position on the patient's face in use,

wherein the hollow body is bendable to adjust a position of the nozzles in use.

2. The nasal assembly according to claim 1, wherein the patient interface and headgear are sized and shaped for children or pre-adults in the range of 2-12 years old.

3. The nasal assembly according to any one of claims 1-2, wherein the patient interface and headgear are sized and shaped for children or pre-adults in the range of 2-3 years old.

4. The nasal assembly according to any one of claims 1-3, wherein the hollow body and nozzles are formed of silicone.

5. The nasal assembly according to any one of claims 1-4, wherein the hollow body and nozzles are formed separately from one another and then attached to one another.

6. The nasal assembly according to any one of claims 1-5, wherein each nozzle includes a cylindrical tube provided to the hollow body that supports the conical tip.

7. The nasal assembly according to any one of claims 1-6, wherein the conical tip includes an outlet opening, the outlet opening having a circular shape.

8. The nasal assembly according to claim 7, wherein the outlet opening has an inside diameter of about 4 mm.

9. The nasal assembly according to any one of claims 1-8, wherein the conical tip includes a widened portion having an outside diameter of about 10 mm.

10. The nasal assembly according to any one of claims 1-9, wherein the hollow body has an inside diameter of about 6 mm.

11. The nasal assembly according to any one of claims 1-10, wherein one end of the hollow body is provided with a plug and the other end is provided with a connector that supports an air delivery connecting member.

12. The nasal assembly according to claim 11, wherein positions of the plug and connector may be interchanged.

13. The nasal assembly according to any one of claims 1-12, wherein the headgear includes headgear straps and relatively rigid headgear yokes provided between the headgear straps and the patient interface.

14. The nasal assembly according to claim 13, wherein the yokes are constructed from rigid or semi-rigid material.

15. The nasal assembly according to any one of claims 13-14, wherein the yokes are constructed from polycarbonate.

16. The nasal assembly according to any one of claims 13-15, wherein the yokes are at least partially covered with foam.

17. The nasal assembly according to any one of claims 13-16, wherein each of the yokes makes an angle of about 120° with respect to a longitudinal axis of the hollow body.

18. The nasal assembly according to any one of claims 12-17, wherein each of the yokes includes a yoke ring for attachment to the hollow body.

19. The nasal assembly according to claim 18, wherein the yoke ring of one yoke is sandwiched between a plug and an end of the hollow body.

20. The nasal assembly according to claim 19, wherein the yoke ring of the other yoke is sandwiched between a connector and the other end of the hollow body, and wherein the connector is adapted to support an air delivery connecting member.

21. The nasal assembly according to claim 20, wherein positions of the plug and connector may be interchanged.

22. The nasal assembly according to any one of claims 13-21, wherein the headgear straps include an upper strap portion that extends over the top of the patient's head in use and a lower strap portion that extends around the back of the patient's head in use.

23. The nasal assembly according to claim 22, wherein the upper and lower strap portions are connected to the yokes via a ladder lock arrangement.

24. The nasal assembly according to any one of claims 1-23, wherein the patient interface contacts the patient's face only at the nose and below the nose in use.

25. The nasal assembly according to any one of claims 1-24, wherein the hollow body is rotatable relative to the headgear to adjust a position of the nozzles in use.

26. A nasal assembly, comprising:

a tubular air chamber that provides at least one lateral inlet; and

a pair of nozzles supported by the tubular air chamber, each nozzle including a conical tip structured to sealingly communicate with a respective nasal passage of a patient's nose in use,

wherein the conical tip includes an outlet opening, the outlet opening having a circular shape.

27. A nasal assembly, comprising:

a patient interface including a hollow body that defines an air chamber and a pair of nozzles supported by the hollow body, each nozzle including a conical tip structured to sealingly communicate with a respective nasal passage of a patient's nose in use; and

headgear provided to the patient interface so as to maintain the patient interface in a desired position on the patient's face in use,

wherein the patient interface contacts the patient's face only at the nose and below the nose in use.

28. A breathing system, comprising:

a flow generator;

air delivery tubing; and

a nasal assembly according to any one of claims 1-27.

29. The breathing system according to claim 28, wherein the air delivery tubing includes a first delivery tube coupled to the hollow body or tubular air chamber, the first delivery tube having an inside diameter that is substantially the same as an inside diameter of the hollow body or tubular air chamber.

30. The breathing system according to claim 29, wherein the hollow body or tubular air chamber have an inside diameter of about 6 mm.

31. The breathing system according to any one of claims 28-30, wherein the air delivery tubing includes a second delivery tube coupled between the first delivery tube and the flow generator, the second delivery tube having an inside diameter that is larger than the inside diameter of the first delivery tube.

32. The breathing system according to claim 31, wherein the second delivery tube has an inside diameter of about 22 mm.

33. The breathing system according to any one of claims 28-32, wherein in use the flow generator provides pressurized air in the range of 4-10 cmH_2O to the patient.

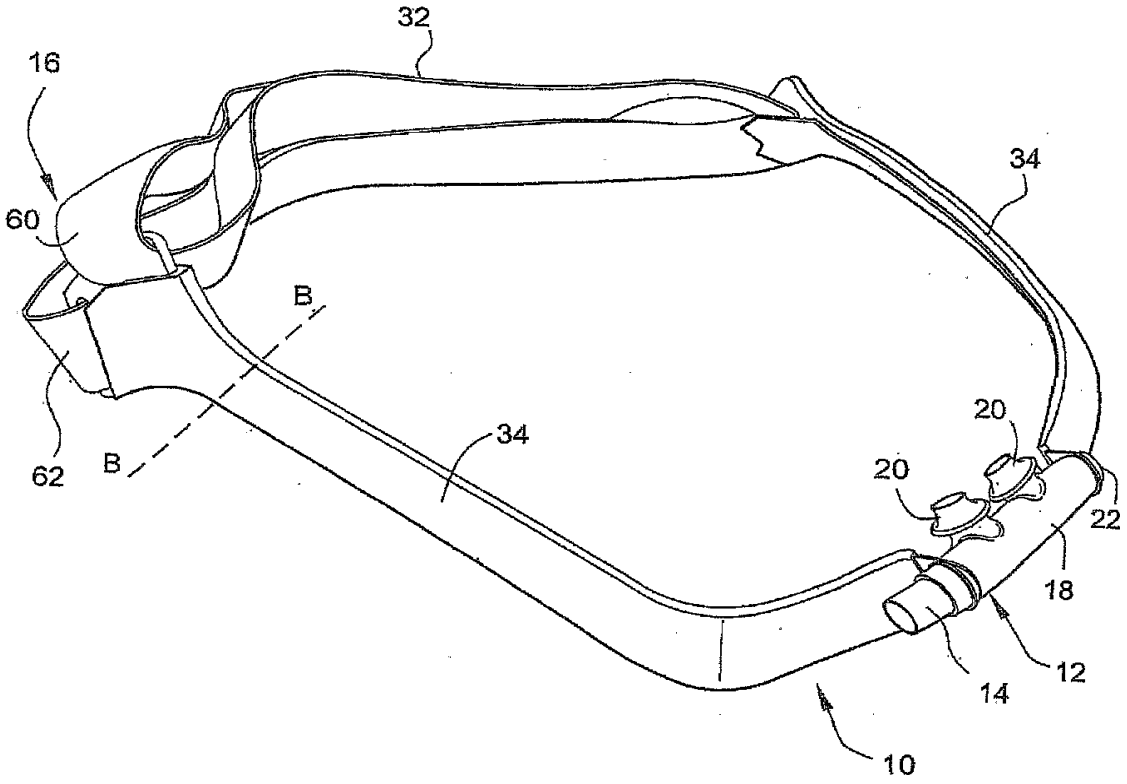

Fig.1

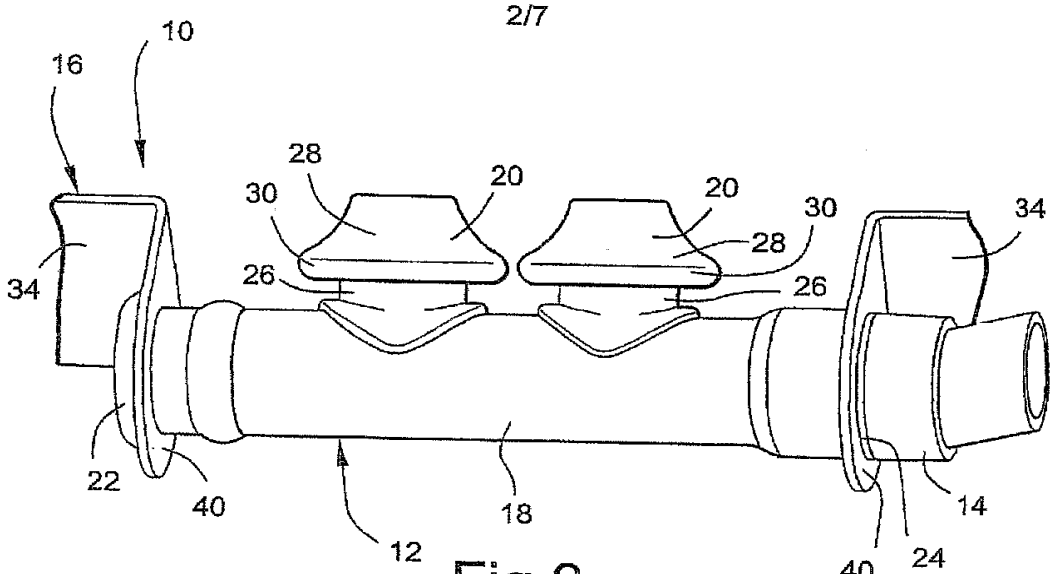
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Fig.2

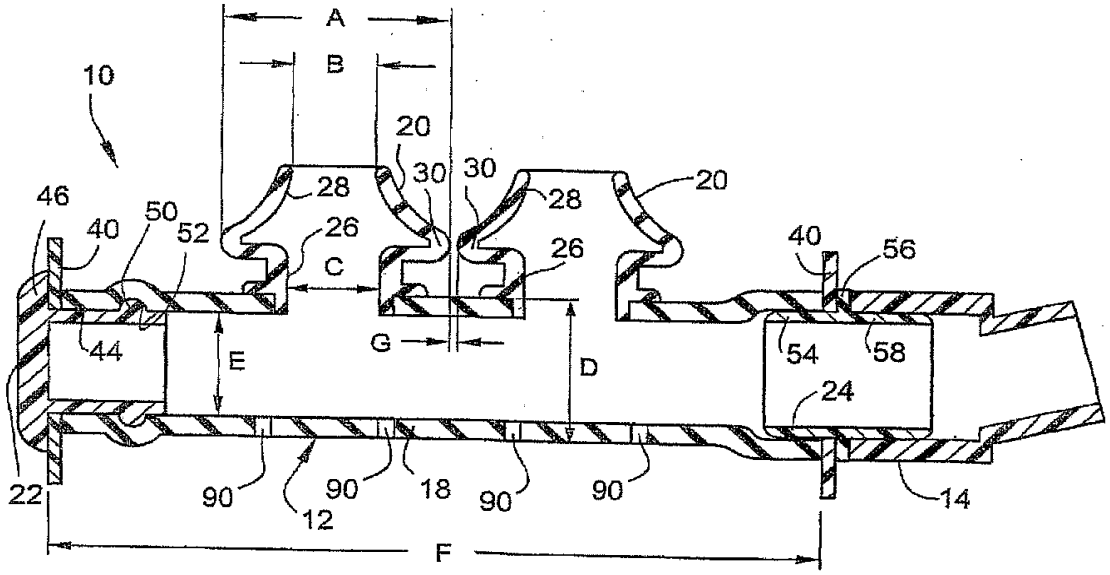
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Fig.3

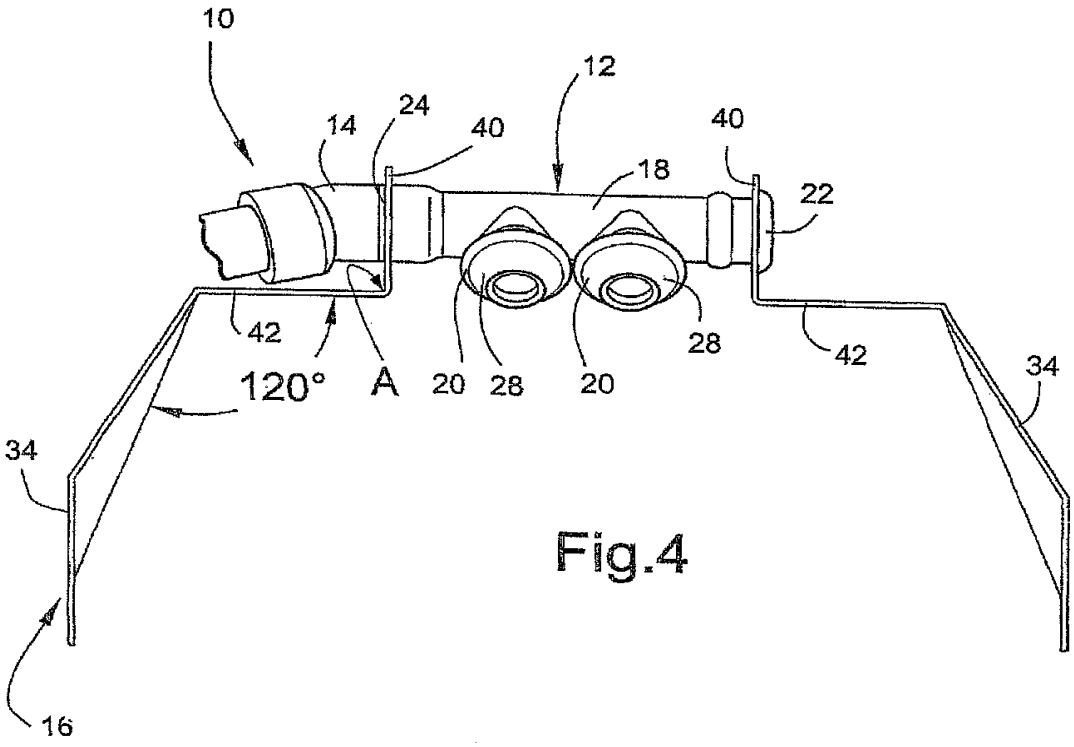
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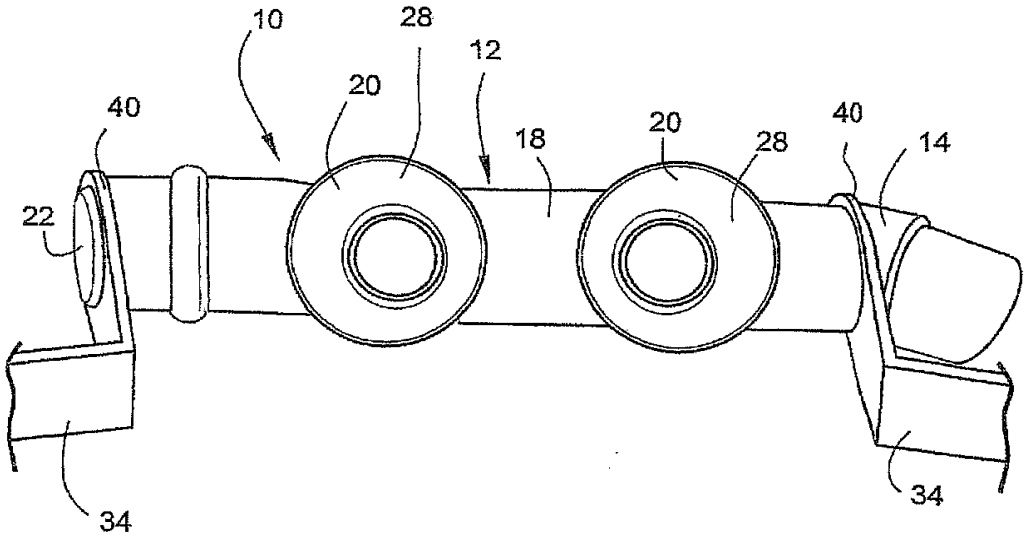
Fig.4


10
28
12
20
40
18
20
28
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22
34
34

Fig.5

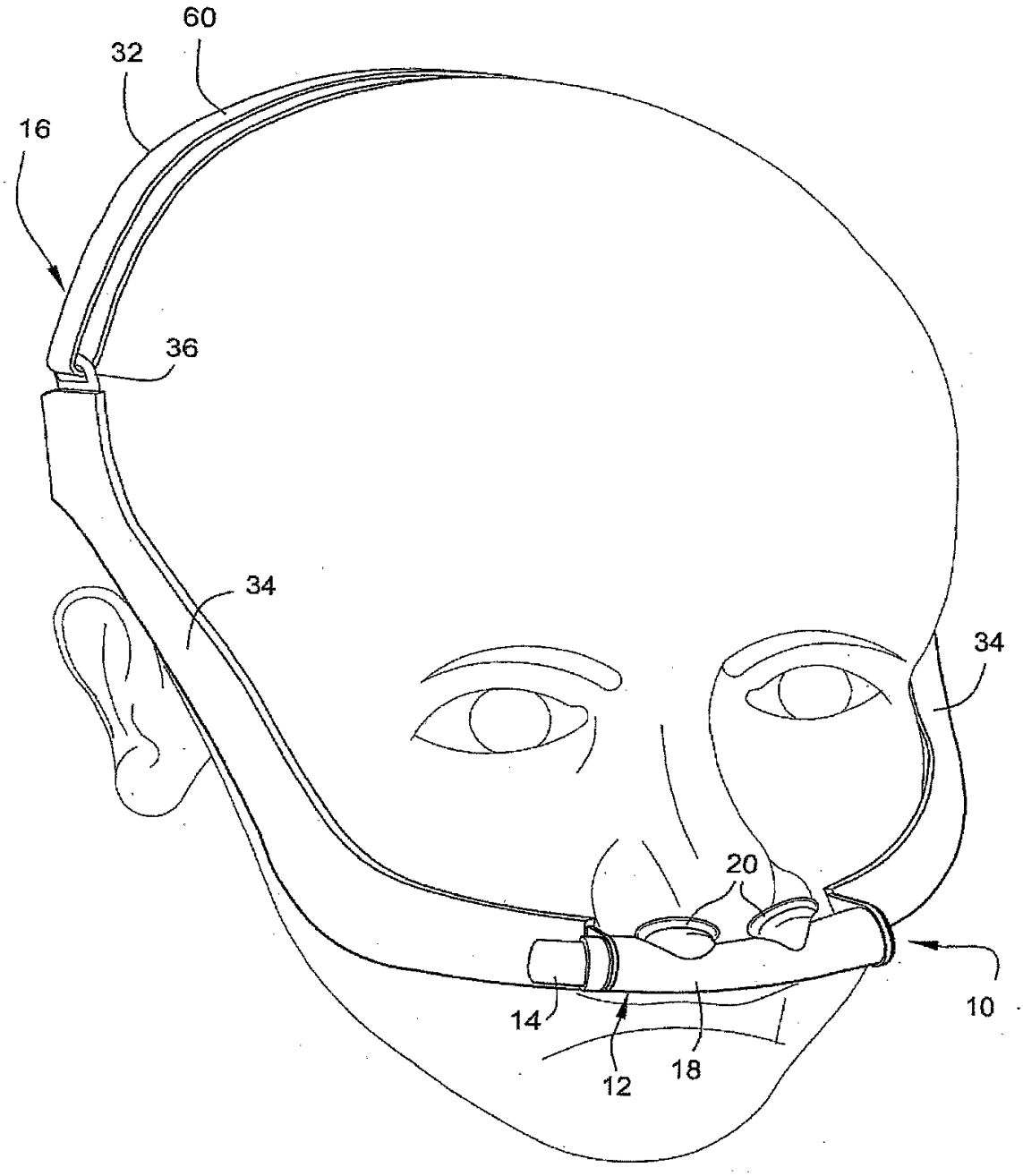

Fig.6

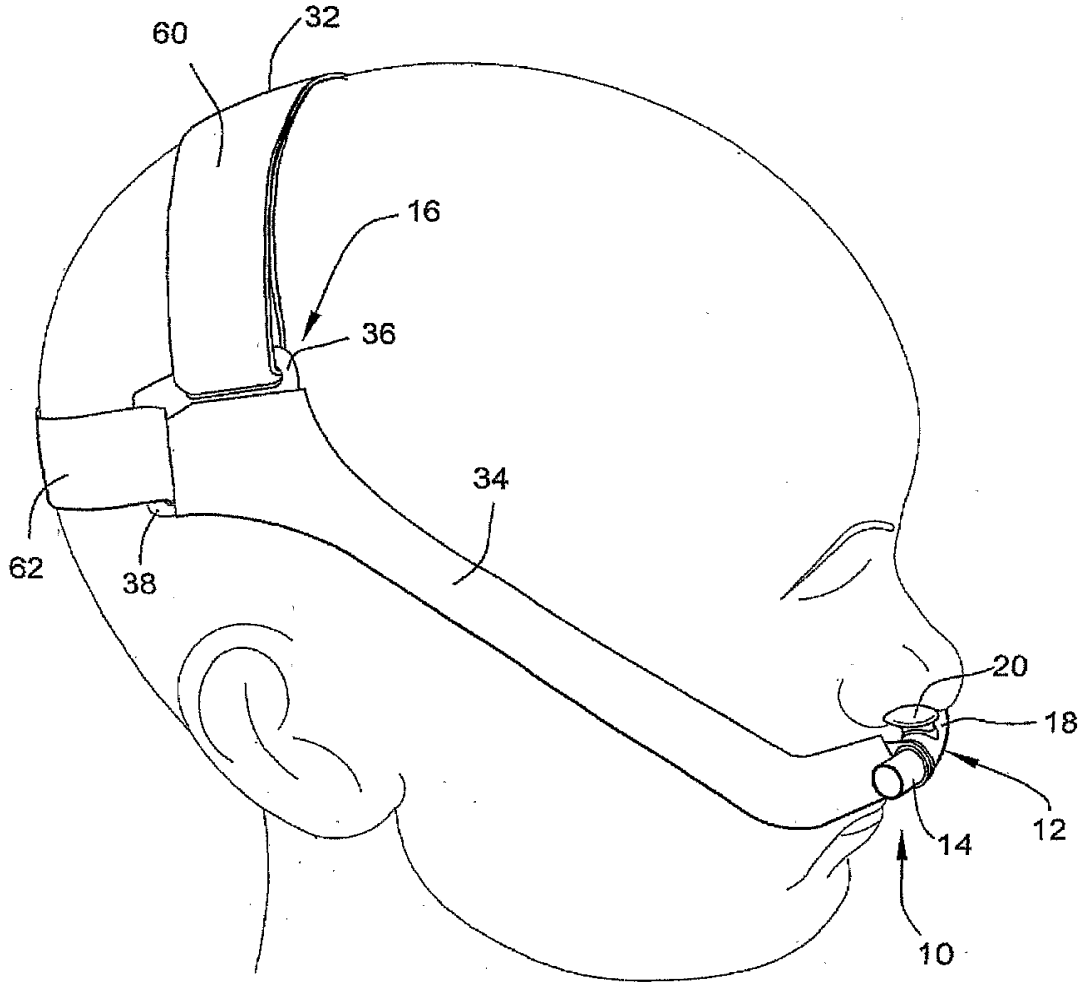

Fig.7

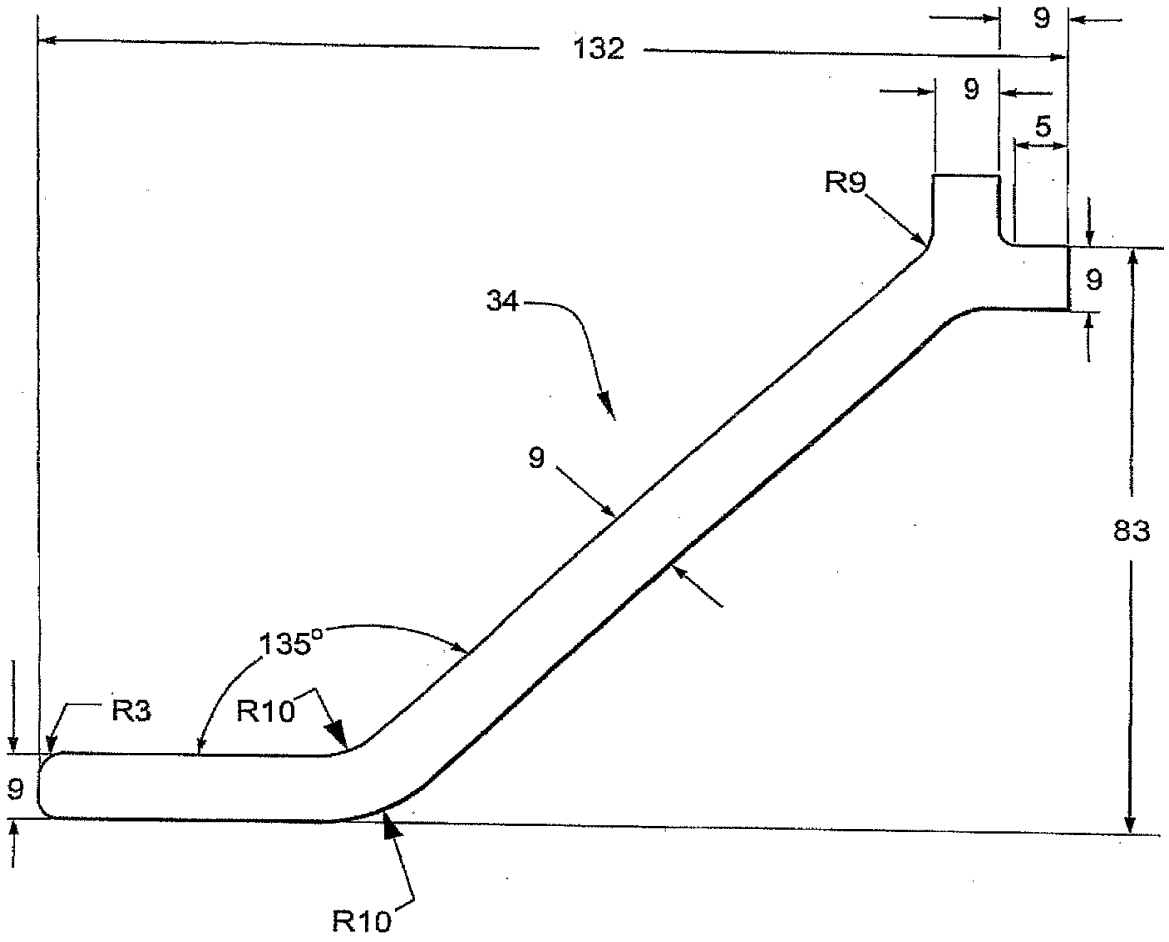

Fig.8

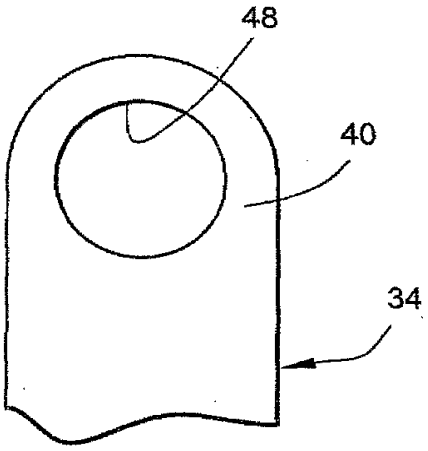

Fig.9

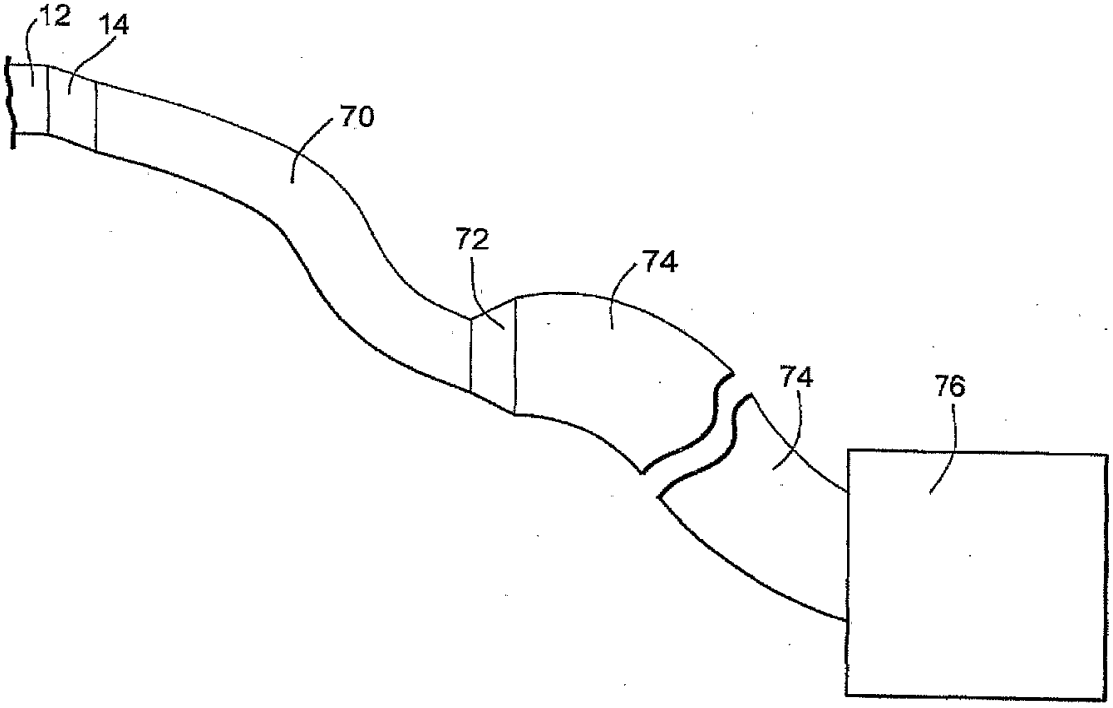

Fig.10

INTERNATIONAL SEARCH REPORT

International application No.
PCT/AU2006/001494

A. CLASSIFICATION OF SUBJECT MATTER

Int. Cl.

A61M 16/06 (2006.01) ***A62B 9/00*** (2006.01)

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

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)
DWPI: IPC A61M 16/-; A62B 9/- & keywords: (nose, nares, nostril, mask, interface, nozzle, outlet, tube, duct, pipe, opening, passage, headgear, strap, band) and similar terms.
Espace: (nasal and assembly); (nasal and mask); and similar terms.

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2004/0226566 A1 (GUNARATNAM ET AL) 18 November 2004 Whole document	1-33
X	US 2004/0020493 A1 (WOOD) 5 February 2004 Whole document	1-33
X	US 2005/0028823 A1 (WOOD) 10 February 2005 Whole document	1-33

[X] Further documents are listed in the continuation of Box C [X] See patent family annex

* Special categories of cited documents:
"A" document defining the general state of the art which is not considered to be of particular relevance
"E" earlier application or patent but published on or after the international filing date
"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)
"O" document referring to an oral disclosure, use, exhibition or other means
"P" document published prior to the international filing date but later than the priority date claimed
"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
"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
"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
"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
06 November 2006	17 NOV 2006
Name and mailing address of the ISA/AU AUSTRALIAN PATENT OFFICE PO BOX 200, WODEN ACT 2606, AUSTRALIA E-mail address: pct@ipaustralia.gov.au Facsimile No. (02) 6285 3929	Authorized officer **KAREN VIOLANTE** Telephone No : (02) 6283 7933

Form PCT/ISA/210 (second sheet) (April 2005)

INTERNATIONAL SEARCH REPORT

International application No.
PCT/AU2006/001494

C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2005/0028821 A1 (WOOD ET AL) 10 February 2005 Whole document	1-33
X	WO 2004/073778 A1 (RESMED LIMITED) 2 September 2004 Whole document	1-33
X	US 6478026 B1 (WOOD) 12 November 2002 Whole document	1-33
Y	US 2005/0061326 A1 (PAYNE, JR) 24 March 2005 Whole document	1-33
Y	WO 2005/016402 A2 (INNOMED TECHNOLOGIES) 24 February 2005 Whole document	1-33
X	WO 2005/063328 A1 (RESMED LTD) 14 July 2005 Whole document	1-26, 28-33
P,X	WO 2005/097247 A1 (RESMED LIMITED) 20 October 2005 Whole document	1-33

Form PCT/ISA/210 (continuation of second sheet) (April 2005)

INTERNATIONAL SEARCH REPORT

International application No.
PCT/AU2006/001494

Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:

2. ☐ Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a)

Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

See extra sheet

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.
2. ☒ As all searchable claims could be searched without effort justifying additional fees, this Authority did not invite payment of additional fees.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:

4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

☐ The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.

☐ The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.

☐ No protest accompanied the payment of additional search fees.

Supplemental Box
(To be used when the space in any of Boxes I to VIII is not sufficient)

Continuation of Box No: III

This International Application does not comply with the requirements of unity of invention because it does not relate to one invention or to a group of inventions so linked as to form a single general inventive concept.

In assessing whether there is more than one invention claimed, I have given consideration to those features which can be considered to potentially distinguish the claimed combination of features from the prior art. Where different claims have different distinguishing features they define different inventions.

This International Searching Authority has found that there are different inventions as follows:

- Claims 1-25 and 28-33 are directed to a nasal assembly and a breathing system. It is considered that the hollow body being bendable to adjust a position of the nozzles in use comprises a first distinguishing feature.
- Claims 26 and 28-33 are directed to a nasal assembly and a breathing system. It is considered that the outlet opening having a circular shape comprises a second distinguishing feature.
- Claims 27 and 28-33 are directed to a nasal assembly and a breathing system. It is considered that the patient interface only contacting the patient's face only at the nose and below the nose in use comprises a third distinguishing feature.

PCT Rule 13.2, first sentence, states that unity of invention is only fulfilled when there is a technical relationship among the claimed inventions involving one or more of the same or corresponding special technical features. PCT Rule 13.2, second sentence, defines a special technical feature as a feature which makes a contribution over the prior art.

The only feature common to all of the claims is that each nozzle includes a conical tip structured to sealingly communicate with a respective nasal passage of a patient's nose in use. However this concept is not novel in the light of: US 2004/0226566 A1 (Gunaratnam et al).

This means that the common feature can not constitute a special technical feature within the meaning of PCT Rule 13.2, second sentence, since it makes no contribution over the prior art.

Because the common feature does not satisfy the requirement for being a special technical feature it follows that it cannot provide the necessary technical relationship between the identified inventions. Therefore the claims do not satisfy the requirement of unity of invention *a posteriori*.

The International Searching Authority believes that a search and examination for the second and third invention will not involve more than negligible additional search and examination effort over that for the first invention and so no additional search fees are required in order to search and examine those inventions.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No.
PCT/AU2006/001494

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 Search Report		Patent Family Member					
US	2004226566	AU	2004212633	CN	1750854	EP	1603619
		US	2006137690	WO	2004/073778		
US	2004020493	AU	13555/02	CA	2364183	CA	2368825
		CA	2416410	EP	1317940	EP	1317941
		US	6478026	US	6595215	US	6776162
		US	6807967	US	6863069	US	6994089
		US	6997177	US	7059328	US	2002059935
		US	2002092527	US	2003116163	US	2005028823
		US	2005034730	US	2005039757	US	2005126574
		US	2005133039	US	2005235999	US	2005236000
		US	2006150982	WO	2005/016402	WO	2005/016407
US	2005028821	AU	2003258103	US	6997187	US	7000613
		US	2005045182	US	2005051177	US	2005133040
		WO	2005/016425	WO	200/5025354	WO	2005/025657
WO	2004/073778	AU	2004212633	CN	1750854	EP	1603619
		US	2004226566	US	2006137690		
US	6478026	AU	13555/02	CA	2364183	CA	2368825
		CA	2416410	EP	1317940	EP	1317941
		US	6595215	US	6776162	US	6807967
		US	6863069	US	6994089	US	6997177
		US	7059328	US	2002059935	US	2002092527
		US	2003116163	US	2004020493	US	2005028823
		US	2005034730	US	2005039757	US	2005126574
		US	2005133039	US	2005235999	US	2005236000
		US	2006150982	WO	2005/016402	WO	2005/016407
US	2005061326	US	6938620	US	2004025885	AU	13555/02
		CA	2364183	CA	2368825	CA	2416410
		EP	1317940	EP	1317941	US	6478026
		US	6595215	US	6776162	US	6807967
		US	6863069	US	6994089	US	6997177
		US	7059328	US	2002059935	US	2002092527
		US	2003116163	US	2004020493	US	2005028823

Form PCT/ISA/210 (patent family annex) (April 2005)

		US	2005034730	US	2005039757	US	2005126574
		US	2005133039	US	2005235999	US	2005236000
		US	2006150982	WO	2005/016402	WO	2005/016407
WO	2005063328	AU	2004308536	EP	1701759		
WO	2005097247	US	2005241644				

Due to data integration issues this family listing may not include 10 digit Australian applications filed since May 2001.

END OF ANNEX

(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
21 May 2004 (21.05.2004)

PCT

(10) International Publication Number
WO 2004/041341 A1

(51) International Patent Classification[7]: A61M 16/06, A62B 18/08

(21) International Application Number: PCT/AU2003/001161

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(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
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(71) Applicant *(for all designated States except US)*: **RESMED LIMITED** [AU/AU]; 97 Waterloo Road, North Ryde, New South Wales 2113 (AU).

(72) Inventors; and
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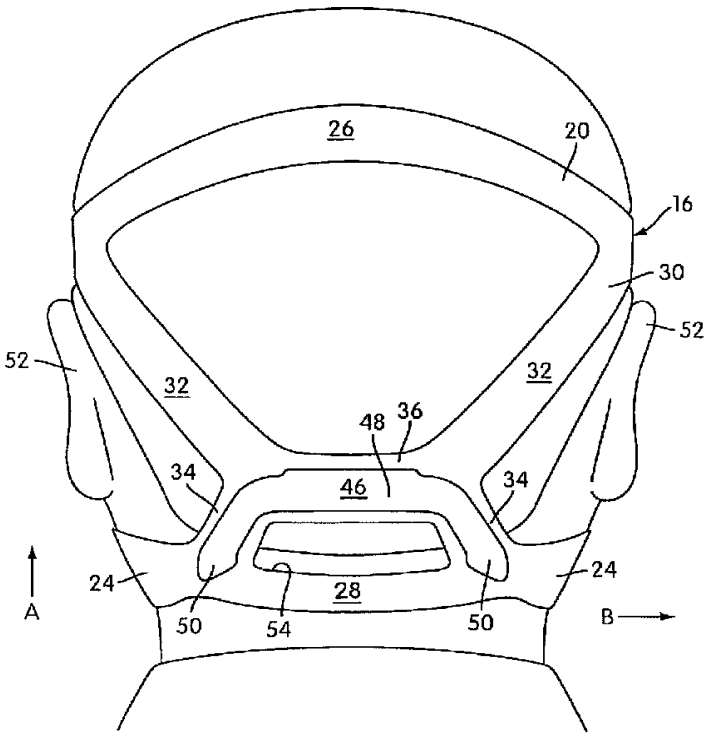
(74) Agents: **DAVIDSON, Geoffrey, Robert** et al.; Halford & Co., Level 7, 1 Market Street, Sydney, New South Wales 2000 (AU).

(81) Designated States *(national)*: AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, YU, ZA, ZM, ZW.

(84) Designated States *(regional)*: ARIPO patent (GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZM, ZW),

[Continued on next page]

(54) Title: HEADGEAR ASSEMBLY FOR A RESPIRATORY MASK ASSEMBLY



(57) Abstract: A respiratory mask assembly for delivering breathable gas to a patient includes a frame (12) and a headgear assembly (16) removably attachable to the frame. The headgear assembly includes a pair of side portions (18) and a rear portion (20) that interconnects the pair of side portions. The pair of side portions includes at least one strap (22,24). The rear portion has at least two layers of material. One of the layers of material has a more rigid construction than the other of the layers of material to resist compression of the at least one strap of the rear portion in a first direction which resists movement of the at least one strap of the rear portion in a first direction which resists movement of the at least one strap of the pair of said straps in the first direction.

WO 2004/041341 A1

Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IT, LU, MC, NL, PT, RO, SE, SI, SK, TR), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

Published:

— *with international search report*

HEADGEAR ASSEMBLY FOR A RESPIRATORY MASK ASSEMBLY

CROSS-REFERENCE TO PRIORITY APPLICATIONS

The present application claims priority to U.S. Provisional Application Serial No. 60/424,694 filed November 8, 2002. This application is hereby incorporated herein by reference in its entirety.

FIELD OF THE INVENTION

The present invention relates to a headgear assembly for use in holding a respiratory mask assembly in position on a patient's face, the mask assembly being used for treatment, e.g., of Sleep Disordered Breathing (SDB) with Non-invasive Positive Pressure Ventilation (NPPV).

BACKGROUND OF THE INVENTION

Respiratory mask assemblies such as the Mirage® nasal mask assembly manufactured by RedMed Ltd. and used for treatment of SDB such as Obstructive Sleep Apnea (OSA) are typically held in position on a patient's head by a headgear assembly. A headgear assembly typically includes a pair of side portions and a rear portion. The side portions are adapted to engage with the patient's mask and the rear portion is adapted to engage the back of the patient's head.

Headgear assemblies are structured to position and stabilize a patient interface, such as a nasal mask, on a patient's face so that a good seal can be maintained. In addition, the headgear assembly should be comfortable so that a patient can wear the mask assembly at night while they sleep. Many prior art headgear assemblies are uncomfortable to wear for long periods. It is desirable that one form of headgear assembly is suitable for a broad range of patients in order to reduce inventory, and ultimately reduce costs.

Completely rigid headgear assemblies are known, but they typically suffer from being uncomfortable to wear for long periods. In addition, because of their rigidity, they typically do not fit a broad range of patients, being suitable only for a subset.

For reasons of costs, it is desirable to be able to cut headgear assemblies from a flat piece of fabric or composite, yet in use the headgear assembly should conform to a complex three-dimensional shape. Hence a problem to overcome is to have a design of headgear assembly which can be easily manufactured by cutting or stamping, and yet in use be able to fit a wide range of head shapes and sizes.

Known forms of headgear assemblies include the ResCap™, ResCap™ II and MIRAGE® headgear, as shown in Figs. 11-16. These headgear assemblies are constructed from fabric or composite layers of fabric and neoprene. Because of the soft flexible nature of the straps in the headgear assembly, there is the possibility of some movement of the headgear assembly on the patient's head, particularly during the course of a night's sleep. Hence, while the headgear assembly may be initially correctly positioned on a patient's head, they may subsequently move to an incorrect position.

A form of connector to enable the headgear assembly to engage with the patient's mask is taught in U.S. Patent No. 6,374,826 (Gunaratnam et al.), the contents of which are hereby incorporated by reference.

U.S. Patent No. 6,422,238 (Lithgow) shows a form of headgear assembly including a quick-release mechanism. The contents of the Lithgow patent are hereby incorporated by reference. The headgear assembly taught by Lithgow includes an upper and lower strap in each side portion extending between the patient's face and the rear of the patient's head. The upper straps lie above the ears on the patient's head. The lower straps lie below the ears on the patient's head.

A problem which can occur with prior art mask assemblies, such as the mask assemblies shown in Figs. 11-16 and taught by Gunaratnam and Lithgow, is that the lower straps of the mask assemblies can ride up the patient's head while in use and cause chafing and irritation of the lower portion of the patient's ears.

SUMMARY OF THE INVENTION

One aspect of the present invention is directed towards a mask assembly having a headgear assembly that offers more comfort to the patient yet does not sacrifice functionality.

Another aspect of the present invention provides a respiratory mask assembly for delivering breathable gas to a patient. The respiratory mask assembly according to one embodiment includes a frame and a headgear assembly removably attachable to the frame. The headgear assembly includes a pair of side portions and a rear portion that interconnects the pair of side portions. The pair of side portions includes at least one strap. The rear portion has at least one strap constructed of at least two layers of material. One of the layers of material has a more rigid construction than the other of the layers of material to resist compression of the at least one strap of the rear portion in a first direction and thereby resist movement of the at least one strap of the pair of side straps in the first direction.

Another aspect of the invention is to provide a means for maintaining flexible headgear straps of a mask assembly in correct relative position on a patient's head in use.

Another aspect of the invention is to provide a comfortable headgear assembly for a mask assembly which fits a wide range of head shapes and sizes.

Another aspect of the invention is to provide a comfortable headgear assembly of a mask assembly which fits a wide range of patients and can be cut from a flat piece of fabric.

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 part of this disclosure and which illustrate, by way of example, principles of this invention.

BRIEF DESCRIPTION OF THE DRAWINGS

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

Fig. 1 is a side view illustrating a mask assembly having a headgear assembly constructed in accordance with an embodiment of the invention mounted on a patient's head;

Fig. 2 is a rear view illustrating the headgear assembly of Fig. 1 mounted on a patient's head;

Fig. 3 is a rear perspective view illustrating the headgear assembly of Fig. 1 mounted on a patient's head;

Fig. 4 is a top view illustrating the headgear assembly of Fig. 1 laid flat;

Fig. 5 is an enlarged top view illustrating an embodiment of a stiffener of the headgear assembly of Fig. 1;

Fig. 6 is an enlarged photographic top view illustrating an embodiment of a stiffener of the headgear assembly of Fig. 1;

Fig. 7 is an enlarged photographic side view illustrating an embodiment of a stiffener of the headgear assembly of Fig. 1;

Fig. 8 is a top view illustrating the headgear assembly of Fig. 1 laid flat and showing typical dimensions of an embodiment (R-radius);

Fig. 9 is a top view illustrating an embodiment of a stiffener of the headgear assembly of Fig. 1 and showing typical dimensions of an embodiment (R-radius);

Fig. 10 is a rear view illustrating a headgear assembly constructed in accordance with another embodiment of the invention mounted on a patient's head;

Fig. 11 is a side view of a prior art ResCap™ headgear assembly;

Fig. 12 is a rear view of a prior art ResCap™ headgear assembly;

Fig. 13 is a side view of a prior art ResCap™ II headgear assembly;

Fig. 14 is a rear view of a prior art ResCap™ II headgear assembly;

Fig. 15 is a side view of a prior art MIRAGE® headgear assembly; and

Fig. 16 is a rear view of a prior art MIRAGE® headgear assembly.

DETAILED DESCRIPTION OF ILLUSTRATED EMBODIMENTS

Fig. 1 shows a respiratory mask assembly 10 that includes a frame 12 and a cushion 14 that may be permanently or removably connected to the frame 12. A headgear assembly 16 is removably attached to the frame 12 and is structured to maintain the frame 12 and cushion 14 in a desired adjusted position on a patient's face. In the illustrated embodiment, the mask assembly 10 is a nasal mask structured to deliver breathable gas to a patient's nose. However,

the mask assembly 10 may be a nasal and mouth mask or the mask assembly 10 may be a full-face mask.

As shown in Figs. 1-4, the headgear assembly 16 includes two side portions 18 with a rear portion 20 connecting the side portions 18. Each side portion 18 comprises an upper side strap 22 and a lower side strap 24. The rear portion 20, which interconnects the two side portions 18, includes a curved upper strap 26, a lower strap 28, and an intermediate strap arrangement 30 therebetween. The intermediate strap arrangement 30 is generally H-shaped and has a pair of upper straps 32, a pair of lower straps 34, and a cross-bar strap 36. The upper straps 32 are angled with respect to the curved upper strap 26 and the lower straps 34 are angled with respect to the lower strap 28. However, the straps of the headgear assembly 16 may have any suitable configuration to maintain the frame 12 and cushion 14 in a desired adjusted position on a patient's face. For example, the upper strap 26 may not be curved with respect to the upper straps 22 and the intermediate strap arrangement 30 may have any suitable shape, i.e., not H-shaped.

Each upper side strap 22 is removably connected to an upper portion of the frame 12 and each lower side strap 24 is removably connected to a lower portion of the frame 12. As shown in Fig. 4, the end portion 38, 40 of each upper and lower strap 22, 24, respectively, has a reduced width that enables each upper and lower strap 22, 24 to be wrapped around a respective clip structure 42 (see Fig. 1) provided on the frame 12. Fastening of the upper and lower straps 22, 24 to the frame 12 may be assisted by use of a hook and loop material, such as VELCRO®. As shown in Fig. 4, the free end of each upper and lower strap 22, 24 includes a strip of hook material 44 attached thereto by stitching, for example. The upper and lower straps 22, 24 are constructed of a loop material that engages the strip of hook material 44 when the upper and lower straps 22, 24 are connected to the frame 12.

However, the upper and lower straps 22, 24 may be connected to the frame 12 in any other suitable manner. For example, the upper and lower straps 22, 24 may include locking clips attached thereto that are adapted to interlockingly engage with the frame 12. Alternatively, the upper and lower straps 22, 24 may be magnetically coupled with the frame 12 so as to interconnect the frame 12 and headgear assembly 16. Further, the frame 12 may include a forehead support movably mounted to an upper portion thereof. In such an

arrangement, the upper straps 22 may be removably connected to clip structures provided on the forehead support.

The straps of the headgear assembly 16 are constructed from a soft, flexible composite material such as Breathe-O-Prene™ manufactured by Accumed Technologies, Inc. As shown in Fig. 7, the straps include two layers of material A, B with one of the layers A having a loop material to facilitate the connection with the strip of hook material 44 provided on the free ends the upper and lower straps 22, 24. However, the straps may be constructed from any other suitable soft, flexible material.

In the illustrated embodiment, a stiffener 46 is attached to the rear portion 20 of the headgear assembly 16. As shown in Figs. 2 and 4-6, the stiffener 46 has a general C-shape including a body 48 and a pair of arm members 50. The stiffener 46 is attached to the H-shaped intermediate strap arrangement 30 such that the body 48 of the stiffener 46 extends along the cross-bar strap 36 and the arm members 50 of the stiffener 46 extend along respective lower straps 34. The body 48 has a width that is greater than a width of the arm members 50. Further, the free ends of the arm members 50 have a greater width than the remaining portion of the arm members 50. However, the stiffener 46 may have any suitable structure and width dimensions. The stiffener 46 is constructed from a semi-rigid skin-compatible material such as thermoplastics, e.g., nylon or polyester or a thermoplastic elastomer, e.g. santoprene. The stiffener 46 has a thickness in the range of 0.8 mm to 1.5 mm, preferably 1 mm.

The stiffener 46 is attached to the corresponding straps 34, 36 with adhesives, stitching, or other known attachment mechanisms or by semi-permanent means such as velcro, pocket sleeve, etc. As shown in Fig. 5, the stiffener 46 is secured to the straps 34, 36 by stitching around the periphery of the stiffener 46. As shown in Fig. 6, the stiffener 46 is secured to the straps by stitching an intermediate portion of the stiffener 46. Fig. 7 is an enlarged view that illustrates the stiffener 46 secured to the straps by stitching. The stitch line is in the range of 2-3 mm, preferably 2.5 mm, from the edge of the stiffener 46.

The stiffener 46 is narrower than the straps 34, 36 so that when the stiffener 46 is attached to the straps 34, 36, the softer material of the straps 34, 36 extends beyond the more rigid material of the stiffener 46, thereby preventing or at least reducing the opportunity for

contact between the patient and the more rigid material of the stiffener 46 that could cause irritation or discomfort.

The stiffener 46 adds to the rigidity of the headgear assembly 16 in certain planes and directions, which assists in stabilizing the mask assembly 10 on the head of the patient during use. In other planes and directions, the headgear assembly 16 has a different rigidity.

For example, the stiffener 46 reduces the flexibility of the straps 34, 36 at the back of the patient's head along the direction of arrow A or in a reverse direction of arrow A, as shown in Fig. 2. The presence of the stiffener 46 stops compression of the straps 34, 36 along the reverse direction of arrow A. In this way, the straps 34, 36 and stiffener 46 should be able to resist the riding up of the lower straps 24 towards the patient's ears 52. In general, the straps 34, 36 and stiffener 46 should be able maintain their positions with respect to the head of the patient when the straps 34, 36 and stiffener 46 are connected to the frame 12. Thus, the likelihood that the lower straps 24 will ride up into the lower portion of the ears 52 of the patient is reduced.

Further, the headgear assembly 16 is shaped to avoid interference with the patient's ears 52. In particular, the upper side strap 22 is connected to the frame 12 above the patient's eyes and patient's ears 52. The lower side strap 24 is connected to the frame 12 and extends below the patient's ear 52. The upper straps 32 and lower straps 34 interconnect the upper and lower straps 22, 24 and are angled sufficiently away from the patient's ears 52. Also, the upper and lower straps 32, 34 are of sufficient length to space the upper and lower straps 22, 24 from the patient's ears 52. Due to the added rigidity provided by the stiffener 46, all the straps of the headgear assembly 16 are better able to maintain a predetermined shape. The thickness of the stiffener 46 may vary across its profile to modify flexibility characteristics, for example, thicker regions may be stiffer.

On the other hand, a certain degree of flexibility of the headgear assembly 16 is provided such that variations in patient physiology can be accommodated to a certain degree. For example, the lower strap 28 has relatively more flexibility along arrow direction B or its reverse direction than straps 34, 36 with the stiffener 46 attached.

The H-shaped intermediate strap arrangement 30 of the headgear assembly 16 also helps maintain the headgear assembly 16 in a desired adjusted position on the patient. As

shown in Fig. 1, the curved upper strap 26 extends across a rear upper portion of the patient's head and the lower strap 28 and cross-bar strap 36 extend across a rear lower portion of the patient's neck and head, respectively. More specifically, the curved upper strap 26 is structured to engage a posterior portion of the parietal bone of the patient's head in order to prevent downward movement of the headgear assembly 16 opposite the direction of arrow A in Fig. 2. The cross-bar strap 36 is structured to engage a lower portion of the occipital bone of the patient's head and the lower strap 28 is structured to engage a rear upper portion of the patient's neck. As a result, the cross-bar strap 36 and the lower strap 28 prevent upward movement of the headgear assembly 16 in the direction of arrow A in Fig. 2. Moreover, the stiffener 46 is structured to resist the riding up of the lower straps 34 and hence the lower straps 24 towards the patient's ears 52. However, the intermediate strap arrangement 30 may have any suitable configuration to maintain the frame 12 and cushion 14 in a desired adjusted position on a patient's face.

Further, the straps 28, 34, and 36 form an opening 54 therebetween that can accommodate any skin folds of a patient which may extend through the opening 54. Specifically, movement of the patient's head can create a fold of skin adjacent the patient's neck. The straps 28, 34, and 36 are structured and positioned on the patient's head such that any skin folds will extend through the opening 54 and not adversely affect the positioning of the headgear assembly 16 on the patient's head. The opening 54 formed between the straps 28, 34, and 36 may have any suitable shape, i.e., trapezoidal or non-trapezoidal shape. The reduced width of strap 28 allows it to stretch over the fatter lower neck, that is, there is a different stretch between strap 36 and strap 28.

Fig. 8 illustrates dimensions of an embodiment of the headgear assembly 16. For example, the overall length of the headgear assembly 16 is in the range of 640-680 mm, preferably 660 mm and the overall height of the headgear assembly 16 is in the range of 175-215 mm, preferably 196.1 mm. The upper straps 32 are angled in the range of 40-50°, preferably 45°, with respect to the upper straps 22 and have a width in the range of 16-22 mm, preferably 19 mm. The curved upper strap 26 has a radius of curvature in the range of 145-170 mm, preferably 166 mm. Further, the lower strap 28 has a width in the range of 17-23 mm, preferably 20 mm, and the end portions 38, 40 of the upper and lower straps 22, 24 have a width in the range of 16-23 mm, preferably 19 mm. In an embodiment of the headgear assembly 16, the dimensions illustrated in Fig. 8 vary ±10%.

Fig. 9 illustrates dimensions of an embodiment of the stiffener 46. For example, the overall length of the stiffener 46 is in the range of 100-140 mm, preferably 120 mm and the overall height of the stiffener 46 is in the range of 40-80 mm, preferably 62.8 mm. The arm members 50 are angled in the range of 110-140°, preferably 125°, with respect to the body 48. In an embodiment of the stiffener 46, the dimensions illustrated in Fig. 9 vary ±10%.

Fig. 10 illustrates another embodiment of the stiffener, indicated as 246. In this embodiment, the stiffener is in the form of a pair of arcuate-shaped stiffeners 246. Each stiffener 246 extends along the upper strap 32, across the cross-bar strap 36, and along the lower strap 34. Similar to the stiffener 46, the stiffeners 246 reduces the flexibility of the straps 32, 34, and 36 at the back of the patient's head along the direction of arrow A or in a reverse direction of arrow A, so as to resist the riding up of the lower straps 24 towards the patient's ears 52.

The straps of the headgear assembly 16 and the stiffener 46, 246 may be formed of a single material, so long as patient comfort and the appropriate rigidity/flexibility are maintained.

It can thus be appreciated that the aspects of the present invention have been fully and effectively accomplished. The foregoing specific embodiments have been provided to illustrate the 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 modification, alterations and substitutions within the spirit and scope of the present invention.

WHAT IS CLAIMED IS:

1. A headgear assembly for attachment to a frame of a respiratory mask assembly for delivering breathable gas to a patient, comprising:

a pair of side portions; and

a rear portion that interconnects the pair of side portions, the pair of side portions including at least one strap,

wherein the rear portion has at least one strap constructed of two layers of material, one of the layers of material having a more rigid construction than the other of the layers of material to resist compression of the at least one strap of the rear portion in a first direction which resists movement of the at least one strap of the pair of side straps in the first direction.

2. The headgear assembly according to claim 1, wherein each of the pair of side portions includes an upper strap removably attachable to an upper portion of the frame and a lower strap removably attachable to a lower portion of the frame, the upper strap extending above the patient's ear and the lower strap extending below the patient's ear, and

wherein the rear portion includes an upper strap, a lower strap, and an intermediate strap arrangement between the upper and lower straps of the rear portion, the intermediate strap arrangement including the at least one strap constructed of two layers of material.

3. The headgear assembly according to claim 2, wherein the at least one strap of the intermediate strap arrangement resists movement of the lower strap of each of the pair of side portions in the first direction which is towards the patient's ear.

4. The headgear assembly according to any one of claims 2 or 3, wherein the at least one strap of the intermediate strap arrangement includes a stiffener attached thereto that adds rigidity of the at least one strap of the intermediate strap arrangement.

5. The headgear assembly according to any one of claims 2-4, wherein the intermediate strap arrangement includes a pair of upper straps angled with respect to the upper strap of the rear portion, a pair of lower straps angled with respect to the lower strap of the rear portion, and a cross-bar strap that extends between the upper and lower straps of the intermediate strap arrangement.

6. The headgear assembly according to any one of claims 4 or 5, wherein the stiffener is generally C-shaped including a body that extends along the cross-bar strap and a pair of arm members that extend along respective lower straps of the intermediate strap arrangement.

7. The headgear assembly according to any one of claims 4-6, wherein the stiffener has an overall length in the range of 100-140 mm, preferably 120 mm, an overall height in the range of 40-80 mm, preferably 62.5 mm, and the arm members are angled in the range of 110-140°, preferably 125°, with respect to the body.

8. The headgear assembly according to any one of claims 4-7, wherein the stiffener comprises a pair of arcuate-shaped stiffeners, each of the pair of stiffeners extending along a respective upper strap and lower strap of the intermediate strap arrangement.

9. The headgear assembly according to any one of claims 5-8, wherein the cross-bar strap of the intermediate strap arrangement, the pair of lower straps of the intermediate strap arrangement, and the lower strap of the rear portion define an opening therebetween that is adapted to allow folds of the patient's skin extend therethrough.

10. The headgear assembly according to any one of claims 1-9, wherein an overall length of the headgear assembly is in the range of 640-680 mm, preferably 660 mm, and an overall height of the headgear assembly is in the range of 175-215 mm, preferably 196.1 mm.

11. The headgear assembly according to any one of claims 2-10, wherein the pair of upper straps of the intermediate strap arrangement are angled with respect to the upper

strap of the rear portion in the range of 40-50°, preferably 45°, and have a width in the range of 16-22 mm, preferably 19 mm.

12. The headgear assembly according to any one of claims 2-11, wherein the upper strap of the rear portion is curved and has a radius of curvature in the range of 145-170 mm, preferably 166 mm.

13. The headgear assembly according to any one of claims 4-12, wherein the stiffener has a thickness in the range of 0.8 mm to 1.5 mm, preferably 1.0 mm.

14. The headgear assembly according to any one of claims 4-13, wherein the stiffener is attached to the at least one strap of the intermediate strap arrangement by at least one of stitching, placing it in a pocket which is permanently attached to the at least one strap of the intermediate strap arrangement, and utilizing a hook and loop fastening system.

15. The headgear assembly according to any one of claims 1-14, wherein the at least one strap of the rear strap portion includes a stiffener attached thereto that adds rigidity of the at least one strap of the rear portion.

16. The headgear assembly according to claim 15, wherein the at least one strap of the rear strap portion with the stiffener attached thereto resists movement of the at least one strap of the pair of side straps in the first direction which is towards the patient's ear.

17. A headgear assembly for stabilizing and positioning a respiratory mask assembly on a patient's head, comprising:

a pair of side straps;

at least two rear straps,

at least one of the pair of side straps and at least two rear straps having a flexible strap; and

a stiffener positioned between the at least one flexible strap and another of the

pair of side straps and at least two rear straps, the stiffener being structured to maintain the at least one flexible strap in correct relative position on the patient's head in use.

18. A headgear assembly for stabilizing and positioning a respiratory mask assembly on a patient's head, comprising:

a pair of side straps; and

at least two rear straps,

wherein at least one of the at least two rear straps has a curved portion with a radius in the range of 145-170 mm.

19. A respiratory mask assembly for delivering breathable gas to a patient comprising a frame and a headgear assembly according to any one of claims 1-18.

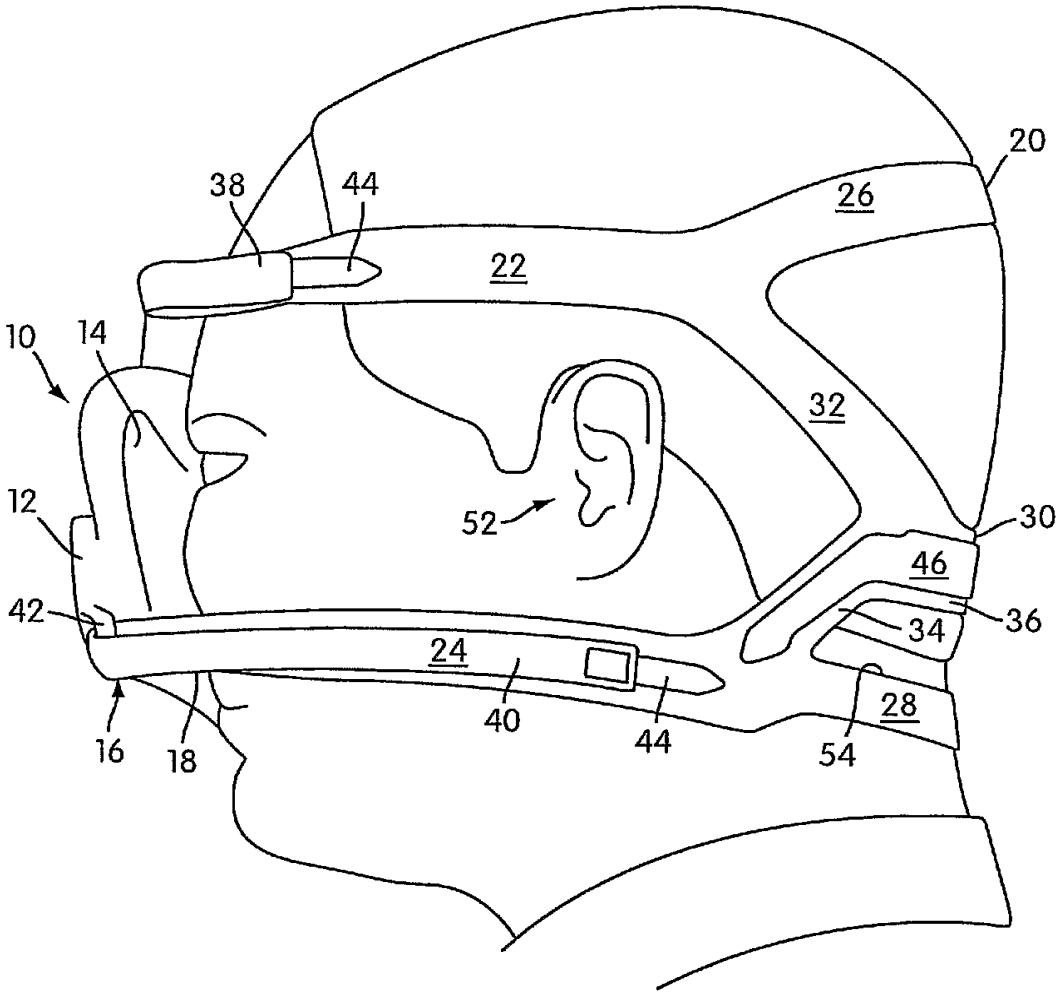


FIG. 1

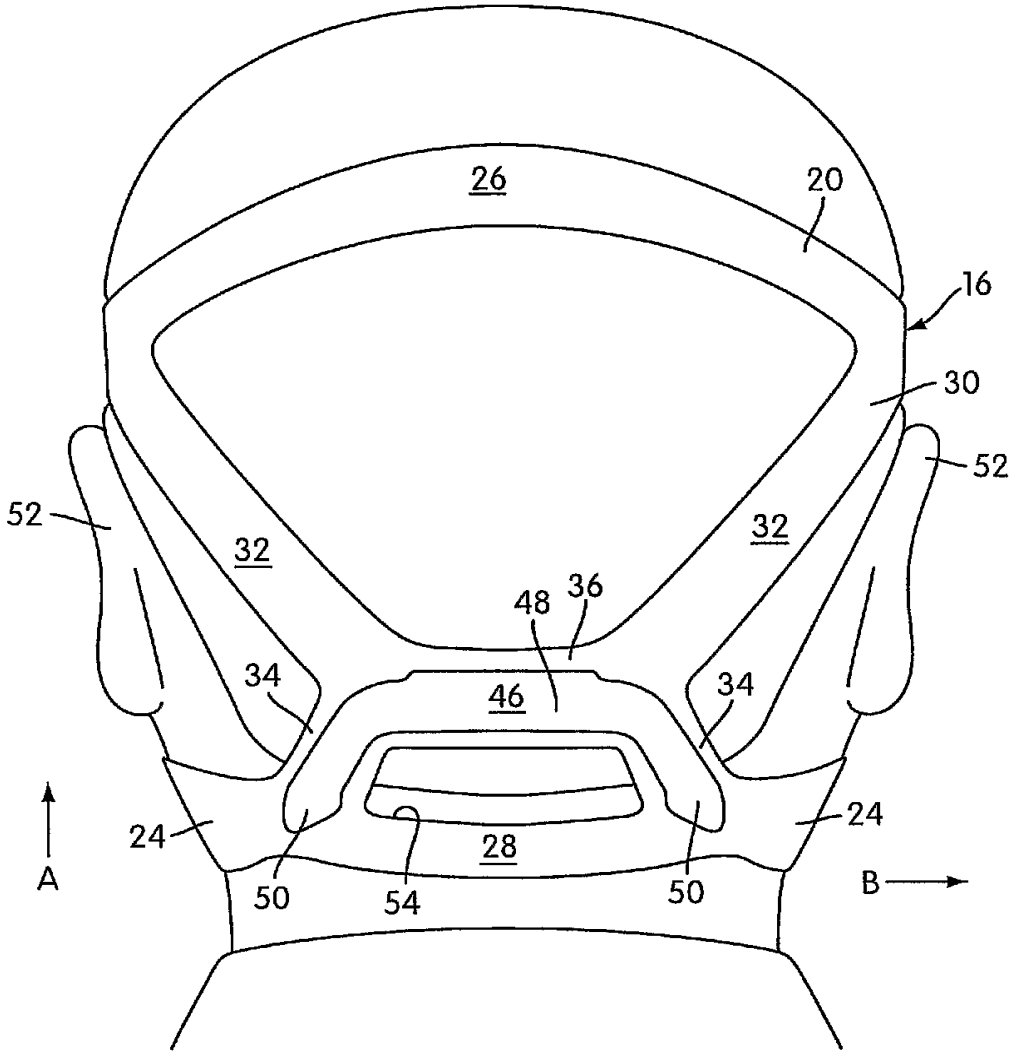


FIG. 2

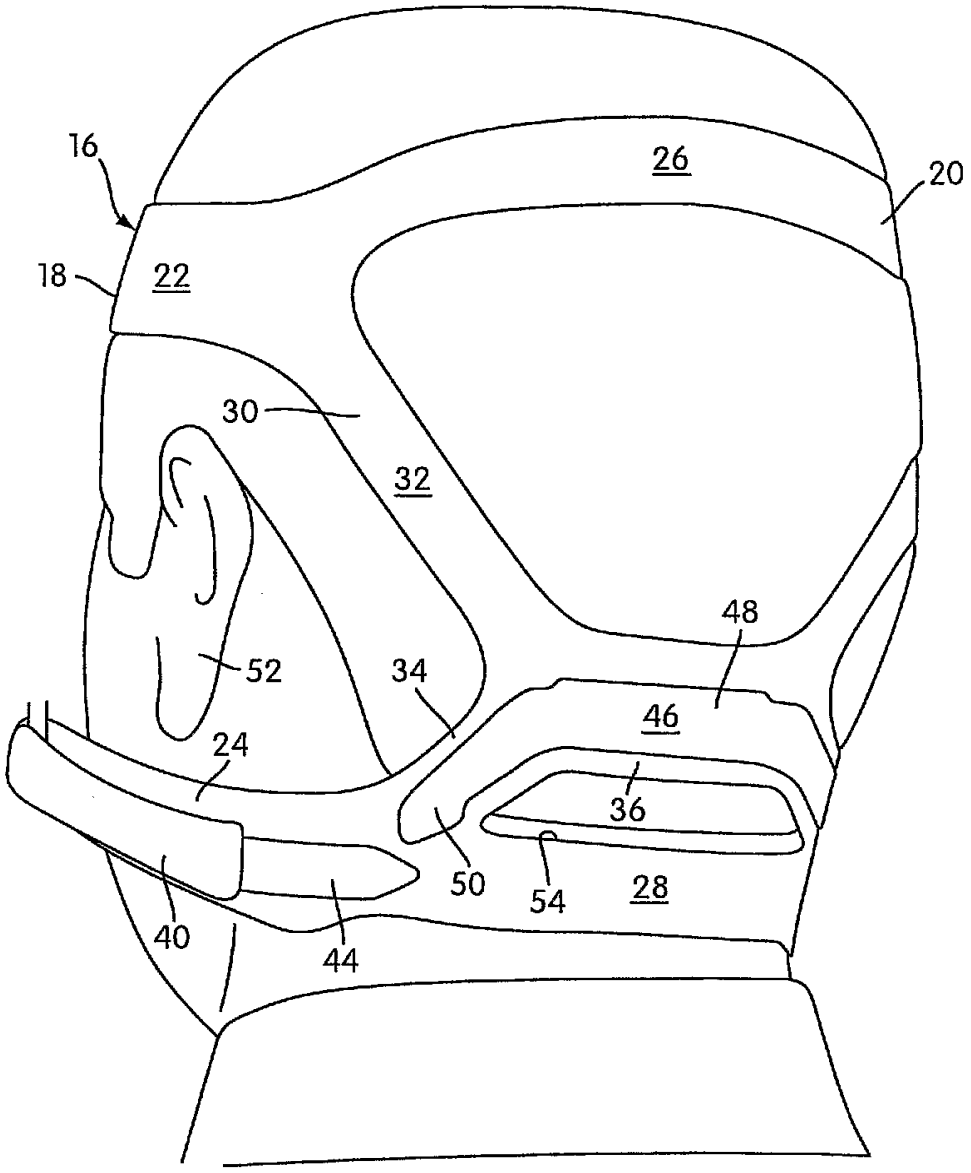


FIG. 3

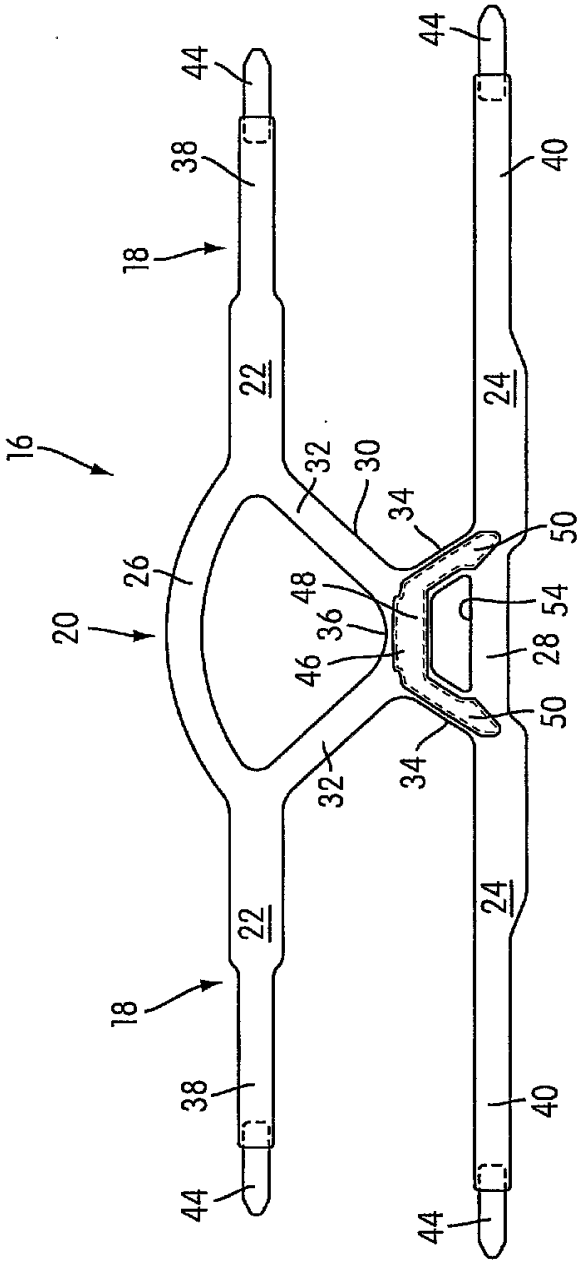

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FIG. 4

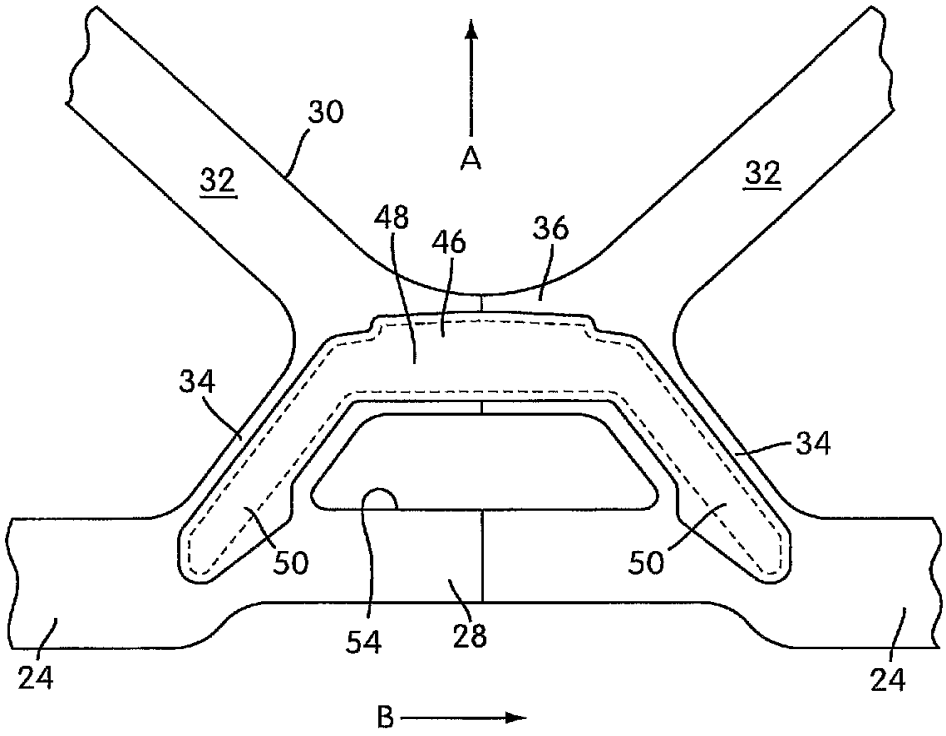

FIG. 5

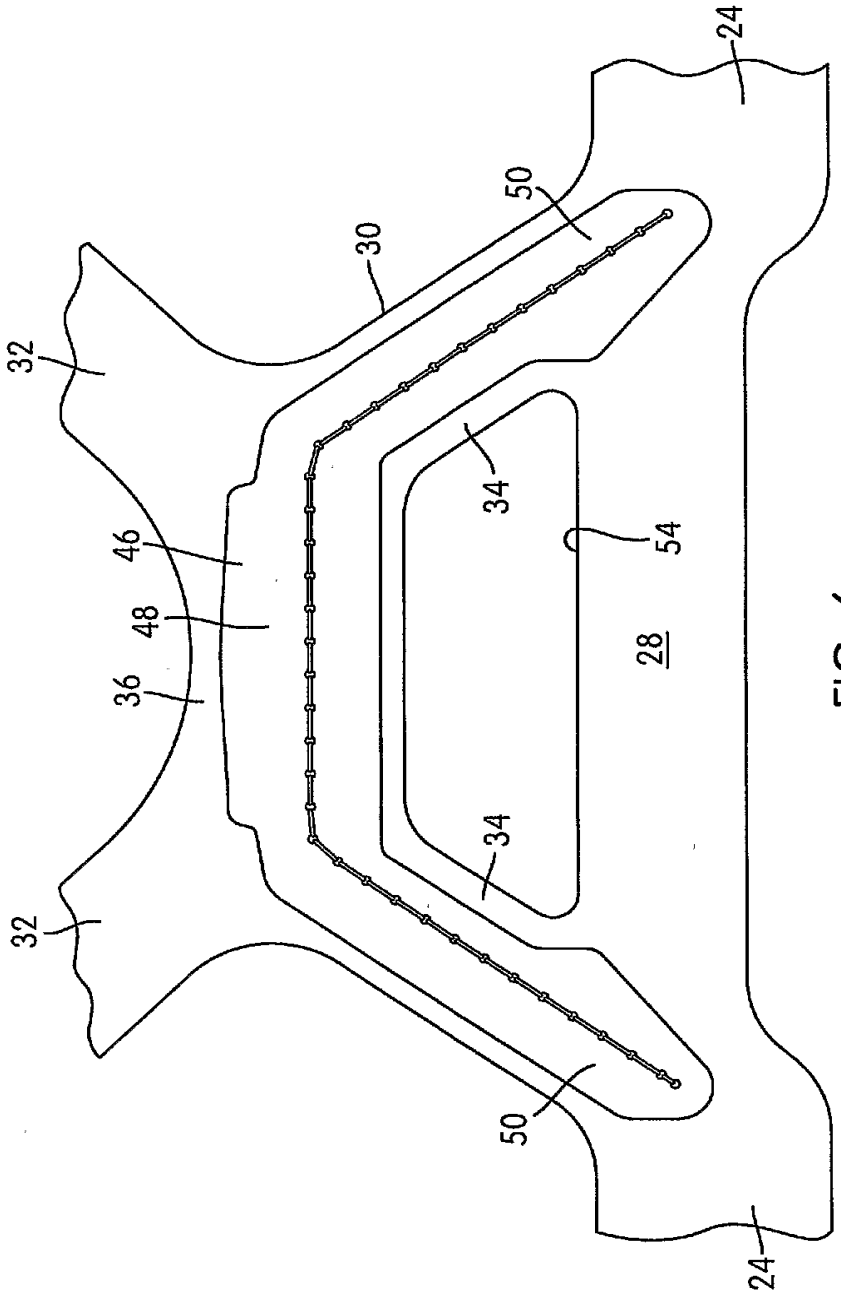

FIG. 6

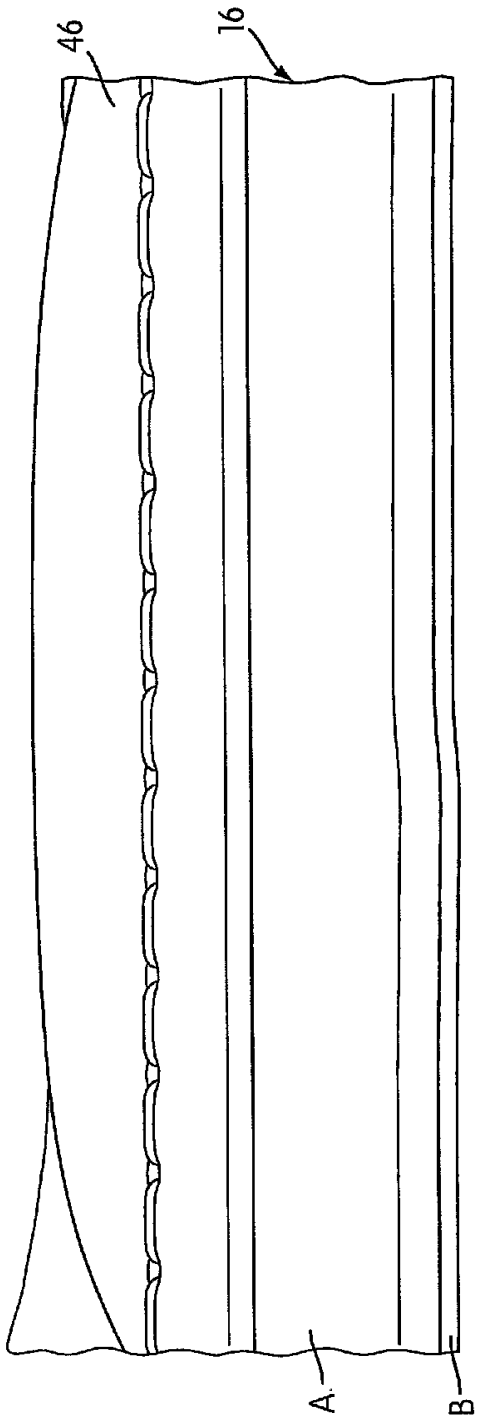

FIG. 7

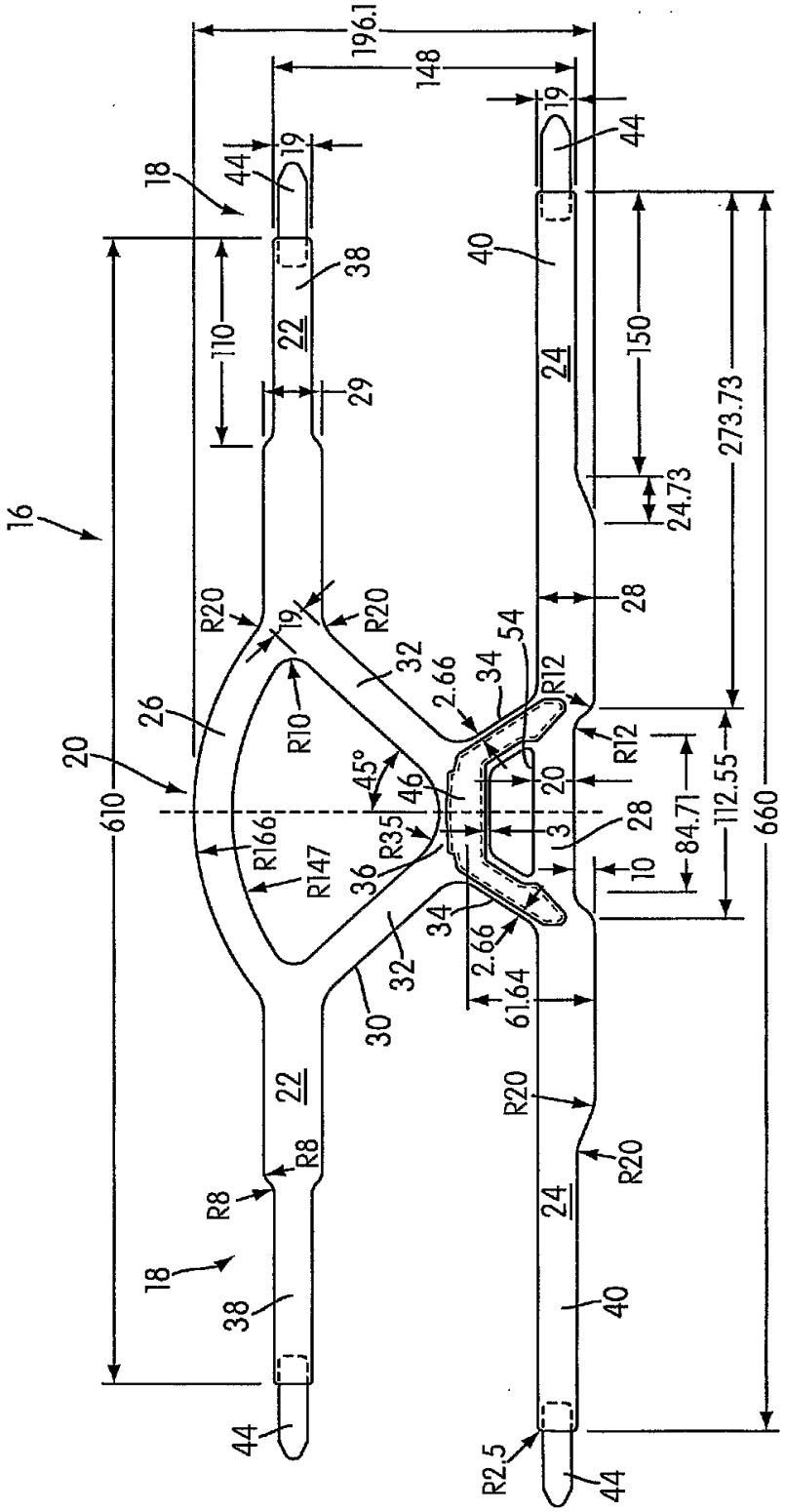
196.1
148
19
44
18
38
40
110
22
24
150
29
273.73
24.73
16
R20
19
28
54
32
2.66
34
R12
26
R10
20
610
45°
46
R166
R35
R147
36
3
28
84.71
112.55
660
10
30
61.64
R8
R2.5

FIG. 8

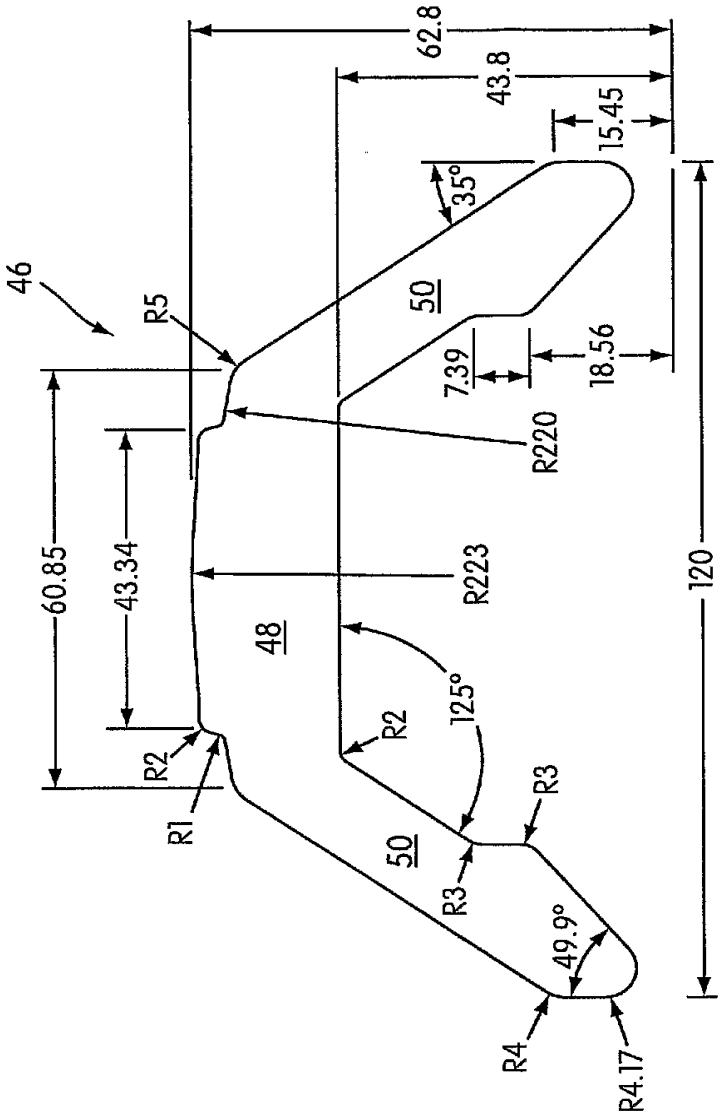
62.8
43.8
15.45
35°
46
R5
50
7.39
18.56
R220
60.85
43.34
R223
120
48
125°
R2
R2
R1
R3
50
R3
49.9°
R4
R4.17

FIG. 9

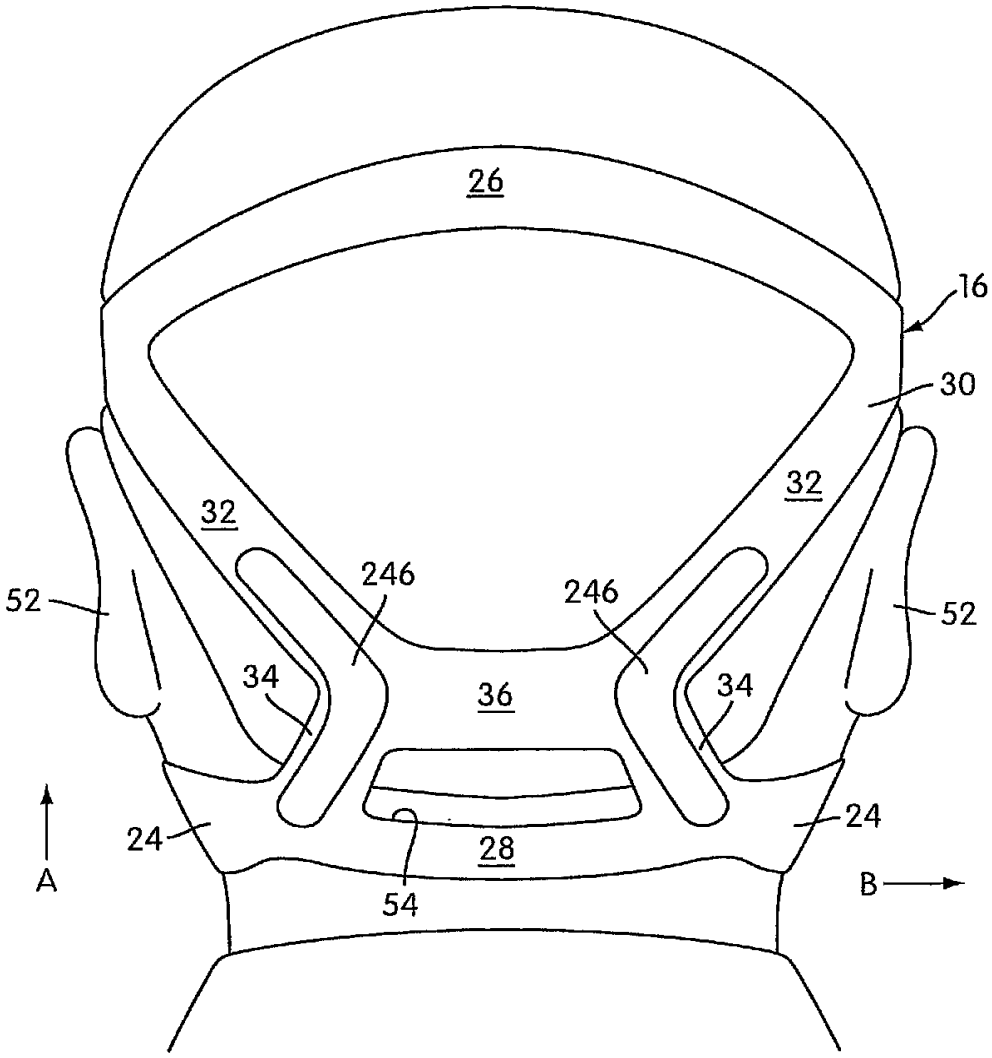

FIG. 10

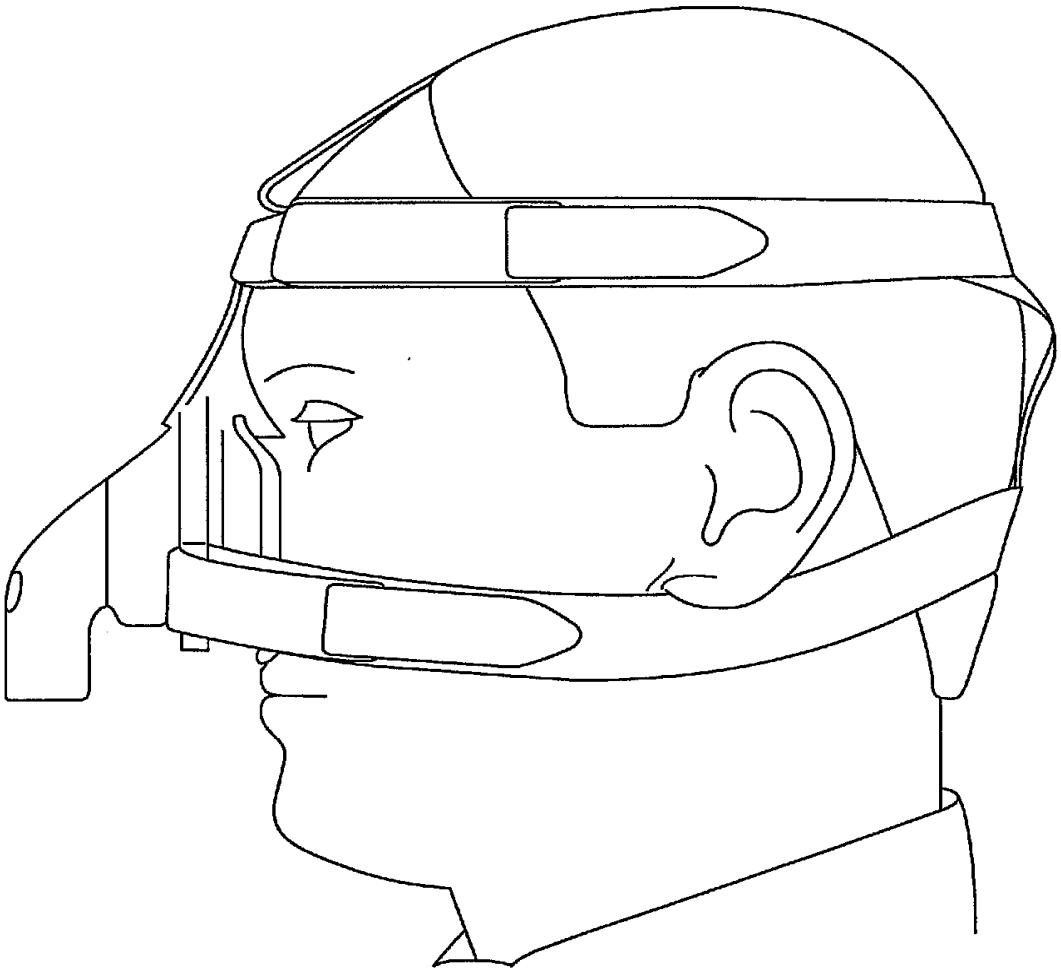

FIG. 11
RELATED ART

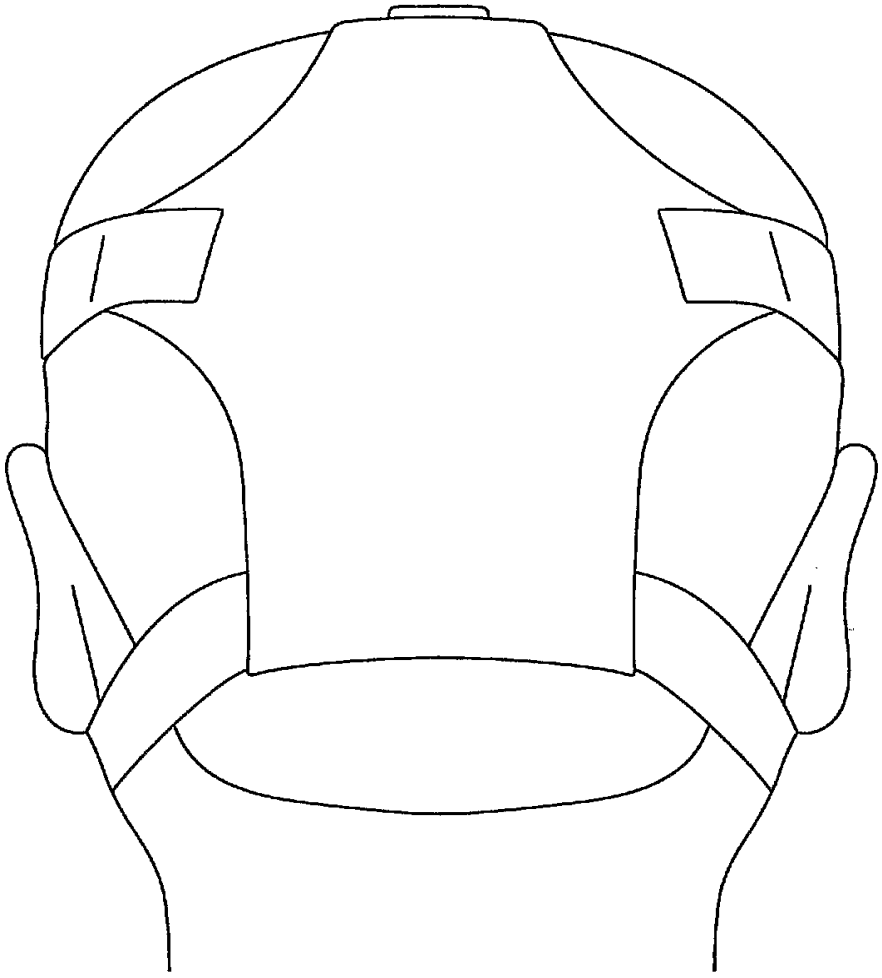

FIG. 12
RELATED ART

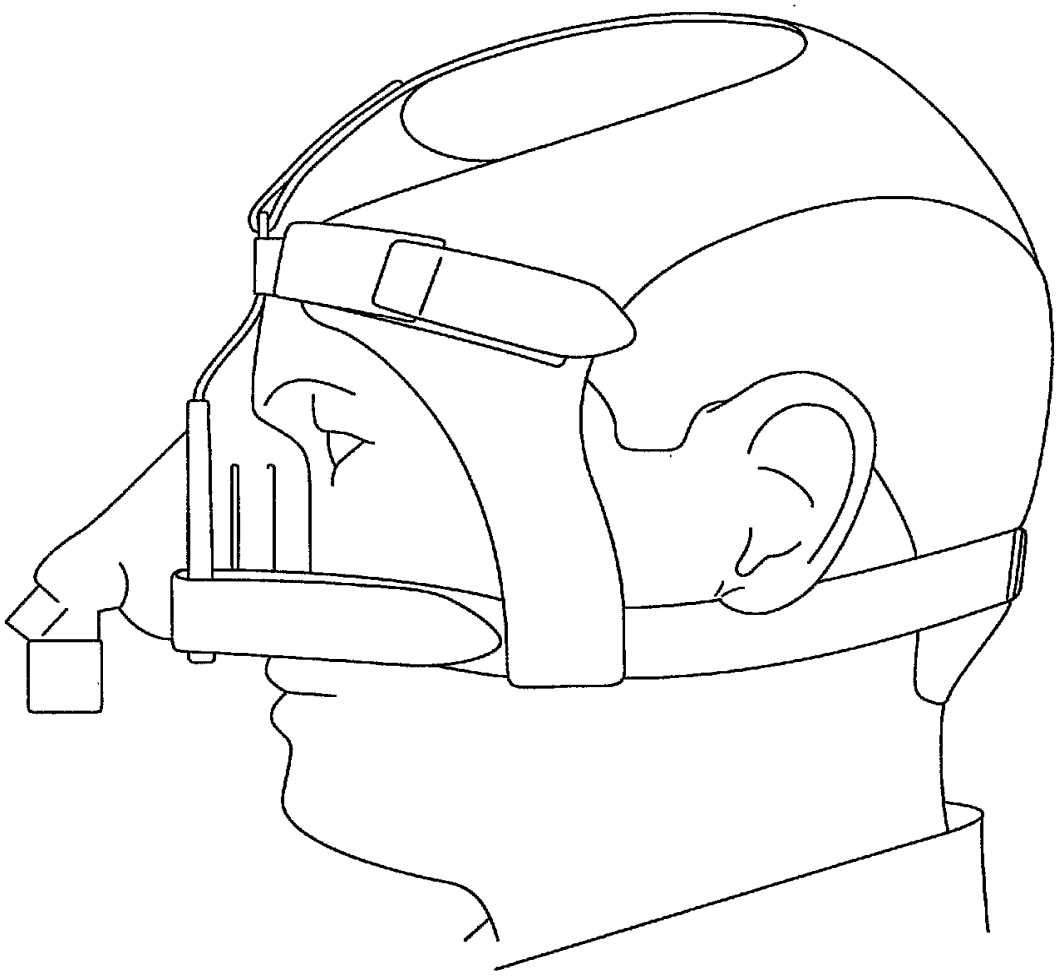

FIG. 13
RELATED ART

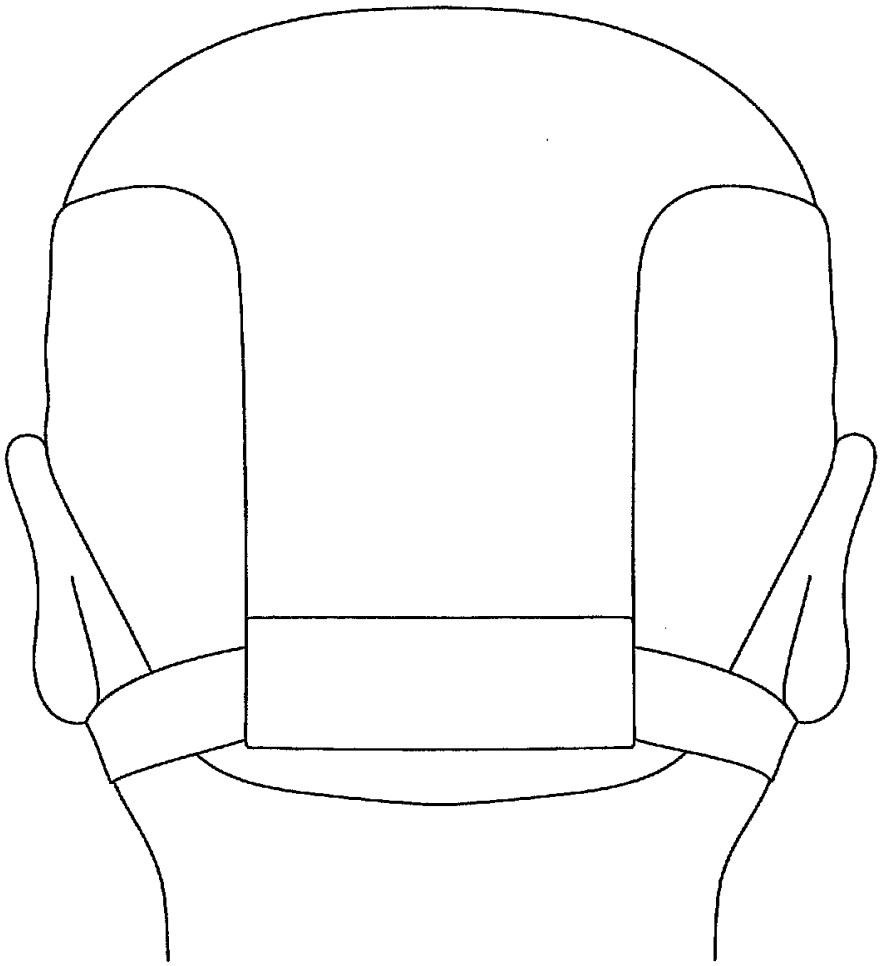

FIG. 14
RELATED ART

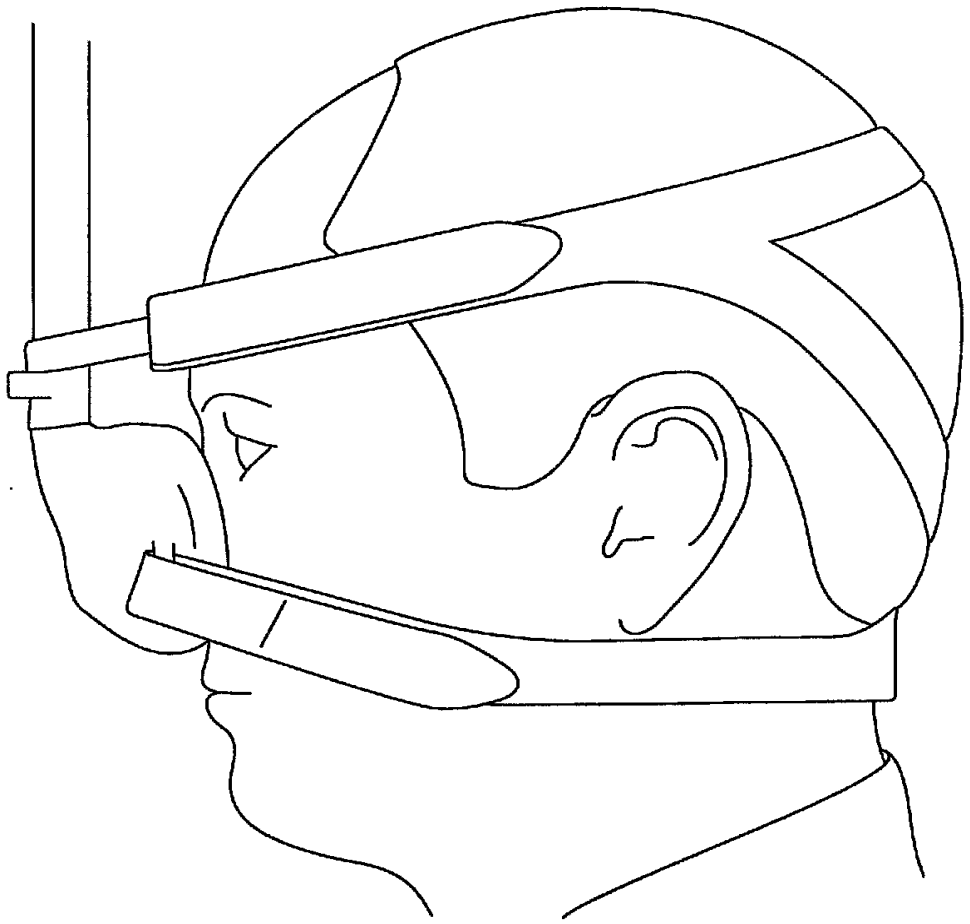

FIG. 15
RELATED ART

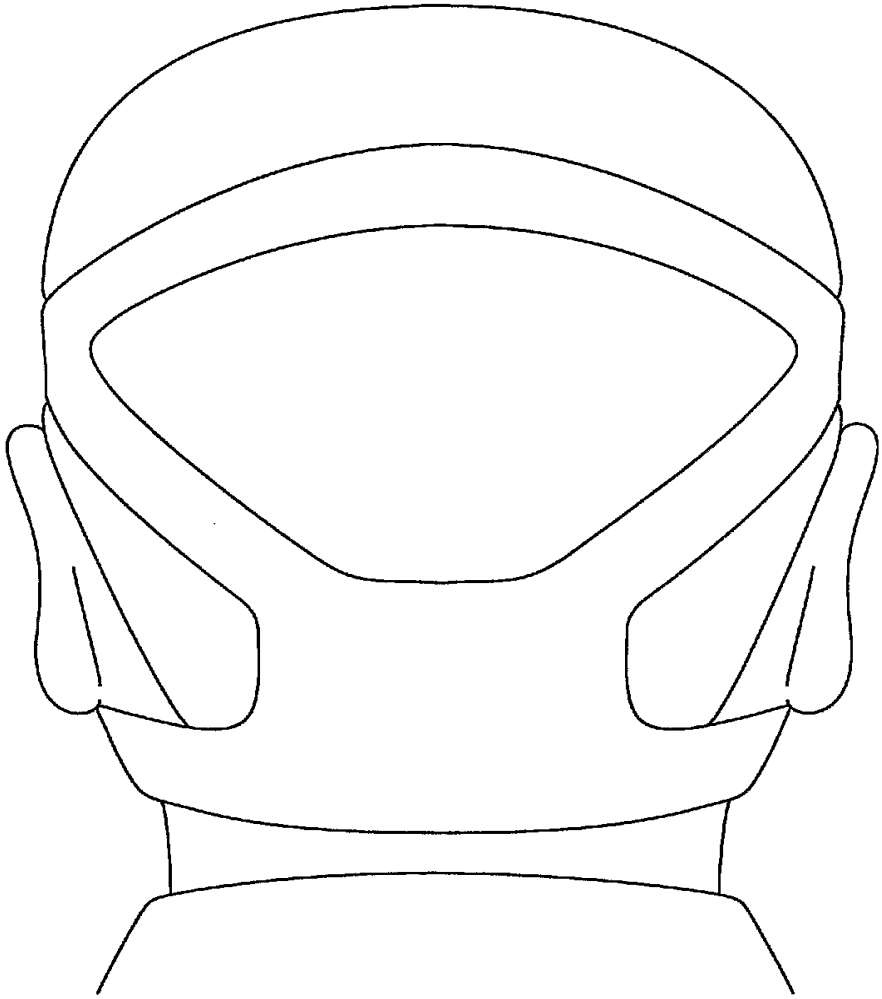

FIG. 16
RELATED ART

INTERNATIONAL SEARCH REPORT

International application No.
PCT/AU03/01161

A. CLASSIFICATION OF SUBJECT MATTER

Int. Cl. [7]: A61M 16/06, A62B 18/08

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
AU IPC A61M 16/06, A62B 18/08

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)
DWPI IPC A61M 16/06, A62B 18/08 and Keywords (harness or headgear or fram, strap) and like terms

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	WO 02/47749 A1 (RESMED LTD) 20 June 2002 page 10, lines 12-17 Figs. 4, 6B	
A	WO 02/47763 A1 (MSA AUER GMBH) 20 June 2002 abstract Fig. 1	
A	WO 02/07806 A1 (MAP MEDIZINTECHNIK FUR ARZT UND PATIENT GMBH & CO KG) 31 January 2002 abstract Figs. 2-5	

☐ Further documents are listed in the continuation of Box C ☒ See patent family annex

* Special categories of cited documents:

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier application or patent but published on or after the international filing date

"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)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"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

"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

"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

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
2 October 2003	14 OCT 2003
Name and mailing address of the ISA/AU AUSTRALIAN PATENT OFFICE PO BOX 200, WODEN ACT 2606, AUSTRALIA E-mail address: pct@ipaustralia.gov.au Facsimile No. (02) 6285 3929	Authorized officer **VINCE BAGUSAUSKAS** Telephone No : (02) 6283 2110

Form PCT/ISA/210 (second sheet) (July 1998)

INTERNATIONAL SEARCH REPORT

International application No.
PCT/AU03/01161

Box I **Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)**

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos :

because they relate to subject matter not required to be searched by this Authority, namely:

2. ☐ Claims Nos :

because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

3. ☐ Claims Nos :

because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a)

Box II **Observations where unity of invention is lacking (Continuation of item 3 of first sheet)**

This International Searching Authority found multiple inventions in this international application, as follows:

See extra page.

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims

2. ☒ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.

3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:

4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

☐ The additional search fees were accompanied by the applicant's protest.

☐ No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

International application No.
PCT/AU03/01161

Supplemental Box
(To be used when the space in any of Boxes I to VIII is not sufficient)

Continuation of Box No: II

The international application does not comply with the requirements of unity of invention because it does not relate to one invention or to a group of inventions so linked as to form a single general inventive concept. In coming to this conclusion the International Searching Authority has found that there are different inventions as follows:

1. Claims 1-17 is directed to a headgear assembly for positioning a respiratory mask assembly on a patients head comprising a pair of side portions, a rear portion and a stiffener located at the rear portion of the headgear assembly. It is considered that the stiffener located at the rear portion of the headgear assembly comprises a first "special technical feature".

2. Claim 18 is directed to a headgear assembly for positioning a respiratory mask assembly on a patients head comprising a pair of side straps, and at least two rear straps wherein at least one of the two rear straps has a curved portion with a radius in the range of 145-170mm. It is considered that the at least one rear strap having a curved portion with a radius in the range of 145-170mm comprises a second "special technical feature".

Since the abovementioned groups of claims do not share any of the technical features identified, a "technical relationship" between the inventions, as defined in PCT rule 13.2 does not exist. Accordingly the international application does not relate to one invention or to a single inventive concept, a priori. It is noted that unity of invention exists between claim 19 and each set of the abovementioned claims since claim 19 is a dependent claim to each set of the abovementioned claims.

However since all these inventions share the same classification under the IPC they could be searched together without effort which would warrant an additional fee. Therefore all the inventions have been searched without extra charge.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No.
PCT/AU03/01161

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 Search Report		Patent Family Member					
WO	0247749	AU	20375/02				
WO	0247763	AU	18131/02	DE	10064471	EP	1341583
		US	2003140402				
WO	0207806	AU	81876/01	DE	10035946	EP	1305070

END OF ANNEX

Form PCT/ISA/210 (citation family annex) (July 1998)

Electronic Patent Application Fee Transmittal	
Application Number:	
Filing Date:	
Title of Invention:	BREATHING ASSISTANCE APPARATUS
First Named Inventor/Applicant Name:	ALASTAIR EDWIN McAULEY
Filer:	Linda L. Palomar/Tiffany Lynch
Attorney Docket Number:	1171/48067/202-PCT-US
Filed as Large Entity	

U.S. National Stage under 35 USC 371 Filing Fees

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Basic Filing:				
National Stage Fee	1631	1	330	330
Natl Stage Search Fee - Report provided	1642	1	430	430
National Stage Exam - all other cases	1633	1	220	220
Pages:				
Claims:				
Claims in excess of 20	1615	11	52	572
Miscellaneous-Filing:				
Petition:				

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				
Extension-of-Time:				
Miscellaneous:				
		Total in USD ($)		**1552**

Electronic Acknowledgement Receipt	
EFS ID:	4578914
Application Number:	12307993
International Application Number:	PCT/NZ07/00185
Confirmation Number:	7084
Title of Invention:	BREATHING ASSISTANCE APPARATUS
First Named Inventor/Applicant Name:	ALASTAIR EDWIN McAULEY
Customer Number:	00279
Filer:	Linda L. Palomar/Tiffany Lynch
Filer Authorized By:	Linda L. Palomar
Attorney Docket Number:	1171/48067/202-PCT-US
Receipt Date:	08-JAN-2009
Filing Date:	
Time Stamp:	15:36:30
Application Type:	U.S. National Stage under 35 USC 371

Payment information:

Submitted with Payment	yes
Payment Type	Deposit Account
Payment was successfully received in RAM	$1552
RAM confirmation Number	970
Deposit Account	201495
Authorized User	
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Charge any Additional Fees required under 37 C.F.R. Section 1.21 (Miscellaneous fees and charges)

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Application Data Sheet	ADSFPH202.pdf	973389 546c6bc4744adae2e294933ff3c475004a9b2d80	no	6
Warnings:					
Information:					
2	Information Disclosure Statement (IDS) Filed (SB/08)	IDSFPH202.pdf	608379 eef3111e2a18f094644230fac35ef8777ef7b86f	no	5
Warnings:					
Information:					
3		DOC010809.pdf	151118 d42fbc8cd1bef3f6053289c9191565d117155c31	yes	9

Multipart Description/PDF files in .zip description

Document Description	Start	End
Preliminary Amendment	1	1
Specification	2	2
Claims	3	8
Applicant Arguments/Remarks Made in an Amendment	9	9

Warnings:					
Information:					
4	Oath or Declaration filed	DOC010809-001.pdf	144199 e0e66f51fe6e148cb0455b9bda39d670ee24db02	no	4
Warnings:					
Information:					
5	Abstract	DOC010809-002.pdf	59559 f324c0c362049e32427cb1354e5c0ebe1c327455	no	2
Warnings:					
Information:					
6	Specification	DOC010809-003.pdf	684787 6e3b6a9b3265ad75bd3923a67f6ec5cb92cf2d2b	no	16

Warnings:					
Information:					
7	Claims	DOC010809-004.pdf	150023 80a7654ebab18c9a27e211aea71b075268dffc93	no	5
Warnings:					
Information:					
8	Drawings-only black and white line drawings	DOC010809-005.pdf	296072 1eec9d045793e02161eb7d39472c0eaaddc88cb1	no	21
Warnings:					
Information:					
9	Documents submitted with 371 Applications	DOC010809-006.pdf	226141 cdcca36a5385f7d31e8118c6f82a440667c3dc55	no	9
Warnings:					
Information:					
10	Foreign Reference	WO2007041786.pdf	1188927 9d70d9a1e33c5bf5f2551c952cfafb62fe83199e	no	30
Warnings:					
Information:					
11	Foreign Reference	WO2004041341.pdf	1128556 2994af8f7bf1b421ee2367295d2e4d8061e4bb6a	no	35
Warnings:					
Information:					
12	Fee Worksheet (PTO-06)	fee-info.pdf	36560 cd091e40bf6125bf54e6302f8db7783d04091647	no	2
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		Total Files Size (in bytes):	5647710		

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New Applications Under 35 U.S.C. 111
If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

National Stage of an International Application under 35 U.S.C. 371
If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office
If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

PTO/SB/14 (07-07)
Approved for use through 06/30/2010. OMB 0651-0032
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Application Data Sheet 37 CFR 1.76	Attorney Docket Number	1171/48067/202-PCT-US
	Application Number	
Title of Invention	A BREATHING ASSISTANCE APPARATUS	

The application data sheet is part of the provisional or nonprovisional application for which it is being submitted. The following form contains the bibliographic data arranged in a format specified by the United States Patent and Trademark Office as outlined in 37 CFR 1.76.
This document may be completed electronically and submitted to the Office in electronic format using the Electronic Filing System (EFS) or the document may be printed and included in a paper filed application.

Secrecy Order 37 CFR 5.2

☐ Portions or all of the application associated with this Application Data Sheet may fall under a Secrecy Order pursuant to 37 CFR 5.2 (Paper filers only. Applications that fall under Secrecy Order may not be filed electronically.)

Applicant Information:

Applicant 1 Remove

Applicant Authority ◉ Inventor ○ Legal Representative under 35 U.S.C. 117 ○ Party of Interest under 35 U.S.C. 118

Prefix	Given Name	Middle Name	Family Name	Suffix
	ALASTAIR	EDWIN	McAULEY	

Residence Information (Select One) ○ US Residency ◉ Non US Residency ○ Active US Military Service

City	AUCKLAND	Country Of Residence[i]	NZ

Citizenship under 37 CFR 1.41(b) [i] NZ

Mailing Address of Applicant:

Address 1	58A NGAPUHI ROAD
Address 2	REMUERA

City	AUCKLAND	State/Province	
Postal Code		Country[i]	NZ

Applicant 2 Remove

Applicant Authority ◉ Inventor ○ Legal Representative under 35 U.S.C. 117 ○ Party of Interest under 35 U.S.C. 118

Prefix	Given Name	Middle Name	Family Name	Suffix
	OLIVER		GLEESON	

Residence Information (Select One) ○ US Residency ◉ Non US Residency ○ Active US Military Service

City	AUCKLAND	Country Of Residence[i]	NZ

Citizenship under 37 CFR 1.41(b) [i] NZ

Mailing Address of Applicant:

Address 1	19A ROPATA AVENUE
Address 2	POINT ENGLAND

City	AUCKLAND	State/Province	
Postal Code		Country[i]	NZ

Applicant 3 Remove

Applicant Authority ◉ Inventor ○ Legal Representative under 35 U.S.C. 117 ○ Party of Interest under 35 U.S.C. 118

Prefix	Given Name	Middle Name	Family Name	Suffix
	EVAN	STUART	ERSTICH	

Residence Information (Select One) ○ US Residency ◉ Non US Residency ○ Active US Military Service

City	AUCKLAND	Country Of Residence[i]	NZ

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Application Data Sheet 37 CFR 1.76	Attorney Docket Number	1171/48067/202-PCT-US
	Application Number	
Title of Invention	A BREATHING ASSISTANCE APPARATUS	

Citizenship under 37 CFR 1.41(b) i	NZ			
Mailing Address of Applicant:				
Address 1	100 MAIN HIGHWAY			
Address 2	ELLERSLIE			
City	AUCKLAND	**State/Province**		
Postal Code		**Country**i	NZ	

Applicant 4 Remove

Applicant Authority ◉ Inventor	◯ Legal Representative under 35 U.S.C. 117	◯ Party of Interest under 35 U.S.C. 118		
Prefix	**Given Name**	**Middle Name**	**Family Name**	**Suffix**
	SIMON	ERIC	FREEMAN	
Residence Information (Select One) ◯ US Residency	◉ Non US Residency	◯ Active US Military Service		
City	AUCKLAND	**Country Of Residence**i	NZ	
Citizenship under 37 CFR 1.41(b) i	NZ			
Mailing Address of Applicant:				
Address 1	53 GLENVAR ROAD			
Address 2	TORBAY			
City	AUCKLAND	**State/Province**		
Postal Code		**Country**i	NZ	

Applicant 5 Remove

Applicant Authority ◉ Inventor	◯ Legal Representative under 35 U.S.C. 117	◯ Party of Interest under 35 U.S.C. 118		
Prefix	**Given Name**	**Middle Name**	**Family Name**	**Suffix**
	NEIL	GLEN	DAVIES	
Residence Information (Select One) ◯ US Residency	◉ Non US Residency	◯ Active US Military Service		
City	AUCKLAND	**Country Of Residence**i	NZ	
Citizenship under 37 CFR 1.41(b) i	NZ			
Mailing Address of Applicant:				
Address 1	22A BROWNS AVENUE			
Address 2	PAKURANGA			
City	AUCKLAND	**State/Province**		
Postal Code		**Country**i	NZ	

Applicant 6 Remove

Applicant Authority ◉ Inventor	◯ Legal Representative under 35 U.S.C. 117	◯ Party of Interest under 35 U.S.C. 118		
Prefix	**Given Name**	**Middle Name**	**Family Name**	**Suffix**
	STEPHEN	JOHN	SCHOENBERG	
Residence Information (Select One) ◯ US Residency	◉ Non US Residency	◯ Active US Military Service		
City	AUCKLAND	**Country Of Residence**i	NZ	
Citizenship under 37 CFR 1.41(b) i	US			

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Application Data Sheet 37 CFR 1.76	Attorney Docket Number	1171/48067/202-PCT-US
	Application Number	
Title of Invention	A BREATHING ASSISTANCE APPARATUS	

Mailing Address of Applicant:					
Address 1	4/78 WAIATARUA ROAD				
Address 2	REMUERA				
City	AUCKLAND	**State/Province**			
Postal Code		**Country**[i]	NZ		

Applicant 7 Remove

Applicant Authority ◉ Inventor	○ Legal Representative under 35 U.S.C. 117	○ Party of Interest under 35 U.S.C. 118		
Prefix	**Given Name**	**Middle Name**	**Family Name**	**Suffix**
	KAMMAN		LAW	

Residence Information (Select One) ○ US Residency ◉ Non US Residency ○ Active US Military Service

City	AUCKLAND	**Country Of Residence**[i]	NZ
Citizenship under 37 CFR 1.41(b) [i]	NZ		

Mailing Address of Applicant:					
Address 1	1616 DOMINION ROAD EXTENSION				
Address 2	MT. ROSKILL				
City	AUCKLAND	**State/Province**			
Postal Code		**Country**[i]	NZ		

Applicant 8 Remove

Applicant Authority ◉ Inventor	○ Legal Representative under 35 U.S.C. 117	○ Party of Interest under 35 U.S.C. 118		
Prefix	**Given Name**	**Middle Name**	**Family Name**	**Suffix**
	CRAIG	ROBERT	PRENTICE	

Residence Information (Select One) ○ US Residency ◉ Non US Residency ○ Active US Military Service

City	AUCKLAND	**Country Of Residence**[i]	NZ
Citizenship under 37 CFR 1.41(b) [i]	NZ		

Mailing Address of Applicant:					
Address 1	95 KIWI ESPLANADE				
Address 2	MANGERE BRIDGE				
City	AUCKLAND	**State/Province**			
Postal Code		**Country**[i]	NZ		

All Inventors Must Be Listed - Additional Inventor Information blocks may be generated within this form by selecting the **Add** button. Add

Correspondence Information:

Enter either Customer Number or complete the Correspondence Information section below.
For further information see 37 CFR 1.33(a).

☐ **An Address is being provided for the correspondence Information of this application.**

Customer Number	00279		
Email Address	PTODOCKET@TREXLAW.COM	Add Email	Remove Email

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Approved for use through 06/30/2010. OMB 0651-0032
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
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Application Data Sheet 37 CFR 1.76	Attorney Docket Number	1171/48067/202-PCT-US
	Application Number	
Title of Invention	A BREATHING ASSISTANCE APPARATUS	

Application Information:

Title of the Invention	A BREATHING ASSISTANCE APPARATUS		
Attorney Docket Number	1171/48067/202-PCT-US	**Small Entity Status Claimed**	☐
Application Type	Nonprovisional		
Subject Matter			
Suggested Class (if any)		**Sub Class (if any)**	
Suggested Technology Center (if any)			
Total Number of Drawing Sheets (if any)	21	**Suggested Figure for Publication (if any)**	

Publication Information:

☐ Request Early Publication (Fee required at time of Request 37 CFR 1.219)

☐ **Request Not to Publish.** I hereby request that the attached application not be published under 35 U.S. C. 122(b) and certify that the invention disclosed in the attached application **has not and will not** be the subject of an application filed in another country, or under a multilateral international agreement, that requires publication at eighteen months after filing.

Representative Information:

Representative information should be provided for all practitioners having a power of attorney in the application. Providing this information in the Application Data Sheet does not constitute a power of attorney in the application (see 37 CFR 1.32).
Enter either Customer Number or complete the Representative Name section below. If both sections are completed the Customer Number will be used for the Representative Information during processing.

Please Select One:	◉ Customer Number	○ US Patent Practitioner	○ Limited Recognition (37 CFR 11.9)
Customer Number	00279		

Domestic Benefit/National Stage Information:

This section allows for the applicant to either claim benefit under 35 U.S.C. 119(e), 120, 121, or 365(c) or indicate National Stage entry from a PCT application. Providing this information in the application data sheet constitutes the specific reference required by 35 U.S.C. 119(e) or 120, and 37 CFR 1.78(a)(2) or CFR 1.78(a)(4), and need not otherwise be made part of the specification.

Prior Application Status			Remove
Application Number	Continuity Type	Prior Application Number	Filing Date (YYYY-MM-DD)
	a 371 of international	PCT/NZ2007/000185	2007-07-13

Additional Domestic Benefit/National Stage Data may be generated within this form by selecting the **Add** button. Add

Foreign Priority Information:

This section allows for the applicant to claim benefit of foreign priority and to identify any prior foreign application for which priority is not claimed. Providing this information in the application data sheet constitutes the claim for priority as required by 35 U.S.C. 119(b) and 37 CFR 1.55(a).

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Application Data Sheet 37 CFR 1.76	Attorney Docket Number	1171/48067/202-PCT-US
	Application Number	
Title of Invention	A BREATHING ASSISTANCE APPARATUS	

			Remove
Application Number	Country [i]	Parent Filing Date (YYYY-MM-DD)	Priority Claimed
548575	NZ	2006-07-14	(•) Yes ( ) No
			Remove
Application Number	Country [i]	Parent Filing Date (YYYY-MM-DD)	Priority Claimed
551103	NZ	2006-11-06	(•) Yes ( ) No
Additional Foreign Priority Data may be generated within this form by selecting the **Add** button.			Add

Assignee Information:

Providing this information in the application data sheet does not substitute for compliance with any requirement of part 3 of Title 37 of the CFR to have an assignment recorded in the Office.

Assignee 1 Remove

If the Assignee is an Organization check here. ☐

Prefix	**Given Name**	Middle Name	**Family Name**	Suffix

Mailing Address Information:

Address 1			
Address 2			
City		**State/Province**	
Country [i]		Postal Code	
Phone Number		Fax Number	
Email Address			

Additional Assignee Data may be generated within this form by selecting the **Add** button. Add

Signature:

A signature of the applicant or representative is required in accordance with 37 CFR 1.33 and 10.18. Please see 37 CFR 1.4(d) for the form of the signature.

Signature	/RAIFORD A. BLACKSTONE, JR./			Date (YYYY-MM-DD)	2009-01-08
First Name	RAIFORD	Last Name	BLACKSTONE	Registration Number	25156

This collection of information is required by 37 CFR 1.76. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 23 minutes to complete, including gathering, preparing, and submitting the completed application data sheet form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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The Privacy Act of 1974 (P.L. 93-579) requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

The information provided by you in this form will be subject to the following routine uses:

1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C. 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether the Freedom of Information Act requires disclosure of these records.

2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.

3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.

4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).

5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.

6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).

7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.

8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspections or an issued patent.

9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

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Approved for use through 12/31/2008. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (**Not for submission under 37 CFR 1.99)**		
	Application Number	
	Filing Date	
	First Named Inventor	ALASTAIR EDWIN McAULEY
	Art Unit	
	Examiner Name	
	Attorney Docket Number	1171/48067/202-PCT-US

U.S.PATENTS						Remove
Examiner Initial*	Cite No	Patent Number	Kind Code[1]	Issue Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1	7318437		2008-01-15	GUNARATNAM ET AL.	
	2	6679257		2004-01-20	ROBERTSON ET AL.	
	3	5148802		1992-09-22	SANDERS ET AL.	
	4	5245995		1993-09-21	SULLIVAN ET AL.	
	5	5477852		1995-12-26	LANDIS ET AL.	
	6	6119694		2000-09-19	CORREA ET AL.	
	7	6907882		2005-06-21	GING ET AL.	
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INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	
	Filing Date	
	First Named Inventor	ALASTAIR EDWIN McAULEY
	Art Unit	
	Examiner Name	
	Attorney Docket Number	1171/48067/202-PCT-US

Examiner Initial*	Cite No	Publication Number	Kind Code[1]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1	20030172936		2003-09-18	WILKIE ET AL.	
	2	20060060200		2006-03-23	HO ET AL.	
	3	20060196511		2006-09-07	LAU ET AL.	
	4	20060237018		2006-10-26	McAULEY ET AL.	
	5	20070089749		2007-04-26	HO ET AL.	

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Examiner Initial*	Cite No	Foreign Document Number[3]	Country Code[2] ¡	Kind Code[4]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear	T[5]
	1	2007/041786	WO		2007-04-19	RESMED LTD		☐
	2	2004/041341	WO		2004-05-21	RESMED LTD		☐

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT (**Not for submission under 37 CFR 1.99)**		
	Application Number	
	Filing Date	
	First Named Inventor	ALASTAIR EDWIN McAULEY
	Art Unit	
	Examiner Name	
	Attorney Docket Number	1171/48067/202-PCT-US

Examiner Initials*	Cite No	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc), date, pages(s), volume-issue number(s), publisher, city and/or country where published.	T[5]
	1		☐

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Examiner Signature		Date Considered	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through a citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

[1] See Kind Codes of USPTO Patent Documents at www.USPTO.GOV or MPEP 901.04. [2] Enter office that issued the document, by the two-letter code (WIPO Standard ST.3). [3] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [4] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. [5] Applicant is to place a check mark here if English language translation is attached.

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	
	Filing Date	
	First Named Inventor	ALASTAIR EDWIN McAULEY
	Art Unit	
	Examiner Name	
	Attorney Docket Number	1171/48067/202-PCT-US

CERTIFICATION STATEMENT

Please see 37 CFR 1.97 and 1.98 to make the appropriate selection(s):

☐ That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(1).

OR

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☐ Fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

☒ None

SIGNATURE

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Signature	/RAIFORD A. BLACKSTONE/	Date (YYYY-MM-DD)	2009-01-08
Name/Print	RAIFORD A. BLACKSTONE, JR.	Registration Number	25156

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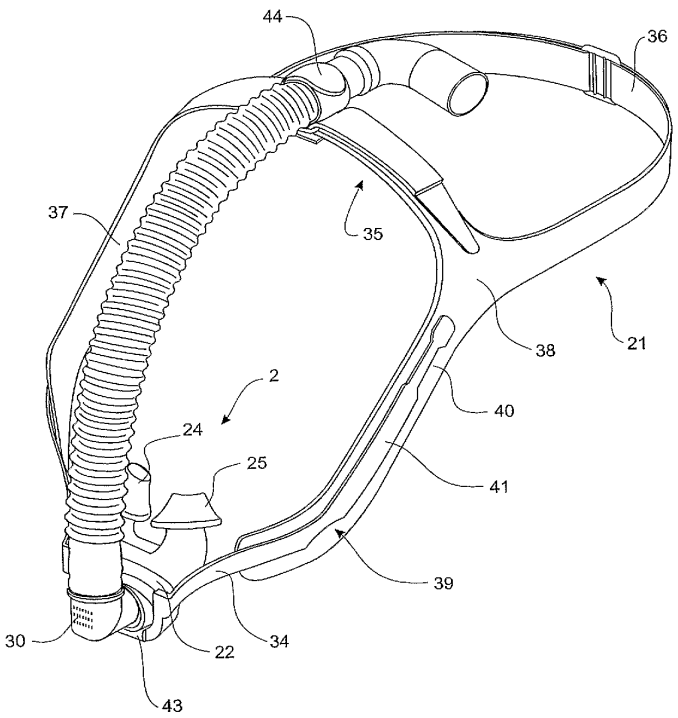

(57) Abstract: Headgear for use with a respiratory mask is described. The headgear comprises a continuous and substantially curved elongate member extending in use below a user's nose and at least two headgear straps capable of attachment to the ends of the elongate member. A mask attachment on the elongate member is disposed to sit below or on one of said user's nose, mouth, upper lip and an inlet to the mask. The attachment is capable of receiving the mask.

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BREATHING ASSISTANCE APPARATUS

BACKGROUND OF THE INVENTION

Technical Field

The present invention relates to apparatus for treating sleep apnoea. More specifically, the present invention provides a nasal interface for the supply of respiratory gases, but most particularly positive pressure gases.

Summary of the Prior Art

In the art of respiration devices, a variety of respiratory masks which cover the nose and/or mouth of a human user in order to provide a continuous seal around the nasal and/or oral areas of the face are well known. Masks that provide gas at positive pressure within the mask for consumption by the user are also well known. The uses for such masks range from high altitude breathing (i.e., aviation applications) to mining and fire fighting applications, to various medical diagnostic and therapeutic applications.

Obstructive Sleep Apnoea (OSA) is a sleep disorder that affects up to at least 5% of the population in which muscles that normally hold the airway open relax and ultimately collapse, sealing the airway. The sleep pattern of an OSA sufferer is characterised by repeated sequences of snoring, breathing difficulty, lack of breathing, waking with a start and then returning to sleep. Often the sufferer is unaware of this pattern occurring. Sufferers of OSA usually experience daytime drowsiness and irritability due to a lack of good continuous sleep.

In an effort to treat OSA sufferers, a technique known as Continuous Positive Airway Pressure (CPAP) was devised. A CPAP device consists of a gases supply (or blower) with a conduit connected to supply pressurised gases to a patient, usually through a nasal mask. The pressurised air supplied to the patient effectively assists the muscles to keep the patient's airway open, eliminating the typical OSA sleep pattern.

The procedure for administering CPAP treatment has been well documented in both the technical and patent literature. Briefly stated, CPAP treatment acts as a pneumatic splint of the airway by the provision of a positive pressure, usually in the range 4 to 20 cm H_2O. The air is supplied to the airway by a motor driven blower whose outlet passes via an air delivery hose to a nose, full face, nose and mouth, or oral mask that is sealingly engaged to a patient's face, preferably by means of a harness or other headgear. An exhaust port is usually also provided in the delivery tube proximate to the mask or on the mask itself. More sophisticated

forms of positive airway pressure devices, such as bi-level devices and auto-titrating devices, are described in US Patent No. 5,148,802 of Respironics, Inc. and US Patent No. 5,245,995 of Rescare Limited, respectively.

One requisite of respiratory masks has been that they provide an effective seal against the user's face to prevent leakage of the gas being supplied. Commonly, in prior mask configurations, a good mask-to-face seal has been attained in many instances only with considerable discomfort for the user. A common complaint of a user of CPAP therapy is pressure sores caused by the mask about the nose and face and in particular in the nasal bridge region of the user. This problem is most crucial in those applications, especially medical applications, which require the user to wear such a mask continuously for hours or perhaps even days. In such situations, the user will not tolerate the mask for long durations and optimum therapeutic or diagnostic objectives thus will not be achieved, or will be achieved with great difficulty and considerable user discomfort.

US Patent No. 5,477,852 of Airways Ltd, Inc. discloses a nasal positive airway pressure device that has a pair of nasal members each having a cannula tip to be inserted into the nares of the patient. Each cannula is tapered from a substantially circular cross section outside the patient's nostril to a substantially oval cross section at the tip inserted into the nostril. An inflatable cuff surrounds each cannula with the interior space of the cuff communicating with the lumen of the cannula through at least one aperture in the sidewall of the cannula. The nasal members are connected to one or more flexible hoses that, in turn, are connected to a source of positive air pressure. In use, positive air pressure is supplied to each cannula tip through the air hoses and nasal members. The positive air pressure inflates the cuffs to hold the nasal members in place and to effect treatment. The nasal device of US Patent No. 5,477,852 is attached to headgear that is located about a patient's head. This headgear could be considered by many patients as cumbersome and uncomfortable.

Conventional nasal masks used for administrating CPAP treatment are also considered uncomfortable and cumbersome, and prior art nasal masks can be noisy due to air leaks. These disadvantages in many cases are a formidable obstacle to patient acceptance of such treatment. Therefore, a substantial number of patients either cannot tolerate treatment or choose to forego treatment. It is believed a number of such patients might benefit from a nasal positive airway pressure apparatus that is more convenient to use and comfortable to wear, thereby resulting in increased treatment compliance.

Innomed Technologies, Inc. manufactures a nasal cannula device called the NASALAIRE™. In this device air or oxygen travels down a wide bore conduit to nasal cannula. The NASALAIRE™ creates a physical seal between the nares and itself, and relies on the absence of leaks around the cannula and the nares to deliver pressure supplied by a continuous positive airway pressure (CPAP) blower to the airway of the wearer.

US6,119,694 of Respironics Georgia, Inc discloses a nasal mask having a nare seal and lateral support members to support the mask.

WO2004/073778 of ResMed Limited discloses a nasal mask including a frame where headgear is provided with rigid sections that extend to the nasal mask.

WO04/041341 of ResMed Limited discloses headgear for a patient mask that includes a sewn on rigid section to the back area of headgear straps to provide rigidity to the straps.

US6,907,882 of ResMed Limited discloses a nasal mask and headgear that is attachable to the frame of the nasal mask. The headgear straps have rigid sections integral with the releasable connectors that attach the headgear to the mask.

DISCLOSURE OF THE INVENTION

It is an object of the present invention to attempt to provide a patient interface that goes some way to overcoming the abovementioned disadvantages in the prior art or which will at least provide the industry with a useful choice.

In a first aspect the present invention consists in headgear for use with a respiratory mask comprising:

a continuous and substantially curved elongate member extending in use below a patient's nose,

at least two headgear straps capable of attachment to the ends of said elongate member, and

a mask attachment on said elongate member disposed to sit below or on one of said user's nose, mouth, upper lip and an inlet to the mask, said attachment capable of receiving said mask.

In a second aspect the present invention consists in a breathing assistance apparatus for use with delivery of respiratory gases to a user comprising:

a mask having a base and body, said body having two flexible nasal pillows that in use rest in a substantially sealed manner against said user's nares,

a continuous and substantially curved elongate member extending in use below a

patient's nose,

at least two headgear straps capable of attachment to the ends of said elongate member, and

a mask attachment on said elongate member disposed below said user's nose, said attachment capable of receiving said mask.

In a third aspect the present invention consists in a breathing assistance apparatus for use with delivery of respiratory gases to a user comprising:

a mask comprising a body and a cushion, said cushion substantially forming a seal with said patient's airways,

headgear comprising substantially flexible, soft straps and a substantially continuous curved elongate member to which said mask is attached, said elongate member extending over said user's cheeks, and

wherein said mask has an inlet extension tube and said curved elongate member is attached or rests beneath said inlet extension tube, anchoring said mask to said user's face in use.

To those skilled in the art to which the invention relates, many changes in construction and widely differing embodiments and applications of the invention will suggest themselves without departing from the scope of the invention as defined in the appended claims. The disclosures and the descriptions herein are purely illustrative and are not intended to be in any sense limiting.

In this specification where reference has been made to patent specifications, other external documents, or other sources of information, this is generally for the purpose of providing a context for discussing the features of the invention. Unless specifically stated otherwise, reference to such external documents is not to be construed as an admission that such documents, or such sources of information, in any jurisdiction, are prior art, or form part of the common general knowledge in the art.

The invention consists in the foregoing and also envisages constructions of which the following gives examples.

BRIEF DESCRIPTION OF THE FIGURES

Preferred forms of the present invention will now be described with reference to the accompanying drawings.

Figure 1 is a block diagram of a humidified continuous positive airway pressure system as might be used in conjunction with the nasal mask of the present invention.

Figure 2 is a perspective view of a first form of a patient interface that is nasal mask and headgear of the present invention.

Figure 3 is an exploded view of the nasal mask and headgear of Figure 2.

Figure 4 is a side view of a mask base of the nasal mask and headgear of Figure 2.

Figure 5 is a perspective end view of the mask base of Figure 4.

Figure 6 is an end view of a body of the nasal mask and headgear of Figure 2, particularly showing two nasal pillows.

Figure 7 is a perspective view of the body of Figure 6.

Figure 8 is a perspective view of a nasal mask of the first form of the present invention but having alternative headgear that includes additional rigid extensions.

Figure 9 is perspective view of a second form of a patient interface and headgear of the present invention.

Figure 10 is an exploded view of the patient interface and headgear of Figure 9.

Figure 11 is an exploded view of a third form of a patient interface and headgear of the present invention.

Figure 12 is an exploded view of a fourth form of a patient interface and headgear of the present invention.

Figure 13 is a perspective view of a fifth form of a patient interface and headgear of the present invention.

Figure 14 is an exploded view of the patient interface and headgear of Figure 13.

Figure 15 is a perspective view of a sixth form of a patient interface and headgear of the present invention.

Figure 16 is a perspective view of a seventh form of a patient interface and headgear of the present invention.

Figure 17 is a cross-sectional view of the patient interface of Figure 16.

Figure 18 is a front view of a nasal pillow of Figure 6.

Figures 19a is a front view of the nasal pillows of Figure 6.

Figures 19b to 19d are graphs of the gradients of various nasal pillow connecting surfaces.

Figure 20 is a perspective view of an eighth form of a patient interface and headgear of the present invention.

Figure 21 is a perspective view of the interface and headgear of Figure 20 showing inner pads on the arms of the headgear.

Figure 22 is an exploded view of the interface and headgear of Figure 20.

Figure 23 is a perspective view of a ninth form of a patient interface and headgear the present invention.

DESCRIPTION OF THE PREFERRED EMBODIMENTS OF THE INVENTION

The breathing assistance apparatus of the present invention including masks and headgear as described in the preferred embodiments of this invention can be used in respiratory care generally or with a ventilator. It is described below with reference to use in a humidified CPAP system.

A humidified Continuous Positive Airway Pressure (CPAP) system is shown in Figure 1. A patient 1 is receiving humidified and pressurised gases through a patient interface 2 connected to a humidified gases transportation pathway or inspiratory conduit 3. Alternative delivery systems may also be used such as, VPAP (Variable Positive Airway Pressure) and BiPAP (Bi-level Positive Airway Pressure) or numerous other forms of respiratory therapy. A nasal mask 2 is illustrated in Figure 7 but other masks such as oral, full face or nasal cannula may be used.

An inspiratory conduit 3 is connected to an outlet 4 of a humidification chamber 5 that contains a volume of water 6. The inspiratory conduit 3 may contain heating means or heater wires (not shown) that heat the walls of the conduit to reduce condensation of humidified gases within the conduit 3.

The humidification chamber 5 is preferably formed from a plastics material and preferably has a highly heat conductive base (for example an aluminium base) that is in direct contact with a heater plate 7 of humidifier 8. The humidifier 8 is provided with control means or an electronic controller 9 that may comprise a microprocessor based controller executing computer software commands stored in associated memory.

The controller 9 preferably receives input from sources such as user input means or a dial 10 through which a user of the device may, for example, set a predetermined required value (preset value) of humidity or temperature of the gases supplied to patient 1. The controller 9 may also receive input from other sources, for example temperature and/or flow

velocity sensors 11, 12, through a connector 13 and a heater plate temperature sensor 14. In response to the user set humidity or temperature value input via the dial 10 and the other inputs, the controller 9 determines when (or to what level) to energise the heater plate 7 to heat the water 6 within the humidification chamber 5. As the volume of the water 6 within the humidification chamber 5 is heated, water vapour begins to fill the volume of the chamber above the water's surface and is passed out of the humidification chamber 5 outlet 4 with the flow of gases (for example air) provided from a gases supply means or blower 15 that enters the chamber 5 through an inlet 16. Exhaled gases from the patient's mouth are passed directly to the ambient surroundings in Figure 1.

The blower 15 is provided with variable pressure regulating means or variable speed fan 21 that draws air or other gases through a blower inlet 17. The speed of the variable speed fan 21 is controlled by an electronic controller 18 (or alternatively the function of the controller 18 may be carried out by the controller 9) in response to inputs from the controller 9 and a user set predetermined required value (preset value) of pressure or the fan speed via dial 19.

Figures 2 and 3 show a first embodiment of a patient interface of the present invention. This patient interface is a nasal mask 2. The nasal mask 2 is comprised of a mask base 22 and body 23. The body 23 is substantially tubular with two nasal pillows 24, 25 extending from it. The nasal pillows 24, 25 are preferably frustoconical in shape and in use rest against a patient's nares, to substantially seal the patient's nares. The body 23 has an external lip 28 that frictionally fits in a channel in the mask base 22.

The body 23 and nasal pillows 24, 25 of the nasal mask of the present invention are shown in further detail in Figures 6 and 7. The body and pillows are preferably integrally moulded in a substantially flexible plastics material. In the preferred form this material is silicone, but other appropriate materials, such as, rubber, thermoset elastomer or thermoplastic elastomer, such as Kraton™ may be used.

The nasal pillows 24, 25 are preferably an elliptical cone and as such are tubular and allow for a passage of gases to flow from the tubing 3 and through the mask body 23. The pillows 24, 25 are preferably angled toward one another and each have a preferably elliptical outlet 26, 27 that may be slightly offset from the centre of each pillow 24, 25, as shown in Figure 6.

Figures 18 and 19a show a nasal pillow 24 with an offset outlet in more detail. The

pillow 24 has an outer profile 200 and inner profile 201 with respective centre points 202, 203. The inner profile 201 (outlet of the nasal pillow 24) is offset inward, by a horizontal spacing 204 and vertical spacing 205. Meaning the outlet 201 of the nasal pillow is offset horizontally 204 towards the middle of the nose and vertically 205 towards the user's upper lip. Offsetting the outlet 201 downwards in this manner allows the outlet to be inserted into a user's nostril without the outer profile 200 pushing the user's upper lip. Offsetting the outlet 201 inwards allows the pillow to better seal on the septum of the user's nose in use.

The outlet 201 may also be angled compared to the outer profile 200. For example in Figure 18, there is a horizontal angle difference between the outer profile 200 and outlet 201 shown as 206. A similar vertical angle difference between the outer profile 200 and outlet 201 is shown as 207.

With the outer profile and inner profile having different sections or offsets allows the gradient of the connecting surface between the profiles to be changeable. This is shown in the graphs of Figures 19b, 19c and 19d. The connecting surface between the inner 201 and outer 200 profiles can have differing gradients, 208, 209, 210. The different gradients 208, 209, 210 of the connecting surface are possible due to the difference in offset difference 211, 212 (horizontal, vertical or angled) between the inner 201 and outer 200 profiles.

There may also be a difference in the rate of change of the gradient (as illustrated in the difference between 208 and 210). This allows easier insertion of the pillow 24 into a user's nostrils due to more lead in and better sealing that may be achieved due to more ergonomic contouring of the connecting surface that contacts the user's nostril.

Referring back to Figure 7, the external lip 28 on the mask body 23 is an area of reduced circumference around the tubular part of the body 23. A projection 47 may be provided on the lip 28 that fits with a corresponding recess or channel (discussed below) on the mask base 22 to ensure correct assembly of the nasal mask.

The mask base 22 is shown in further detail in Figures 4 and 5. The mask base 22 is a ring or sleeve type attachment. The base 22 is preferably made from a substantially hard (rigid) plastics material, such as polypropylene, polycarbonate or acetyl. However, other appropriate materials may be used. The base 22 has an internal circumferential recessed area or channel 45 on one side and a semi-tubular projection 29 on its other side. When assembling the mask body 23 to the mask base 22 the channel 45 receives the lip 28. These parts are maintained together by friction fit, however other types of fitting may be provided for, such as

a snap or bump fitted part or the body may be over moulded to a clip that causes the fitting to the mask body 23. In this form the friction fitting of the lip 28 to the recessed area 45 is assisted by elongate projections 49 extending along the central part 50 of the mask base 22. The projection 47 on the mask body 23 allows for correct fitting or keying of the mask base to the mask body, such that when the lip 28 is fitted into the recessed area 45, the projection 47 enters the recess 48 formed in the mask base 22.

The semi-tubular projection 29 is curved in this embodiment such that a ball jointed connector end 46 such that a connector 30 can be fitted into it. The projection 29 forms a socket for the connector end 46 and the connector end can swivel within the socket. The connector 30 is attached to a tube 31 to allow for gases to be passed to the nasal mask 2. The tubing 31 may be attached to inspiratory conduit 3 or the tubing 31 may simply be the inspiratory conduit 3.

In alternative embodiments the projection 29 may not be semi-circular but the inner surface of the base 22 may be curved and form a socket for receiving the connector end 46.

The base 22 has an extension or partial lip 32 extending beneath the semi-tubular projection (socket) 29. A slot 33 is created between the socket 29 and extension 32. The extension and slot is used to fit the mask base 22 to the headgear 21. In this embodiment the extension 32 is substantially curved to follow the shaped of the projection 29. However, in other forms the extension may be substantially straight or otherwise shaped.

In use, the nasal mask is assembled with headgear 21. The headgear 21 in the preferred form is comprised of headgear straps 35, 36, 37, 38 and a substantially curved and elongate member 34. The member 34 is curved and substantially rigid, or at least more rigid than the headgear straps.

The headgear straps 35, 36, 37, 38 are preferably made from a composite foam layered material, such as Breathoprene™. The headgear 21 preferably includes a first strap 35 and a second strap 36. The first strap 35 extends in use over the forehead or top front area of a patient's head. The second strap 36 extends around the back of the patient's head. The headgear 21 also has side straps 37, 38 that in use extend down the cheeks of a patient and the ends of the straps terminate in the upper lip area of the patient in use.

Referring to Figure 2, the curved and elongate member 34 is comprised of a central section 42 and contoured side arms 41, 54. A substantial length of each of the side arms 41, 54 overlaps and is attached to the side straps 37, 38. However, the side straps 37, 38 only

extend partially along the length of the side arms 41, 54 so as to terminate beneath the cheek or near the upper lip region. As the side straps 37, 38 are made from a soft foam type material they provide a comfortable fitting of the headgear and curved member 34, while the substantially rigid side arms 41, 54 provide rigidity and stability to the headgear 21 and nasal mask 2. The attachment between the side straps and rigid extension side arms may be made by gluing, sewing or other appropriate fastening.

Preferably the side arms of the curved member 34 are integrally moulded with the central section 42. The curved member 34 is preferably three dimensionally moulded to a shape to substantially match the cheek contours of a human. The side arms 41, 54 are preferably of thinner width (cross-section) than the central section 42. As the side arms 41, 54 are moulded of a plastics material to be substantially thin they are capable of being bent or adjusted to allow for better and more comfortable fit to a patient. The side arms 41, 54 may also include weakened or narrow areas 39 to allow for additional bending, moulding or twisting of the arms 41, 54 to better fit the headgear to individual patients. For example, in the embodiment shown in Figures 2 and 3, the narrowed area 39 corresponds to the cheek bone area of a patient and allows for the side arms 41, 54 to easier bend or twist to fit the contours of the patient's face.

In alternative embodiments the side arms may have weakened areas that are narrower in cross-section to that of the remainder of the side arms. A narrower cross-section area would also provide a weakened area that may be easily manipulated.

In alternative embodiments of the present invention the side straps of the headgear may not extend under and along the length of the curved member but be attached to the distal ends of the straps. This attachment may be by hook and loop material, as is known in the art, or by other attachment methods as known in the art. In this form, the arms of the curved member may have padding underneath them or no padding at all.

Referring to Figure 3, the curved elongate member has a central section 42 that in an assembled form supports the mask base and body such that the pillows 24, 25 rest against the patient's nares. The central section 42 is a half circle that is integrally moulded with the side arms 41, 54. The central section 42 has a raised area 43 on its exterior, at the apex of the half circle. The raised area 43 is shaped to receive the mask base 22. To assemble, a patient merely needs to slide the mask base 22 into the central section 42 such that the raised area 43 fits into the slot 33 on the mask base 22.

The side arms 41, 54 of the curved member 34 preferably have varying cross-sectional thickness. The ends of the arms 41, 54 attached to the central section 42 are thicker over the most curved parts 55, 56 of the arms, whereas the straighter parts of the arms 57, 58 have a narrow cross-section. Therefore, the thicker ends 55, 56 hold their shape better.

In alternative embodiments, the mask base 22 may be formed integrally with the curved member 34. Therefore, the central section and base would be one and would not be able to be separated from one another.

An example of this is shown in Figures 20 to 22, the eighth embodiment of the patient interface and headgear 300. Here, the mask base 301 and the curved elongate member 302 are integrally formed, for example, by moulding or the like. The elongate member comprises arms 303, 304 similar to that described above. Also the mask body 305 has integral nasal pillows 306, 307 similar to that described above in relation to Figure 2.

As can be seen in Figures 21 and 22 in this eighth embodiment the headgear straps 308, 309 do not extend down the arms 303, 304 as with other embodiments. In this embodiment the headgear straps 308, 309 attach through recesses 310, 313 at the end of the arms 303, 304 extending along the arms are inner pads 311,312 that rest against the patient's cheekbones in use and provide comfort to the patient's face. The pads 311, 312 only extend up to near the attachment recesses 309, 310. The pads are preferably made from a foam type material, such as the laminated material that the headgear straps are made from. The pads 311, 312 preferably do not extend beyond the edges of the arms 303,304.

Referring back to Figures 2 and 3, alternatively, the curved member 34 may be formed as two separate pieces. That is, the central section 42 may be formed as two parts with a central split seam, the two left and right halves joined in use. The two left and right parts could either be joined along a seam as described above, with the base 22 slotting into the slot 33 as described above, or alternatively, each of the two left and right arms may be attached one to each side of the base 22.

Where a "substantially continuous elongate member" or "curved member" is referred to in this specification, it refers to any of the options for the curved member 34 outlined above.

The side arms 41, 54 may also include a loop 40 or detached section. This is where a section of the side arms 41 is not attached to the strap 38, 37 lying underneath. Thus the detached section 40 of the side arms forms a loop to which a tubing attachment 44 (such as that shown attached to another strap in Figures 2 and 3) may be looped to the side arms 41, 54

and the tubing 31 attached to either of the side arms.

The connector 30 in the preferred form is a ball and socket jointed connector to allow for the tubing 31 to swivel in the mask base 22. The tubing 31 may be attached to any of the headgear straps. However, a tube attachment 44 is shown where the tubing is attached by fasteners, such as hook and loop fastener, to the first strap 35. In other embodiments the tubing 31 may be attached to either the side straps 37, 38 or merely allowed to fall freely from the nasal mask 2.

Although a ball and socket joint, as described above, between the mask base 22 and tubing 31 is preferred other connections may be utilised, such as a flexible piece of silicone, or other appropriate connection. The connection between the base and tubing must be able to be flexed or rotated to allow for the tubing to be moved without causing the dislodgement of the nasal mask 2 from the user's nares.

The mask body 23 may be provided with nasal pillows of various different sizes, such that user's may remove an existing mask body and simply attach a different sized body to the mask base 22.

Alternative headgear may be used with the patient interface of the present invention. In particular, alternative headgear is shown in use with the first form of the patient interface (of Figure 2) in Figure 8. Here the headgear may include an additional strap 53 extending from the cheek region of the side straps 41 and extending behind the user's head. This lower additional strap 53 may also include substantially rigid arms 51 similar to the arms 41 described above. Any number of connecting straps 52 may also be provided between the upper strap 36 and lower strap 53. Again, the arms 51 would provide stability and rigidity to the additional strap 53.

In the embodiment described above, when the patient interface of the first form is in use, the user's face causes the mask base 22 and body 23 to clip with the curved member 34. This is due to the angle of the curved member 34 and fixing of the mask base 22 and body 23 to the curved member 34.

Further, in all forms, the curved member 34 transfers the load of the patient interface away from the user's nose and to the cheek regions of the user.

A second form of the patient interface and headgear of the present invention is shown in Figures 9 and 10. In this embodiment a mouthpiece 100 is attached to the substantially tubular mask body 23 substantially below the nasal pillows 24, 25. The mouthpiece 100 is

preferably a flap that is fittable within the patient's mouth. A gases pathway extends through the mask body 23 and through the centre of the mouthpiece 100, such that in use a patient or user is supplied with gases via the nasal pillows 24, 25 and the mouthpiece 100. The flap 100 is preferably made from a silicone plastics material but other appropriate materials such as rubber, thermoset elastomer or thermoplastic elastomer, such as Kraton™ may be used. The flap 100 is preferably integrally moulded with the mask body 23 and nasal pillows 24, 25. In use the flap 100 sits within the user's mouth between the user's teeth and lips.

In this second form the headgear and particularly the curved member 34 is substantially the same as that described in relation to the first embodiment.

A third form of the patient interface and headgear of the present invention is shown in Figure 11. In this embodiment a mouthpiece as well as a nose blocking device is attachable to the mask base 22. The mouthpiece 110 and nose blocking device 111 are preferably integrally formed. The mouthpiece 110 has an inner vestibular shield 112 that is similar to the flap 100 described above. Therefore the vestibular shield 112 in use sits within the patient's mouth between the patient's teeth and lips and provides an at least partial seal between the user and the shield 112.

A tubular extension 113 extends through the mouthpiece 110 to the mask base 22 from the vestibular shield 112. The extension allows for gases to be passed to the patient from the conduit 31.

The nose blocking device 111 in use rests under the user's nose and blocks the user's nares.

In this third form the headgear and particularly the curved member 34 is substantially the same as that described in relation to the first embodiment.

A fourth embodiment of the patient interface and headgear of the present invention is shown in Figure 12. In this embodiment a mouthpiece 120, 121 is attachable via a tubular extension 122 to the mask base 22. The mouthpiece is made up of an outer mouthpiece flap 120 and an inner vestibular shield 121. The shield 121 is substantially the same as that described in reference to the third embodiment. The outer mouthpiece flap 120 rests in use outside the user's mouth and substantially seals about the user's mouth. The outer mouthpiece flap 120 and an inner vestibular shield 121 are described in further detail in United States patent number 6679257, the entire contents of which is herein incorporated by reference.

In the fourth form of the headgear and particularly the curved member 34 is

substantially the same as that described in relation to the first embodiment.

A fifth form of the patient interface and headgear of the present invention is shown in Figures 13 and 14. This embodiment is very similar to the fourth embodiment except the mouthpiece is simply an outer mouthpiece flap 130. This flap 130 is fittable to the mask base 22 by way of the tubular extension 131. Again, as above, the headgear and particularly the curved member 34 are substantially the same as that described in relation to the first embodiment.

A sixth form of the patient interface and headgear of the present invention is shown in Figure 15. In this embodiment the patient interface is a full face mask 140 that extends over a user's nose and mouth and under the user's chin in use. The mask 140 has a body 142 made from a substantially rigid plastics material and a cushion 144 made from a substantially soft plastics material. The mask and cushion are preferably similar to that described in more detail in United States patent application number 11/368004, the entire contents of which is incorporated herein by reference.

A tubular inlet port 143 is formed in the mask body 142. The tubing 31 is attachable to the port 143 to provide gases to the user wearing the mask.

The headgear is substantially similar to that described in relation to Figure 2 (the second form); however, the curved member 141 differs. The curved member 141 does not have a mask base similar to that described in the second form in which to attach to. Therefore, the curved member 141 has a central section 145 that curves under the inlet port 143, effectively anchoring on the inlet port. The curved member 141 is moulded in substantially the same manner as described with reference to the second form.

A seventh form of the patient interface and headgear of the present invention is shown in Figures 16 and 17. Here, the headgear and curved member is similar to that described above in the sixth embodiment, where the curved member 141 has a central section that curves under and anchors onto an inlet port 151 on a patient interface 150. The patient interface 150 is an integral mouth mask 152 and nasal pillows 153. The mouth mask 152 preferably extends under the user's 155 chin, as shown in Figure 17.

The interface 150 has a substantially rigid body 154 that has substantially soft cushion 156 attached to it. The cushion 156 is preferably of the type disclosed in United States patent number 6951218 (the entire contents of which is incorporated herein by reference) having an inner 157 and outer 158 cushions.

Integrally formed in the outer cushion 158 are nasal pillows 153. Preferably two nasal pillows 159, 160 are formed in the cushion 158. These are substantially tubular and carry gases in use from the inside of the interface 150 to the user's 155 nares. The outer cushion 158 and nasal pillows 159, 160 are preferably made from a soft pliable plastics material such as silicone but other appropriate materials such as rubber or KRATON™ may be used.

A similar but slightly different embodiment to that of Figure 16 is a ninth embodiment of the present invention, as shown in Figure 23. Here the interface 400 is substantially the same as the interface 150 of Figure 16 and 17. The interface 400 has a body 401 with integral nasal pillows 402, 403. The nasal pillows may be integrally formed with the body or separately formed and simply assembled to the body before use. The nasal pillows 402, 403, as above, are substantially tubular and carry gases in use from the inside of the interface 400 to the user's nares. Again, nasal pillows are preferably made from a soft pliable plastics material such as silicone but other appropriate materials such as rubber or KRATON™ may be used.

In this embodiment the body 401 may be made of a more rigid material than the nasal pillows or simply be made from a soft pliable plastics material as are the nasal pillows.

Attached to an inlet 404 of the body 401 is an elongate member 405 similar to that described in any of the embodiments detailed above, but particularly that of Figures 20 to 22. The elongate member 405 has arms 406, 407 that extend along a user's cheekbones then up towards the user's ears when in use. The arms 406, 407 are preferably made from a substantially rigid material, preferably a plastics material. For the users comfort each of the arms 406, 407 have inner pads (only one pad 408 is shown in Figure 23) extending along their inner sides, particularly where the arms are incident on the user's face.

The arms 406, 407 have recesses 409, 410 at there ends to which headgear straps 411, 412 are attached. The arms 406, 407 may also each have optional side hooks (of which only one side hook 413 is shown), again made out of a substantially rigid material, to which additional side headgear straps 414, 415 may be attached.

At the centre of the elongate member 405 is formed an integral inlet 416 that matches and attaches to the inlet 404 on the body. This integral inlet 416 receives a conduit or tube 417 that is connected in use to a supply of gases. Preferably the tube 417 has a swivelable elbow 418 (for example, a ball joint socket similar to the one described above). Preferably on the elbow 418 are a number of holes 419 that provide an exhaust vent for gases exhaled by the patient in use.

In this ninth embodiment of the patient interface and headgear the interface is a mouth mask and nasal pillows. In alternative forms the patient interface may be a full face mask that is attached to an elongate member and headgear similar in form to those described above and particularly in relation to Figure 23.

CLAIMS:

1. Headgear for use with a respiratory mask comprising:

a continuous and substantially curved elongate member extending in use below a patient's nose,

at least two headgear straps capable of attachment to the ends of said elongate member, and

a mask attachment on said elongate member disposed to sit below or on one of said user's nose, mouth, upper lip and an inlet to the mask, said attachment capable of receiving said mask.

2. Headgear according to claim 1 wherein said at least two straps are substantially flexible, soft straps each extending down a user's cheekbones in use and terminating at each of said strap's ends in said user's upper lip area and said a substantial portion of said elongate member is attached to each of said straps.

3. Headgear according to claim 2 wherein the length of said at least two straps that extends in use along said user's cheekbones is attached to said elongate member, said elongate member providing rigidity to said length of said at least two straps.

4. Headgear according to claim 1 wherein said elongate member has two ends each of which is attached to one of said at least two straps, said elongate member having at least one pad extending along the inner side of the elongate member in at least the areas where the elongate member is incident on said patient's cheekbones.

5. Headgear according to claim 4 wherein said at least one pad are substantially the same width as said elongate member.

6. Headgear according to any one of claims 1 to 5 wherein said continuous elongate member is substantially rigid compared to said straps.

7. Headgear according to any one of claims 1 or 6 wherein said continuous elongate

member includes two side arms and a central section.

8. Headgear according to claim 7 wherein said side arms and said central section are formed as a single item.

9. Headgear according to claim 7 or 8 wherein said at least one pad is two pads one each extending substantially along the length of each said side arm.

10. Headgear according to claim 7 wherein said side arms and said central section are formed as two separate items.

11. Headgear according to any of claims 7 to 10 wherein said side arms have at least one weakened or narrow area to allow for manipulation of said side arms.

12. Headgear according to any of claims 7 to 11 wherein a mask base is capable of frictionally fitting to said central section, such that said central section places said mask base near a breathing orifice of a user.

13. Headgear according to claim 12 wherein said mask base is integrally formed with said central section.

14. Headgear according to any of claims 1 to 13 wherein said curved elongate member is moulded in a three dimensional manner to fit the contours of said patient's cheeks.

15. A breathing assistance apparatus for use with delivery of respiratory gases to a user comprising:

a mask having a base and body, said body having two flexible nasal pillows that in use rest in a substantially sealed manner against said user's nares,

a continuous and substantially curved elongate member extending in use below a patient's nose,

at least two headgear straps capable of attachment to the ends of said elongate member, and

a mask attachment on said elongate member disposed below said user's nose, said attachment capable of receiving said mask.

16. A breathing assistance apparatus according to claim 15 wherein said at least two straps are substantially flexible, soft straps each extending down a user's cheekbones in use and terminating at each of said strap's ends in said user's upper lip area and said a substantial portion of said elongate member is attached to each of said straps.

17. A breathing assistance apparatus according to claim 15 wherein the length of said at least two straps that extends in use along said user's cheekbones is attached to said elongate member, said elongate member providing rigidity to said length of said at least two straps.

18. A breathing assistance apparatus according to claim 15 wherein said elongate member has two ends each of which is attached to one of said at least two straps, said elongate member having at least one pad extending along the inner side of the elongate member in at least the areas where the elongate member is incident on said patient's cheekbones.

19. A breathing assistance apparatus according to claim 18 wherein said at least one pad are substantially the same width as said elongate member.

20. A breathing assistance apparatus according to any one of claims 15 to 19 wherein said continuous elongate member is substantially rigid compared to said straps.

21. A breathing assistance apparatus according to any one of claims 15 or 20 wherein said nasal pillows are substantially elliptical and have gases outlets that are offset from the centre of said elliptical pillows.

22. A breathing assistance apparatus according to one of claims 15 to 22 wherein said breathing assistance apparatus includes humidification means adapted to, in use, be in fluid communication with said source of gases and said transportation means and adapted to in use humidify said gases.

23. A breathing assistance apparatus according to any one of claims 15 to 22 wherein said continuous elongate member includes two side arms and a central section.

24. A breathing assistance apparatus according to claim 23 wherein said side arms and said central section are formed as a single item.

25. A breathing assistance apparatus according to claim 23 wherein said side arms and said central section are formed as two separate items.

26. A breathing assistance apparatus according to claim 18 wherein said at least one pad is two pads one each extending substantially along the length of each said side arm.

27. A breathing assistance apparatus according to any of claims 23 to 26 wherein said side arms have at least one weakened or narrow area to allow for manipulation of said side arms.

28. A breathing assistance apparatus according to any of claims 23 to 27 wherein said base frictionally fits to said central section, and said body to said base, such that said central section suspends said base below said user's nares, and when said body is attached to said base, said nasal pillows rest against said user's nares.

29. A breathing assistance apparatus according to any of claims 23 to 28 wherein said base is integrally formed with said central section.

30. A breathing assistance apparatus according to any of claims 23 to 29 wherein said side arms attach one to each side of said base.

31. A breathing assistance apparatus according to any of claims 15 to 30 wherein said curved elongate member is moulded in a three dimensional manner to fit the contours of said user's cheeks.

32. A breathing assistance apparatus for use with delivery of respiratory gases to a user comprising:

a mask comprising a body and a cushion, said cushion substantially forming a seal with said patient's airways,

headgear comprising substantially flexible, soft straps and a substantially continuous curved elongate member to which said mask is attached, said elongate member extending over said user's cheeks, and

wherein said mask has an inlet extension tube and said curved elongate member is attached or rests beneath said inlet extension tube, anchoring said mask to said user's face in use.

33. A breathing assistance apparatus according to claim 32 wherein said continuous elongate member is substantially rigid compared to said straps.

34. A breathing assistance apparatus according to claim 32 or 33 wherein said mask is a full face mask where said body extends to cover said patient's mouth and nose.

35. A breathing assistance apparatus according to any one of claims 32 to 34 wherein said curved elongate member is moulded in a three dimensional manner to fit the contours of said user's cheeks.

36. Headgear as described herein with reference to the accompanying figures.

37. A breathing assistance apparatus as described herein with reference to the accompanying figures.

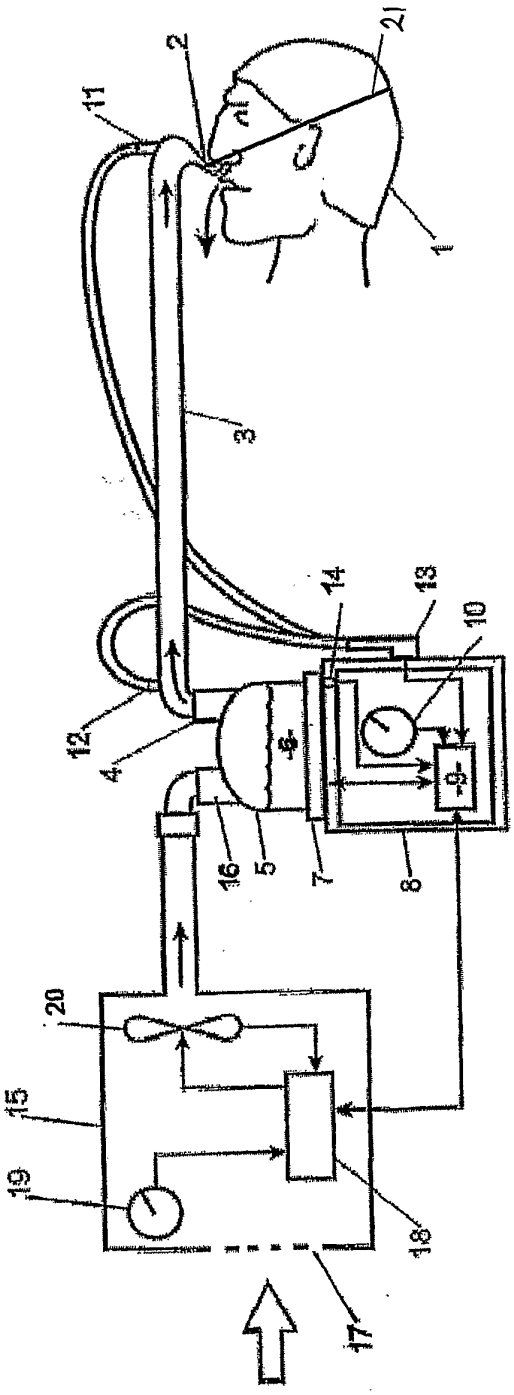


FIGURE 1

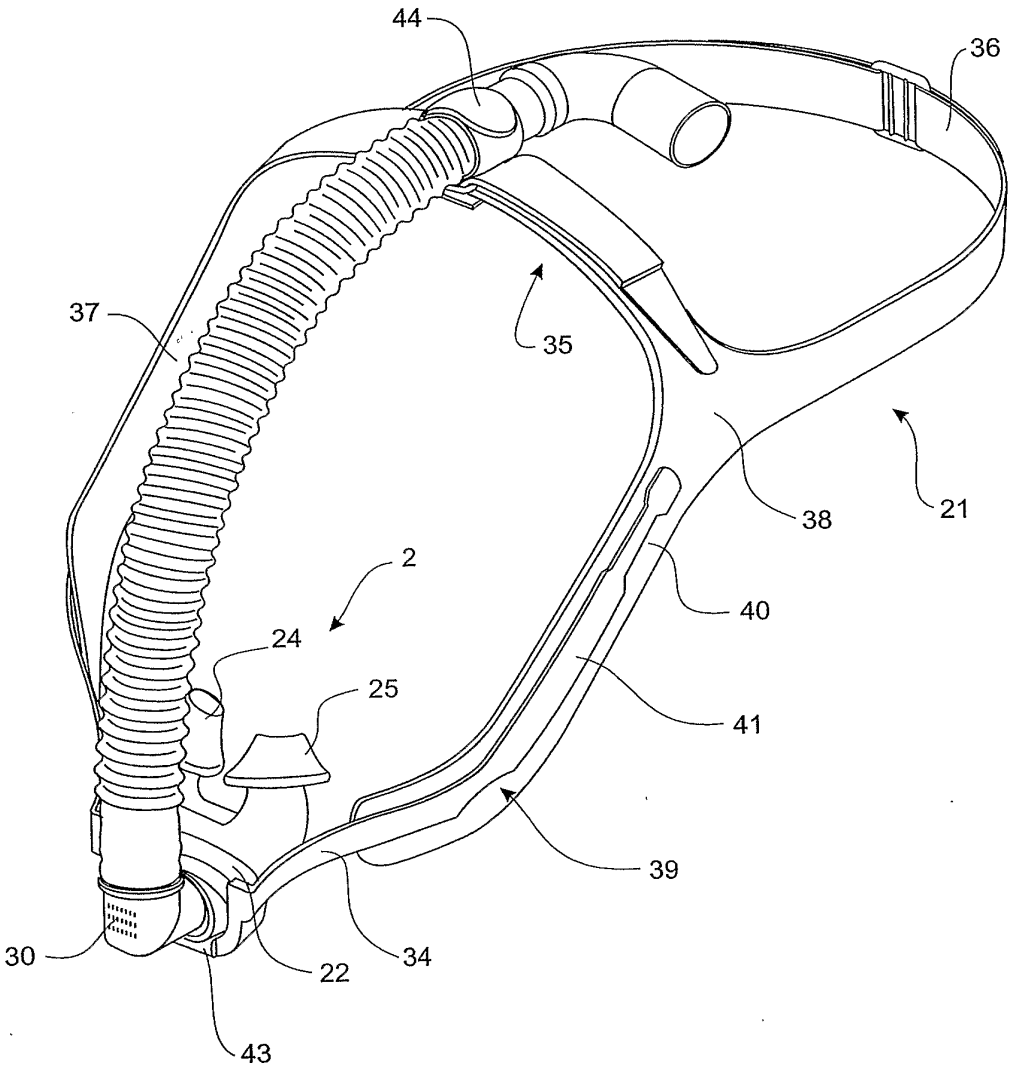


FIGURE 2

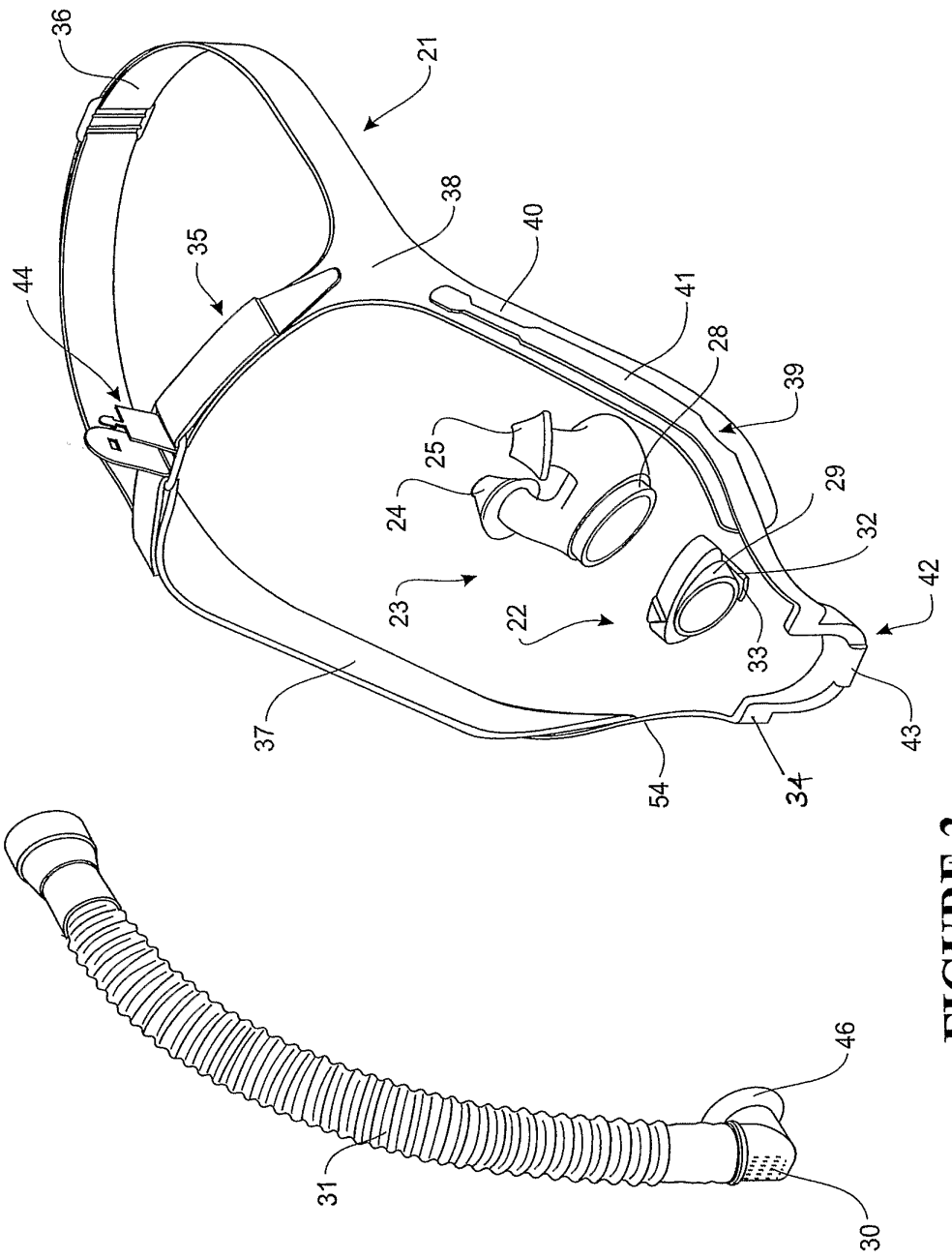


FIGURE 3

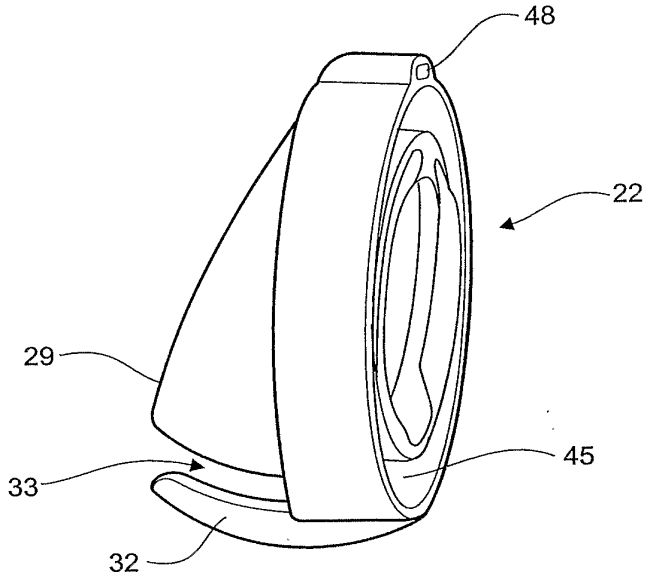


FIGURE 4

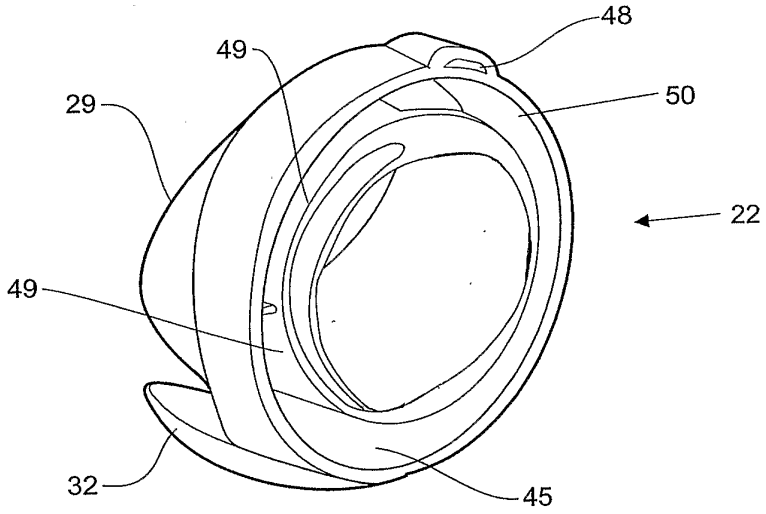


FIGURE 5

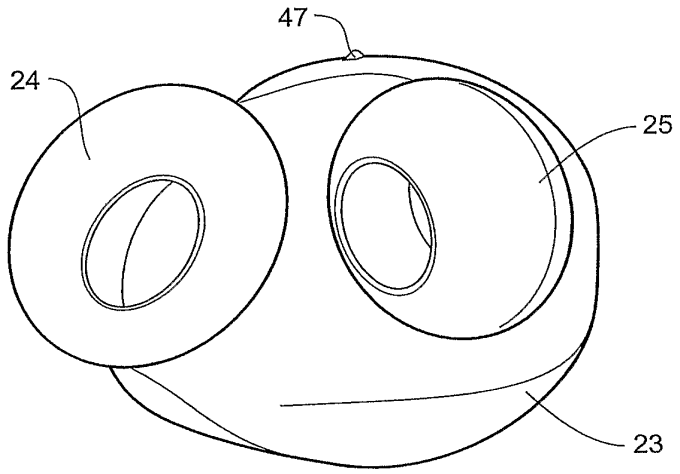


FIGURE 6

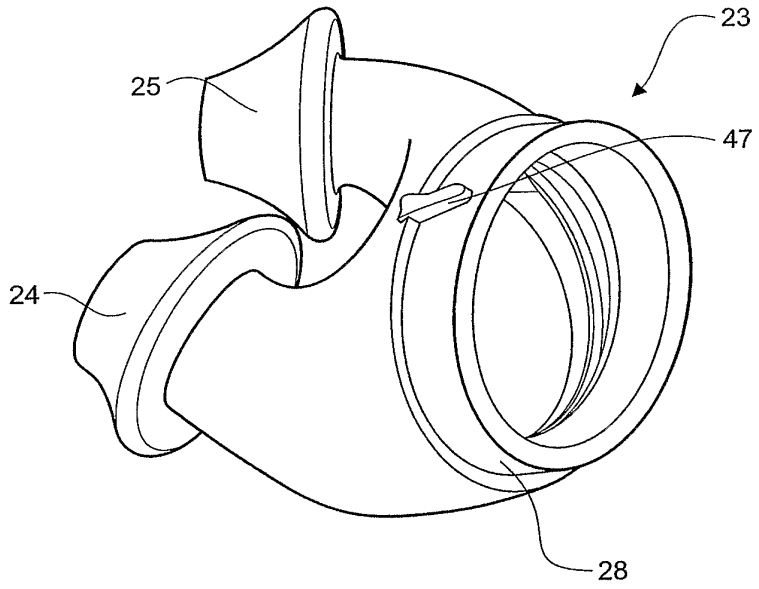


FIGURE 7

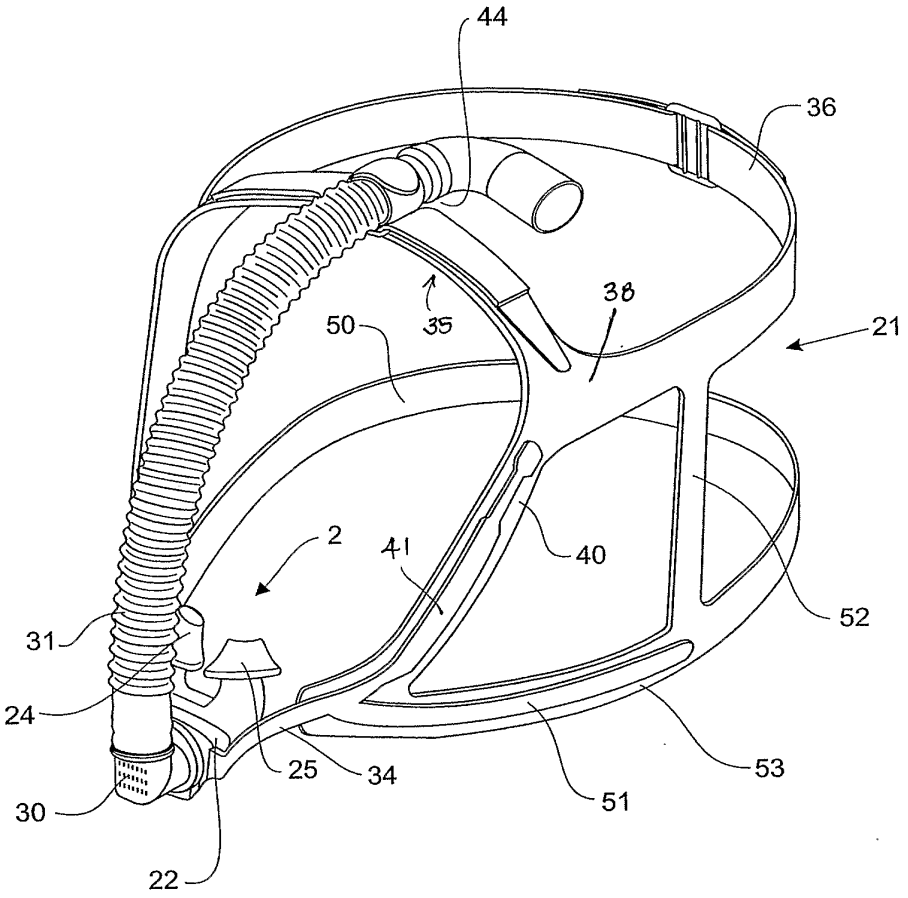


FIGURE 8

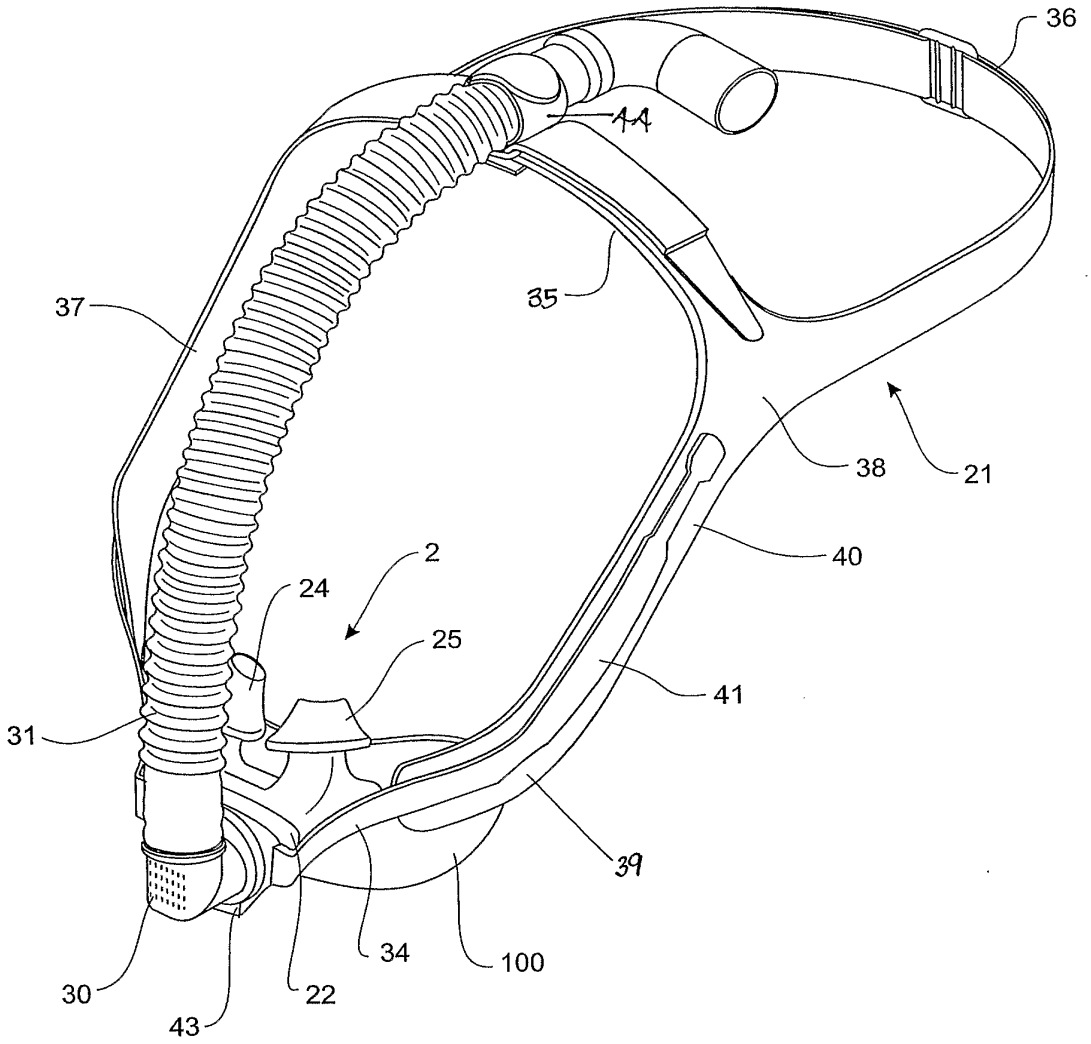


FIGURE 9

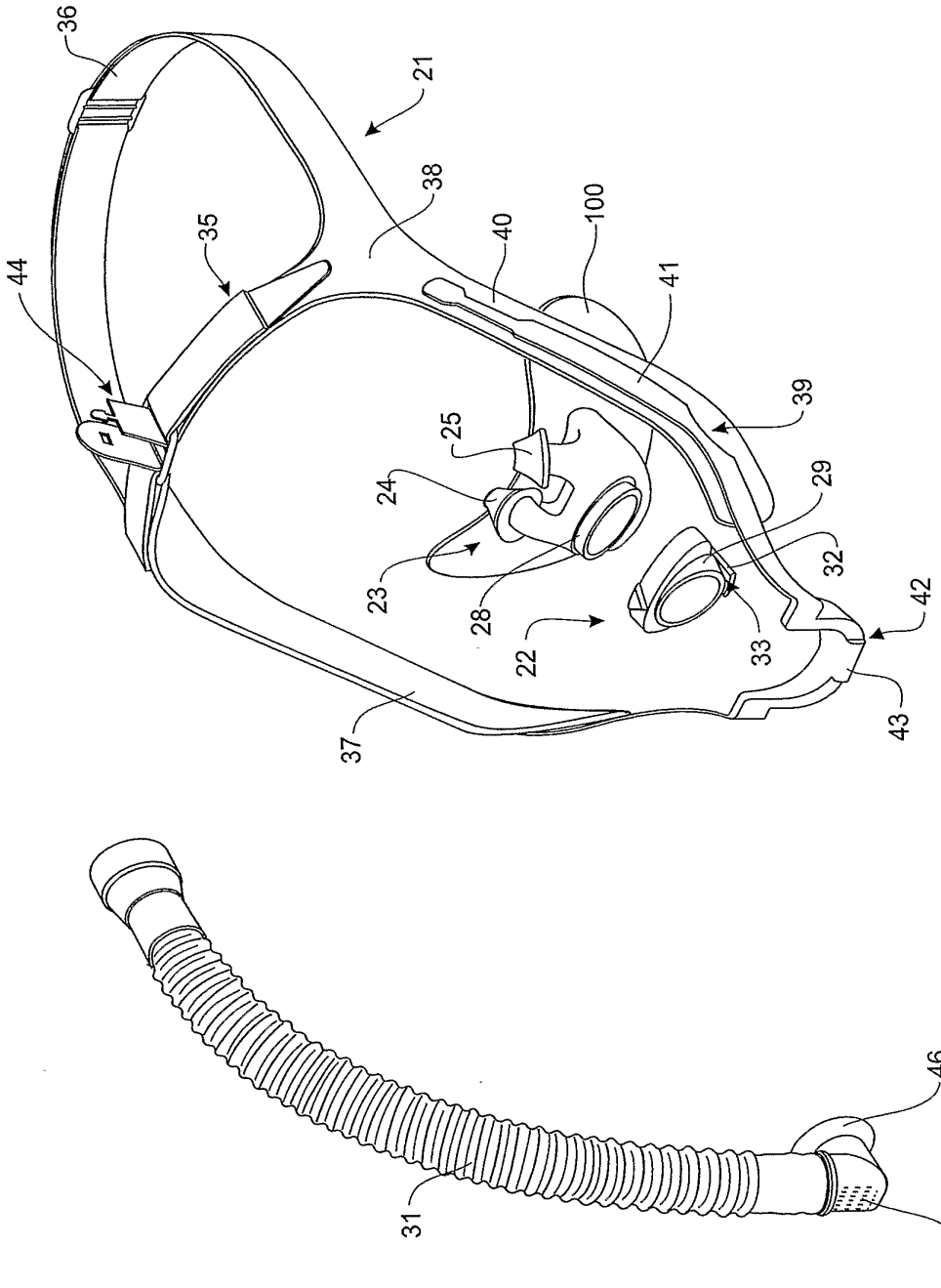


FIGURE 10

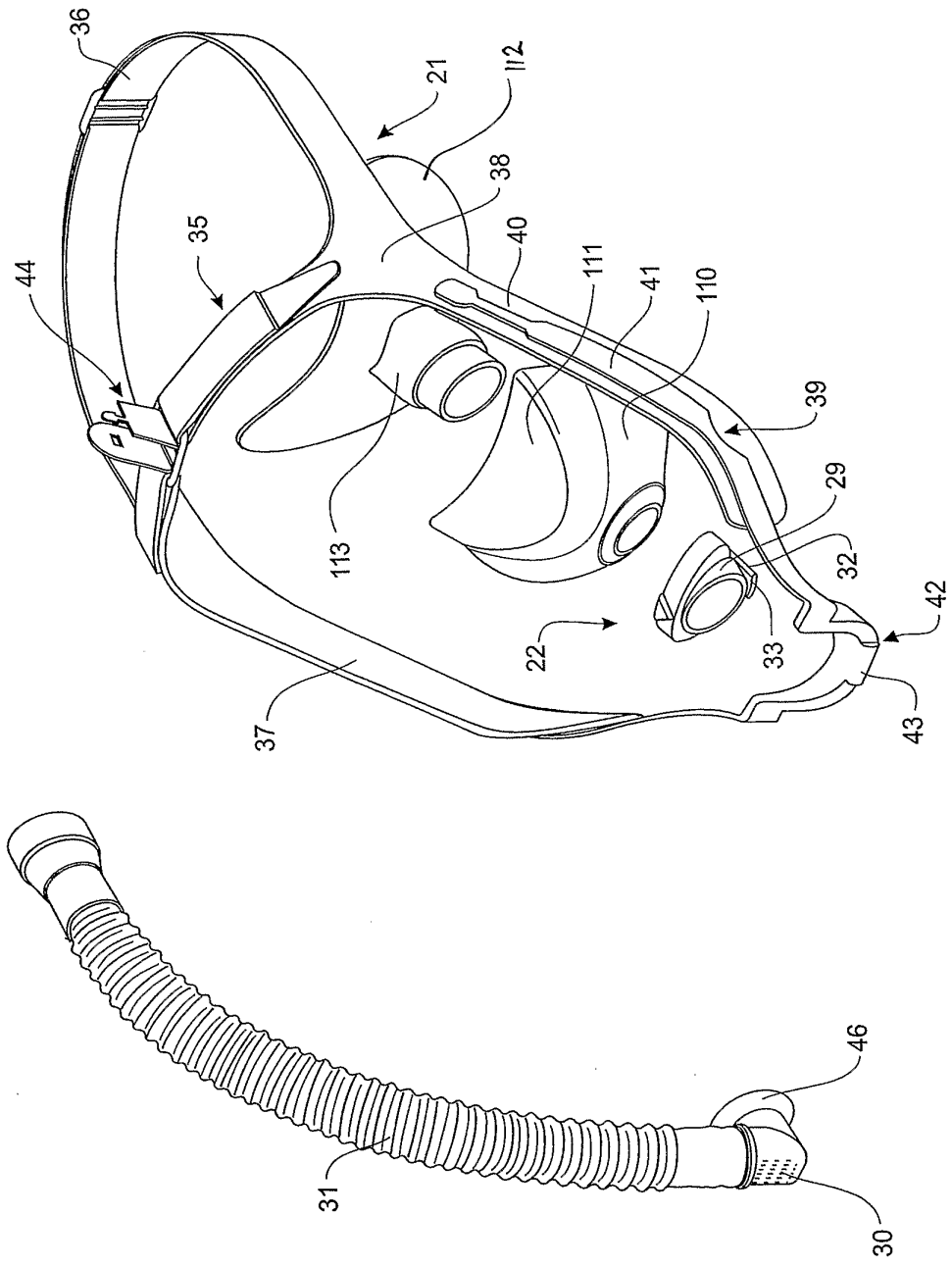


FIGURE 11

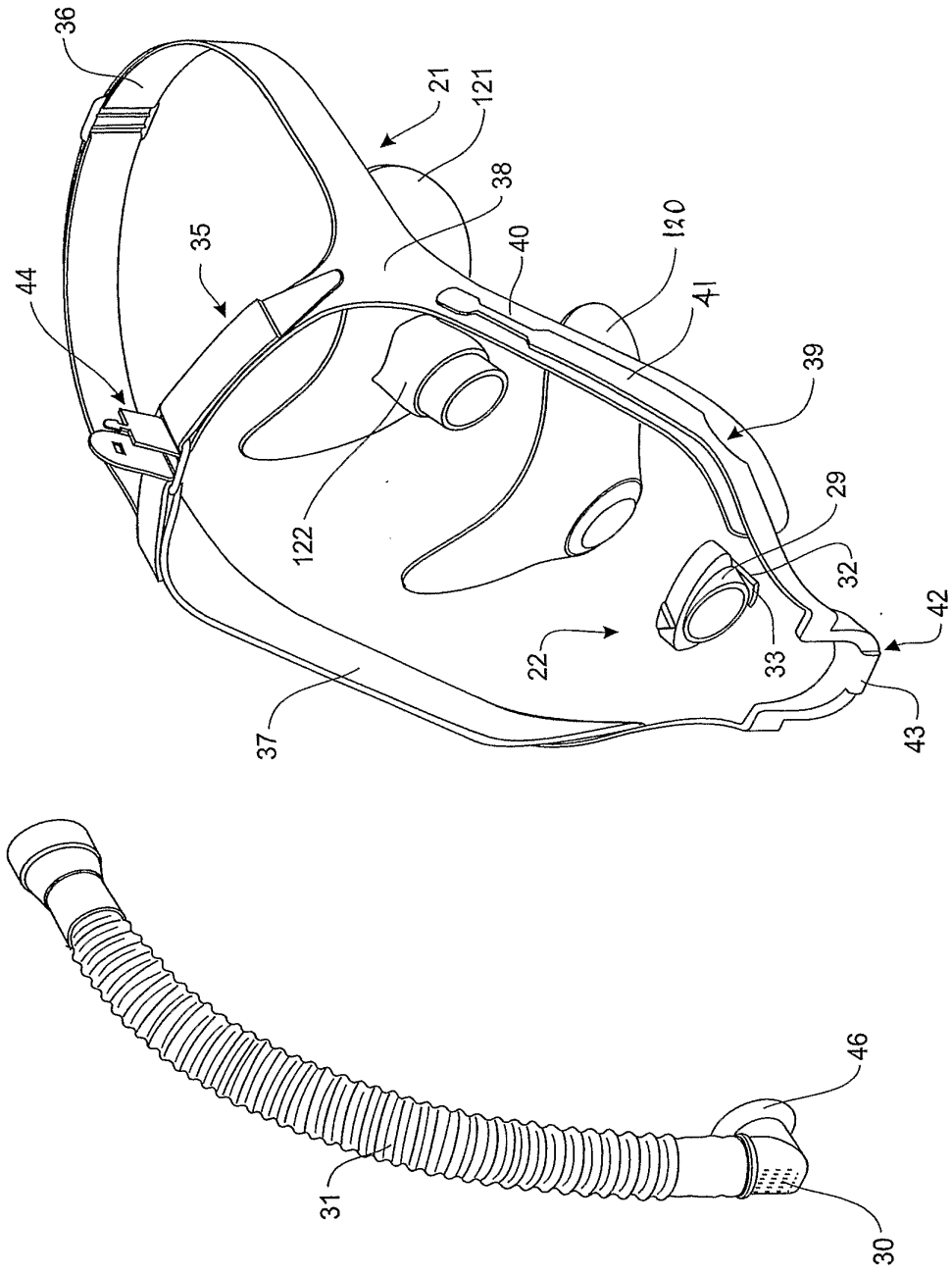


FIGURE 12

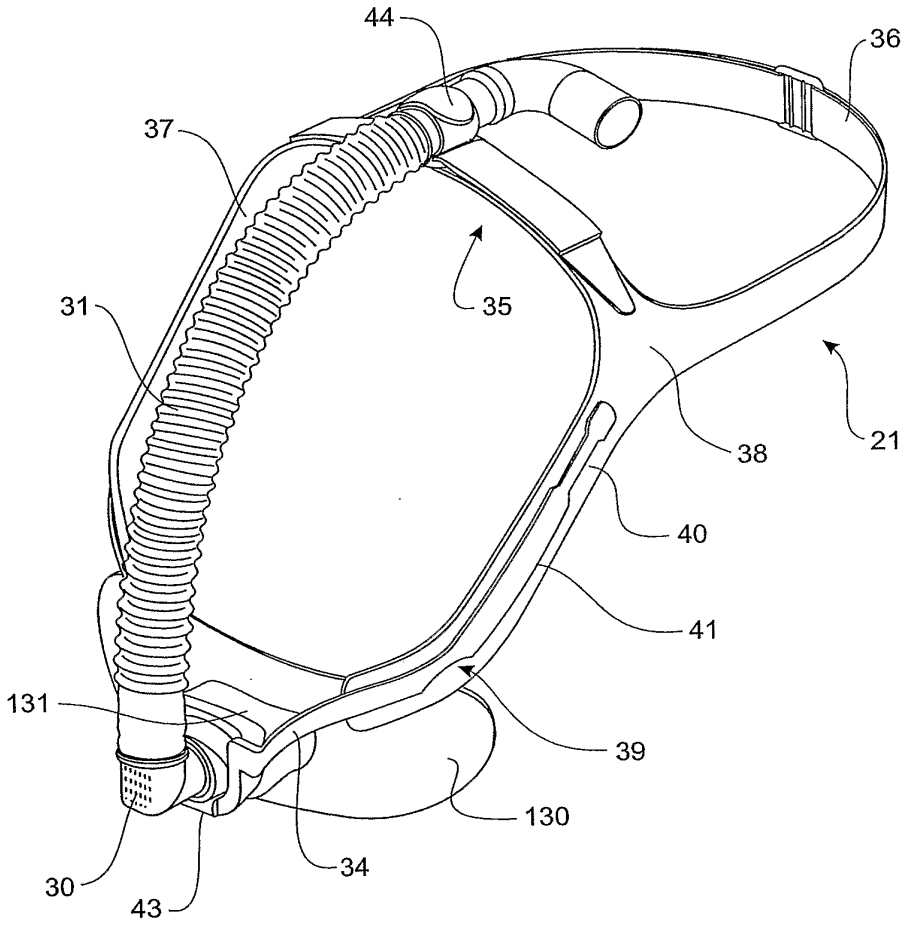


FIGURE 13

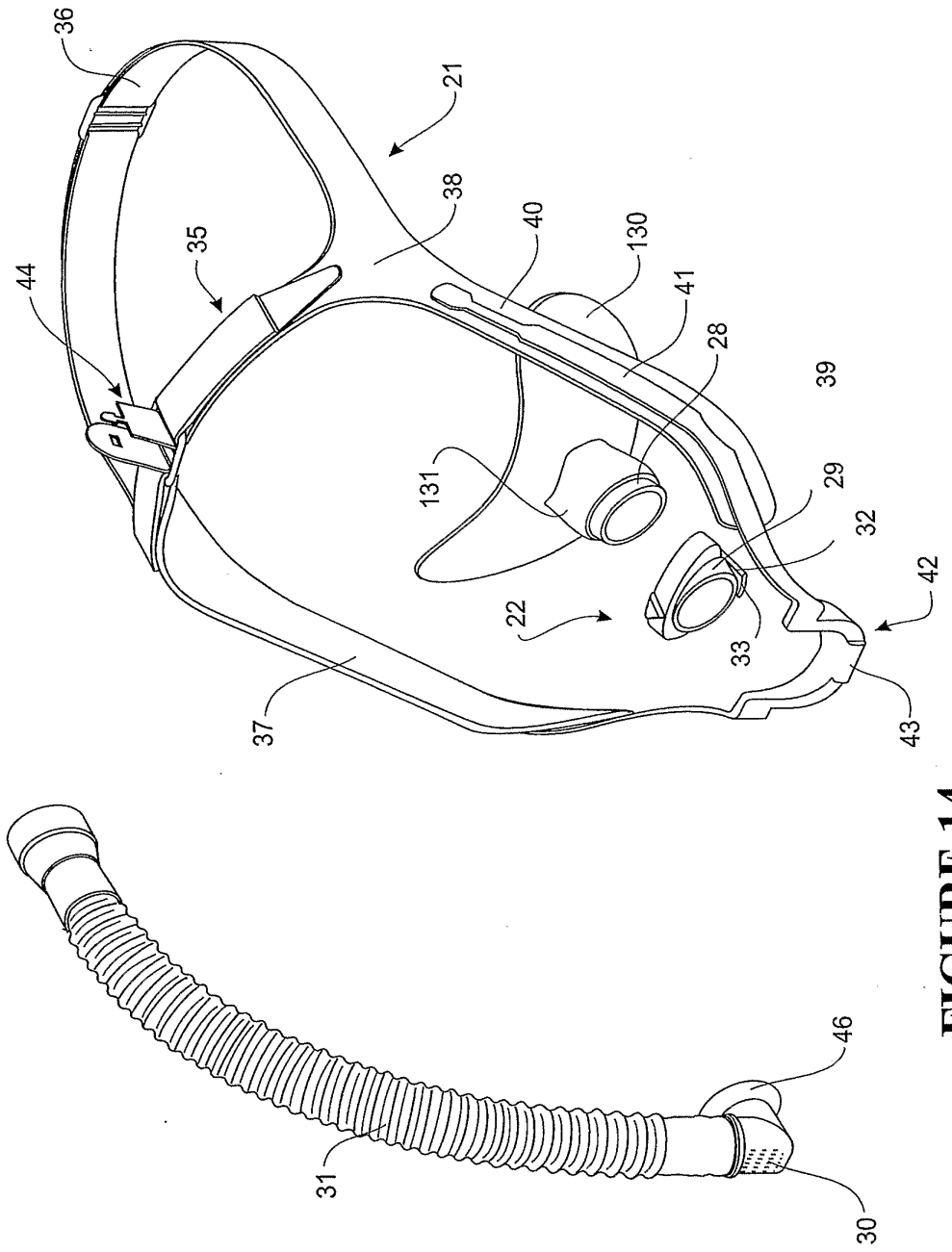
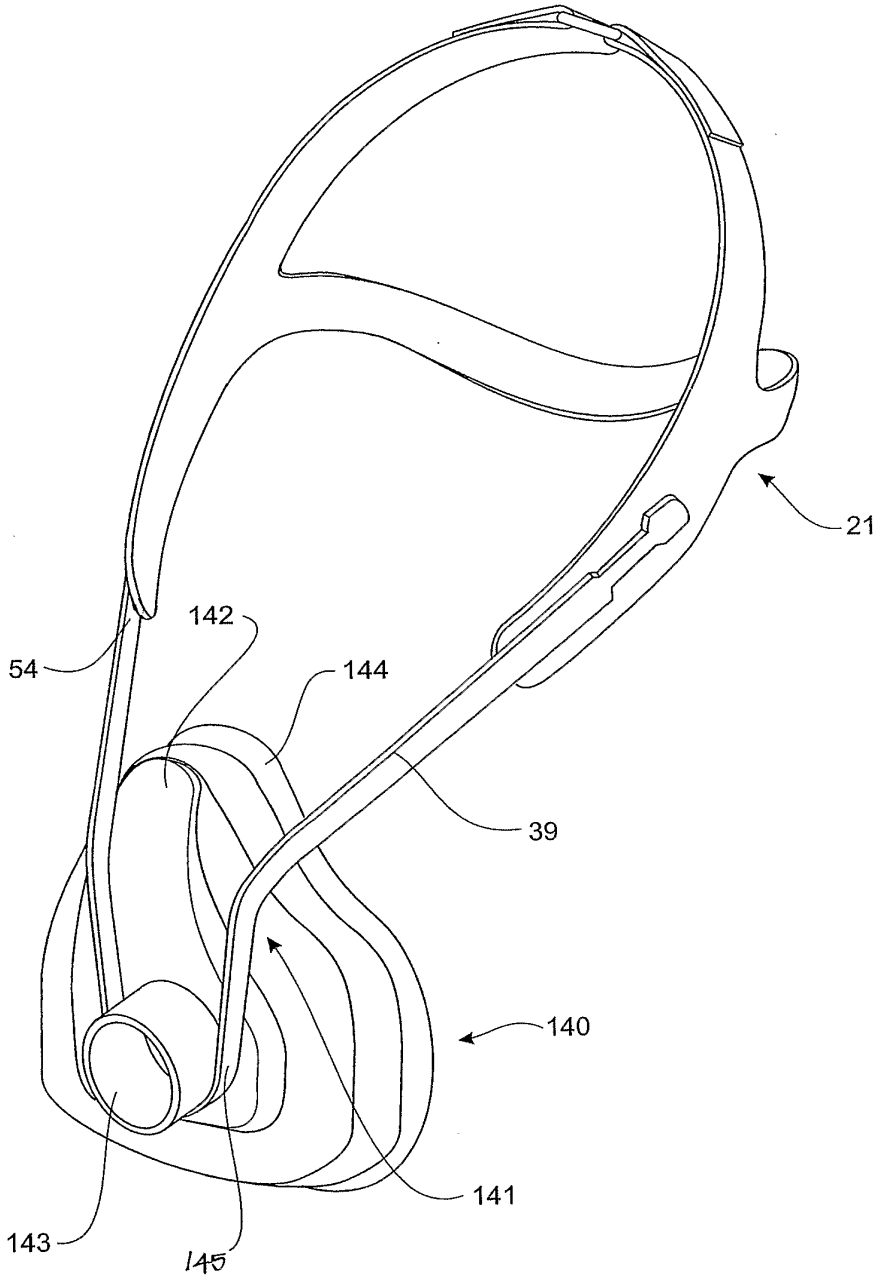


FIGURE 14



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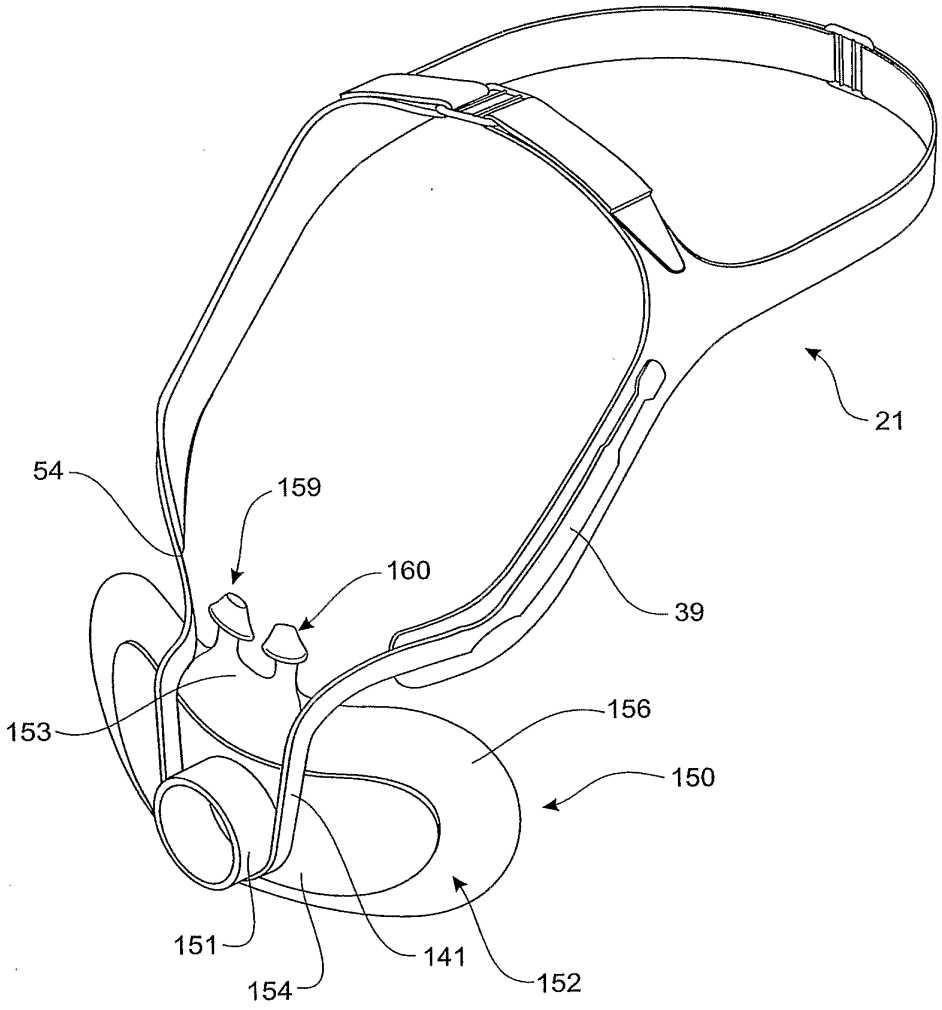

FIGURE 16

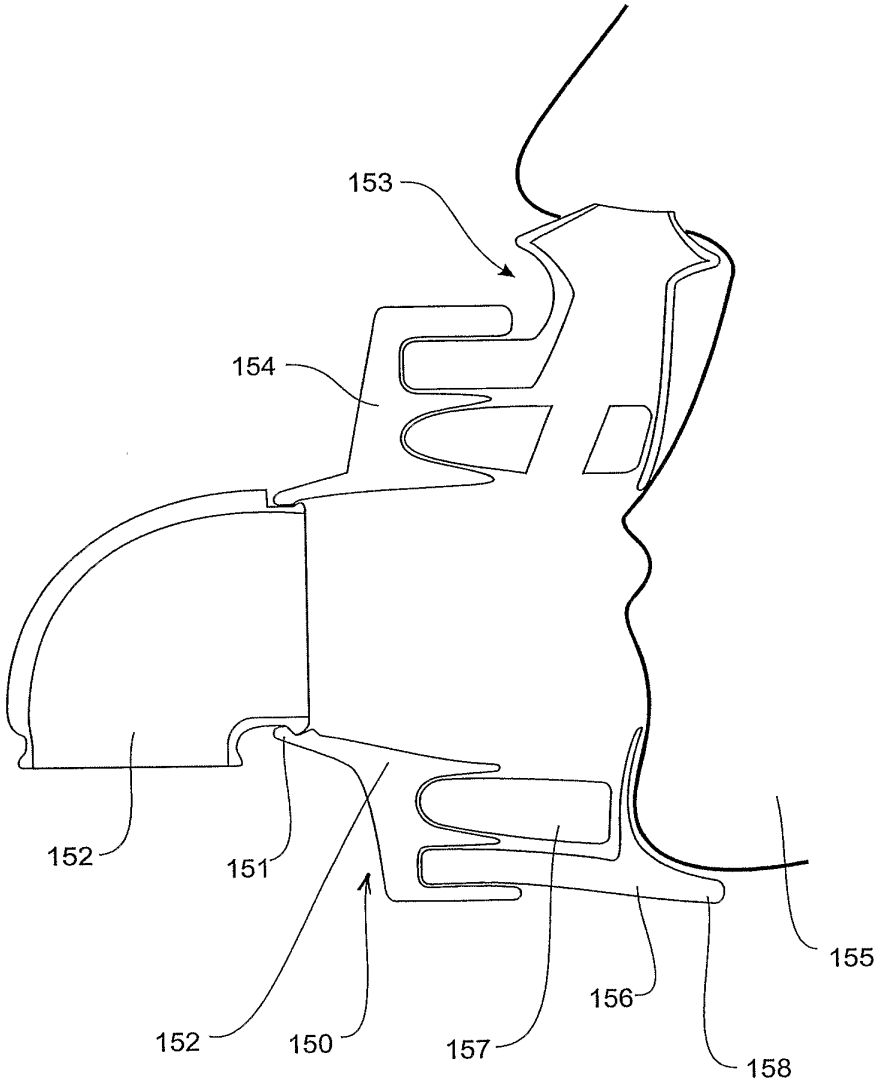

FIGURE 17

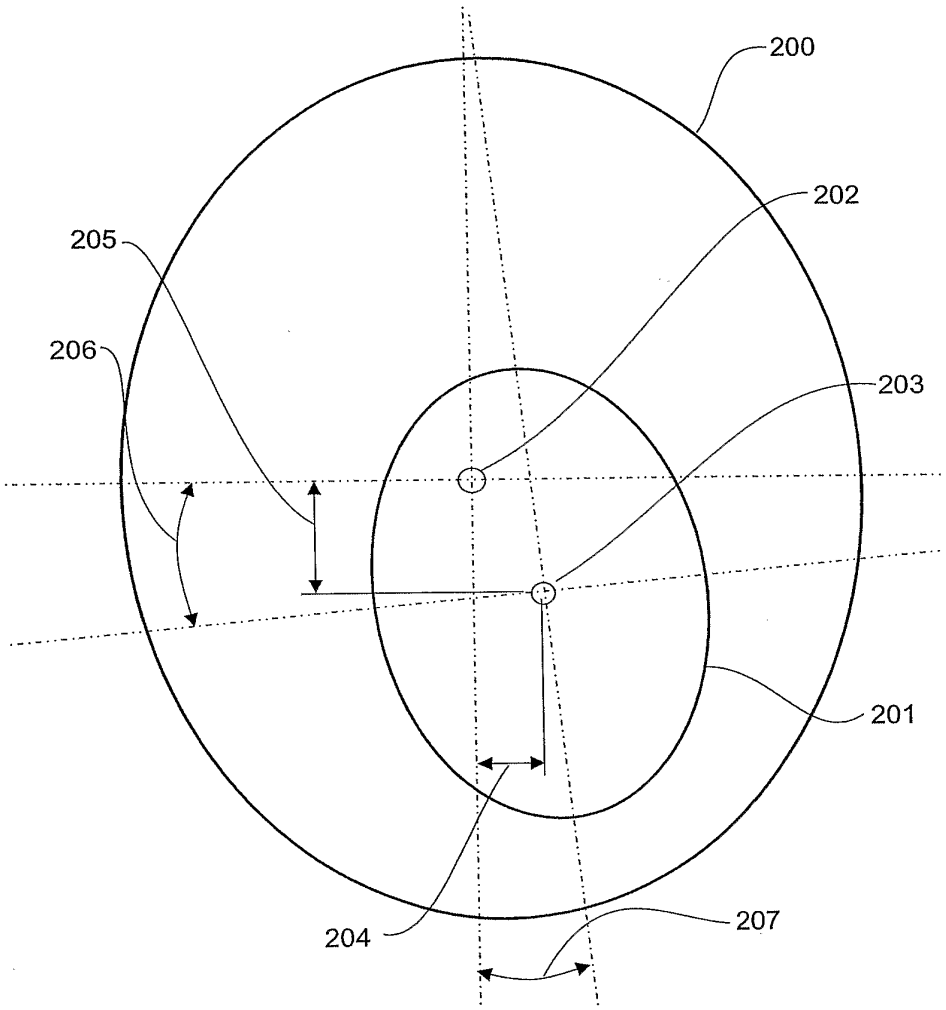

FIGURE 18

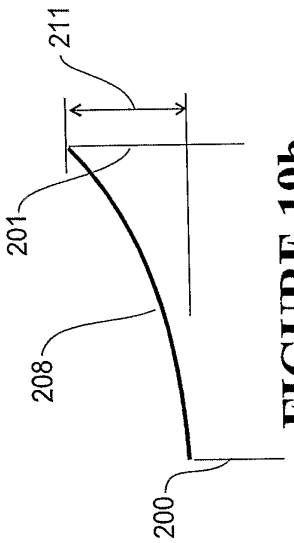

FIGURE 19b

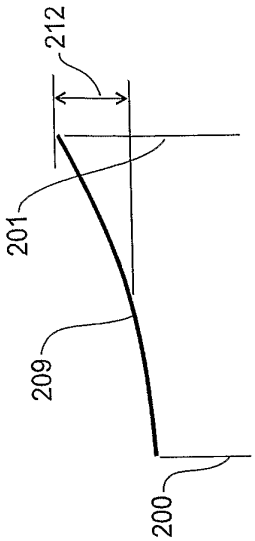

FIGURE 19c

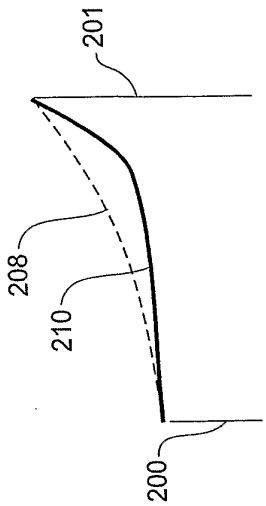

FIGURE 19d

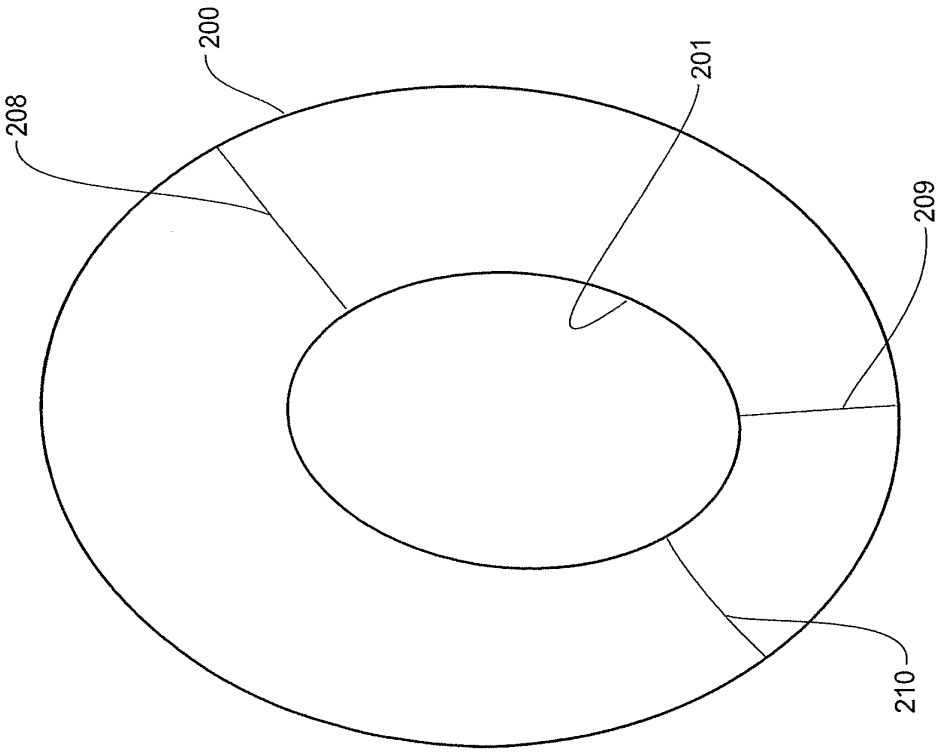

FIGURE 19a

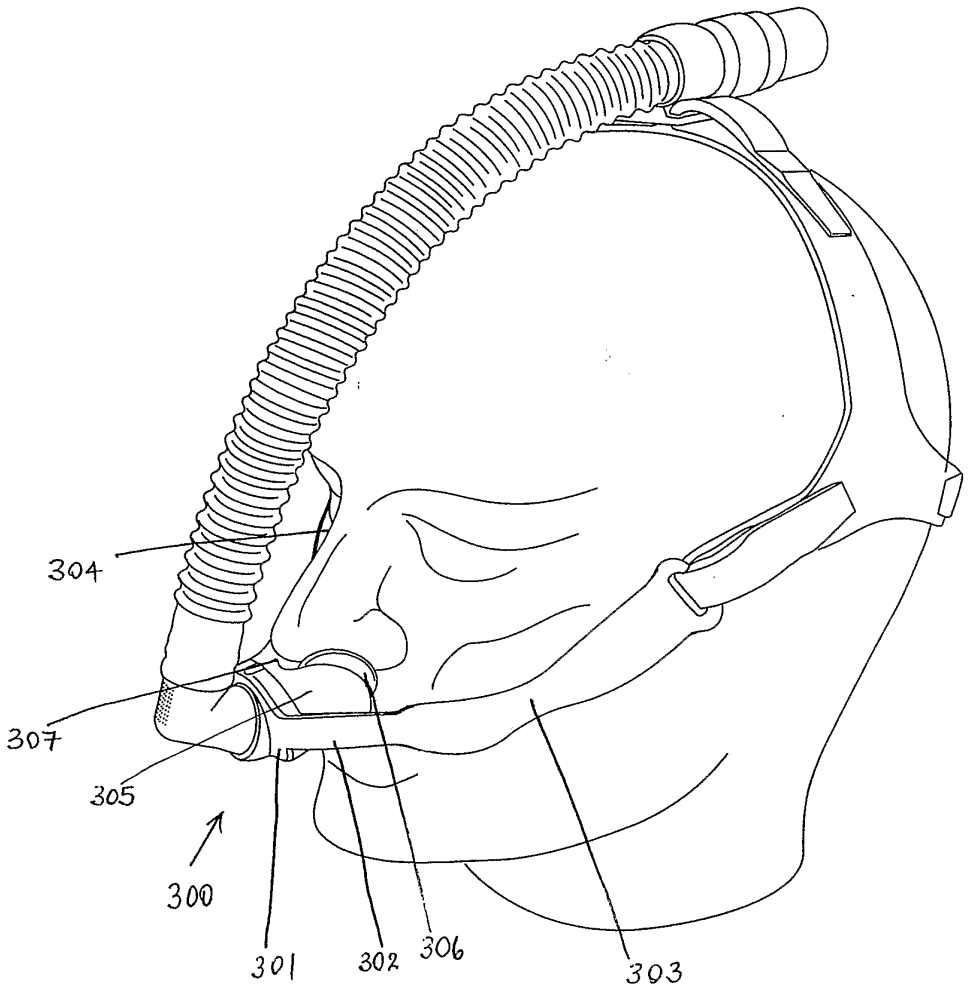

FIGURE 20

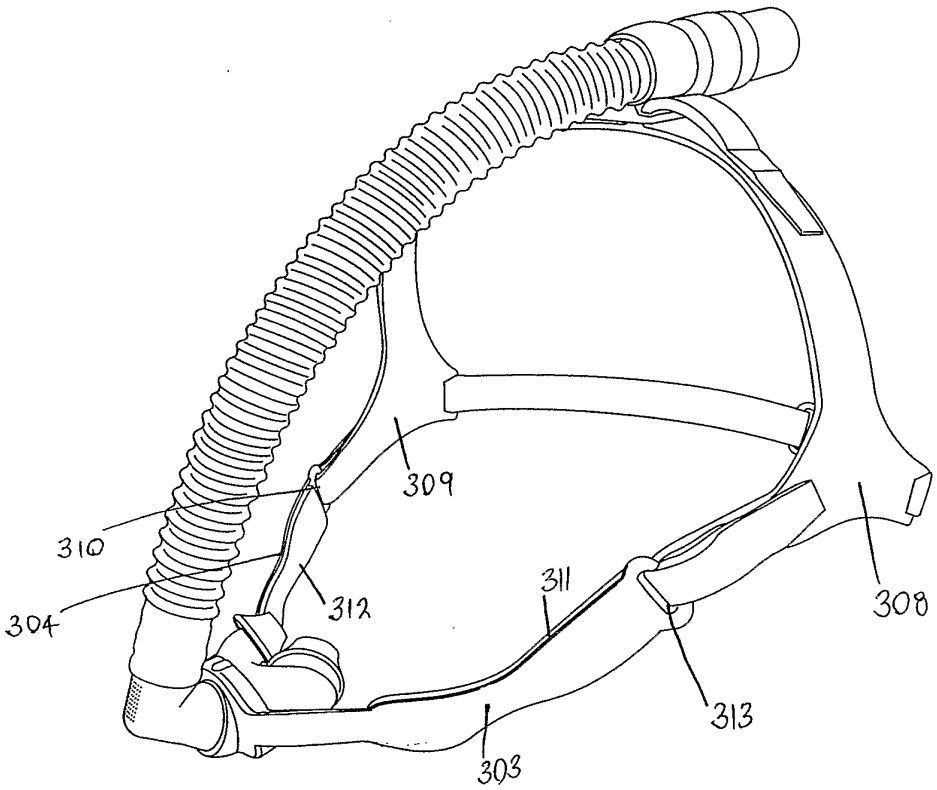

FIGURE 21

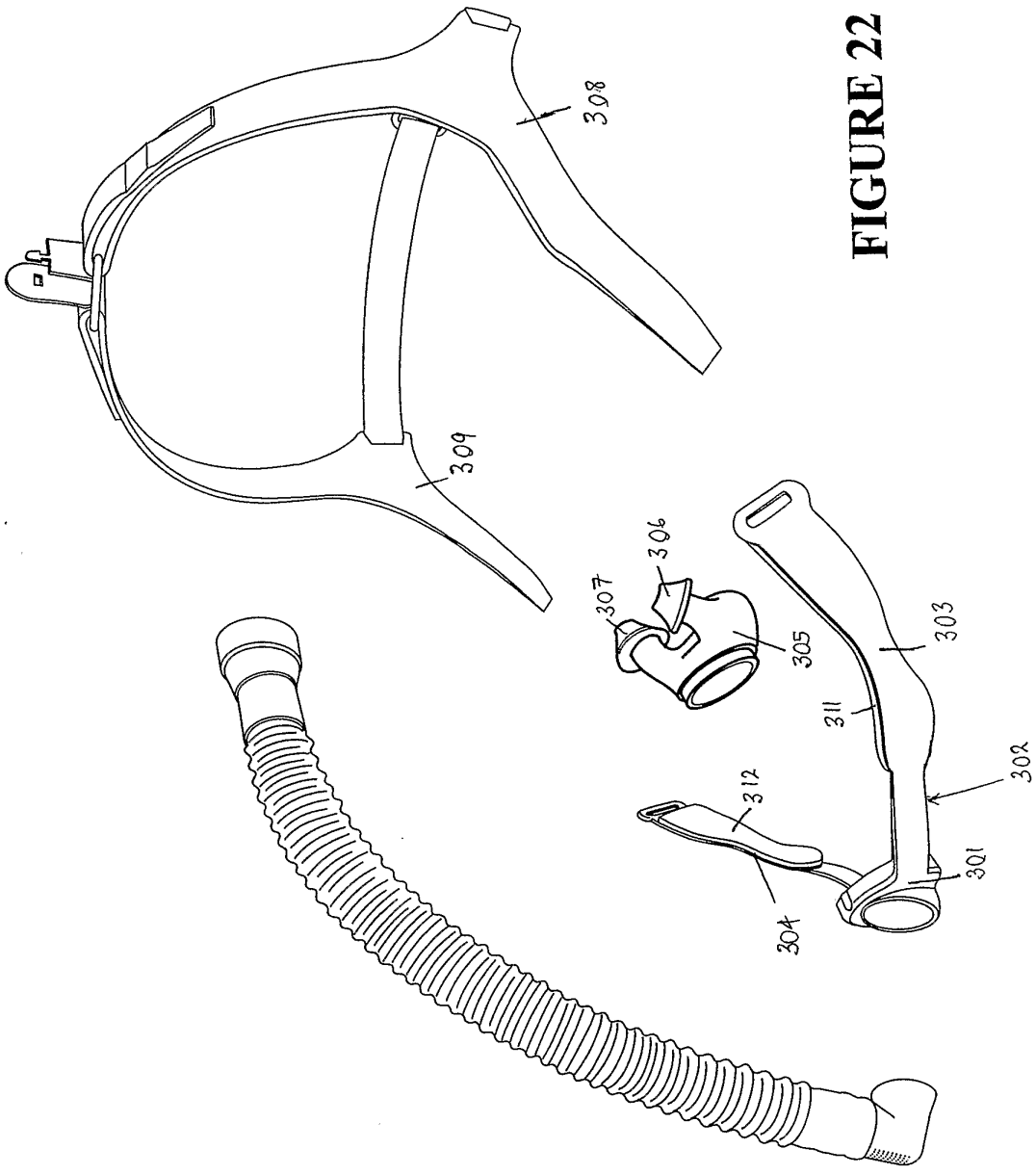

FIGURE 22

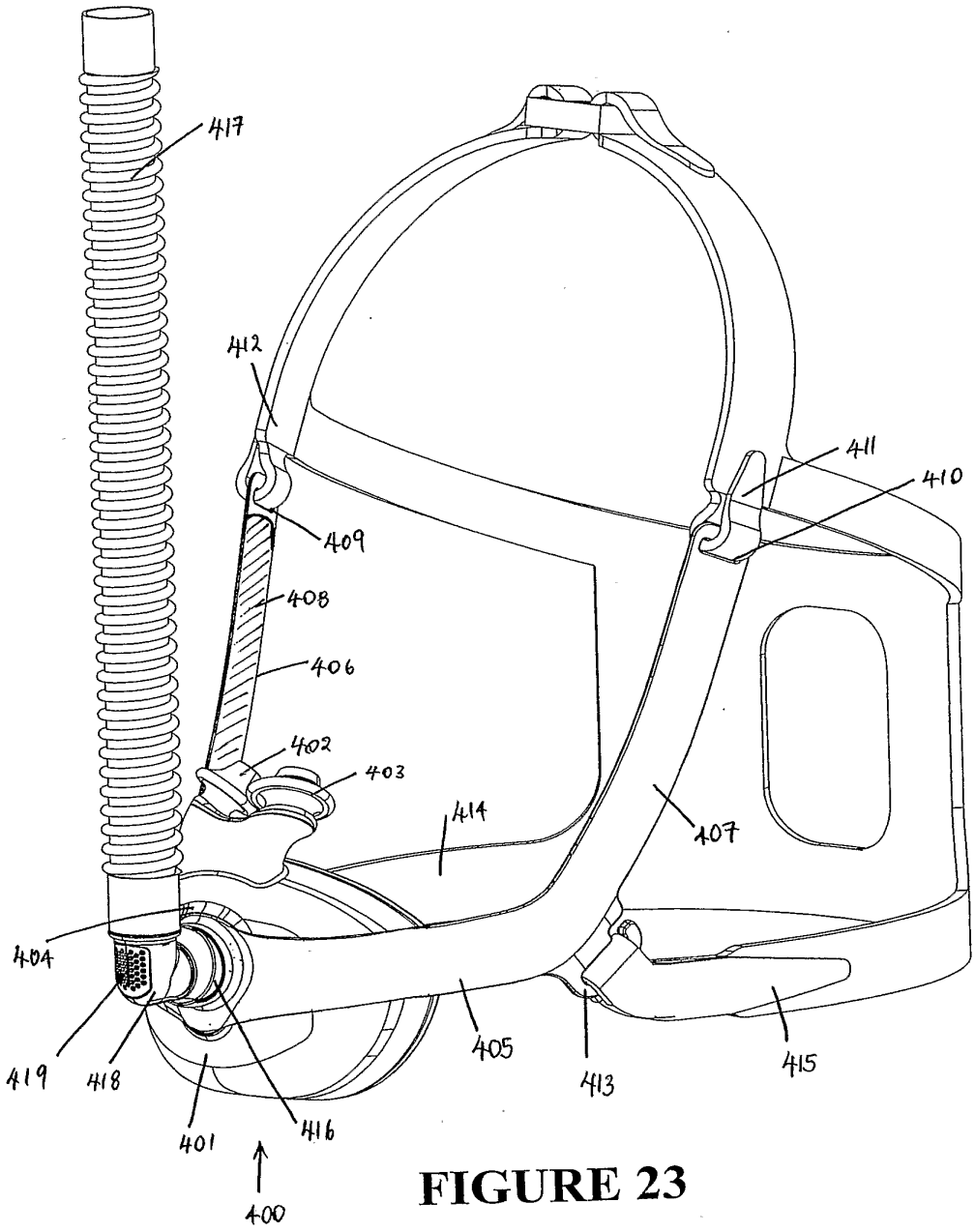
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FIGURE 23

Document made available under the Patent Cooperation Treaty (PCT)

International application number: PCT/NZ2007/000185

International filing date: 13 July 2007 (13.07.2007)

Document type: Certified copy of priority document

Document details: Country/Office: NZ
Number: 548575
Filing date: 14 July 2006 (14.07.2006)

Date of receipt at the International Bureau: 05 October 2007 (05.10.2007)

Remark: Priority document submitted or transmitted to the International Bureau in compliance with Rule 17.1(a) or (b)

Ministry of Economic Development
Manatū Ōhanga
Intellectual Property Office of New Zealand

PCT/NZ2007/000185

CERTIFICATE

This certificate is issued in support of an application for Patent registration in a country outside New Zealand pursuant to the Patents Act 1953 and the Regulations thereunder.

I hereby certify that annexed is a true copy of the Provisional Specification as filed on 14 July 2006 with an application for Letters Patent number 548575 made by FISHER & PAYKEL HEALTHCARE LIMITED.

Dated 17 August 2007.

Neville Harris
Commissioner of Patents, Trade Marks and Designs

COMMISSIONER OF PATENTS, TRADEMARKS & DESIGNS
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NEW ZEALAND

PATENTS ACT, 1953

PROVISIONAL SPECIFICATION

"BREATHING ASSISTANCE APPARATUS"

We, **FISHER & PAYKEL HEALTHCARE LIMITED**, a company duly incorporated under the laws of New Zealand, of 15 Maurice Paykel Place, East Tamaki, Auckland, New Zealand, do hereby declare this invention to be described in the following statement:

TECHNICAL FIELD

The present invention relates to apparatus for treating sleep apnoea. More specifically, the present invention provides a nasal interface for the supply of respiratory gases, but most particularly positive pressure gases.

BACKGROUND ART

In the art of respiration devices, there are well known variety of respiratory masks which cover the nose and/or mouth of a human user in order to provide a continuous seal around the nasal and/or oral areas of the face such that gas may be provided at positive pressure within the mask for consumption by the user. The uses for such masks range from high altitude breathing (i.e., aviation applications) to mining and fire fighting applications, to various medical diagnostic and therapeutic applications.

Obstructive Sleep Apnoea (OSA) is a sleep disorder that affects up to at least 5% of the population in which muscles that normally hold the airway open relax and ultimately collapse, sealing the airway. The sleep pattern of an OSA sufferer is characterised by repeated sequences of snoring, breathing difficulty, lack of breathing, waking with a start and then returning to sleep. Often the sufferer is unaware of this pattern occurring. Sufferers of OSA usually experience daytime drowsiness and irritability due to a lack of good continuous sleep.

In an effort to treat OSA sufferers, a technique known as Continuous Positive Airway Pressure (CPAP) was devised. A CPAP device consists of a gases supply (or blower) with a conduit connected to supply pressurised gases to a patient, usually through a nasal mask. The pressurised air supplied to the patient effectively assists the muscles to keep the patient's airway open, eliminating the typical OSA sleep pattern.

The procedure for administering CPAP treatment has been well documented in both the technical and patent literature. Briefly stated, CPAP treatment acts as a pneumatic splint of the airway by the provision of a positive pressure, usually in the range 4 to 20 cm H_2O. The air is supplied to the airway by a motor driven blower whose outlet passes via an air delivery hose to a nose (or nose and/or mouth) mask that is sealingly engaged to a patient's face, preferably by means of a harness or other headgear. An exhaust port is also usually provided in the delivery tube proximate to the mask or the mask itself. More sophisticated forms of positive airway pressure devices, such as bi level devices and auto-titrating devices, are described in US Patent No. 5,148,802 of Respironics, Inc. and US Patent No. 5,245,995 of Rescare Limited, respectively.

One requisite of respiratory masks has been that they provide an effective seal against the user's face to prevent leakage of the gas being supplied. Commonly, in prior mask configurations, a good mask-to-face seal has been attained in many instances only with considerable discomfort for the user. A common complaint of a user of CPAP therapy is pressure sores caused by the mask about the nose and face and in particular in the nasal bridge region of the user. This problem is most crucial in those applications, especially medical applications, which require the user to wear such a mask continuously for hours or perhaps even days. In such situations, the user will not tolerate the mask for long durations and optimum therapeutic or diagnostic objectives thus will not be achieved, or will be achieved with great difficulty and considerable user discomfort.

US Patent No. 5,477,852 of Airways Ltd, Inc. discloses a nasal positive airway pressure device that has a pair of nasal members each having a cannula tip to be inserted into the nares of the patient. Each cannula is tapered from a substantially circular cross section outside the patient's nostril to a substantially oval cross section at the tip inserted into the nostril. An inflatable cuff surrounds each cannula with the interior space of the cuff communicating with the lumen of the cannula through at least one aperture in the sidewall of the cannula. The nasal members are connected to one or more flexible hoses that, in turn, are connected to a source of positive air pressure. In use, positive air pressure is supplied to each cannula tip through the air hoses and nasal members. The positive air pressure inflates the cuffs to hold the nasal members in place and to effect treatment. The nasal device of US Patent No. 5,477,852 is attached to headgear that is located about a patient's head; this headgear could be considered by many patients as cumbersome and uncomfortable.

Conventional nasal masks used for administrating CPAP treatment are also considered uncomfortable and cumbersome, and prior art nasal masks can be noisy (due to air leaks). These disadvantages in many cases are a formidable obstacle to patient acceptance of such treatment. Therefore, a substantial number of patients either cannot tolerate treatment or choose to forego treatment. It is believed a substantial number of such patients could benefit from a nasal positive airway pressure apparatus that is more convenient to use and comfortable to wear, thereby resulting in increased treatment compliance.

As oxygen is supplied as a dry gas it is well known in the art to either heat and/or humidify gases before delivering these to a patient. In particular when delivering oxygen, or and oxygen and air mixture, it has proven beneficial to humidify the gases first. In

WO01/41854 of Vapotherm, Inc. a system is disclosed that allows the delivery of humidified oxygen through a nasal cannula. This system uses a narrow bore conduit and nasal cannula with a high resistance to gas flows, thereby requiring the oxygen be of a high pressure. Air, as well as oxygen can also be passed down the conduit and nasal cannula and it too must be of a high pressure. This system allows the delivery of high flows of oxygen enriched air to the patient, but is limited in the flows achievable due to the narrow bore of the cannula resulting in high resistance gas flow and excessive velocity and noise upon exiting the cannula. Furthermore, the narrowness of the nasal cannula in this system allows easy expiration of gases between the prongs and nares and therefore does not create any positive airway pressure.

Innomed Technologies, Inc. manufactures a nasal cannula device called the NASALAIRE™. In this device air or oxygen travels down a wide bore conduit to nasal cannula. The NASALAIRE™ creates a physical seal between the nares and itself, and relies on the absence of leaks around the cannula and the nares to deliver pressure supplied by a continuous positive airway pressure (CPAP) blower to the airway of the wearer.

US6,119,694 of Respironics Georgia, Inc discloses a nasal mask having a nare seal and lateral support members to support the mask.

WO2004/073778 of ResMed Ltd discloses a nasal mask including a frame where headgear is provided with rigid sections that extend to the nasal mask.

WO04/041341 of ResMed Ltd discloses headgear for a patient mask that includes sewn sections to provide rigidity to the headgear.

DISCLOSURE OF THE INVENTION

It is an object of the present invention to attempt to provide a patient interface that goes some way to overcoming the abovementioned disadvantages in the prior art or which will at least provide the industry with a useful choice.

Accordingly in a first aspect the present invention may broadly be said to consist in a breathing assistance apparatus for use with delivery of respiratory gases to a patient comprising:

a nasal mask comprising a base and body, said body having flexible nasal pillows that in use rest in a substantially sealing manner against a patient's nares,

headgear comprising substantially flexible, soft straps and a substantially curved elongate member to which said nasal mask is attached, said elongate member extending over

said patient's cheekbones and below said patient's nose, said nasal mask being attached to said elongate member below said patient's nose.

In a second aspect the present invention may broadly be said to consist in a breathing assistance apparatus for use with delivery of respiratory gases to a patient comprising:

a nasal mask comprising a base and body, said body having flexible nasal pillows that in use rest in a substantially sealing manner against a patient's nares,

headgear comprising substantially flexible, soft straps and a continuous substantially curved elongate member to which said nasal mask is attached, said elongate member extending over said patient's cheekbones and below said patient's nose, said nasal mask being attached to said elongate member below said patient's nose.

Preferably said nasal pillows are substantially elliptical and have gases outlets that are offset from the centre of said elliptical pillows.

Preferably said breathing assistance apparatus includes humidification means adapted to, in use, be in fluid communication with said source of gases and said transportation means and adapted to in use humidify said gases.

Preferably said continuous elongate member includes two side arms and a central section.

Preferably said side arms and said central section are formed as a single item.

Alternatively said side arms and said central section are formed as two separate items.

Preferably said flexible soft straps only extend partially along each of said side arms.

Preferably said side arms have at least one weakened or narrow area to allow for manipulation of said side arms.

Preferably said base frictionally fits to said central section and said body to said base such that said central section suspends said base below said patient's nares and when said body is attached to said base said body with said nasal pillows rest against said patient's nares.

Alternatively said base is integrally formed with said central section.

Alternatively said side arms attach one to each side of said base.

This invention may also be said broadly to consist in the parts, elements and features referred to or indicated in the specification of the application, individually or collectively, and any or all combinations of any two or more of said parts, elements or features, and where specific integers are mentioned herein which have known equivalents in the art to which this invention relates, such known equivalents are deemed to be incorporated herein as if

individually set forth.

The invention consists in the foregoing and also envisages constructions of which the following gives examples.

BRIEF DESCRIPTION OF THE DRAWINGS

Preferred forms of the present invention will now be described with reference to the accompanying drawings.

Figure 1 is a block diagram of a humidified continuous positive airway pressure (system) as might be used in conjunction with the nasal mask of the present invention.

Figure 2 is a perspective view of the nasal mask of the present invention.

Figure 3 is an exploded view of the nasal mask of Figure 2.

Figure 4 is a side view of a mask base of the nasal mask of the present invention.

Figure 5 is a perspective end view of the mask base of Figure 4.

Figure 6 is an end view of a body of the nasal mask, particularly showing two nasal pillows.

Figure 7 is a perspective view of the body of Figure 6.

Figure 8 is a perspective view of a second form of the nasal mask of the present invention where the headgear includes additional rigid extensions.

DESCRIPTION OF THE PREFERRED EMBODIMENTS OF THE INVENTION

The breathing assistance apparatus of the present invention and nasal mask as described in the preferred embodiment of this invention can be used in respiratory care generally or with a ventilator. It is described below with reference to use in a humidified CPAP system.

A humidified Continuous Positive Airway Pressure (CPAP) system is shown Figure 1 in which a patient 1 is receiving humidified and pressurised gases through a patient interface (nasal mask) 2 connected to a humidified gases transportation pathway or inspiratory conduit 3. It should be understood that delivery systems could also be VPAP (Variable Positive Airway Pressure) and BiPAP (Bi-level Positive Airway Pressure) or numerous other forms of respiratory therapy. The inspiratory conduit 3 is connected to an outlet 4 of a humidification chamber 5 that contains a volume of water 6. The inspiratory conduit 3 may contain heating means or heater wires (not shown) that heat the walls of the conduit to reduce condensation of humidified gases within the conduit.

The humidification chamber 6 is preferably formed from a plastics material and preferably has a highly heat conductive base (for example an aluminium base) that is in direct contact with a heater plate 7 of humidifier 8. The humidifier 8 is provided with control means or an electronic controller 9 that may comprise a microprocessor based controller executing computer software commands stored in associated memory.

The controller 9 receives input from sources such as user input means or a dial 10 through which a user of the device may, for example, set a predetermined required value (preset value) of humidity or temperature of the gases supplied to patient 1. The controller 9 may also receive input from other sources, for example temperature and/or flow velocity sensors 11, 12, through a connector 13 and a heater plate temperature sensor 14. In response to the user set humidity or temperature value input via the dial 10 and the other inputs, the controller 9 determines when (or to what level) to energise the heater plate 7 to heat the water 6 within the humidification chamber 5. As the volume of the water 6 within the humidification chamber 5 is heated, water vapour begins to fill the volume of the chamber above the water's surface and is passed out of the humidification chamber 5 outlet 4 with the flow of gases (for example air) provided from a gases supply means or blower 15 that enters the chamber 5 through an inlet 16. Exhaled gases from the patient's mouth are passed directly to the ambient surroundings in Figure 1.

The blower 15 is provided with variable pressure regulating means or variable speed fan 21 that draws air or other gases through a blower inlet 17. The speed of the variable speed fan 21 is controlled by an electronic controller 18 (or alternatively the function of the controller 18 may carried out by the controller 9) in response to inputs from the controller 9 and a user set predetermined required value (preset value) of pressure or the fan speed via dial 19.

Figures 2 and 3 show the preferred form of the patient interface of the present invention. This patient interface is a nasal mask 2. The nasal mask 2 is comprised of a mask base 22 and body 23. The body 23 is substantially tubular with two nasal pillows 24, 25 extending from it. The nasal pillows 24, 25 are preferably frustoconical in shape and in use rest against a patient's nares, to substantially seal the patient's nares. The body 23 has an external lip 28 that frictionally fits with the mask base 22.

The body 23 and nasal pillows 24, 25 of the nasal mask of the present invention are shown in further detail in Figures 6 and 7. The body and pillows are preferably integrally

moulded in a substantially flexible plastics material. In the preferred form this material is silicone, but other appropriate materials, such as, rubber, thermoset elastomer or thermoplastic elastomer, such as Kraton™ may be used.

The nasal pillows 24, 25 are preferably elliptical in shape but are tubular and allow for a passage of gases passed from tubing 3 and through the mask body 23. The pillows 24, 25 are preferably angled toward one another and each have a preferably elliptical outlet 26, 27 that may be slightly offset from the centre of each pillow 24, 25, as shown in Figure 6.

The external lip 28 on the mask body 23 is an area of reduced circumference around the tubular part of the body 23. A projection 47 may be provided on the lip 28 that fits with a corresponding recess (discussed below) on the mask base 22 to ensure correct assembly of the nasal mask.

The mask base 22 is shown in further detail in Figures 4 and 5. The mask base 22 is a ring or sleeve type attachment. The base 22 is preferably made from a substantially hard (rigid) plastics material, such as polypropylene, polycarbonate or acetyl; however, other appropriate materials may be used. The base 22 has an internal recessed area 45 on one side and a semi-tubular projection 29 on its other side. When assembling the mask body 23 to the mask base 22 the internal recessed area 45 receives the lip 28. These parts are maintained together from a friction fit, however other types of fitting may be provided for, such as snap or bump fitted part. In this form the friction fitting of the lip 28 to the recessed area 45 is assisted by elongate projections 49 extending along the central part 50 of the mask base 22. The projection 47 on the mask body 23 allows for correct fitting or keying of the mask base to the mask body, such that when the lip 28 is fitted into the recessed area 45 the projection 47 enters the recess 48 formed in the mask base 22.

The semi-tubular projection 29 is curved in this embodiment such that a ball jointed connector end 46 of a connector 30 can be fitted into it. The projection 29 effectively forms a socket for the connector end 46 and the connector end can swivel within the socket. The connector 30 is connected to a tube 31 to allow for gases to be passed to the nasal mask 2. The tubing 31 may be attached to inspiratory conduit 3 or the tubing 31 may simply be the inspiratory conduit 3.

The base 22 has a substantially curved extension or partial lip 32 extending beneath the semi-tubular projection (socket) 29. A slot 33 is created between the socket 29 and extension 32. The extension and slot is used to fit the mask base 22 to the headgear 21.

In use, the nasal mask is assembled with headgear 21. The headgear 21 in the preferred form is comprised of headgear straps 35, 36, 37, 38 and a substantially elongate member 34. The member 34 is curved and substantially rigid, or at least more rigid than the headgear straps.

The headgear straps 35, 36, 37, 38 are preferably made from a composite foam layered material, such as Breathoprene™. The headgear 21 preferably includes a first strap 35 and second strap 36. The first strap 35 extends in use over the forehead or top front area of a patient's head. The second strap 36 extends around the back of the patient's head. The headgear 21 also has side straps 37, 38 that in use extend down the cheeks of a patient.

The curved member 34 is comprised of a central section 42 and contoured side arms 41. A substantial length of each of the side arms overlaps and is attached to the side straps 37, 38. However, the side straps 37, 38 only extend partially along the length of the side arms 41. As the side straps are made from a soft foam type material, the side straps provide a comfortable fitting of the headgear and member, while the substantially rigid side arms 41 provide rigidity and stability to the headgear 21 and nasal mask 2. The attachment between the side straps and rigid extension side arms is by gluing, sewing or other appropriate fastening.

Preferably the side arms of the curved member 34 are integrally moulded with the central section 42 and the side arms 41 are preferably of thinner width than the central section 42. As the side arms 41 are made of a thin piece of plastics material they are able to be bent or adjusted to allow for better and more comfortable fit to a patient. The side arms 41 may also include weakened or narrow areas 39 to allow for additional bending, moulding or twisting of the arms 34 to better fit the headgear to individual patients. For example, in the embodiment shown in Figures 2 and 3, the narrowed area 39 corresponds to the cheek bone area of a patient and allows for the side arms to easier bend or twist to fit the contours of the patient's face.

Referring to Figure 3 the curved elongate member has a central section 42 that in the assembled form supports the mask base and body such that the pillows 24, 25 rest against the patient's nares. The central section 42 is a half circle that is integrally moulded with the side arms 41. The central section 42 has a raised area 43 on its exterior, at the apex of the half circle. The raised area 43 is shaped to receive the mask base 22. To assemble a patient merely needs to slide the mask base 22 into the central section 42 such that the raised area 43 fits into the slot 33 on the mask base 22. It should be noted that in alternative embodiments, the mask base 22 can be formed integrally with the curved member 34. It should also be noted that the

curved member 34 could be formed as two separate pieces. That is, central section 42 is formed as two parts with a central split seam, the two left and right halves joined in use. The two left and right parts could either be joined along a seam as described above, with the base 22 slotting into the slot 33 as described above, or alternatively, each of the two left and right arms could attach one to each side of the base 22.

It should be noted that where a substantially continuous elongate member is referred to in this specification, it refers to any of the options outlined above.

The side arms 41 may also include a loop 40. This is where a section of the side arms 41 is not attached to the strap 38, 37 underneath. Thus that section 40 of the side arms forms a loop to which a tube attachment (44, such as that shown attached to another strap in Figures 2 and 3) may be looped to the side arms and the tube attached to either of the side arms.

The connector 30 in the preferred form is a ball and socket jointed connector to allow for the tubing 31 to swivel in the mask base 22. The tubing 31 may be attached to any of the headgear straps. However, a tube attachment 44 is shown where the tubing is attached by fasteners, such as hook and loop fastener, to the first strap 35. In other embodiments the tubing 31 may be attached to either the side straps 37, 38 or merely allowed to fall freely from the nasal mask 2.

Although a ball and socket joint, as described above, between the mask base 22 and tubing 31 is preferred other connections may be utilised, such as a flexible piece of silicone, or other appropriate connection. The connection between the base and tubing must be able to be flexed or rotated to allow for the tubing to be moved without causing the dislodgement of the nasal mask 2 from the patient's nares.

The mask body 23 may be provided with nasal pillows of various different sizes, such that patient's may remove an existing mask body and simply attach a different sized body to the mask base 22.

A further form of the nasal mask and headgear of the present invention is shown in Figure 8. Here the headgear may include an additional strap 53 extending from the cheek region of the side straps 41 and extending behind the user's head. This lower additional strap 53 may also include substantially rigid arms 51 similar to the arms 41 described above. Any number of connecting straps 52 may also be provided between the upper strap 36 and lower strap 53. Again, the arms 51 would provide stability and rigidity to the additional strap 53.

DATED THIS 14th DAY OF July 2006
AJ PARK
PER
AGENTS FOR THE APPLICANT

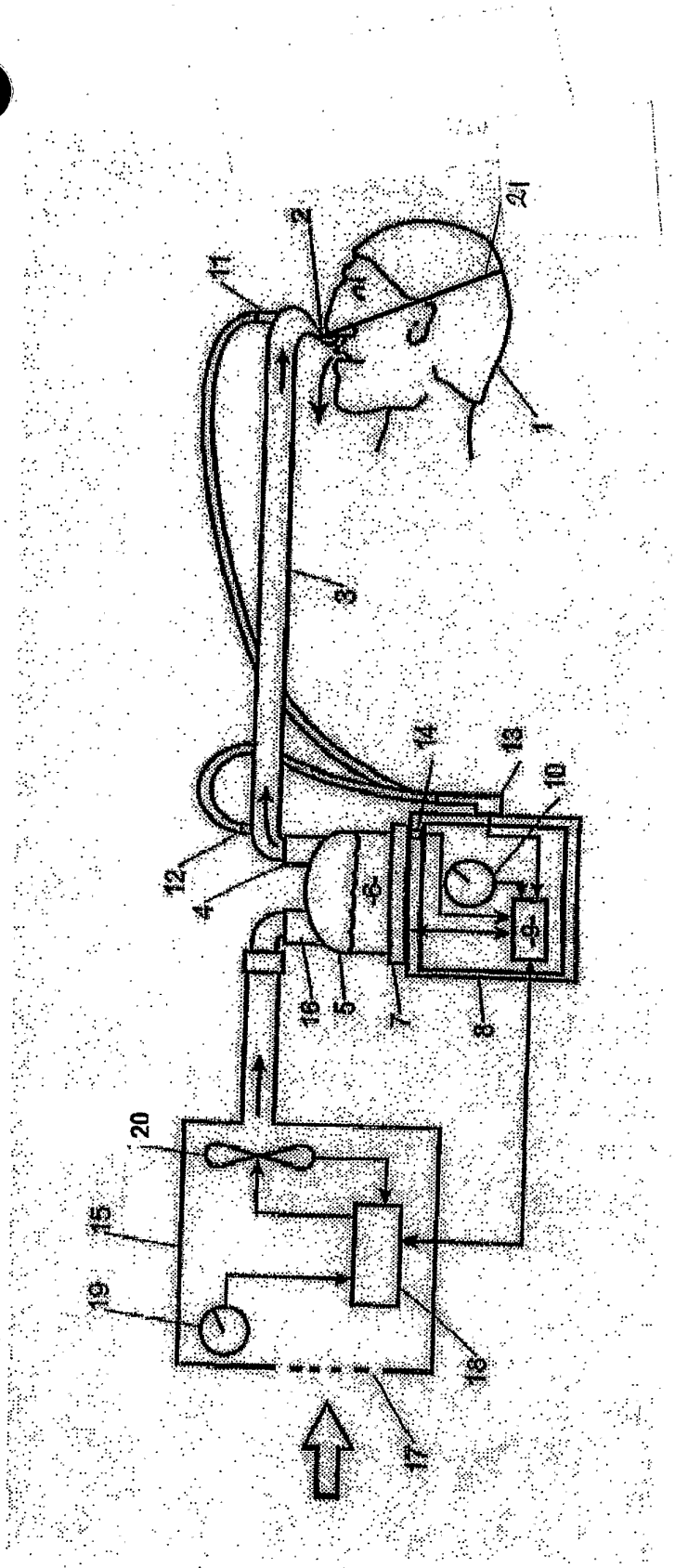

Figure 1

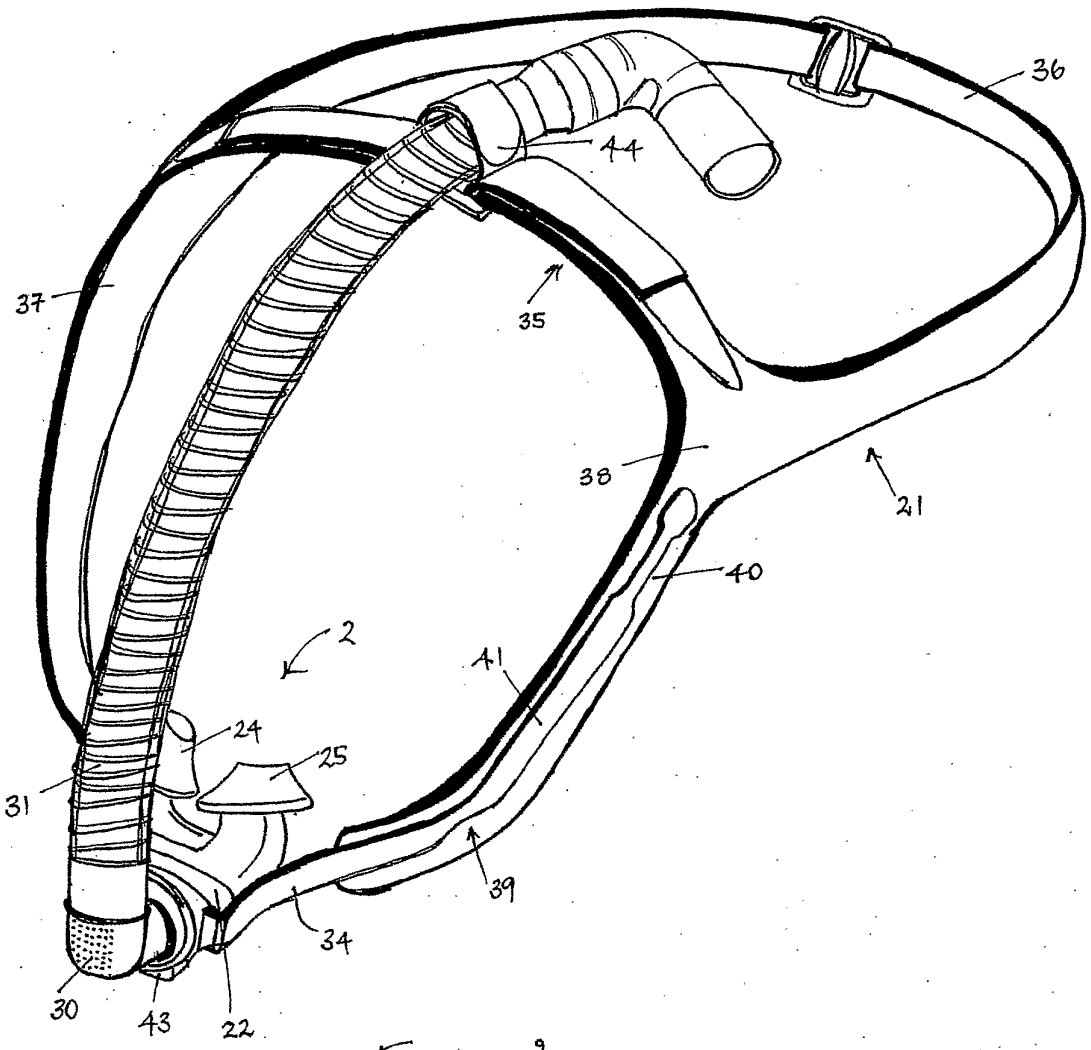

Figure 2

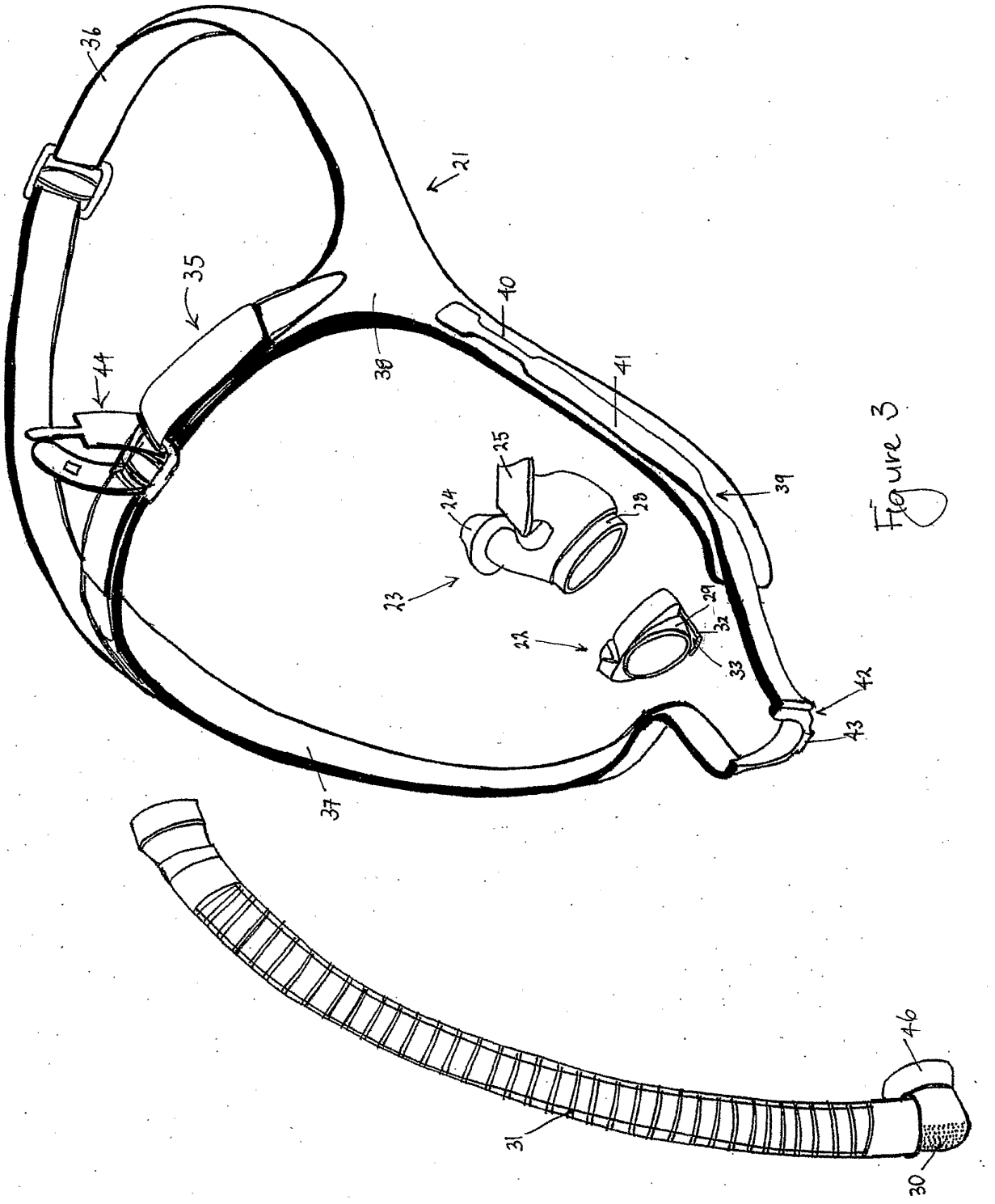

Figure 3

curved member 34 could be formed as two separate pieces. That is, central section 42 is formed as two parts with a central split seam, the two left and right halves joined in use. The two left and right parts could either be joined along a seam as described above, with the base 22 slotting into the slot 33 as described above, or alternatively, each of the two left and right arms could attach one to each side of the base 22.

It should be noted that where a substantially continuous elongate member is referred to in this specification, it refers to any of the options outlined above.

The side arms 41 may also include a loop 40. This is where a section of the side arms 41 is not attached to the strap 38, 37 underneath. Thus that section 40 of the side arms forms a loop to which a tube attachment (44, such as that shown attached to another strap in Figures 2 and 3) may be looped to the side arms and the tube attached to either of the side arms.

The connector 30 in the preferred form is a ball and socket jointed connector to allow for the tubing 31 to swivel in the mask base 22. The tubing 31 may be attached to any of the headgear straps. However, a tube attachment 44 is shown where the tubing is attached by fasteners, such as hook and loop fastener, to the first strap 35. In other embodiments the tubing 31 may be attached to either the side straps 37, 38 or merely allowed to fall freely from the nasal mask 2.

Although a ball and socket joint, as described above, between the mask base 22 and tubing 31 is preferred other connections may be utilised, such as a flexible piece of silicone, or other appropriate connection. The connection between the base and tubing must be able to be flexed or rotated to allow for the tubing to be moved without causing the dislodgement of the nasal mask 2 from the patient's nares.

The mask body 23 may be provided with nasal pillows of various different sizes, such that patient's may remove an existing mask body and simply attach a different sized body to the mask base 22.

A further form of the nasal mask and headgear of the present invention is shown in Figure 8. Here the headgear may include an additional strap 53 extending from the cheek region of the side straps 41 and extending behind the user's head. This lower additional strap 53 may also include substantially rigid arms 51 similar to the arms 41 described above. Any number of connecting straps 52 may also be provided between the upper strap 36 and lower strap 53. Again, the arms 51 would provide stability and rigidity to the additional strap 53.

DATED THIS 14th DAY OF July 2006
AJ PARK
PER
AGENTS FOR THE APPLICANT

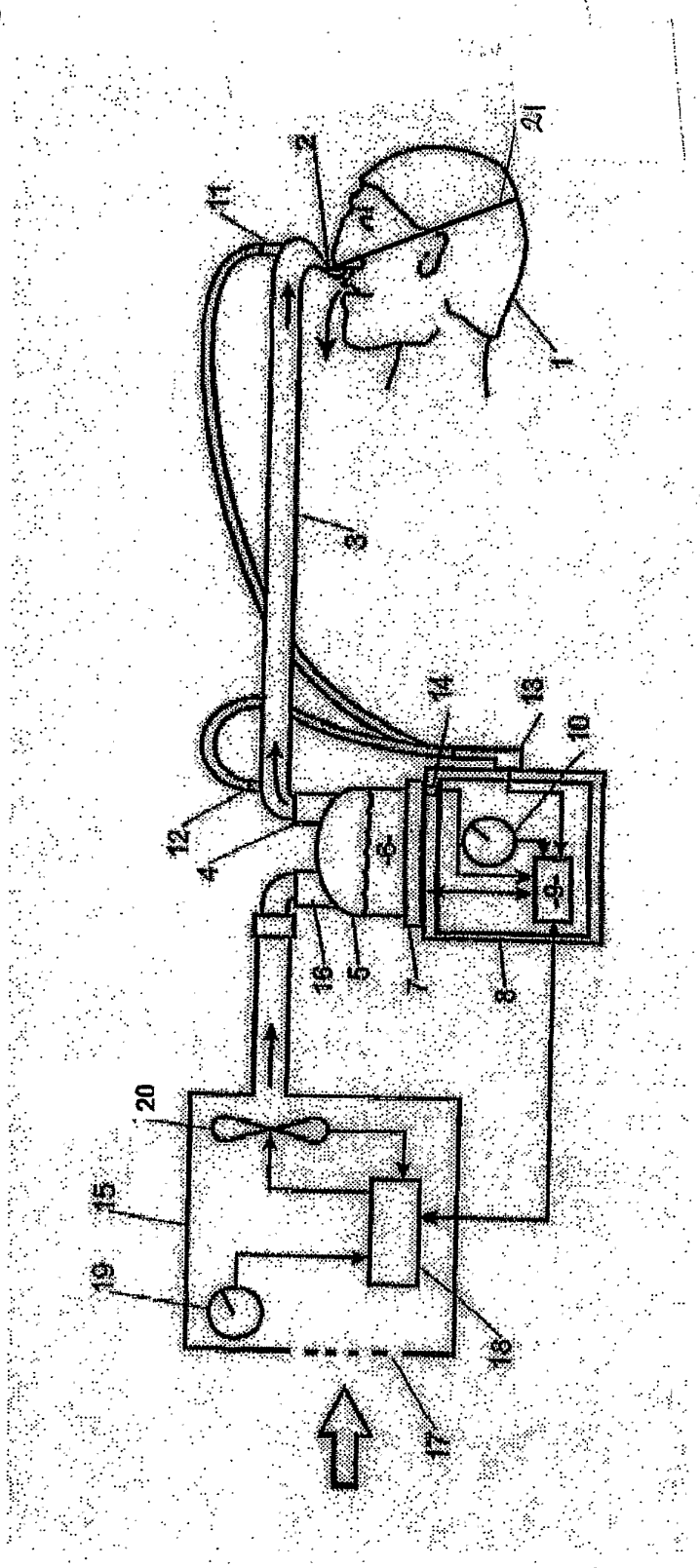

Figure 1

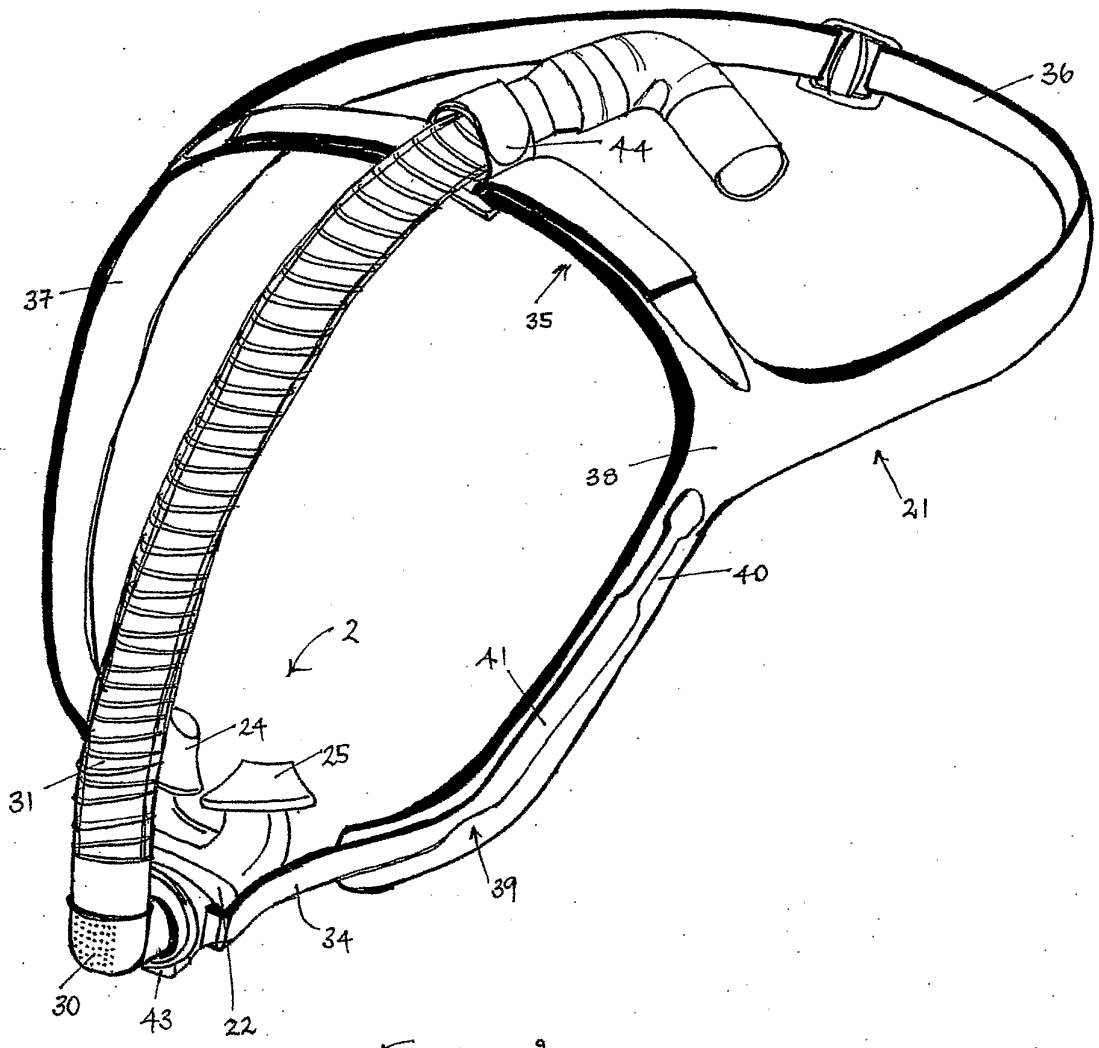

Figure 2

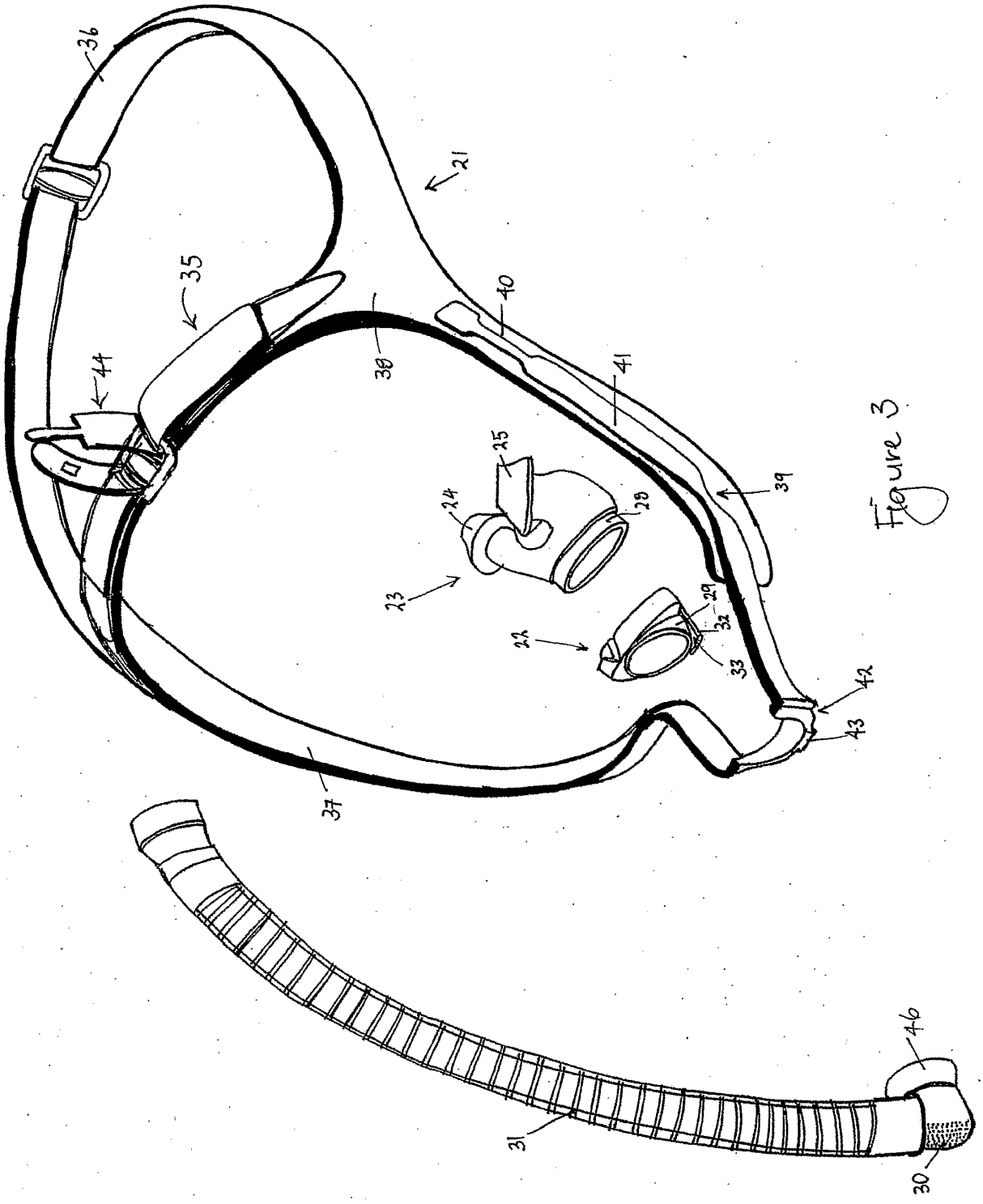

Figure 3

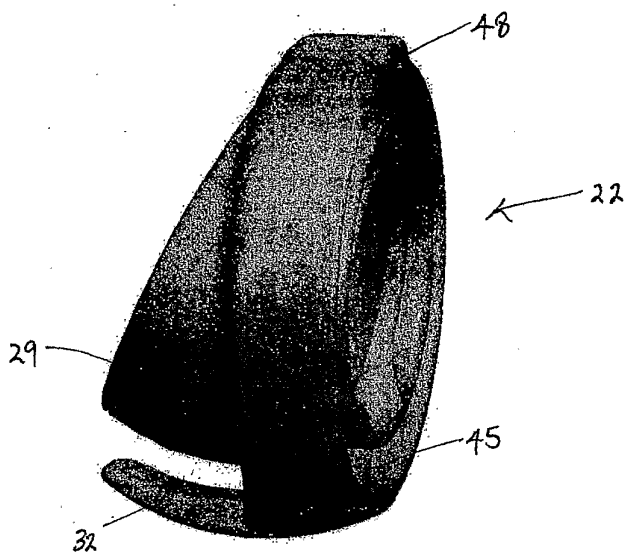

Figure 4

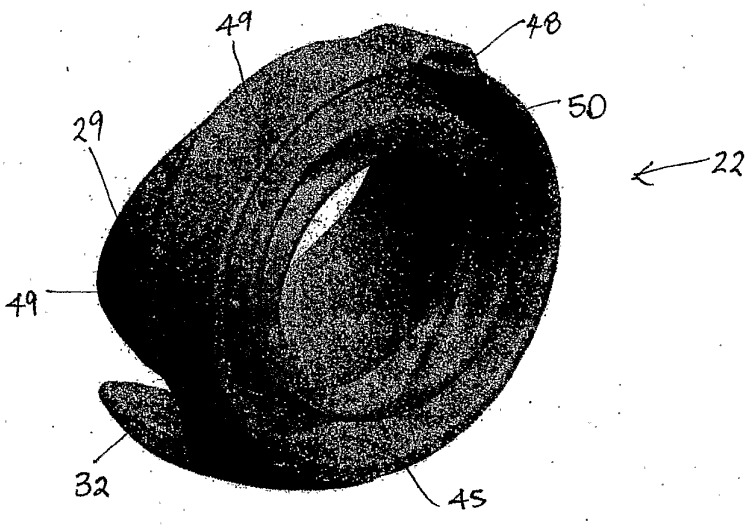

Figure 5

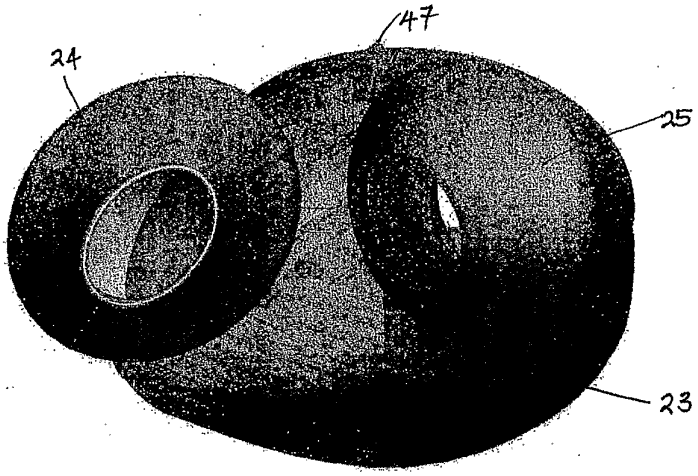

Figure 6

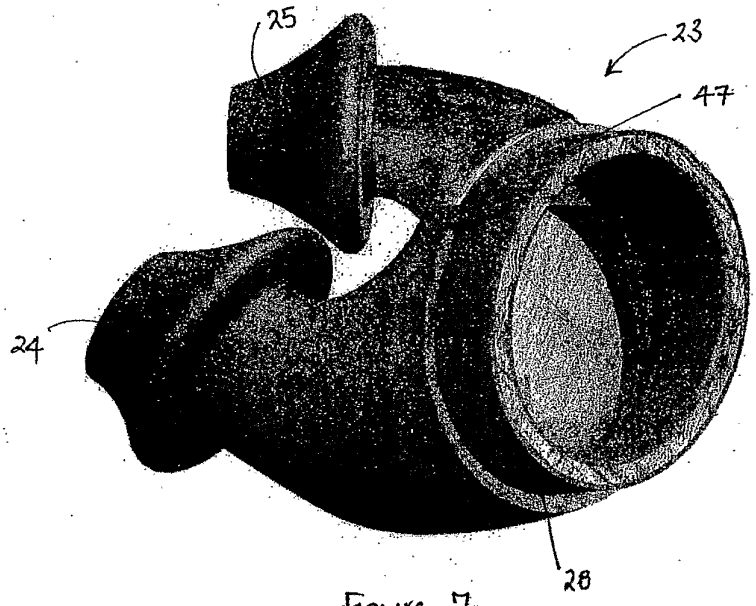

Figure 7

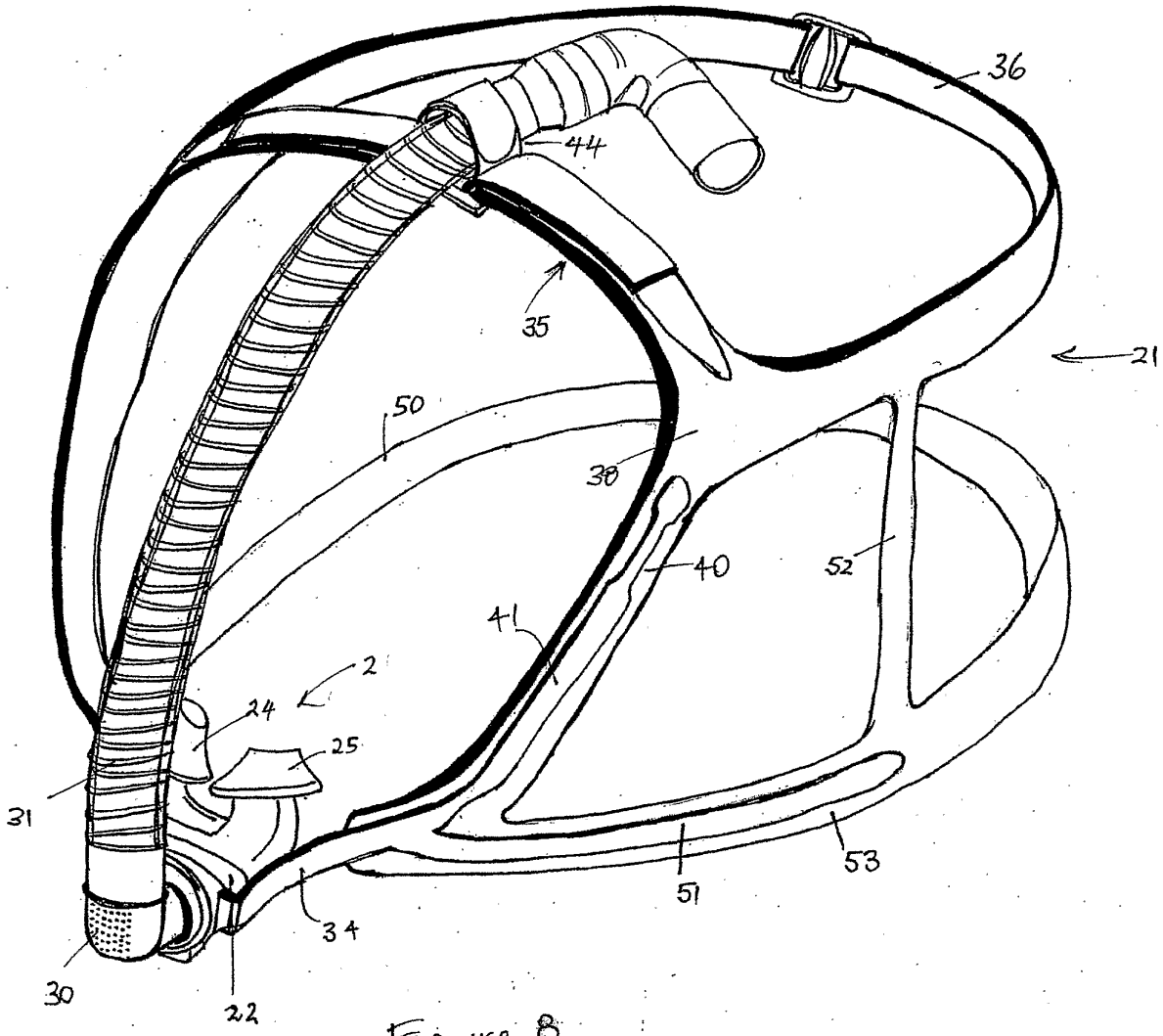

Figure 8

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Ministry of Economic Development
Manatū Ōhanga
Intellectual Property Office of New Zealand

PCT/NZ2007/000185

CERTIFICATE

This certificate is issued in support of an application for Patent registration in a country outside New Zealand pursuant to the Patents Act 1953 and the Regulations thereunder.

I hereby certify that annexed is a true copy of the Provisional Specification as filed on 6 November 2006 with an application for Letters Patent number 551103 made by FISHER & PAYKEL HEALTHCARE LIMITED.

Dated 17 August 2007.

Neville Harris
Commissioner of Patents, Trade Marks and Designs

COMMISSIONER OF PATENTS, TRADEMARKS & DESIGNS
NEW ZEALAND

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NEW ZEALAND

PATENTS ACT, 1953

PROVISIONAL SPECIFICATION

"BREATHING ASSISTANCE APPARATUS"

We, **FISHER & PAYKEL HEALTHCARE LIMITED**, a company duly incorporated under the laws of New Zealand, of 15 Maurice Paykel Place, East Tamaki, Auckland, New Zealand, do hereby declare this invention to be described in the following statement:

TECHNICAL FIELD

The present invention relates to apparatus for treating sleep apnoea. More specifically, the present invention provides an interface for the supply of respiratory gases, but most particularly positive pressure gases.

BACKGROUND ART

In the art of respiration devices, there are well known variety of respiratory masks which cover the nose and/or mouth of a human user in order to provide a continuous seal around the nasal and/or oral areas of the face such that gas may be provided at positive pressure within the mask for consumption by the user. The uses for such masks range from high altitude breathing (i.e., aviation applications) to mining and fire fighting applications, to various medical diagnostic and therapeutic applications.

Obstructive Sleep Apnoea (OSA) is a sleep disorder that affects up to at least 5% of the population in which muscles that normally hold the airway open relax and ultimately collapse, sealing the airway. The sleep pattern of an OSA sufferer is characterised by repeated sequences of snoring, breathing difficulty, lack of breathing, waking with a start and then returning to sleep. Often the sufferer is unaware of this pattern occurring. Sufferers of OSA usually experience daytime drowsiness and irritability due to a lack of good continuous sleep.

In an effort to treat OSA sufferers, a technique known as Continuous Positive Airway Pressure (CPAP) was devised. A CPAP device consists of a gases supply (or blower) with a conduit connected to supply pressurised gases to a patient, usually through a nasal mask. The pressurised air supplied to the patient effectively assists the muscles to keep the patient's airway open, eliminating the typical OSA sleep pattern.

The procedure for administering CPAP treatment has been well documented in both the technical and patent literature. Briefly stated, CPAP treatment acts as a pneumatic splint of the airway by the provision of a positive pressure, usually in the range 4 to 20 cm H_2O. The air is supplied to the airway by a motor driven blower whose outlet passes via an air delivery hose to a nose (or nose and/or mouth) mask that is sealingly engaged to a patient's face, preferably by means of a harness or other headgear. An exhaust port is also usually provided in the delivery tube proximate to the mask or the mask itself. More sophisticated forms of positive airway pressure devices, such as bi level devices and auto-titrating devices, are described in US Patent No. 5,148,802 of Respironics, Inc. and US Patent No. 5,245,995 of Rescare Limited, respectively.

One requisite of respiratory masks has been that they provide an effective seal against the user's face to prevent leakage of the gas being supplied. Commonly, in prior mask configurations, a good mask-to-face seal has been attained in many instances only with considerable discomfort for the user. A common complaint of a user of CPAP therapy is pressure sores caused by the mask about the nose and face and in particular in the nasal bridge region of the user. This problem is most crucial in those applications, especially medical applications, which require the user to wear such a mask continuously for hours or perhaps even days. In such situations, the user will not tolerate the mask for long durations and optimum therapeutic or diagnostic objectives thus will not be achieved, or will be achieved with great difficulty and considerable user discomfort.

US Patent No. 5,477,852 of Airways Ltd, Inc. discloses a nasal positive airway pressure device that has a pair of nasal members each having a cannula tip to be inserted into the nares of the patient. Each cannula is tapered from a substantially circular cross section outside the patient's nostril to a substantially oval cross section at the tip inserted into the nostril. An inflatable cuff surrounds each cannula with the interior space of the cuff communicating with the lumen of the cannula through at least one aperture in the sidewall of the cannula. The nasal members are connected to one or more flexible hoses that, in turn, are connected to a source of positive air pressure. In use, positive air pressure is supplied to each cannula tip through the air hoses and nasal members. The positive air pressure inflates the cuffs to hold the nasal members in place and to effect treatment. The nasal device of US Patent No. 5,477,852 is attached to headgear that is located about a patient's head; this headgear could be considered by many patients as cumbersome and uncomfortable.

Conventional masks used for administrating CPAP treatment are also considered uncomfortable and cumbersome, and prior art nasal masks can be noisy (due to air leaks). These disadvantages in many cases are a formidable obstacle to patient acceptance of such treatment. Therefore, a substantial number of patients either cannot tolerate treatment or choose to forego treatment. It is believed a substantial number of such patients could benefit from a nasal positive airway pressure apparatus that is more convenient to use and comfortable to wear, thereby resulting in increased treatment compliance.

As oxygen is supplied as a dry gas it is well known in the art to either heat and/or humidify gases before delivering these to a patient. In particular when delivering oxygen, or and oxygen and air mixture, it has proven beneficial to humidify the gases first. In

WO01/41854 of Vapotherm, Inc. a system is disclosed that allows the delivery of humidified oxygen through a nasal cannula. This system uses a narrow bore conduit and nasal cannula with a high resistance to gas flows, thereby requiring the oxygen be of a high pressure. Air, as well as oxygen can also be passed down the conduit and nasal cannula and it too must be of a high pressure. This system allows the delivery of high flows of oxygen enriched air to the patient, but is limited in the flows achievable due to the narrow bore of the cannula resulting in high resistance gas flow and excessive velocity and noise upon exiting the cannula. Furthermore, the narrowness of the nasal cannula in this system allows easy expiration of gases between the prongs and nares and therefore does not create any positive airway pressure.

Innomed Technologies, Inc. manufactures a nasal cannula device called the NASALAIRE™. In this device air or oxygen travels down a wide bore conduit to nasal cannula. The NASALAIRE™ creates a physical seal between the nares and itself, and relies on the absence of leaks around the cannula and the nares to deliver pressure supplied by a continuous positive airway pressure (CPAP) blower to the airway of the wearer.

US6,119,694 of Respironics Georgia, Inc discloses a nasal mask having a nare seal and lateral support members to support the mask.

WO2004/073778 of ResMed Ltd discloses a nasal mask including a frame where headgear is provided with rigid sections that extend to the nasal mask.

WO04/041341 of ResMed Ltd discloses headgear for a patient mask that includes sewn sections to provide rigidity to the headgear.

DISCLOSURE OF THE INVENTION

It is an object of the present invention to attempt to provide a patient interface that goes some way to overcoming the abovementioned disadvantages in the prior art or which will at least provide the industry with a useful choice.

Accordingly in a first aspect the present invention may broadly be said to consist in a breathing assistance apparatus for use with delivery of respiratory gases to a patient comprising:

a mask comprising a base and body, said body having flexible nasal pillows that rest in use against a patient's nares, at least one of said mask or said nasal pillows substantially forming a seal with at least one of said patient's airways,

headgear comprising substantially flexible, soft straps and a substantially curved elongate member to which said mask is attached, said elongate member extending over said

patient's cheeks and below said patient's nose, said mask being attached to said elongate member below said patient's nose.

Preferably said curved elongate member is moulded in a three dimensional manner to fit the contours of said patient's cheeks.

In a second aspect the present invention may broadly be said to consist in a breathing assistance apparatus for use with delivery of respiratory gases to a patient comprising:

a mask comprising a base and body, said body having flexible nasal pillows that rest in use against a patient's nares, at least one of said mask or said nasal pillows substantially forming a seal with at least one of said patient's airways,

headgear comprising substantially flexible, soft straps and a continuous substantially curved elongate member to which said mask is attached, said elongate member extending over said patient's cheeks and below said patient's nose, said nasal mask being attached to said elongate member below said patient's nose.

Preferably said curved elongate member is moulded in a three dimensional manner to fit the contours of said patient's cheeks.

Preferably said nasal pillows are substantially elliptical and have gases outlets that are offset from the centre of said elliptical pillows.

Preferably said breathing assistance apparatus includes humidification means adapted to, in use, be in fluid communication with said source of gases and said transportation means and adapted to in use humidify said gases.

Preferably said continuous elongate member includes two side arms and a central section.

Preferably said side arms and said central section are formed as a single item.

Alternatively said side arms and said central section are formed as two separate items.

Preferably said flexible soft straps only extend partially along each of said side arms.

Preferably said side arms have at least one weakened or narrow area to allow for manipulation of said side arms.

Preferably said base frictionally fits to said central section and said body to said base such that said central section suspends said base below said patient's nares and when said body is attached to said base said body with said nasal pillows rest against said patient's nares.

Alternatively said base is integrally formed with said central section.

Alternatively said side arms attach one to each side of said base.

Accordingly in a third aspect the present invention may broadly be said to consist in a breathing assistance apparatus for use with delivery of respiratory gases to a patient comprising:

a mask comprising a base and body, said mask substantially forming a seal with said patient's airways,

headgear comprising substantially flexible, soft straps and a substantially curved elongate member to which said mask is attached, said elongate member extending over said patient's cheeks.

Preferably said mask is a full face mask where said body extends to cover said patient's mouth and nose.

Preferably said curved elongate member is moulded in a three dimensional manner to fit the contours of said patient's cheeks.

This invention may also be said broadly to consist in the parts, elements and features referred to or indicated in the specification of the application, individually or collectively, and any or all combinations of any two or more of said parts, elements or features, and where specific integers are mentioned herein which have known equivalents in the art to which this invention relates, such known equivalents are deemed to be incorporated herein as if individually set forth.

The invention consists in the foregoing and also envisages constructions of which the following gives examples.

BRIEF DESCRIPTION OF THE DRAWINGS

Preferred embodiments of the present invention will now be described with reference to the accompanying drawings.

Figure 1 is a block diagram of a humidified continuous positive airway pressure (system) as might be used in conjunction with a mask and headgear of the present invention.

Figure 2 is a perspective view of a mask of the first embodiment of the present invention, the mask being a nasal mask.

Figure 3 is an exploded view of the nasal mask and headgear of Figure 2.

Figure 4 is a side view of a mask base of the nasal mask of Figure 2.

Figure 5 is a perspective end view of the mask base of Figure 4.

Figure 6 is an end view of a body of the nasal mask of the first embodiment,

particularly showing two nasal pillows.

Figure 7 is a perspective view of the body of Figure 6.

Figure 8 is a perspective view of a nasal mask of the first embodiment of the present invention having alternative headgear that includes additional rigid extensions.

Figure 9 is an illustration of a second embodiment of a patient interface and headgear of the present invention.

Figure 10 is an exploded illustration of the patient interface and headgear of Figure 9.

Figure 11 is an exploded illustration of a third embodiment of a patient interface and headgear of the present invention.

Figure 12 is an exploded illustration of a fourth embodiment of a patient interface and headgear of the present invention.

Figure 13 is an illustration of a fifth embodiment of a patient interface and headgear of the present invention.

Figure 14 is an exploded illustration of the patient interface and headgear of Figure 13.

Figure 15 is an illustration of a sixth embodiment of a patient interface and headgear of the present invention.

Figure 16 is an illustration of a seventh embodiment of a patient interface and headgear of the present invention.

Figure 17 is a cross-sectional illustration of the patient interface and headgear of Figure 17.

Figure 18 is an illustration of a nasal pillow of a patient interface of the present invention.

Figures 19a to 19d are illustrations of a nasal pillow of a patient interface of the present invention.

DESCRIPTION OF THE PREFERRED EMBODIMENTS OF THE INVENTION

The breathing assistance apparatus of the present invention including masks and headgear as described in the preferred embodiments of this invention can be used in respiratory care generally or with a ventilator. It is described below with reference to use in a humidified CPAP system.

A humidified Continuous Positive Airway Pressure (CPAP) system is shown Figure 1 in which a patient 1 is receiving humidified and pressurised gases through a patient interface

(nasal mask) 2 connected to a humidified gases transportation pathway or inspiratory conduit 3. Alternative delivery systems may also be used such as, VPAP (Variable Positive Airway Pressure) and BiPAP (Bi-level Positive Airway Pressure) or numerous other forms of respiratory therapy. The inspiratory conduit 3 is connected to an outlet 4 of a humidification chamber 5 that contains a volume of water 6. The inspiratory conduit 3 may contain heating means or heater wires (not shown) that heat the walls of the conduit to reduce condensation of humidified gases within the conduit.

The humidification chamber 6 is preferably formed from a plastics material and preferably has a highly heat conductive base (for example an aluminium base) that is in direct contact with a heater plate 7 of humidifier 8. The humidifier 8 is provided with control means or an electronic controller 9 that may comprise a microprocessor based controller executing computer software commands stored in associated memory.

The controller 9 receives input from sources such as user input means or a dial 10 through which a user of the device may, for example, set a predetermined required value (preset value) of humidity or temperature of the gases supplied to patient 1. The controller 9 may also receive input from other sources, for example temperature and/or flow velocity sensors 11, 12, through a connector 13 and a heater plate temperature sensor 14. In response to the user set humidity or temperature value input via the dial 10 and the other inputs, the controller 9 determines when (or to what level) to energise the heater plate 7 to heat the water 6 within the humidification chamber 5. As the volume of the water 6 within the humidification chamber 5 is heated, water vapour begins to fill the volume of the chamber above the water's surface and is passed out of the humidification chamber 5 outlet 4 with the flow of gases (for example air) provided from a gases supply means or blower 15 that enters the chamber 5 through an inlet 16. Exhaled gases from the patient's mouth are passed directly to the ambient surroundings in Figure 1.

The blower 15 is provided with variable pressure regulating means or variable speed fan 21 that draws air or other gases through a blower inlet 17. The speed of the variable speed fan 21 is controlled by an electronic controller 18 (or alternatively the function of the controller 18 may carried out by the controller 9) in response to inputs from the controller 9 and a user set predetermined required value (preset value) of pressure or the fan speed via dial 19.

Figures 2 and 3 show a first embodiment of a patient interface of the present invention.

This patient interface is a nasal mask 2. The nasal mask 2 is comprised of a mask base 22 and body 23. The body 23 is substantially tubular with two nasal pillows 24, 25 extending from it. The nasal pillows 24, 25 are preferably frustoconical in shape and in use rest against a patient's nares, to substantially seal the patient's nares. The body 23 has an external lip 28 that frictionally fits with the mask base 22.

The body 23 and nasal pillows 24, 25 of the nasal mask of the present invention are shown in further detail in Figures 6 and 7. The body and pillows are preferably integrally moulded in a substantially flexible plastics material. In the preferred form this material is silicone, but other appropriate materials, such as, rubber, thermoset elastomer or thermoplastic elastomer, such as Kraton™ may be used.

The nasal pillows 24, 25 are preferably elliptical in shape but are tubular and allow for a passage of gases passed from tubing 3 and through the mask body 23. The pillows 24, 25 are preferably angled toward one another and each have a preferably elliptical outlet 26, 27 that may be slightly offset from the centre of each pillow 24, 25, as shown in Figure 6.

Figures 18 and 19 show a nasal pillow 24 with an offset outlet in more detail. The pillow 24 has an outer profile 200 and inner profile 201 with respective centre points 202, 203. The inner profile 201 (outlet of the nasal pillow 24) is offset inward, by a horizontal spacing 204 and vertical spacing 205. Meaning the outlet 201 of the nasal pillow is offset horizontally 204 towards the middle of the nose and vertically 205 towards the user's upper lip. Offsetting the outlet 201 downwards in this manner allows the outlet to be inserted into the nostril without the outer profile 200 pushing the user's upper lip. Offsetting the outlet 201 inwards allow it to better seal on the septum of the user's nose in use.

The outlet 201 may also be angled compared to the outer profile 200. For example in Figure 18, there is a horizontal angle difference between the outer profile 200 and outlet 201 shown as 206. A similar vertical angle difference between the outer profile 200 and outlet 201 shown as 207.

With the outer profile and inner profile having different sections or offsets allows the gradient of the connecting surface between the profiles to be changeable. This is shown in Figures 19a, 19b, 19c and 19d. The connecting surface between the inner 201 and outer 200 profiles can have differing gradients, 208, 209, 210. The different gradients 208, 209, 210 of the connecting surface are possible due to the difference in offset difference 211, 212 (horizontal, vertical or angled) between the inner 201 and outer 200 profiles.

There may also be a difference in the rate of change of the gradient (as illustrated in the difference between 208 and 210). This allows easier insertion of the pillow 24 into a user's nostrils due to more lead in and better sealing that may be achieved due to more ergonomic contouring of the connecting surface that contacts the user's nostril.

Referring back to Figure 7, the external lip 28 on the mask body 23 is an area of reduced circumference around the tubular part of the body 23. A projection 47 may be provided on the lip 28 that fits with a corresponding recess (discussed below) on the mask base 22 to ensure correct assembly of the nasal mask.

The mask base 22 is shown in further detail in Figures 4 and 5. The mask base 22 is a ring or sleeve type attachment. The base 22 is preferably made from a substantially hard (rigid) plastics material, such as polypropylene, polycarbonate or acetyl; however, other appropriate materials may be used. The base 22 has an internal circumferential recessed area 45 on one side and a semi-tubular projection 29 on its other side. When assembling the mask body 23 to the mask base 22 the internal recessed area 45 receives the lip 28. These parts are maintained together by friction fit, however other types of fitting may be provided for, such as a snap or bump fitted part or the body may be over moulded to a clip that causes the fitting to the mask body 23. In this form the friction fitting of the lip 28 to the recessed area 45 is assisted by elongate projections 49 extending along the central part 50 of the mask base 22. The projection 47 on the mask body 23 allows for correct fitting or keying of the mask base to the mask body, such that when the lip 28 is fitted into the recessed area 45, the projection 47 enters the recess 48 formed in the mask base 22. The semi-tubular projection 29 is curved in this embodiment such that a ball jointed connector end 46 such that a connector 30 can be fitted into it. The projection 29 effectively forms a socket for the connector end 46 and the connector end can swivel within the socket. The connector 30 is connected to a tube 31 to allow for gases to be passed to the nasal mask 2. The tubing 31 may be attached to inspiratory conduit 3 or the tubing 31 may simply be the inspiratory conduit 3.

In alternative embodiments the projection 29 may not be semi-circular but the inner surface of the base 22 may form be curved and form a socket for receiving the connector end 46.

The base 22 has an extension or partial lip 32 extending beneath the semi-tubular projection (socket) 29. A slot 33 is created between the socket 29 and extension 32. The extension and slot is used to fit the mask base 22 to the headgear 21. In this embodiment the

extension 32 is substantially curved to follow the shaped of the projection 29. However, in other forms the extension may be substantially straight or otherwise shaped.

In use, the nasal mask is assembled with headgear 21. The headgear 21 in the preferred form is comprised of headgear straps 35, 36, 37, 38 and a substantially curved and elongate member 34. The member 34 is curved and substantially rigid, or at least more rigid than the headgear straps.

The headgear straps 35, 36, 37, 38 are preferably made from a composite foam layered material, such as Breathoprene™. The headgear 21 preferably includes a first strap 35 and a second strap 36. The first strap 35 extends in use over the forehead or top front area of a patient's head. The second strap 36 extends around the back of the patient's head. The headgear 21 also has side straps 37, 38 that in use extend down the cheeks of a patient.

Referring to Figure 2, the curved and elongate member 34 is comprised of a central section 42 and contoured side arms 41, 54. A substantial length of each of the side arms 41, 54 overlaps and is attached to the side straps 37, 38. However, the side straps 37, 38 only extend partially along the length of the side arms 41, 54. As the side straps 37, 38 are made from a soft foam type material they provide a comfortable fitting of the headgear and curved member 34, while the substantially rigid side arms 41, 54 provide rigidity and stability to the headgear 21 and nasal mask 2. The attachment between the side straps and rigid extension side arms may be made by gluing, sewing or other appropriate fastening.

Preferably the side arms of the curved member 34 are integrally moulded with the central section 42. The curved member 34 is preferably three dimensionally moulded to a shape to substantially match the cheek contours of a human. The side arms 41, 54 are preferably of thinner width (cross-section) than the central section 42. As the side arms 41, 54 are moulded of a plastics material to be substantially thin they are capable of being bent or adjusted to allow for better and more comfortable fit to a patient. The side arms 41, 54 may also include weakened or narrow areas 39 to allow for additional bending, moulding or twisting of the arms 34 to better fit the headgear to individual patients. For example, in the embodiment shown in Figures 2 and 3, the narrowed area 39 corresponds to the cheek bone area of a patient and allows for the side arms to easier bend or twist to fit the contours of the patient's face.

In alternative embodiments the side arms may have weakened areas that are narrower in cross-section to that of the remainder of the side arms. A narrower cross-section area would

also provide a weakened area that may be easily manipulated.

In alternative embodiments of the present invention the side straps of the headgear may not extend under and along the length of the curved member but be attached to the distal ends of the straps. This attachment may be by hook and loop material, as is known in the art, or by other attachment methods as known in the art. In this form, the arms of the curved member may have padding underneath them or no padding at all.

Referring to Figure 3, the curved elongate member has a central section 42 that in the assembled form supports the mask base and body such that the pillows 24, 25 rest against the patient's nares. The central section 42 is a half circle that is integrally moulded with the side arms 41, 54, as discussed above. The central section 42 has a raised area 43 on its exterior, at the apex of the half circle. The raised area 43 is shaped to receive the mask base 22. To assemble, a patient merely needs to slide the mask base 22 into the central section 42 such that the raised area 43 fits into the slot 33 on the mask base 22.

The side arms 41, 54 of the curved member 34 preferably have varying cross-sectional thickness. The ends of the arms 41, 54 attached to the central section 42 are thicker over the most curved parts 55, 56 of the arms, whereas the straighter parts of the arms 57, 58 have a narrow cross-section. Therefore, the thicker ends 55, 56 hold their shape better.

In alternative embodiments, the mask base 22 may be formed integrally with the curved member 34. Therefore, the central section and base would be one and would not be able to be separated from one another. Also, the curved member 34 may be formed as two separate pieces. That is, the central section 42 is formed as two parts with a central split seam, the two left and right halves joined in use. The two left and right parts could either be joined along a seam as described above, with the base 22 slotting into the slot 33 as described above, or alternatively, each of the two left and right arms may be attached one to each side of the base 22.

Where a substantially continuous elongate member is referred to in this specification, it refers to any of the options for the curved member 34 outlined above.

The side arms 41, 54 may also include a loop 40. This is where a section of the side arms 41 is not attached to the strap 38, 37 lying underneath. Thus that section 40 of the side arms forms a loop to which a tubing attachment 44 (such as that shown attached to another strap in Figures 2 and 3) may be looped to the side arms 41, 54 and the tubing 31 attached to either of the side arms.

The connector 30 in the preferred form is a ball and socket jointed connector to allow for the tubing 31 to swivel in the mask base 22. The tubing 31 may be attached to any of the headgear straps. However, a tube attachment 44 is shown where the tubing is attached by fasteners, such as hook and loop fastener, to the first strap 35. In other embodiments the tubing 31 may be attached to either the side straps 37, 38 or merely allowed to fall freely from the nasal mask 2.

Although a ball and socket joint, as described above, between the mask base 22 and tubing 31 is preferred other connections may be utilised, such as a flexible piece of silicone, or other appropriate connection. The connection between the base and tubing must be able to be flexed or rotated to allow for the tubing to be moved without causing the dislodgement of the nasal mask 2 from the patient's nares.

The mask body 23 may be provided with nasal pillows of various different sizes, such that patient's may remove an existing mask body and simply attach a different sized body to the mask base 22.

Alternative headgear may be used with the patient interface of the present invention; in particular, alternative headgear is shown in use with the first form of the patient interface (of Figure 2) in Figure 8. Here the headgear may include an additional strap 53 extending from the cheek region of the side straps 41 and extending behind the user's head. This lower additional strap 53 may also include substantially rigid arms 51 similar to the arms 41 described above. Any number of connecting straps 52 may also be provided between the upper strap 36 and lower strap 53. Again, the arms 51 would provide stability and rigidity to the additional strap 53.

In the embodiment described above, when the patient interface of the first form is in use, the users face causes the mask base 22 and body 23 to clip with the curved member 34. This is due to the angle of the curved member 34 and fixing of the mask base 22 and body 23 to the curved member 34. Further, the curved member 34 transfers the load of the patient interface away from the patient's nose and to the cheek regions of the patient.

A second embodiment of the patient interface and headgear of the present invention is shown in Figures 9 and 10. In this embodiment a mouthpiece 100 is attached to the substantially tubular mask body 23 substantially below the nasal pillows 24, 25. The mouthpiece 100 is preferably a flap that is fittable within the patient's mouth. A gases pathway extends through the mask body 23 and through the centre of the mouthpiece 100, such

that in use a patient is supplied with gases via the nasal pillows 24, 25 and the mouthpiece 100. The flap 100 is preferably made from a silicone plastics material but other appropriate materials such as rubber, thermoset elastomer or thermoplastic elastomer, such as Kraton™ may be used. The flap 100 is preferably integrally moulded with the mask body 23 and nasal pillows 24, 25. In use the flap 100 sits within the patient's mouth between the patient's teeth and lips.

In this second embodiment the headgear and particularly the curved member 34 is substantially the same as that described in relation to the first embodiment.

A third embodiment of the patient interface and headgear of the present invention is shown in Figure 11. In this embodiment a mouthpiece as well as a nose blocking device is attachable to the mask base 22. The mouthpiece 110 and nose blocking device 111 are preferably integrally formed. The mouthpiece 110 has an inner vestibular shield 112 that is similar to the flap 100 described above. Therefore the vestibular shield 112 in use sits within the patient's mouth between the patient's teeth and lips and provides an at least partial seal between the user and the shield 112.

A tubular extension 113 extends through the mouthpiece 110 to the mask base 22 from the vestibular shield 112. The extension allows for gases to be passed to the patient from the conduit 31.

The nose blocking device 111 in use rests under the user's nose and blocks the user's nares.

In this third embodiment the headgear and particularly the curved member 34 is substantially the same as that described in relation to the first embodiment.

A fourth embodiment of the patient interface and headgear of the present invention is shown in Figure 12. In this embodiment a mouthpiece 120, 121 is attachable via a tubular extension 122 to the mask base 22. The mouthpiece is made up of an outer mouthpiece flap 120 and an inner vestibular shield 121. The shield 121 is substantially the same as that described in reference to the third embodiment. The outer mouthpiece flap 120 rests in use outside the user's mouth and substantially seals about the user's mouth. The outer mouthpiece flap 120 and an inner vestibular shield 121 are described in further detail in United States patent number 6679257, the entire contents of which is herein incorporated by reference.

In this fourth embodiment the headgear and particularly the curved member 34 is substantially the same as that described in relation to the first embodiment.

A fifth embodiment of the patient interface and headgear of the present invention is shown in Figures 13 and 14. This embodiment is very similar to the fourth embodiment except the mouthpiece is simply an outer mouthpiece flap 130. This flap 130 is fittable to the mask base 22 by way of the tubular extension 131. Again, as above, the headgear and particularly the curved member 34 are substantially the same as that described in relation to the first embodiment.

A sixth embodiment of the patient interface and headgear of the present invention is shown in Figure 15. In this embodiment the patient interface is a full face mask 140 that extends over a user's nose and mouth and under the user's chin in use. The mask 140 has a body 142 made from a substantially rigid plastics material and a cushion 144 made from a substantially soft plastics material. The mask and cushion are preferably very similar to that described in more detail in United States patent application number 11/368004, the entire contents of which is herein incorporated by reference.

A tubular inlet port 143 is formed in the mask body 142. The tubing 31 is attachable to the port 143 to provide gases to the user wearing the mask.

The headgear is substantially similar to that described in relation to Figure 2 (the second embodiment); however, the curved member 141 differs. The curved member 141 does not have a mask base similar to that described in the second embodiment in which to attach to. Therefore, the curved member 141 has a central section 145 that curves under the inlet port 143, effectively anchoring on the inlet port. The curved member 141 is moulded in substantially the same manner as described with reference to the second embodiment.

A seventh embodiment of the patient interface and headgear of the present invention is shown in Figures 16 and 17. Here, the headgear and curved member is similar to that described above in the sixth embodiment, where the curved member 141 has a central section that curves under and anchors onto an inlet port 151 on a patient interface 150. The patient interface 150 is an integral mouth mask 152 and nasal pillows 153. The mouth mask 152 preferably extends under the user's 155 chin, as shown in Figure 17.

The interface 150 has a substantially rigid body 154 that has substantially soft cushion 156 attached to it. The cushion 156 is preferably of the type disclosed in United States patent number 6951218, the entire contents of which is herein incorporated by reference, having an inner 157 and outer 158 cushions.

Integrally formed in the outer cushion 158 are nasal pillows 153. Preferably two nasal

pillows 159, 160 are formed in the cushion 158. These are substantially tubular and carry gases in use from the inside of the interface 150 to the user's 155 nares. The outer cushion 158 and nasal pillows 159, 160 are preferably made from a soft pliable plastics material such as silicone but other appropriate materials such as rubber or KRATON™ may be used.

5

DATED THIS 6th DAY OF November 2006
AJ PARK
PER
AGENTS FOR THE APPLICANT

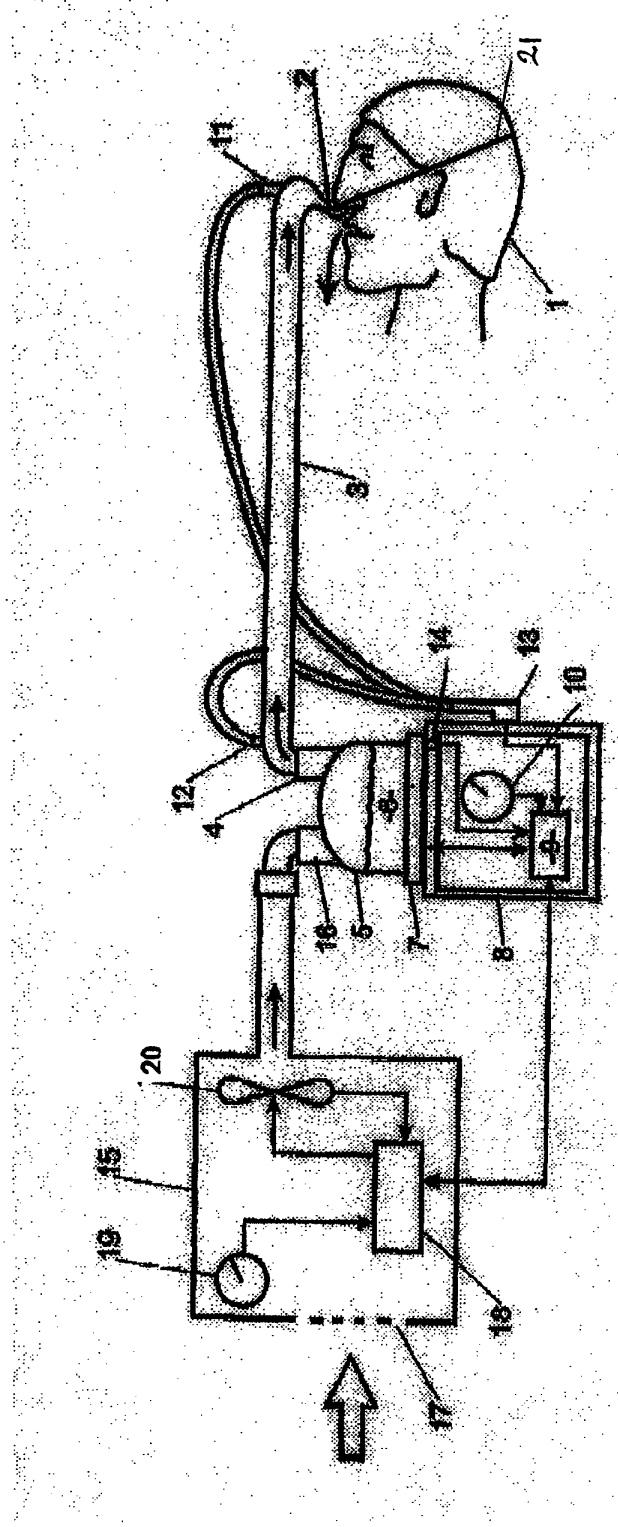

Figure 1

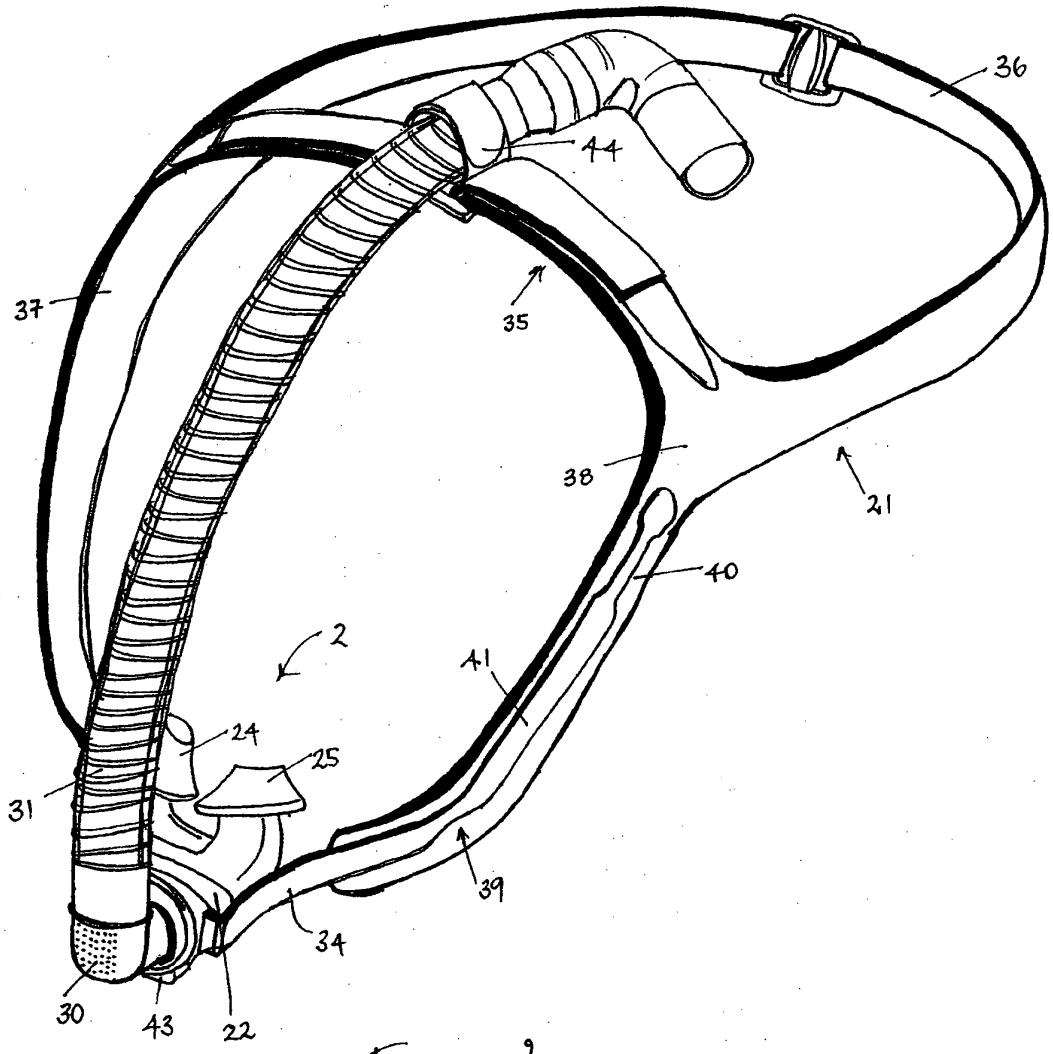

Figure 2

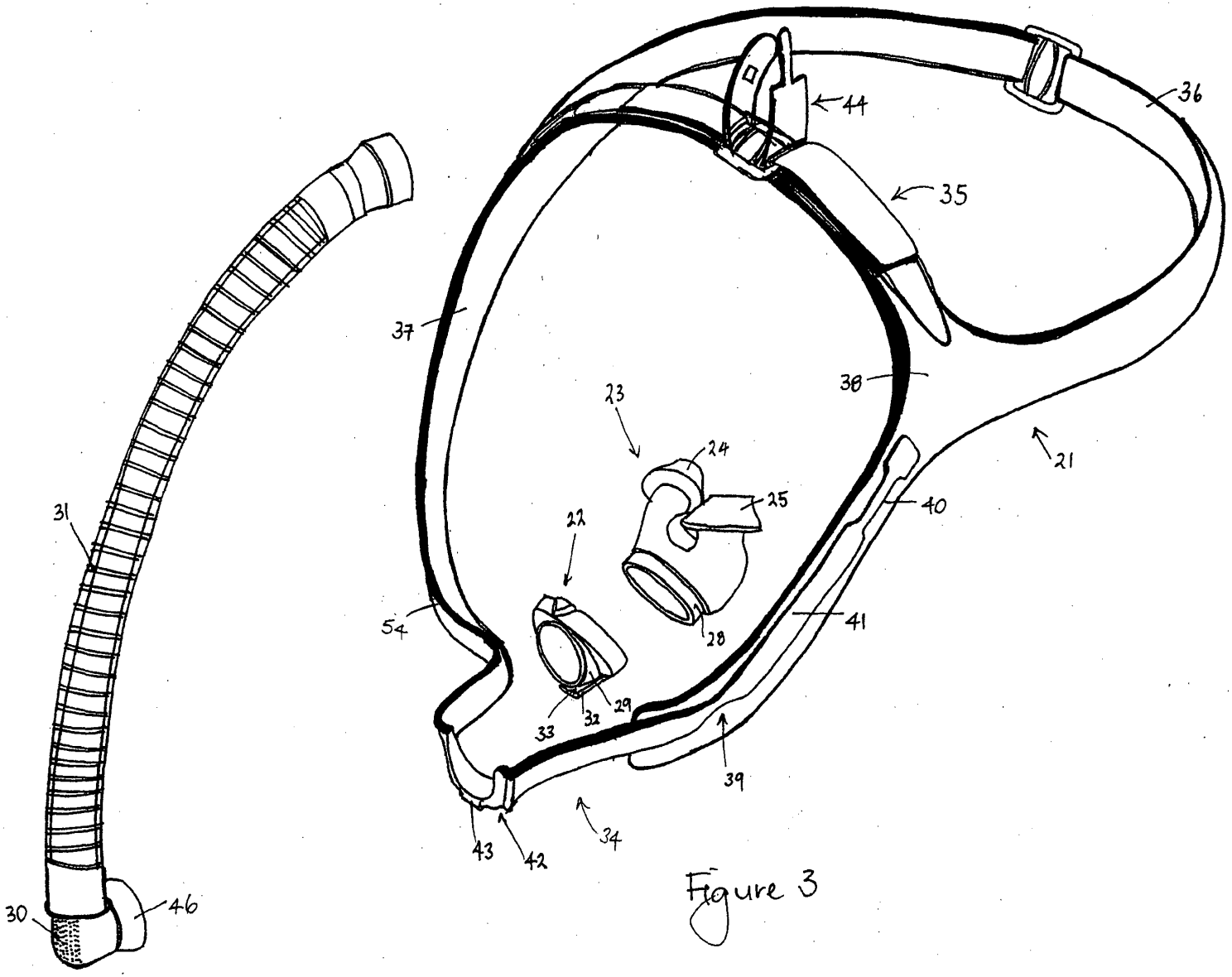

Figure 3

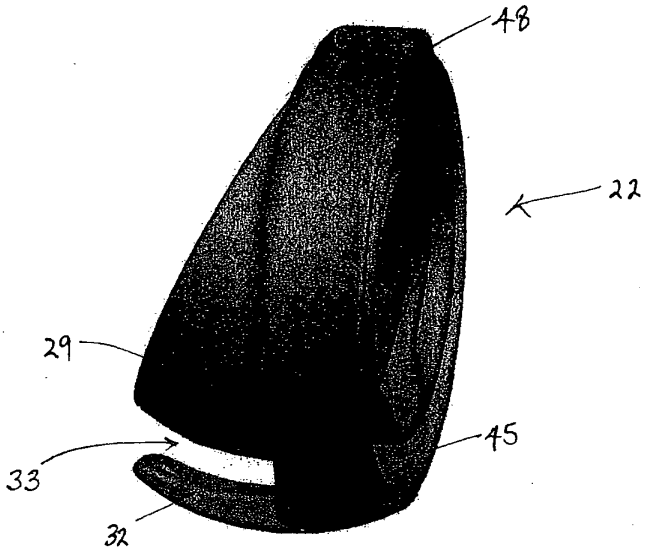

Figure 4

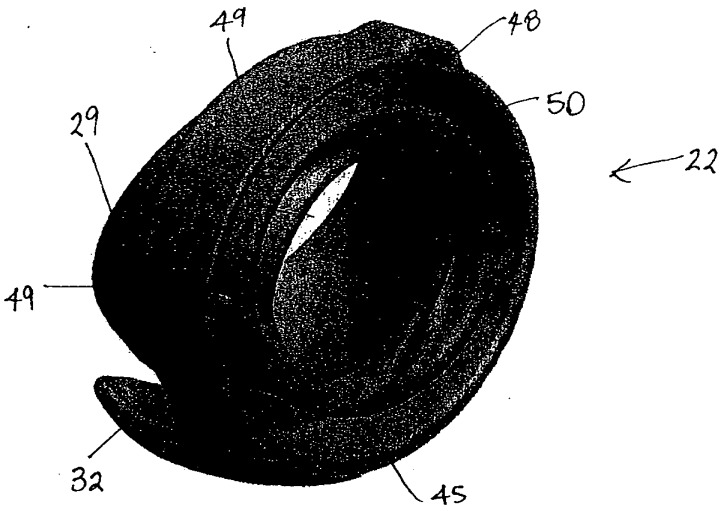

Figure 5

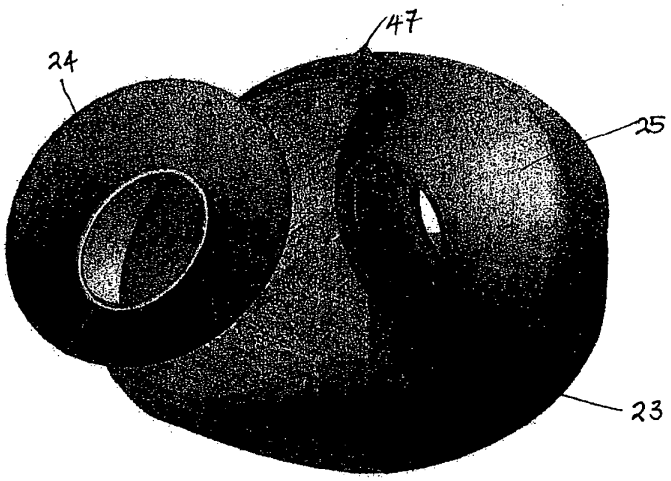

Figure 6

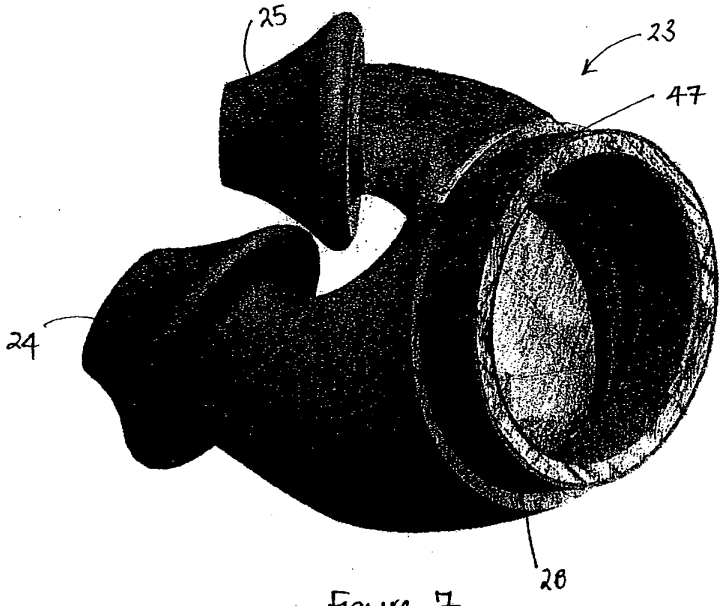

Figure 7

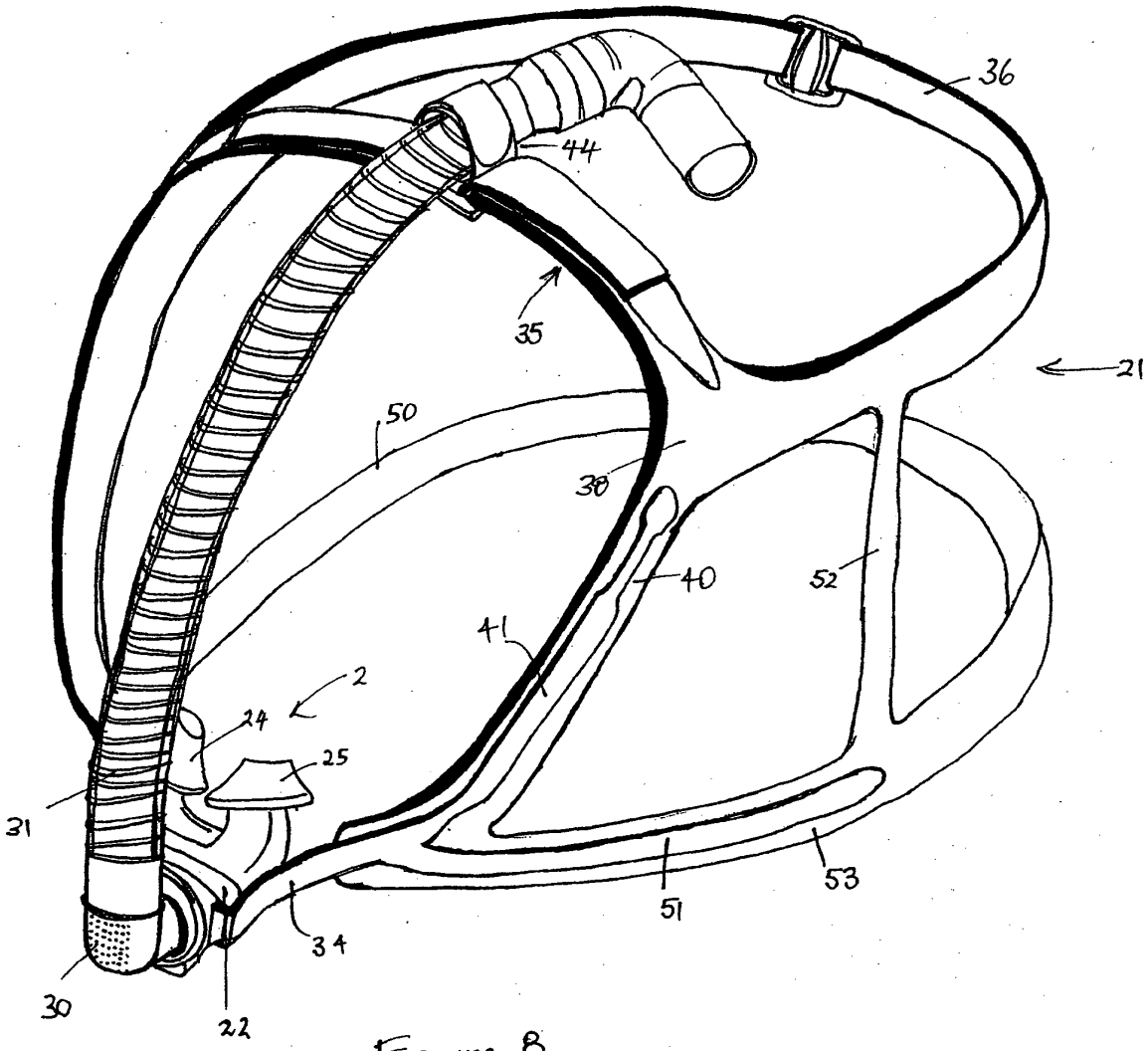

Figure 8

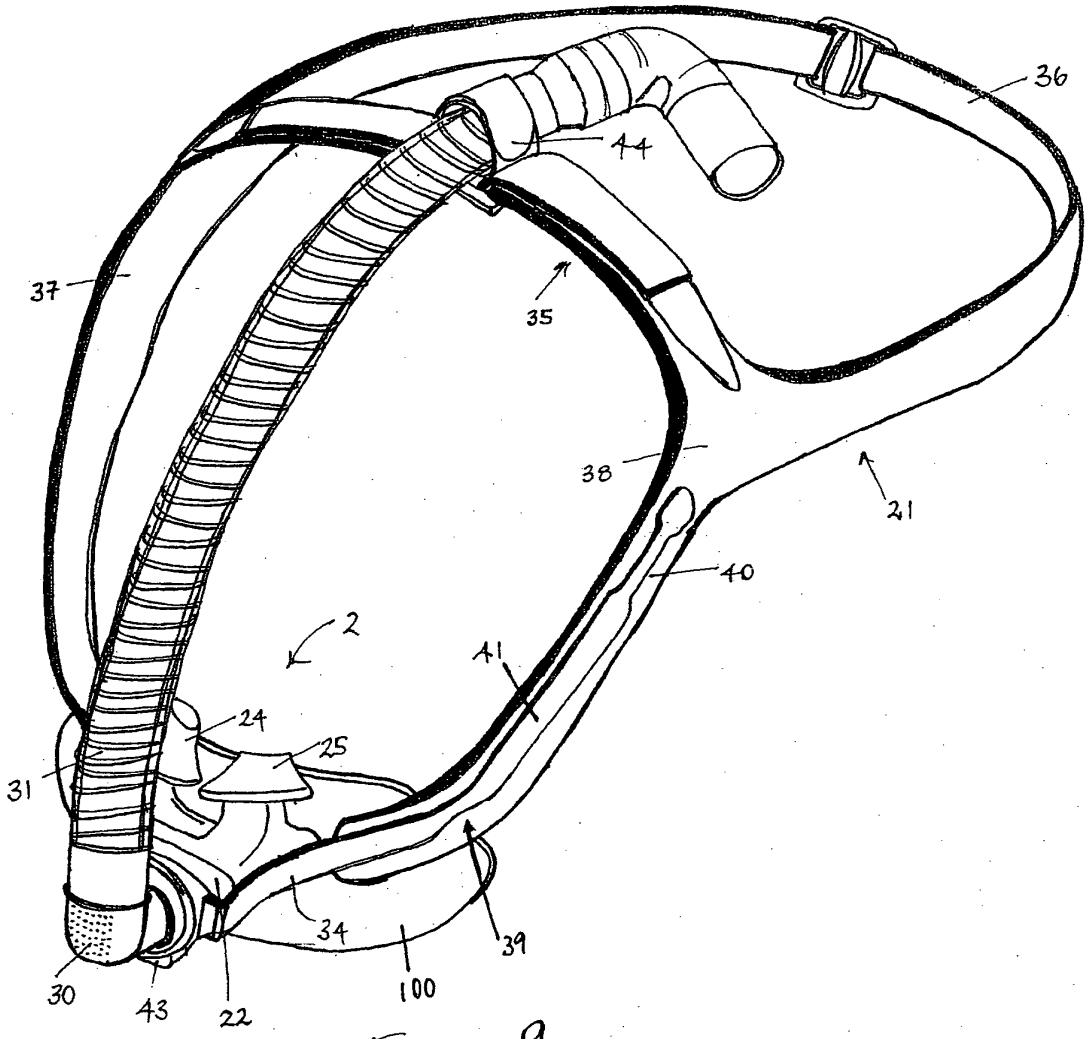

Figure 9

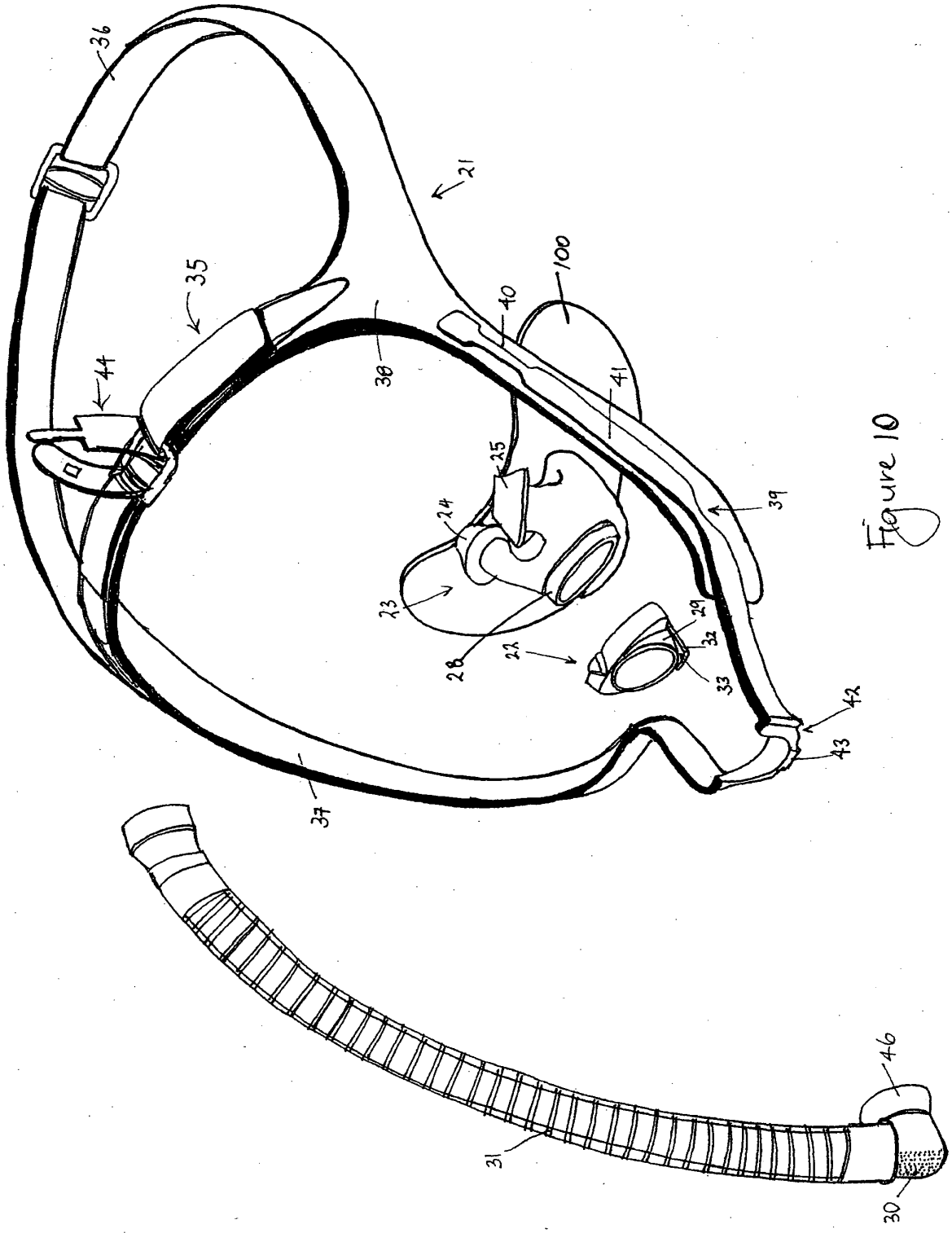

Figure 10

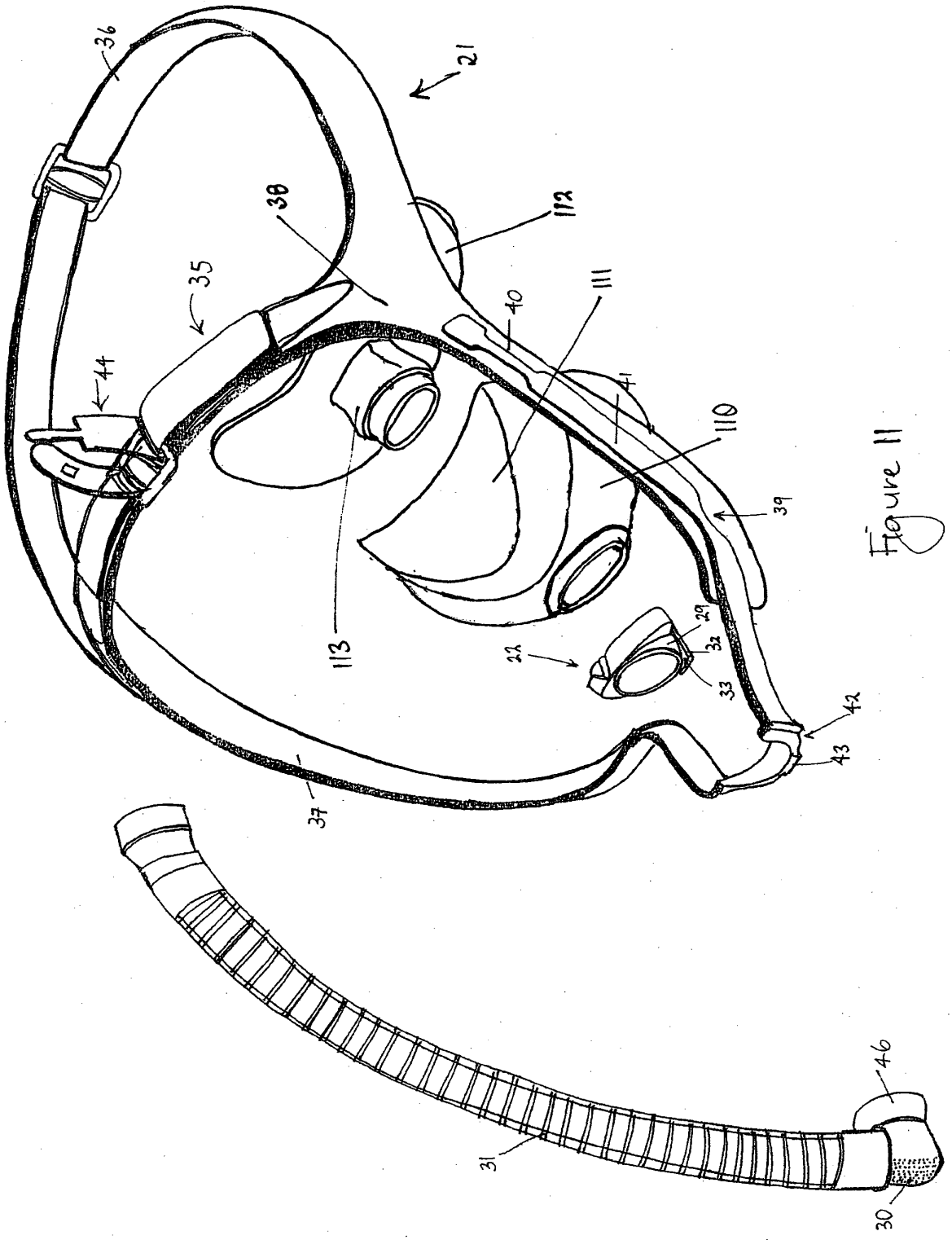

Figure 11

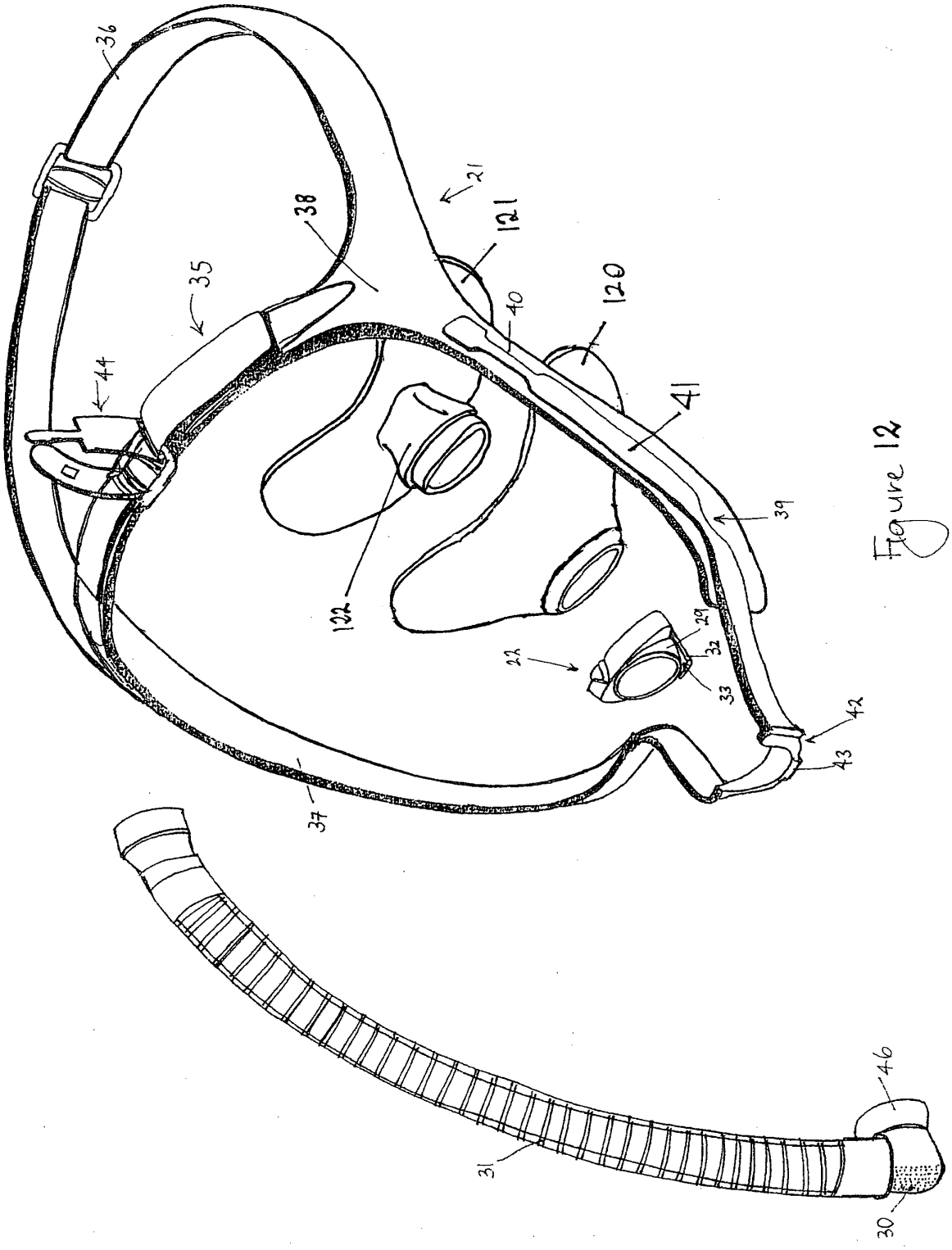

Figure 12

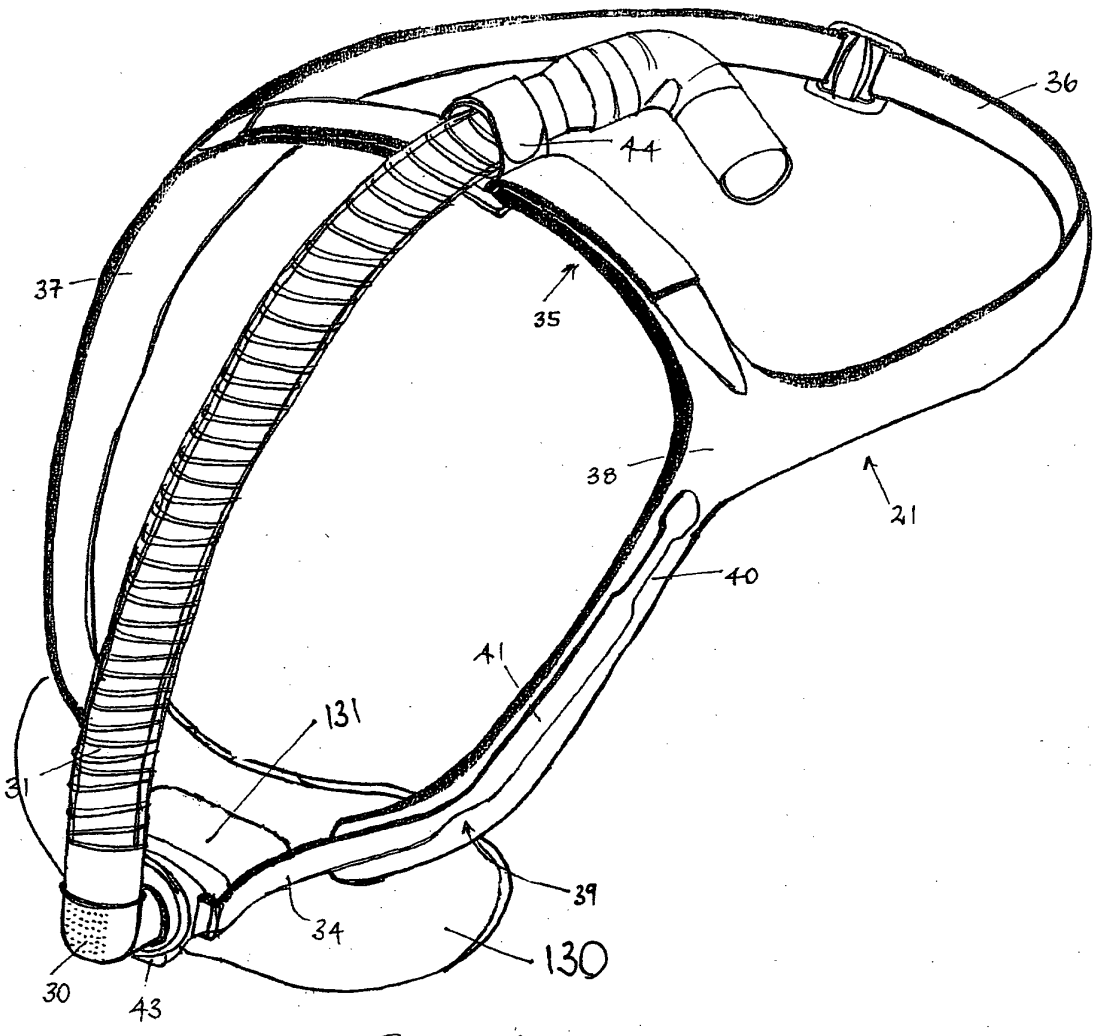

Figure 13

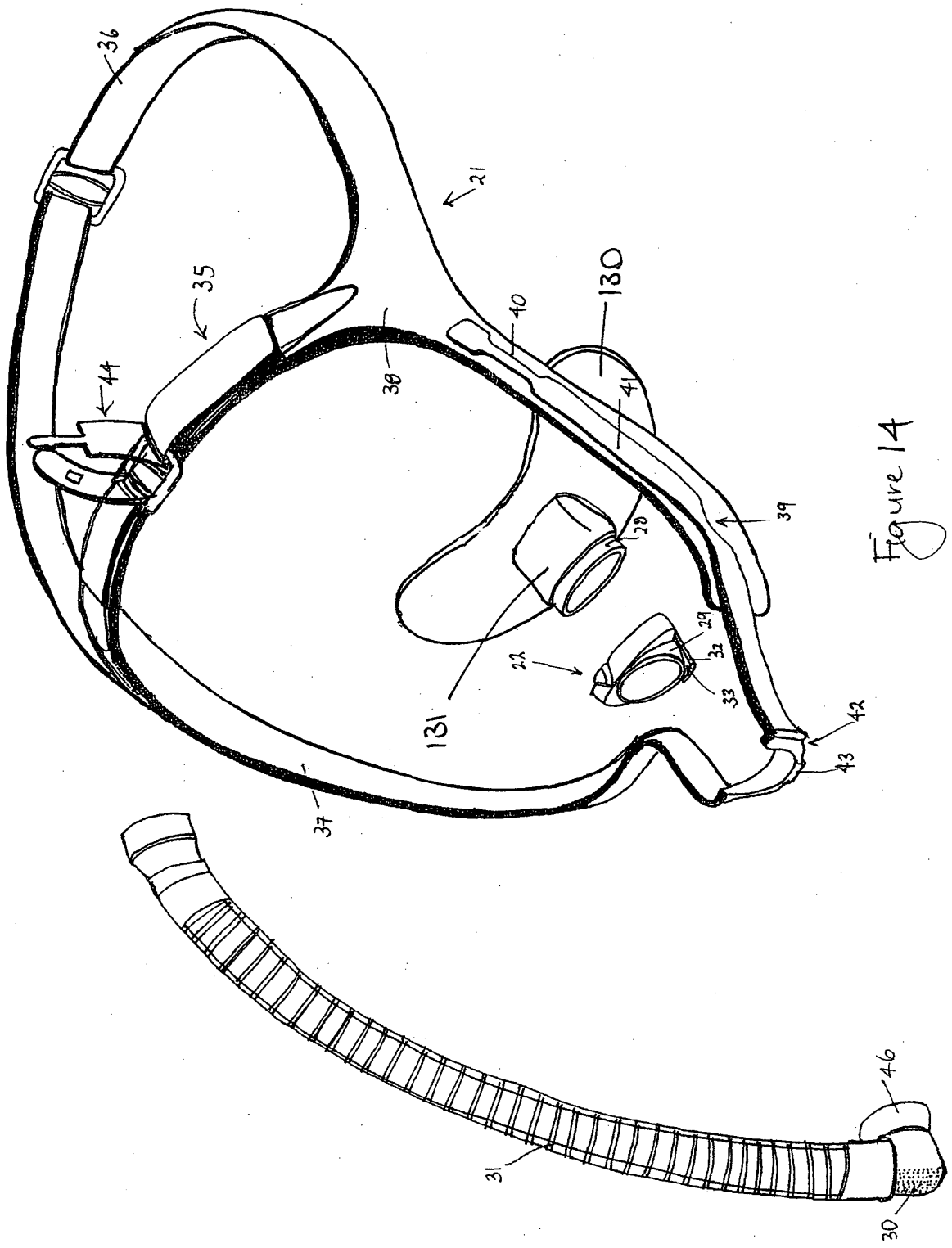

Figure 14

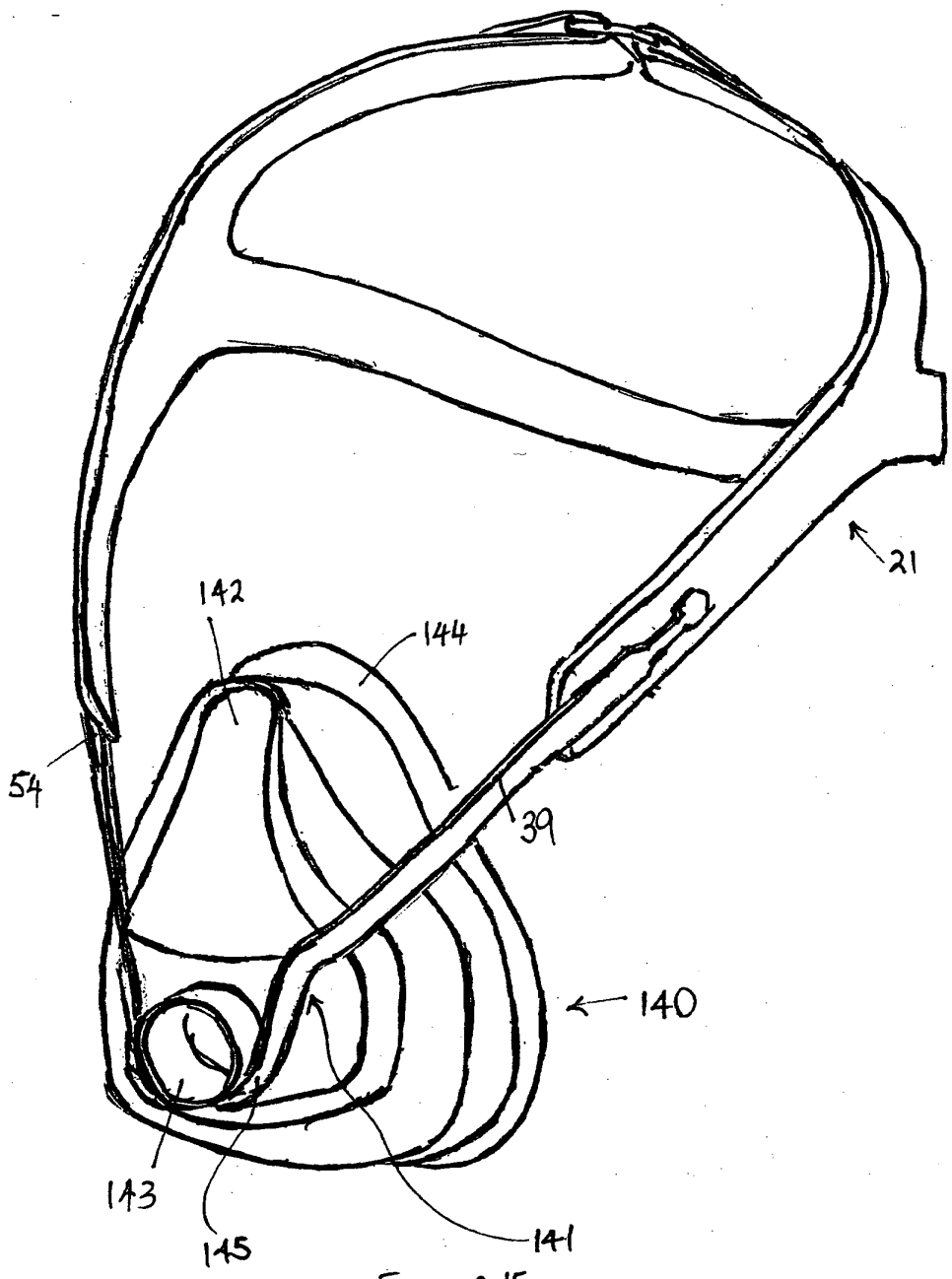

Figure 15

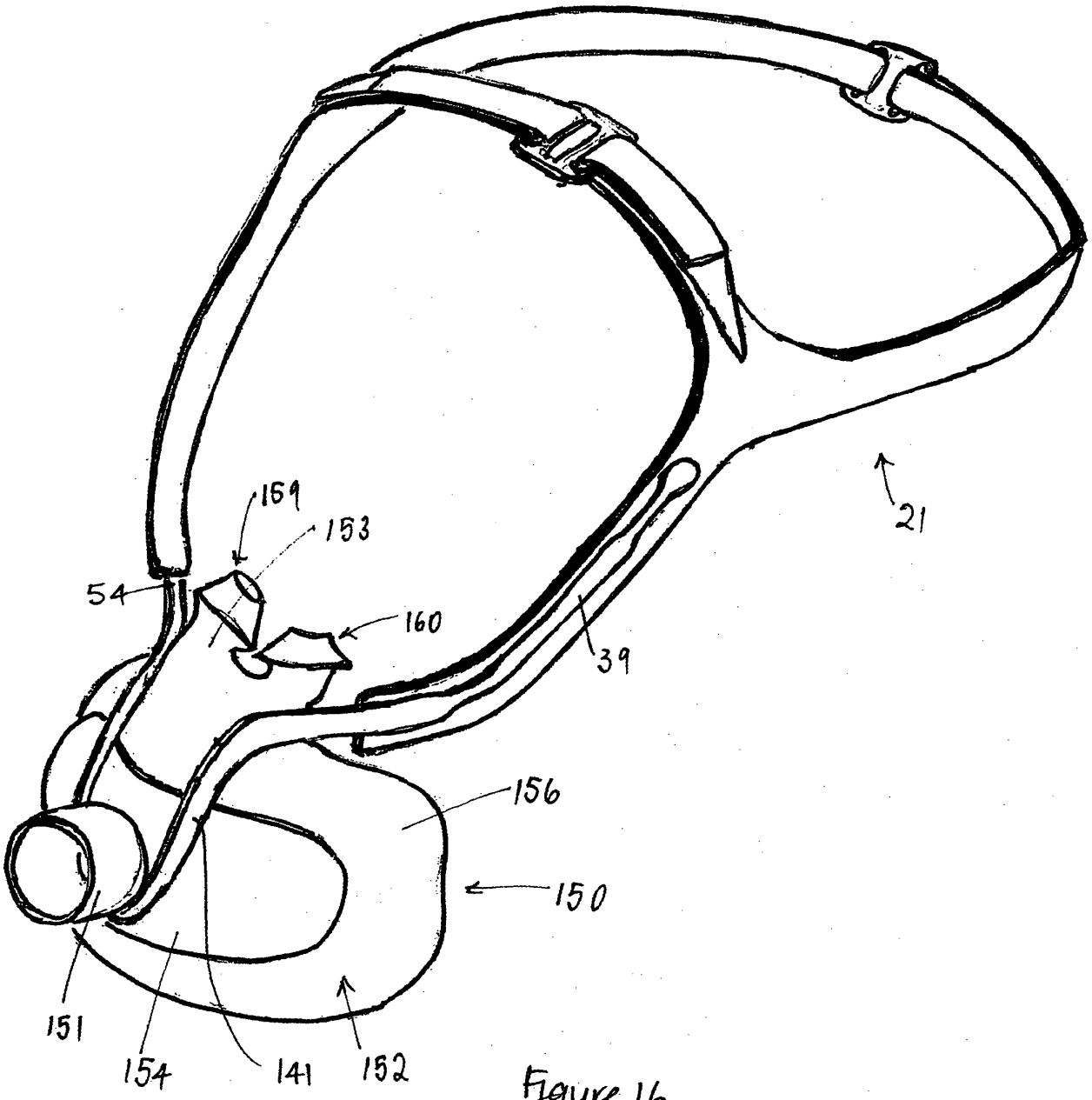

Figure 16

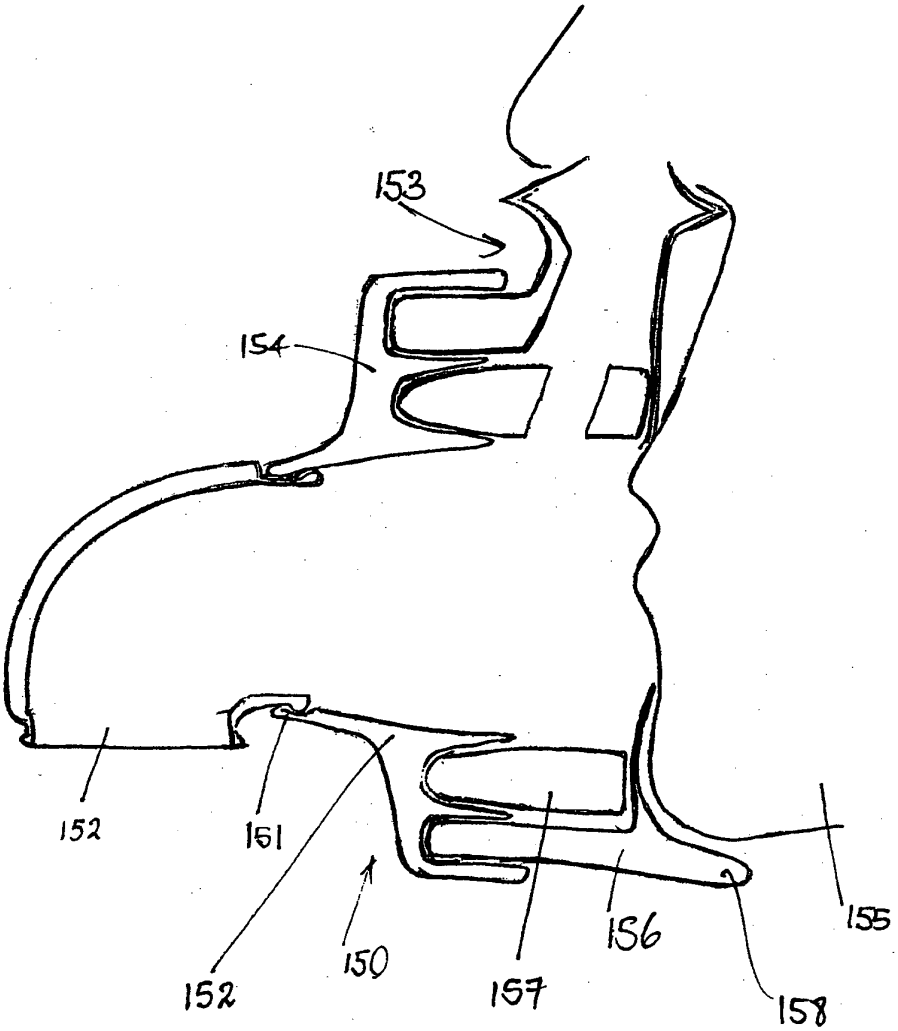

Figure 17

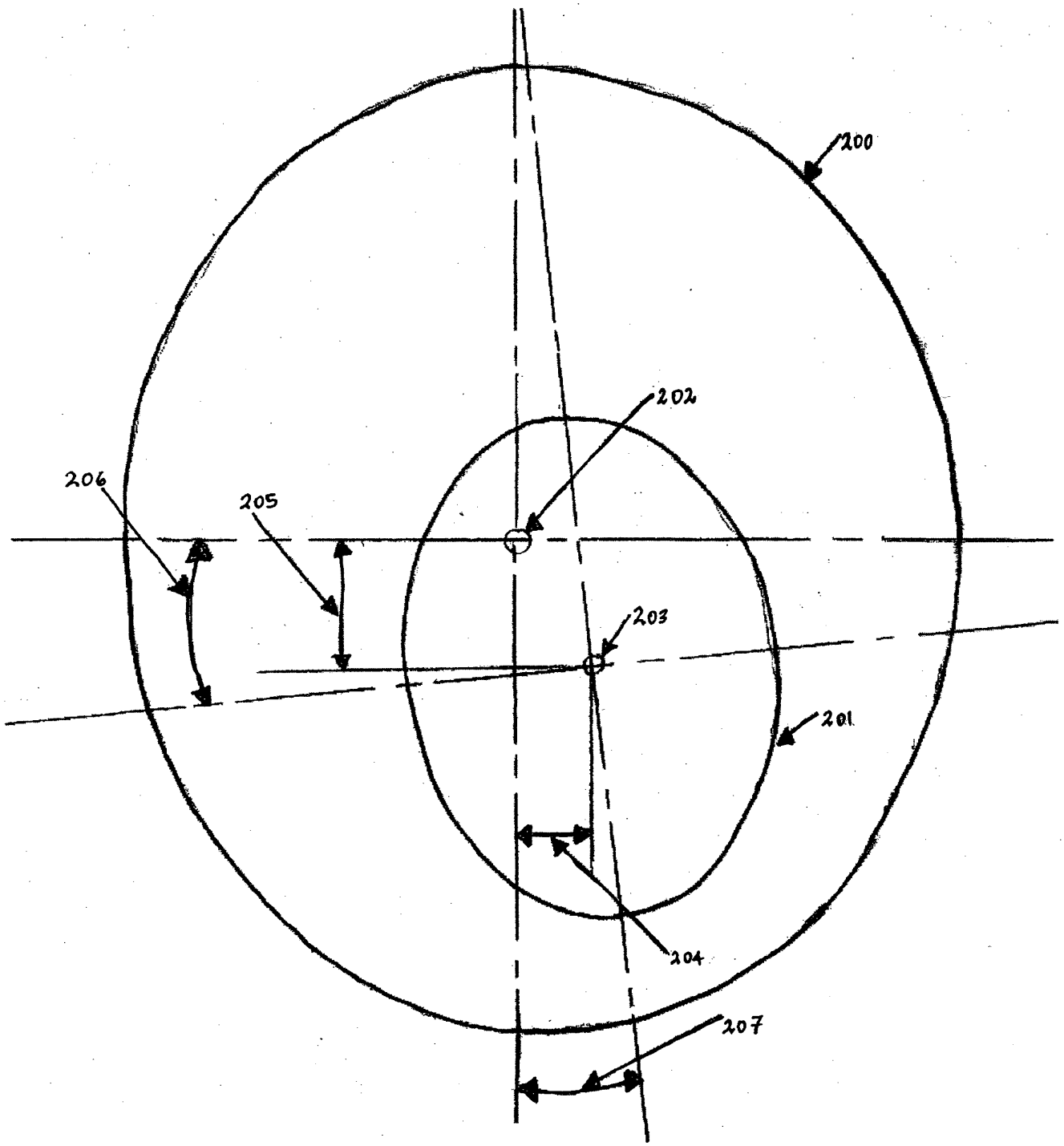

Figure 18

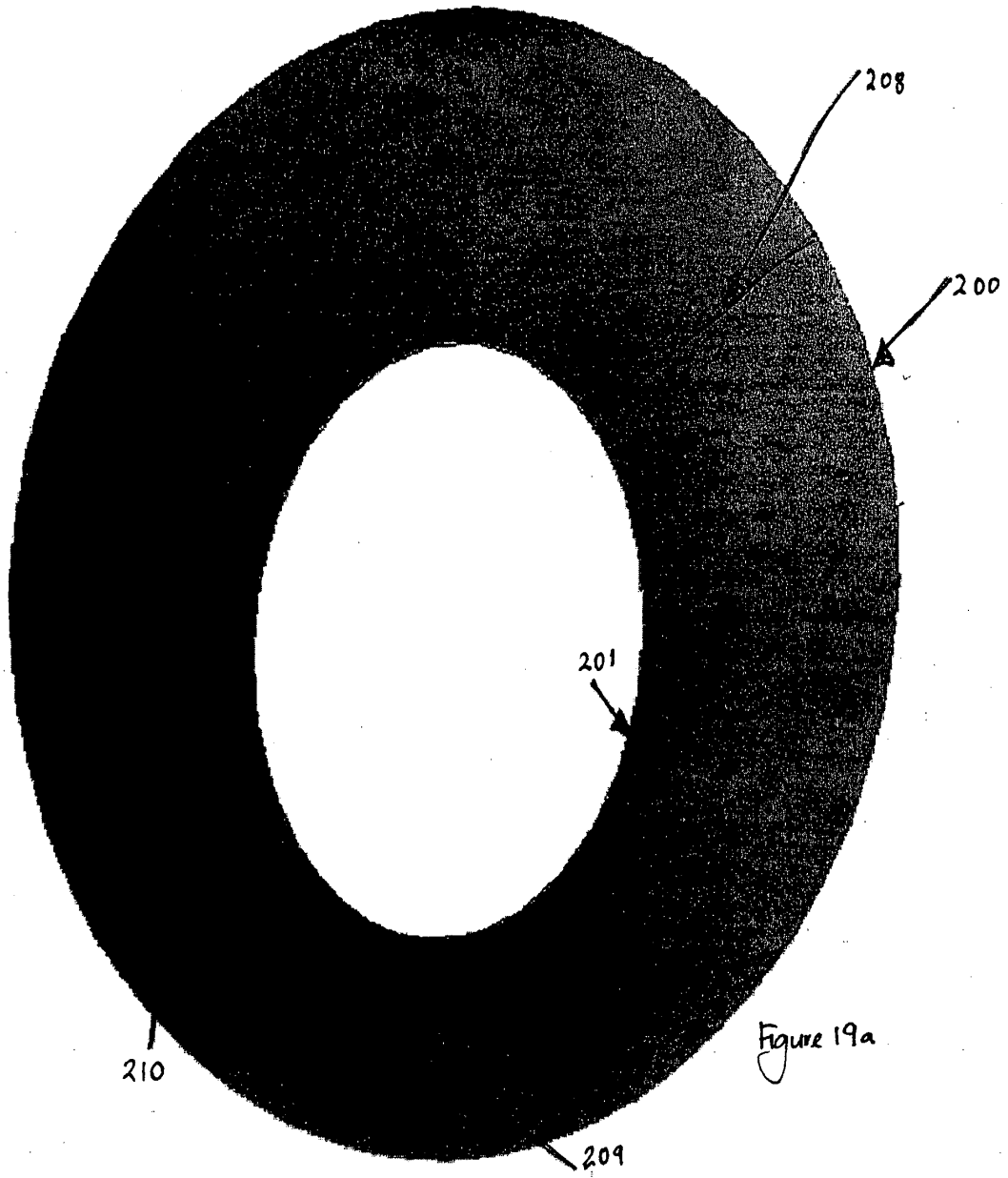

Figure 19a

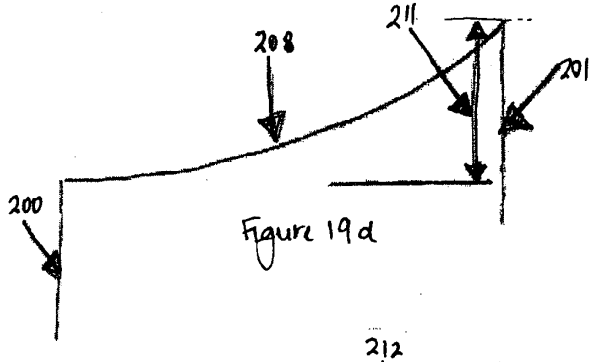

Figure 19d

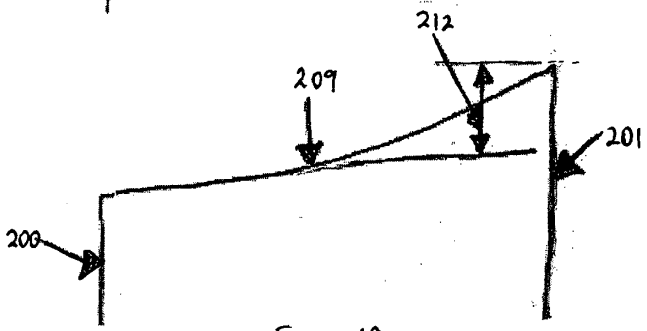

Figure 19c

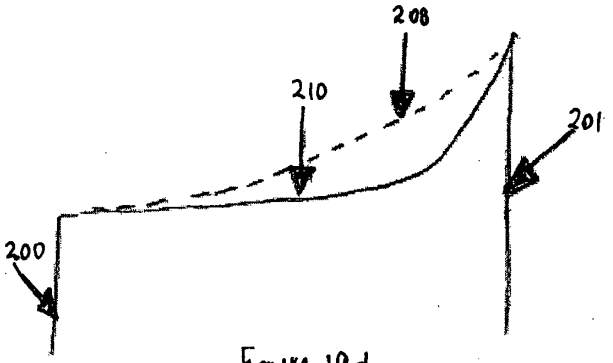

Figure 19d

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	Application Number	12307993
	Filing Date	2009-01-08
	First Named Inventor	ALASTAIR EDWIN McAULEY
	Art Unit	
	Examiner Name	
	Attorney Docket Number	1171/48067/202

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	2	7219669		2007-05-22	LOVELL ET AL.	
	3	6631718		2003-10-14	LOVELL	
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	First Named Inventor	ALASTAIR EDWIN McAULEY
	Art Unit	
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	Application Number	12307993
	Filing Date	2009-01-08
	First Named Inventor	ALASTAIR EDWIN McAULEY
	Art Unit	
	Examiner Name	
	Attorney Docket Number	1171/48067/202

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☐ See attached certification statement.

☐ Fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

☒ None

SIGNATURE

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/RAIFORD A. BLACKSTONE/	Date (YYYY-MM-DD)	2009-03-04
Name/Print	RAIFORD A. BLACKSTONE, JR.	Registration Number	25156

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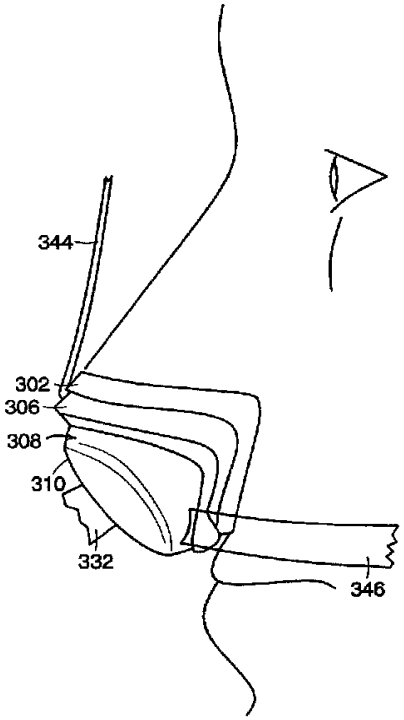
(54) Title: NOSE MASK

(57) Abstract: A nasal mask (301) includes a shell (308) forming a chamber (390) having an inlet (332) and at least one outlet and a seal (302). The seal (302) is disposed proximate the outlet for contacting and sealing with external skin proximate at least one naris at a base of a nose of a user donning the mask. Substantially all of the sealing occurs between the seal (302) and the external skin.



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NOSE MASK

Cross-Reference to Related Applications

This application is a continuation-in-part of U.S.S.N. 09/328,120, filed June 8, 1999, and is also a continuation-in-part of U.S.S.N. 09/328,027, filed June 8, 1999, both of which are incorporated herein by reference.

Technical Field

The present invention relates to respiratory apparatus and more specifically to a nasal mask useful for providing pressurized air or therapeutic gas to a patient suffering from an airflow limitation or other respiratory ailment.

Background Information

Patients suffering from a variety of medical conditions often require supplementary respiratory support. Depending on the nature and severity of the condition, this respiratory support can range from providing an elevated oxygen concentration cloud to the vicinity of the nose and mouth, to forcing ventilation of the lungs by intubating the trachea. In general, a supply of pressurized air or therapeutic gas is provided by a tube or conduit to a delivery apparatus designed to conform to particular body structure.

One style of delivery apparatus is a mask which provides the gas to a nasal area of the patient. Nasal masks are often employed in the treatment of sleep apnea syndrome, characterized by intermittent upper airway obstruction during sleep. Due to the resulting blood oxygen desaturation and frequent arousals from sleep, persons suffering from this condition are often unable to achieve deep sleep for extended periods, are chronically tired, and are physically compromised.

Because nasal masks are often worn by persons in unmonitored environments for extended periods, such as in the home during sleep, the nasal mask should be comfortable to wear and conform well to the nasal area. If the mask is deemed too bulky, too heavy, or to fit poorly, the patient will either not wear the mask, wear the mask improperly, or only wear the mask occasionally when the discomfort associated with the respiratory condition exceeds the discomfort of wearing the mask.

One problem associated with nasal masks relates to the conformance of the mask to the nasal area, which is complexly contoured and differs from patient to patient. Customized masks manufactured to suit particular patients tend to be costly; therefore, masks for general use are typically made in several generic sizes, each size designed to accommodate a range of patients. If the mask does not form a good seal around the patient's nose, leakage can occur, reducing the effectiveness of the treatment. When poorly fitting masks are used with variably regulated air supply systems responsive to patient breathing, such as those developed for treating sleep apnea, mask leakage can induce improper system response which may exacerbate the patient's condition. Regulated air supply systems and delivery apparatus for treatment of sleep apnea are disclosed in Patent Cooperation Treaty international application number PCT/US93/05095, published on December 9, 1993, as international publication number WO 93/24169; U.S. Pat. Application No. 08/184,976 filed January 24, 1994; U.S. Pat. No. 5,199,424; U.S. Pat. No. 5,245,995; U.S. Pat. No. 5,522,382; U.S. Pat. No. 5,645,054; U.S. Pat. No. 6,019,101; and U.S. Des. Pat. No. D398,987, the disclosures of all of which are herein incorporated by reference.

One method of reducing leakage is to provide a compliant sealing flange or surface around a perimeter of the mask in combination with a strap to bias the mask into sealing engagement with the nasal contour of the patient. Typically, the greater the retention force applied by the strap, the better the seal; however, both the strap and the mask can cause excessive pressure on delicate areas, resulting in irritation and patient discomfort.

The retention force required to prevent leakage is also a function of forces and torques induced in the mask. For example, the weight of the conduit supplying air or gas to the mask tends to pull the mask downward, away from the patient's nasal area, when the patient is sitting. Additionally, any movement of the head from side-to-side or up and down can cause lifting of an edge or sliding of the mask and strap. The more rapid the movement, the more pronounced the effect. Mask slippage and displacement are exacerbated in masks employing large diameter, heavy, or stiff tubes which deliver relatively large volumetric flow rates of air, such as those employed in sleep apnea treatment systems.

For nasal masks used by patients when sleeping, the strap and seal arrangement should also accommodate unconscious or reflexive head and body movements. The discomfort associated with masks which apply too much pressure to the head, neck, or nasal area discourage use of the mask during sleep when it is most needed. As a result, treatment is compromised and the patient is ill served by the apparatus.

Accordingly, there exists a need to overcome the limitations of known designs by providing an improved nasal mask which provides a consistent, reliable nasal area seal while being comfortable to wear. Other desirable features would include ease of manufacture and low cost.

Summary of the Invention

Devices of the present invention allow for comfortable delivery of a breathable gas to a user. More particularly, devices of the invention seal with the external skin surrounding the nares at the base of the nose and/or along the inner rim of the nares of a user. The seal is both comfortable for the patient and reliable. Both the softness of a gel seal according to the invention and the design of devices according to the invention which invite minimal contact

between the user's epidermal areas and the device, combine to create this comfortable and reliable seal about the user's nares.

In one aspect of the invention a nasal mask includes a shell and a first seal. The shell forms a chamber having an inlet and at least one outlet. The first seal is disposed proximate the outlet for contacting and sealing with external skin proximate at least one naris at a base of a nose of a user donning the mask. Substantially all of the sealing occurs between the seal and the external skin.

Certain embodiments of this aspect of the invention may include any or all of the following features. A nasal mask can include both a second seal and a second outlet. The first seal can be integral with the second seal. The nasal mask also can include a malleable element disposed within the shell. Additionally, a seal of a nasal mask can include a bladder. The bladder can be filled with silicone gel, molded in a predetermined configuration, and/or bonded to the shell.

A conduit can be attached to the inlet of a nasal mask. The conduit can include an angled portion, a rotary connection, and/or a ball and socket connection. Additionally, the conduit can have a side wall defining a lumen within the side wall. The side wall can contain at least one opening in communication with the lumen.

A headgear apparatus can be attached to the mask for retaining the mask on a user. A retainer can be disposed about the inlet and cooperate with the headgear apparatus to retain the mask on a user. One or more connectors can attach the headgear apparatus to the mask. One or more of the connectors can attach to the retainer.

Another aspect of the invention includes a system for treating a respiratory ailment in a recumbent or sleeping user. The system includes a nasal mask as described above connected to a controlled, breathable gas source with a conduit. The nasal mask may include any of the features described above.

Another aspect of the invention comprises a seal for use with a nasal mask including a bladder filled with a molded material in a predetermined configuration. The material has a durometer value less than about ten on a Shore OOO scale. The seal is configured typically with a slight crown to seal against external skin proximate at least one naris at a base of a nose of a user. The material can be silicone.

The bladder can have at least one protrusion on a side thereof for contacting the external skin proximate at least one naris at a base of a nose of a user and/or can be substantially planar on a side thereof for contacting a shell of the nasal mask. The seal can have a thickness and can form at least one aperture therethrough disposable proximate a naris. A thickness of the bladder proximate the aperture can be less than a thickness of the seal remote therefrom.

Brief Description of the Drawings

The invention, in accordance with preferred and exemplary embodiments, together with further advantages thereof, is more particularly described in the following detailed description, taken in conjunction with the accompanying drawings.

In the drawings, like reference characters generally refer to the same parts throughout the different views. Also, the drawings are not necessarily to scale, emphasis instead generally being placed upon illustrating principles of the invention.

FIG. 1A is a schematic perspective view of one embodiment of the invention;

FIG. 1B is a schematic exploded perspective view of the embodiment of FIG. 1A;

FIG. 2A is a schematic front view of the embodiment of FIG. 1A;

FIG. 2B is a schematic exploded front view of the embodiment of FIG. 1A;

FIG. 3A is a schematic side view of the embodiment of FIG. 1A;

FIG. 3B is a schematic exploded side view of the embodiment of FIG. 1A;

FIG. 4A is a schematic top view of the embodiment of FIG. 1A;

FIG. 4B is a schematic cross-sectional view of the embodiment of FIG. 1A taken along line A-A of FIG. 4A;

FIG. 5 shows a user donning the nasal mask of FIG. 1A;

FIG. 6 shows a schematic representation of a gas source in communication with a nasal mask;

FIG. 7 is a section through one embodiment of a seal;

FIG. 8A is a schematic perspective view of the seal of the embodiment of FIG. 1A;

FIG. 8B is a schematic side view of the seal of FIG. 8A;

FIG. 8C is a schematic top view of the seal of FIG. 8A.

FIG. 9 is a schematic perspective view of an alternative embodiment of the invention;

FIG. 10A is a schematic exploded perspective view of the embodiment depicted in FIG. 9;

FIG. 10B is a schematic exploded side view of the components of the embodiment depicted in FIG. 9;

FIG. 11 is a schematic front view of the nasal mask of FIG. 9;

FIG. 12 is a schematic perspective view of another alternative embodiment of the invention;

FIG. 13 is a schematic cross-sectional view of the embodiment depicted in FIG. 12 taken along line C-C of FIG. 12; and

FIG. 14 shows a user donning the nasal mask of FIG. 12.

Description

The present invention provides a comfortable, reliably sealing nasal mask for delivering a breathable gas to a user. In particular a seal bonded to a shell of the nasal mask is particularly soft. This seal rests comfortably on the external skin surrounding the nares at the base of the nose and/or along the inner rim of the nares of a user.

The design of nasal masks according to this invention provides solutions to several common problems with current designs. First, the nasal mask's contact with the user's face is minimal compared with current masks. Second, the seal distributes contact pressure, unlike many current masks. Third, the design allows the user to comfortably lie in almost any position. Fourth, the design provides a comfortable fit and a reliable seal for a wide range of the population compared with many current masks which either must be stocked in multiple sizes or simply do not properly fit on users with faces of a certain shape.

Referring to FIGS. 1A – 4B, in one embodiment of a nasal mask 1 depicted in a variety of orientations, a seal 2 covers an upper shell 6. Typically, the seal 2 is bonded to at least a

portion of the upper shell 6. Useful bonding agents include, but are not limited to, tetrahyrdofuran ("THF") and/or ultraviolet cured adhesives. Alternative attachment methods are acceptable. For example, mechanically interlocking features, such as a tapered dovetail or flange, could be employed with mating recesses. A malleable element 4 is typically disposed within the upper shell 6 by a process such as, but without limitation, injection molding the upper shell 6 around the malleable element 4. Alternatively, the malleable element 4 can be disposed within a lower shell 8, disposed on the surface of the upper shell 6, and/or disposed between the upper shell 6 and lower shell 8.

The upper shell 6 is contoured such that two outlets 34, 36 protrude from it symmetrically along its mid-line. The malleable element 4 has holes in it that correspond to and are disposed around the outlets 34, 36 in the upper shell 6. The lower portion of a shell 8 is affixed to the upper portion of the shell 6. The two portions of the shell, for example, but without limitation, can be heated and welded together, welded together with a solvent and/or bonded together with a bonding agent. The shell portions 6, 8 typically, are manufactured from a flexible material, for example, but without limitation, by a molding process using a compliant polymer. Each of the two portions of the shell, for example, but without limitation, can be manufactured from a thermopolymer elastomer. A flange 42 seats the upper shell 6 securely on the lower shell 8 and allows for a larger surface area for affixing the upper shell 6 to the lower shell 8. The combination of the upper and lower shells 6, 8 produces a chamber 30. When in communication with a source of breathable gas, this chamber 30 contains the breathable gas. The gas in the chamber 30 is available to the user donning the nasal mask, and the gas, typically, is pressurized such that the gas is forced into the user's airway, holding open the airway. The chamber 30 is substantially leakage-free due to the bond between the seal 2 and the upper shell 6 (or other attachment methods) and the compliance of the seal 2 against a user's skin

The malleable element 4 is a double ring of a soft metal. Alternatively, the malleable element 4 can be constructed from any material that is formable and is capable of retaining the shape into which it is formed against the force of, for example, the flexible shell portions 6, 8 trying to regain their memory shape. The combination of the compliant and resilient shell portions 6, 8 and the malleable element 4 with sufficient rigidity to hold the shell portions 6, 8 in a selected configuration produces a "custom-fit" as desired by a particular user. Because the shell portions 6, 8 are resilient, the shell portions 6, 8 can be reformed any number of times as desired by a particular user. Typically, a user will adjust the fit of nasal mask 1 by bending the nasal mask 1 along its mid-line and the mid-line of the malleable element 4 contained within the nasal mask 1 into a "V" shape, as shown for example, in FIG. 8B. Bending the malleable element 4 in this manner adjusts the fit of the outlets 34, 36 and complementary domes 38, 40 of the seal 2, which overlie the outlets 34, 36, to the external skin of the nares of a user donning a nasal mask, including the inner rim of the nares. The midline can be seen, for example, as line A-A in FIG. 4A. Increasing the pitch of a side of the "V" will move the particular outlet and complementary dome closer to the other outlet and complementary dome, while decreasing the pitch of a side of the "V" will move the particular outlet and complementary dome away from the other outlet and complementary dome. Additionally, the malleable element 4 can be bent in other directions, allowing the nasal mask 1 to be formed into a variety of configurations.

The nasal mask 1 includes an inlet 32 into which a swivel connector 12 fits. The swivel connector 12 has a slightly concave shape on the end that fits into the inlet 32. A conduit elbow 14 fits onto the swivel connector 12 over a flange 28 on the swivel connector 12. The connection between the inlet 32 and the swivel connector 12 and/or the connection between the swivel connector 12 and the conduit elbow 14 can be a permanent and inseparable connection or the connection can be a selectively removable connection. The swivel connector 12 produces a swivel mount connection between the conduit elbow 14 and the inlet 32. In this type of

connection, the conduit elbow 14 is capable of being rotated 360 degrees about an axis extending through the center of the inlet 32. In an alternative embodiment, the connection is characterized by a ball and socket connection. In this alternative type of connection, the conduit elbow has a second angular degree of freedom in addition to the single rotational degree of freedom of the swivel mount connection. The conduit elbow 14 may be manufactured from, for example, but without limitation to, polycarbonate. The swivel connector 12 also can be manufactured from, for example, but without limitation, polypropylene.

The conduit elbow 14 is shown with an angled portion of about ninety degrees, as well as apertures 20 as seen in FIG. 2B, only one aperture being labeled for the sake of clarity. These apertures 20 allow the release of gases exhaled by the user. In current hose designs, a user can be disturbed by gasses escaping from the hose through the apertures because of noise or a "blowing" sensation. The apertures 20 of this embodiment of the invention are designed to prevent escaping gases from disturbing a user. More than one aperture 20 is used (in this embodiment three apertures 20 are used) in order to diffuse the flow of exhaled gas. Additionally, the apertures 20 do not have sharp edges at their perimeter so that noise of gas moving through the apertures 20 is reduced. The apertures 20 are positioned on a remote side of the conduit elbow 14 so that gas is vented in a single direction rather than multiple directions. The nasal mask 1 can optionally include more than one inlet to allow for additional hoses and/or sources of gas to be connected. Also, one or more outlets can be included optionally to allow for drainage of any condensation formed within the chamber 30 of the shell 6, 8 and/or to attach monitoring devices such as pressure, temperature, or flow sensors.

In addition, a retainer 10 is disposed about the inlet 32. Two tabs 22, 22' included on the inlet 32 mate with two slots 24, 26, respectively, and hold the retainer 10 in a particular angular orientation. The retainer 10 has four connection points, two lower connection points 18, 18' and two upper connection points 16, 16'. Typically, the tabs 22, 22' hold the retainer 10 in an

orientation such that the upper connection points 16, 16' are above the lower connection points 18, 18'. These connection points 16, 16', 18, 18' allow for connection between the retainer 10 and a headgear apparatus. The retainer 10 can be constructed from, for example, but without limitation, a polycarbonate. Alternative embodiments may have a different number of connection points and/or may have a mechanically different method of fastening a headgear apparatus to a nasal mask. Fastening devices such as, but without limitation, snaps, hook and eye closures, hook and loop fasteners, or the like, may be used.

Now referring to FIG. 5, when the nasal mask 1 is donned by a user, the nasal mask 1 is maintained on the area around a user's nares with a headgear apparatus 48. The headgear apparatus 48 is shown as straps 44, 46, 52 which rest on the head as indicated in FIG. 5. The straps 44, 46, 52 of the headgear apparatus 48 do not fall across the ears of a user. Avoiding contact between the straps 44, 46, 52 and the ears of a user increases the comfort level of a user wearing the headgear apparatus 48. The straps 44, 46, 52 may be manufactured from elastic materials such as, but not limited to, nylon webbing, nylon covered neoprene and Velstretch™, available from Velcro USA Inc., Manchester, NH, and may further include optional padding, if desired. The headgear apparatus 48 also can be reinforced with a beam element 50 that allows the headgear apparatus 48 to retain a roughly helmet shape when not placed on the head of a user. The beam element 50 may be plastically or elastically deformable and may be manufactured, for example, from a polymer, metal, or other suitable material. According to one embodiment, the beam element may have a substantially flat cross-section, so as not to create an uncomfortable ridge if rested upon. Maintaining the helmet shape allows a user to more easily don the headgear. Those skilled in the art appreciate that other equivalent headgear apparatus configurations and headgear apparatus materials may be employed.

The headgear apparatus 48 is connected to the retainer 10. Specifically, the headgear apparatus 48 includes two upper retention straps 44, only one upper retention strap is shown, the

other being hidden from view, and two lower retention straps 46, only one lower retention strap is shown, the other being hidden from view, each of which is attached to a corresponding one of two upper connection points 16, 16', only one upper connection point 16 is shown, the other 16' being hidden from view, or two lower connection points 18, 18' only one lower connection point 18 is shown, the other 18' being hidden from view, respectively. The connection points 16, 16', 18, 18' are a unitary part of the retainer 10. Modes of construction other than unitary construction will be appreciated by those skilled in the art.

This four point restraining system allows for the nasal mask 1 to be securely positioned against the nares of a user. The lower connection points 18, 18', in concert with the lower retention straps 46, generally maintain the nasal mask 1 against a user's face. The seal 2 rests against the external skin at the base of a user's nose and/or along the rim of the nares (the "naric area"). The upper connection points 16, 16' in concert with the upper retention straps 44 provide additional retention force on the upper portion of the nasal mask 1, closest to a user's eyes. This additional force retains the nasal mask 1 securely against the external skin surrounding the nares at the base of a user's nose and/or along the rim of a user's nares. The upper retention straps 44 do not block the vision of a user.

In use, a user would loop each of the lower and upper retention straps 44, 46 through each of the lower and upper connection points 16, 16', 18, 18', respectively. A hook and loop system can be used to maintain the straps 44, 46 at a desired adjustment. The loops are located along the majority of the straps 44, 46 but not at a distal tip portion of the straps 44, 46. Hooks are located on the distal tip portion such that when the distal tip of a strap is passed through a connector, the strap folds over on itself and the hooks engage the loops. Alternatively, the correct length of a strap can be adjusted and a snap on the distal tip can engage with a clip along the strap. Thus, a user only has to adjust a strap once rather than adjusting the straps each time a user dons the nasal mask.

The properly adjusted retention straps 44, 46 of the headgear apparatus 48 secure proper contact between the seal 2 and the naric area. The additional force provided by the upper connection points 16, 16' and the upper retention straps 44 ensures that the nasal mask 1 rests securely against a user's naric area during a wide range of sleeping behaviors such as entering and maintaining a preferred sleeping position or performing involuntary movements during sleep.

Referring to FIG. 6, a breathable gas source 74 connected to a nasal mask 70 with a conduit 72 and optionally controlled with a controller unit 76 is schematically depicted. The breathable gas source 74 could be any of a variety of configurations, including, but not limited to, a constant flow air pump, a responsive variable flow air pump, a pressure regulated oxygen tank, or the like, as discussed in the references cited hereinabove.

Now referring to FIG. 7, a section through the seal 2 is shown. Typically, the seal 2 is a bladder that is formed from a film 60, 64 and that is filled with a soft material 62. Typically, the fill material 62 has a durometer value of less than about ten on the Shore OOO scale. For example, certain types of silicone gel meet this durometer value, such as, but not limited to, molded silicone commercially available from Bragel, Inc. Pomona, CA as a finished product or chemical silicone constituents, such as a base and a cross-link, such as those available from Applied Silicone Corporation, Ventura, CA, that combine to form, when cured, such a finished product.

As stated hereinabove, according to one embodiment, the seal fill material has a durometer value of less than about ten on the Shore or Type OOO scale. Such low durometer values on this scale can be measured using apparatus and test methodology generally in accordance with Type A, B, C, D, DO, O, OO durometer test method of American Society for Testing and Materials (ASTM) Designation D 2240-97$^{\varepsilon 1}$: Standard Test Method for Rubber Property – Durometer Hardness, approved February 10, 1997, and revised editorially in February

1999, the disclosure of which is incorporated herein. As is known by those skilled in the art of testing the durometer of ultrasoft gels and sponge rubber on the Shore OOO scale, a 0.5 inch hemispherical end indentor shape is used in combination with a 113 gram-force main spring.

According to this test method, the procedure for obtaining measurements of a specimen's durometer is stated as follows:

> Place the specimen on a hard, horizontal surface. Hold the durometer in a vertical position with the point of the indentor at least 12 mm (0.5 in.) from any edge of the specimen, unless it is known that identical results are obtained when measurements are made with the indentor at a lesser distance. Apply the presser foot to the specimen as rapidly as possible, without shock, keeping the foot parallel to the surface of the specimen. Apply just sufficient pressure to obtain firm contact between presser foot and specimen.

When the durometer measurement is made as stated, while maintaining sufficient pressure to maintain contact, but without permitting the presser foot of the measuring apparatus to compress the silicone gel specimen, thereby forcing a portion of the specimen into the aperture formed about the indentor and binding the indentor, reliable, repeatable readings on the Shore OOO scale can be recorded.

Furthermore, the aforementioned test method states:

> NOTE 9 – The type of durometer should be selected with the knowledge that readings below 10 or above 90 are not considered reliable by the manufacturer. It is suggested that readings in these ranges not be recorded.

Although readings below 10 on the Shore scale are not considered reliable by ASTM, the Shore OOO scale is the lowest scale for durometer by Shore readings. In effect, the aforementioned seal fill material is too soft for measurement by ASTM approved Shore durometer test methods. However, a reference of below ten on the Shore OOO scale measured as described hereinabove is Applicant's preferred method for characterization of the seal softness in accordance with the invention. Further, this methodology is generally known by those skilled in the art and represents industry accepted measurement standards.

The bladder itself, typically, is made from a thermopolymer material. The bladder can be formed from, for example, but not limited to, a urethane film or a polyurethane film. Urethane films are commercially available, for example, from Deerfield Urethane, Inc., Deerfield, MA, and polyurethane films are commercially available, for example, from Elf Atochem S.A. Paris, France. The film forming the bladder can be thicker in some portions relative to other portions. For example, FIG. 7 depicts a relatively thinner portion of the film 60 and a relatively thicker portion of the film 64. Typically, the film 64 on the side of the seal that is bonded to the shell is thicker than the film 60 on the side of the seal which contacts the face of a user. In one embodiment, the seal has about a 75 μm thick urethane film on the side bonded to the shell and has about a 50 μm thick urethane film on the side which contacts the face of a user. Accordingly, when the seal 2 is bonded to the shell 6, for example with a bonding agent such as tetrahydrofuran or an ultraviolet cured adhesive, sufficient margin exists to prevent the film from being breached due to attack by the bonding agent. The film disposed against the user's skin, however, is maintained relatively thin so as not to stiffen the seal 2.

Now referring to FIGS. 8A, 8B, and 8C, the seal 2 has two domes 38, 40 that cover the two outlets 34, 36. The domes 38, 40 have a complementary space on the bonded side of the seal 2 that accepts the two outlets 34, 36. The domes in certain embodiments can protrude into the nares from about 0.1 inches to about 0.375 inches, more preferably 0.115 inches to about 0.250 inches. This depth can vary in other embodiments. Moreover, in some embodiments, the seal can seal around the inner rim of the nares. The contact, between the seal 2 and the external skin surrounding the nares at the base of the nose and/or the inner rim of the nares is minimal. Each of these domes 38, 40 are elliptical and have an elliptical opening in them that is about 0.35 inches along its short axis and 0.45 inches along its long axis. An opening in each dome 38, 40 communicates with the opening in the two outlets 34, 36, respectively. The domes 38, 40 have a generally convex sealing surface for sealing with the external skin surrounding the nares and/or

along the inner rim of the nares thereby to produce an annular seal about the nares. The convex domes allow devices according to the invention to conform to the nasal area, particularly when the device is pressurized during use. The pressure further deforms the seal 2 to comply with the naric area. Thus, rather than having a device that forces the naric area to conform to the device or that extends into the nares substantially irritating the delicate mucous membrane therein, which is uncomfortable for a user, devices according to the invention conform to the naric area.

The seal 2 is about 0.225 inches thick, not including the area in which the two domes 38, 40 are located, and the seal 2 has a substantially planar side, typically the side that contacts the upper shell 6. The domes 38, 40 protrude about 0.225 inches above the surface of the seal 2. The seal 2 has a generally oval shape with two rounded portions 56, 58 on either side of the seal 2. The seal 2 also has an area 78 where the shape is concave instead of a smooth, convex arc. This concave area 78 can better accommodate the contours of the face of a user between the upper lip and the base of the nose. This slightly concave portion is reflected in other components of certain embodiments. For example, referring to FIG. 1B, a concave portion 80, 82, 84 of the upper shell 6, lower shell 8, and retainer 10, respectively, is shown. Each side of the seal 2 is shown bent at about a 15 degree angle α, β from planar. However, depending upon a particular user, the seal can be bent, as well as the shell 6, 8 and malleable element 4, at a variety of angles to suit a particular user's facial contours and the position of a user's nares.

Now referring to FIGS. 9-11, an alternative embodiment of a nasal mask 201 has many, but not all, of the features of the nasal mask 1 embodiment shown in FIGS. 1-8C. Two differences between this alternative nasal mask 201 embodiment and the nasal mask 1 embodiment shown in FIGS. 1-8C are, respectively, that a retainer 210 connects to an inlet 232 in a different manner than the retainer 10 connects to the inlet 32 and that the retainer 210 is configured differently than the retainer 10.

The retainer 210 is disposed about the inlet 232 to facilitate retention of the mask 201 on a user. Two tabs 222, 222' included on the inlet 232 mate with two slots 226, 224 formed in the retainer 210 in a particular angular orientation. The retainer 210 has three connection points disposed remotely from the inlet 232, two lower connection points 218, 218' and one upper connection point 216. The nasal mask 201 is substantially symmetrical, as best seen in FIG. 11. Typically, the tabs 222, 222' hold the retainer 210 in an orientation such that the upper connection point 216 is above the lower connection points 218, 218' and all connection points 216, 218, 218' are disposed symmetrically about a vertical centerline B-B of the mask 201. Also, a depressed annular region 280 on the inlet 232 mates with the edges of an aperture passing through the retainer 210. The retainer aperture and the inlet 232 are generally sized in an interference fit so that the retainer 210 is properly retained by the cooperation of the tabs 222, 222', the slots 226, 224, and the depressed annular region 280 when fully seated against a lower shell 208. The depressed annular region 280 does not completely encircle the inlet 232, thus forming the two tabs 222, 222'. The retainer 210 can be constructed from, for example, but without limitation, a polycarbonate material.

The connection points 216, 218, 218' form slots which allow for connection of the retainer 210 with straps of a headgear apparatus below. A three point restraining system permits the nasal mask 201 to be securely and gently biased against the nares of a user. The lower connection points 218, 218' in concert with retention straps, generally maintain the nasal mask 201 against a user's face. The seal 202 rests against the external skin at the base of a user's nose and/or along the rim of the nares (the "naric area"). The upper connection point 216 in concert with an upper retention strap provides additional retention force on the upper portion of the nasal mask 201, closest to a user's eyes. This additional force retains the nasal mask 201 securely against the external skin surrounding the nares at the base of a user's nose and/or along the rim of a user's nares. The upper retention strap passes slidably through the upper connection point 216,

best seen in FIG. 10B, and this single strap connects to other portions of a headgear apparatus. The upper retention strap is configured and oriented so as not to block the vision of a user.

In use, a user loops each of the lower retention straps through respective slots in each of the lower connection points 218, 218'. A hook and loop fastener system can be used to maintain the straps at a desired adjustment. The loops may be located along the majority of the lengths of the straps to provide a wide range of adjustment, with the hooks being located on the distal tip portions of the straps, such that when the distal tip of a strap is passed through a slot in a connector, the strap folds over on itself and the hooks engage the loops. Once the straps are adjusted, a user can slip the pre-formed loop into and out of the lower connection points 218, 218' at a notch that is cut into an edge of each of the lower connections points 218, 218'. The notch typically is removed from a portion of the lower connection points 218, 218' towards the centerline of the nasal mask 201 (line B-B in FIG. 11). Removing a notch from this portion allows the straps to be engaged and disengaged with the retainer 210 easily, while at the same time minimizes the possibility that the straps will slip out of their respective lower connection points 218, 218' while the nasal mask 201 is in use. Further, once the straps are adjusted a first time, they need not be adjusted again, merely being slipped out of the lower connection points 218, 218' by the notches.

Now referring to FIGS. 12-14, another alternative embodiment of a nasal mask 301 is shown, which has similar components to those described above. The nasal mask 301 includes a soft seal 302 affixed to a shell 308, for example by bonding. The shell 308 includes a convex portion 310 and a flange 306. The seal 302 is affixed to the flange 306. Bonding agents and alternative means to affix the seal 302 to the shell 308 are described in more detail, above. The shell 308, typically is manufactured from a flexible material by a molding process. The shell 308 has a generally triangular shape that also is convex and is contoured such that a chamber 390 is formed by the sides of the shell 308 and the convex portion 310 of the shell 308. When in

fluidic communication with a source of breathable gas, the chamber 390 contains the breathable gas. The gas in the chamber 390 is available to the user donning the nasal mask 301, and the gas, typically, is pressurized such that the gas is forced in to the user's airway, holding open the airway. The chamber 390 is substantially leakage-free due to the bond or interface between the seal 302 and the shell 308 as well as the conformance of the seal 302 against a user's skin.

Disposed within a perimeter portion of the shell 308, such as the flange 306, is a malleable element 304, best seen in FIG. 13. In this embodiment, the malleable element 304 is a wire made from a relatively soft metal, such as aluminum or copper, disposed about the opening of and within the flange 306 of the shell 308. Alternatively, the malleable element 304 can be affixed to a surface of the shell 308. The malleable element 304 can be constructed from any material that is formable and is capable of retaining the shape into which it is formed against the force of, for example, the flexible shell 308 trying to regain its memory shape. The combination of the compliant and resilient shell 308 and the malleable element 304, having sufficient rigidity to hold the shell 308 in a selected configuration, produces a "custom-fit" as desired by a particular user. Because the shell 308 is compliant, the perimeter and overall configuration of the opening of shell 308 can be reformed repeatedly, as necessary, by a particular user.

The nasal mask 301 also forms an inlet 332 in the shell 308 through which a breathable gas enters the chamber 390. A headgear apparatus retains the nasal mask 301 in the proper orientation against a user's naric area. The apparatus can include a retainer with other components, as described above, or the apparatus can be integral with the nasal mask 301. The apparatus connects to the nasal mask 301 either directly, or indirectly, through a retainer, with a strap 346 (only one is shown and labeled) positioned at either side of the upper lip. The straps 346 are directed to the nape of the neck, below the ears, of a user donning the nasal mask 301. A third strap 344 connects with the nasal mask 301 either directly, or indirectly, through a retainer, and is directed from the tip of the nose, between the eyes, and over the head of a user donning

the nasal mask 301. The nasal mask 301 is maintained comfortably in sealing relation with the user's naric area with the headgear apparatus. This restraining system permits the nasal mask 301 to be securely and gently biased against a user's naric area. More particularly, the seal 302 is in contact with the external skin proximate the nares at the base of the user's nose. A chevron-shaped section 302a of the seal 302 seals against the base of the nose, from the tip along each side, and another section 302b of the seal 302 seals against the area above the upper lip or at the upper lip itself. As such, the chamber 390 is positioned immediately outside the user's nostrils and encloses the space between the edge of the base of the user's nose, proximate the nares, and the general area of the upper lip, best shown in FIG. 14. The soft seal 302 has the features of soft seals described above, allowing for a comfortable and air-tight seal about the user's naric area. Additionally, the positioning of the seal obviates any pressure that otherwise might be applied to the bridge of the nose in other designs.

The seal itself, in some embodiments, is about 0.25 inches (0.64 cm) to about 0.375 inches (0.953 cm) in depth and, at the contact point between the seal and a user's skin, is about 0.25 inches (0.64 cm) to about 0.375 inches (0.953 cm) in width. Also, in certain embodiments, the shell is a flexible thermoplastic elastomer, such as polyurethane or vinyl compounds, and is about 1.1 inches (2.8 cm) to about 1.7 inches (4.3 cm) at its widest point. This width is generally the width of a human's nasal area as measured from the outer edge of one naris to the outer edge of the other naris, although any shell width that fits generally within a human's nasal area is acceptable. For example, but without limitation, these dimensions can be increased or decreased by about 10%. The shell also is shaped to fit within the naric area. Some relevant dimensions for sizing the shell and seal include the length of the philtrum (generally about 0.4 inches (1.0 cm) to about 0.8 inches (2.0 cm)) as well as the amount to which a nose protrudes (generally about 0.7 inches (1.8 cm) to about 1.2 inches (about 3.0 cm)). Also, the chamber, in certain embodiments, at its widest point, is slightly smaller than the width of the shell.

Variations, modifications, and other implementations of what is described herein will occur to those of ordinary skill in the art without departing from the spirit and the scope of the invention as claimed. Accordingly, the invention is to be defined not by the preceding illustrative description, but instead by the spirit and scope of the following claims.

What is claimed is:

Claims

1. A nasal mask comprising:

a shell forming a chamber having an inlet and at least one outlet; and

a first seal disposed proximate the outlet for contacting and sealing with external skin proximate at least one naris at a base of a nose of a user donning the mask, wherein substantially all of the sealing occurs between the seal and the external skin.

2. The nasal mask of claim 1 further comprising a second seal and wherein the shell further comprises a second outlet.

3. The nasal mask of claim 2 wherein the first seal is integral with the second seal.

4. The nasal mask of claim 1 further comprising a malleable element disposed within the shell.

5. The nasal mask of claim 1 wherein the seal comprises a bladder.

6. The nasal mask of claim 5 wherein the bladder is filled with silicone gel.

7. The nasal mask of claim 6 wherein the gel is molded in a predetermined configuration.

8. The nasal mask of claim 1 wherein the seal is bonded to the shell.

9. The nasal mask of claim 1 further comprising a conduit attached to the inlet.

10. The nasal mask of claim 9 wherein the conduit comprises an angled portion.

11. The nasal mask of claim 9 wherein the conduit comprises a rotary connection.

12. The nasal mask of claim 9 wherein the conduit comprises a ball and socket connection.

13. The nasal mask of claim 9 wherein the conduit comprises a side wall defining a lumen within, wherein the side wall contains at least one opening in communication with the lumen.

14. The nasal mask of claim 1 further comprising a headgear apparatus attached to the mask for retaining the mask on a user.

15. The nasal mask of claim 14 further comprising a retainer disposed about the inlet and cooperating with the headgear apparatus to retain the mask on a user.

16. The nasal mask of claim 15 wherein the headgear apparatus further comprises at least one connector for attaching the headgear apparatus to the mask.

17. The nasal mask of claim 16 wherein the connector attaches to the retainer.

18. A system for treating a respiratory ailment in a recumbent or sleeping user comprising:

a nasal mask comprising a shell forming a chamber having an inlet and at least one outlet and a first seal disposed proximate the outlet for contacting and sealing with external skin proximate at least one naris at a base of a nose of a user donning the mask, wherein substantially all of the sealing occurs between the seal and the external skin;

a controlled, breathable gas source; and

a conduit connecting the mask with the gas source.

19. A seal for use with a nasal mask, the seal comprising a bladder filled with a molded material in a predetermined configuration, the material having a durometer value less than about ten on a Shore OOO scale, wherein the seal is configured to seal against external skin proximate at least one naris at a base of a nose of a user.

20. The seal of claim 19 wherein the bladder is substantially planar on a side thereof for contacting a shell of the nasal mask.

21. The seal of claim 19 wherein the bladder has at least one protrusion on a side thereof for contacting the external skin proximate at least one naris at a base of a nose of a user.

22. The seal of claim 19 wherein the seal has a thickness and forms at least one aperture therethrough disposable proximate a naris.

23. The seal of claim 22 wherein a thickness of the seal proximate the aperture is less than a thickness of the seal remote therefrom.

24. The seal of claim 19 wherein the material comprises silicone.

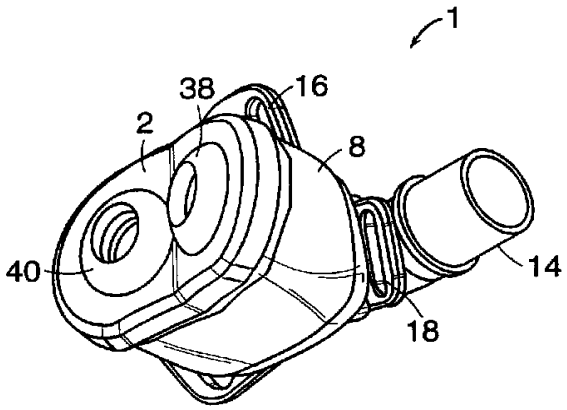

FIG. 1A

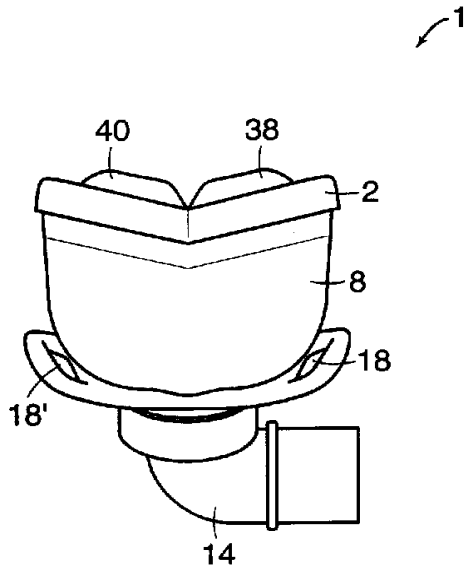

FIG. 2A

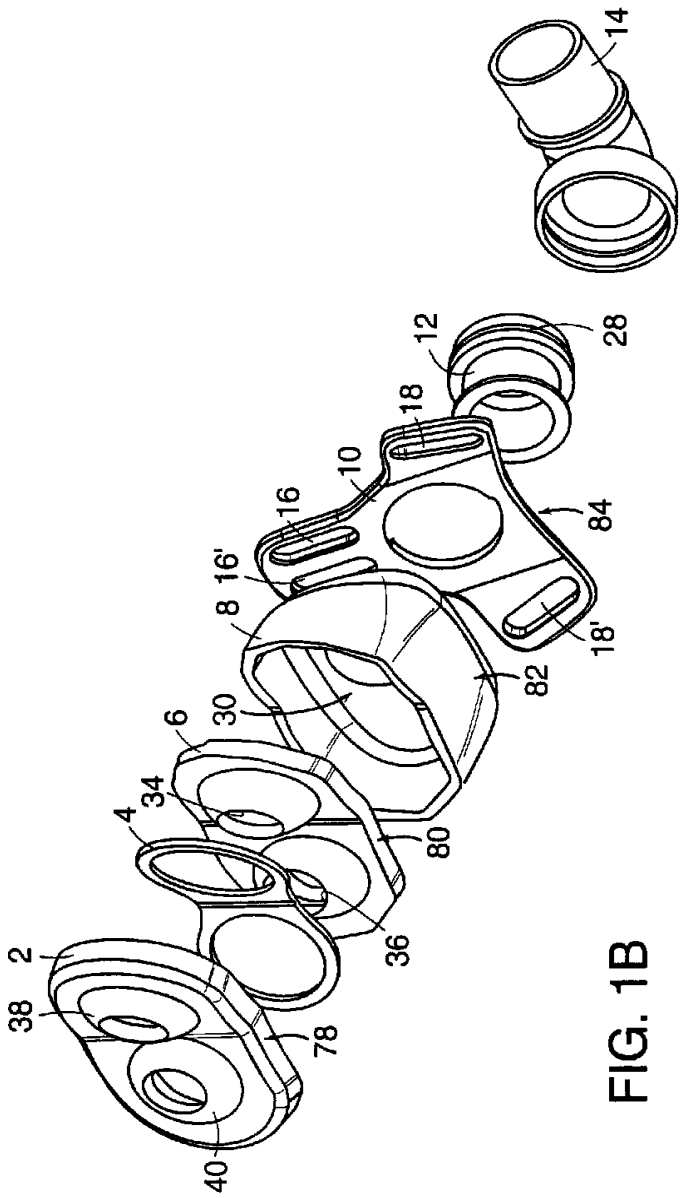

FIG. 1B

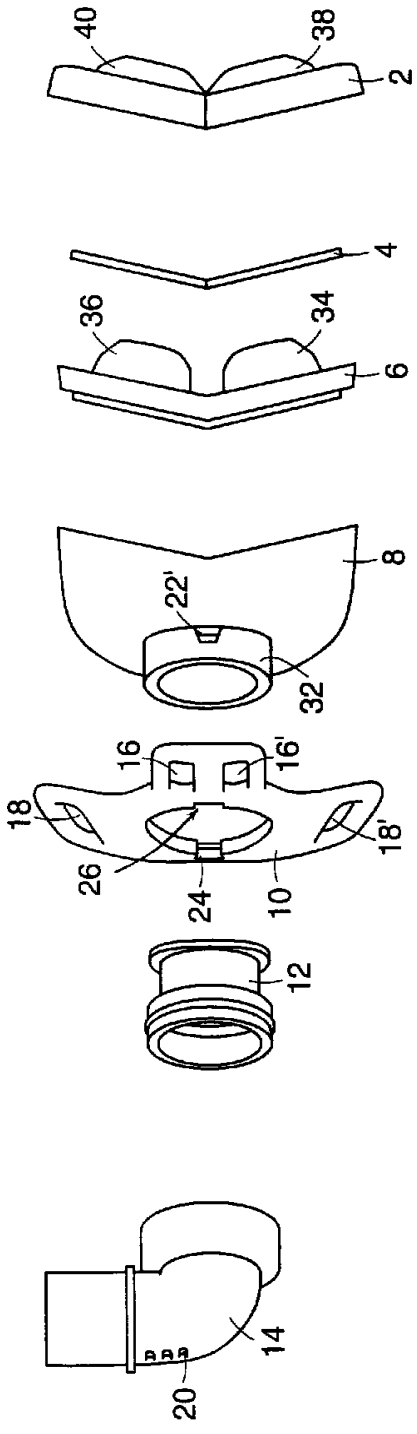

FIG. 2B

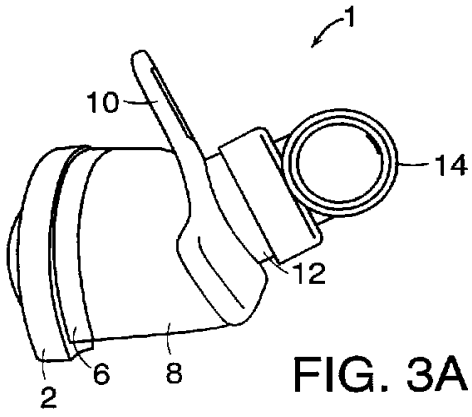

FIG. 3A

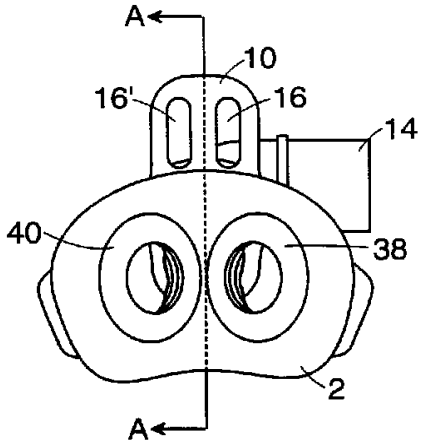

FIG. 4A

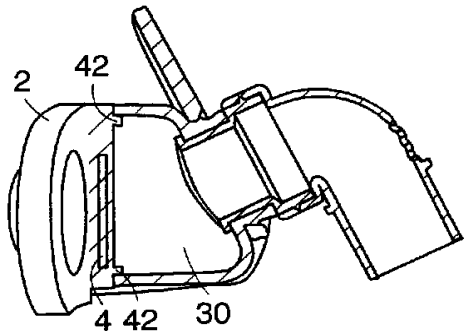

FIG. 4B

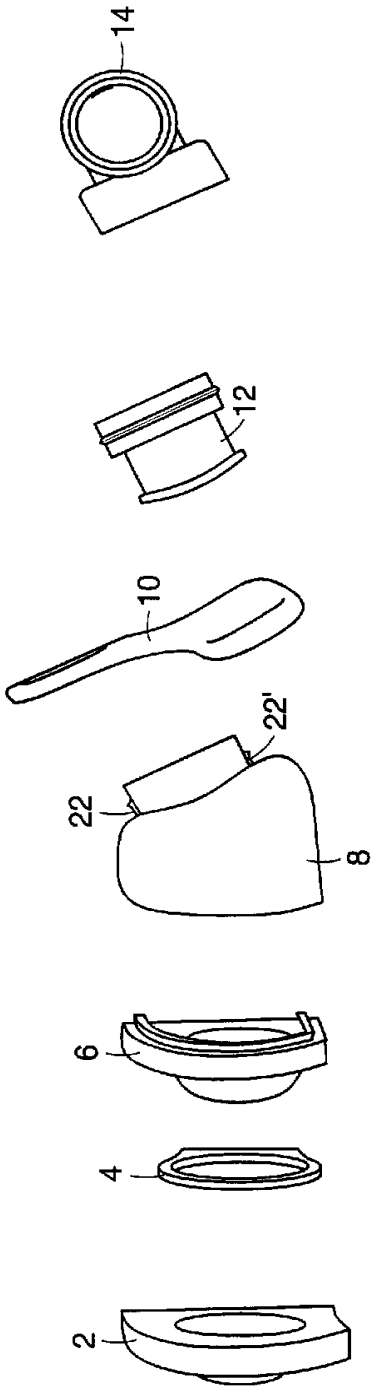

FIG. 3B

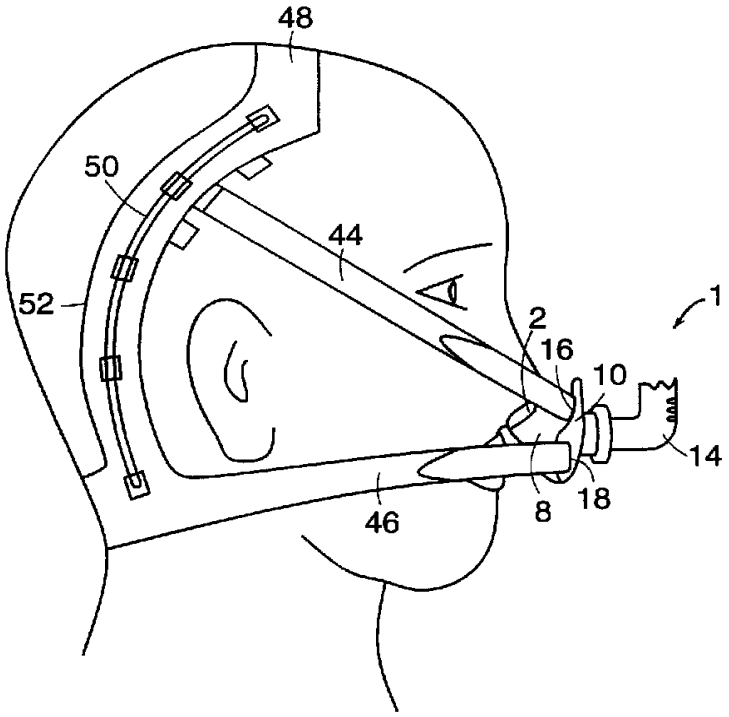

FIG. 5

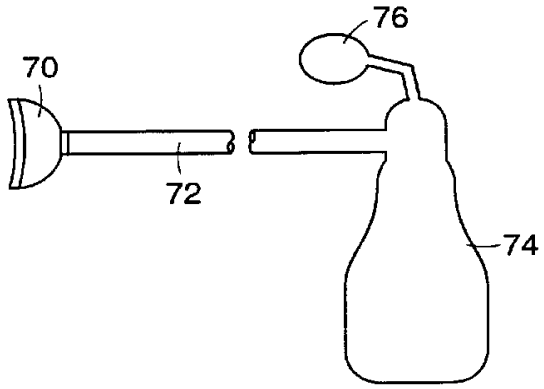

FIG. 6

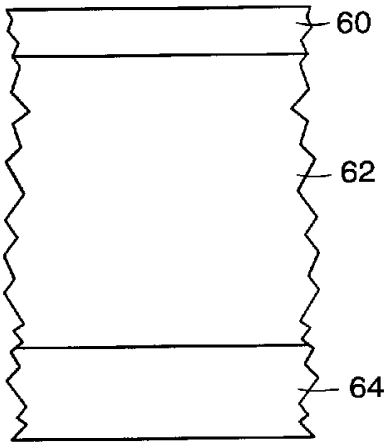

FIG. 7

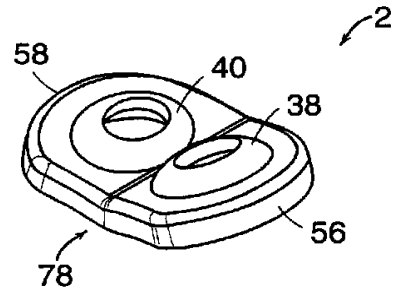

FIG. 8A

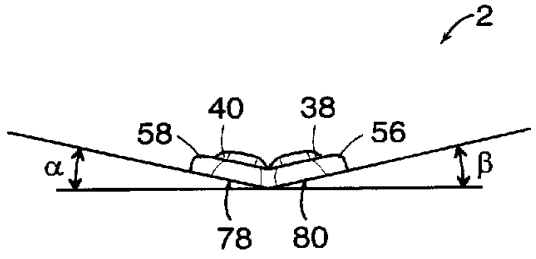

FIG. 8B

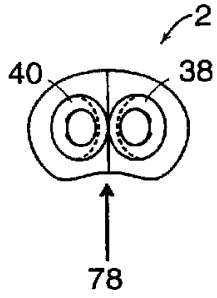

FIG. 8C

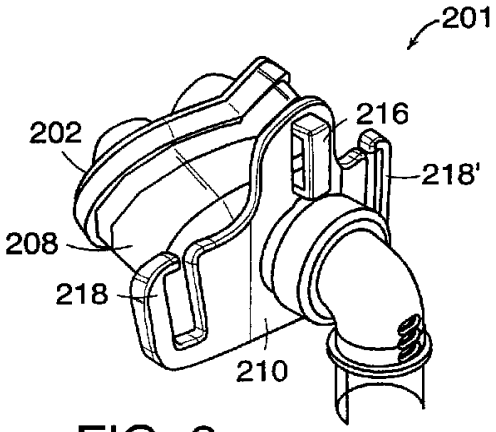

FIG. 9

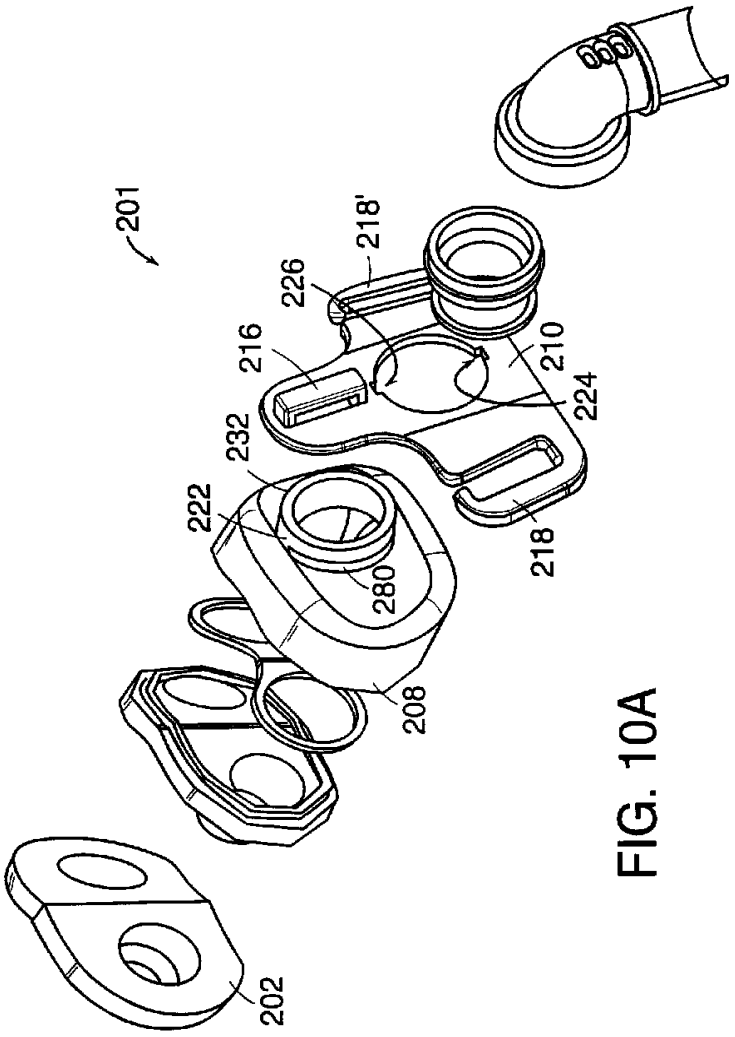

FIG. 10A

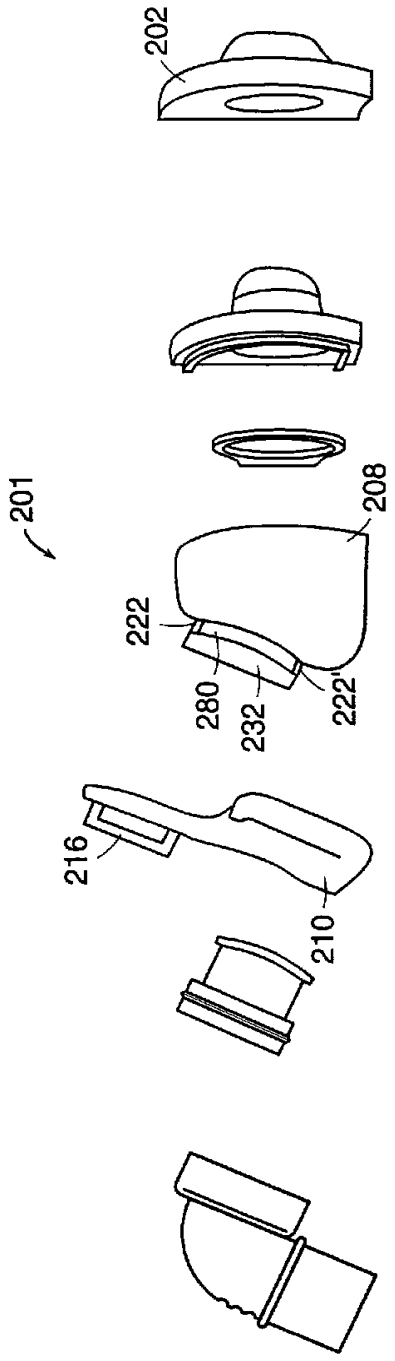

FIG. 10B

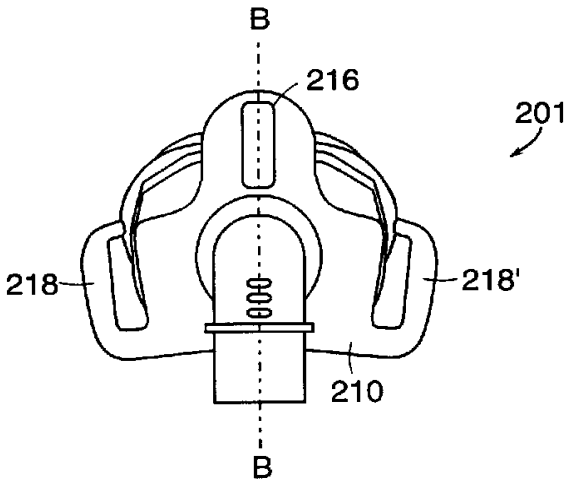

FIG. 11

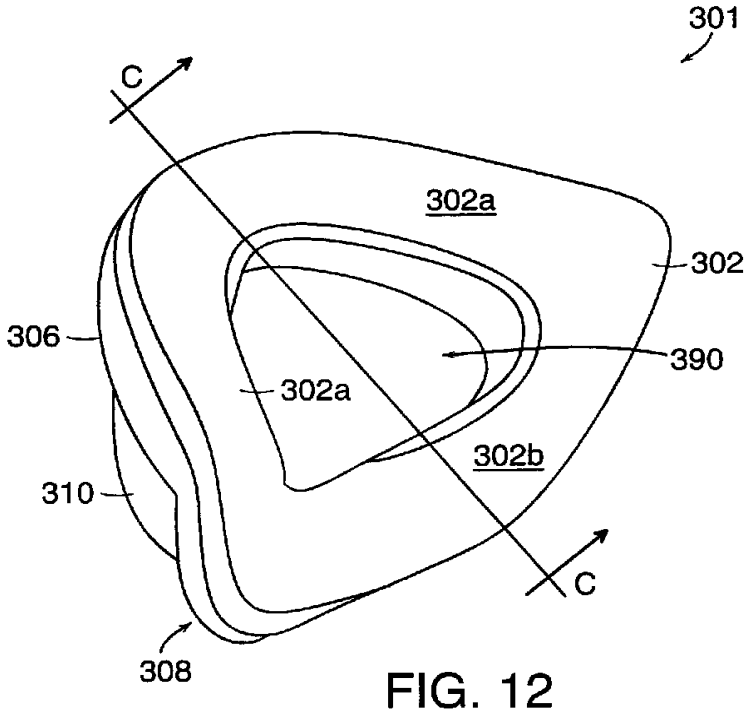

FIG. 12

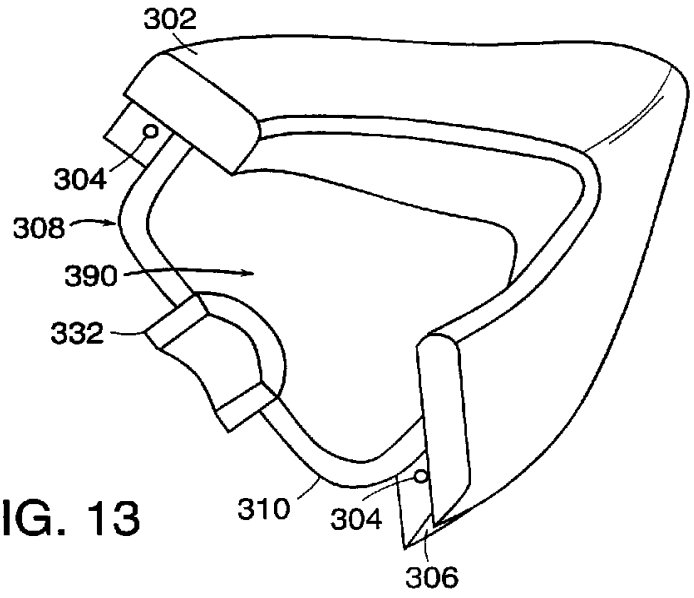

FIG. 13

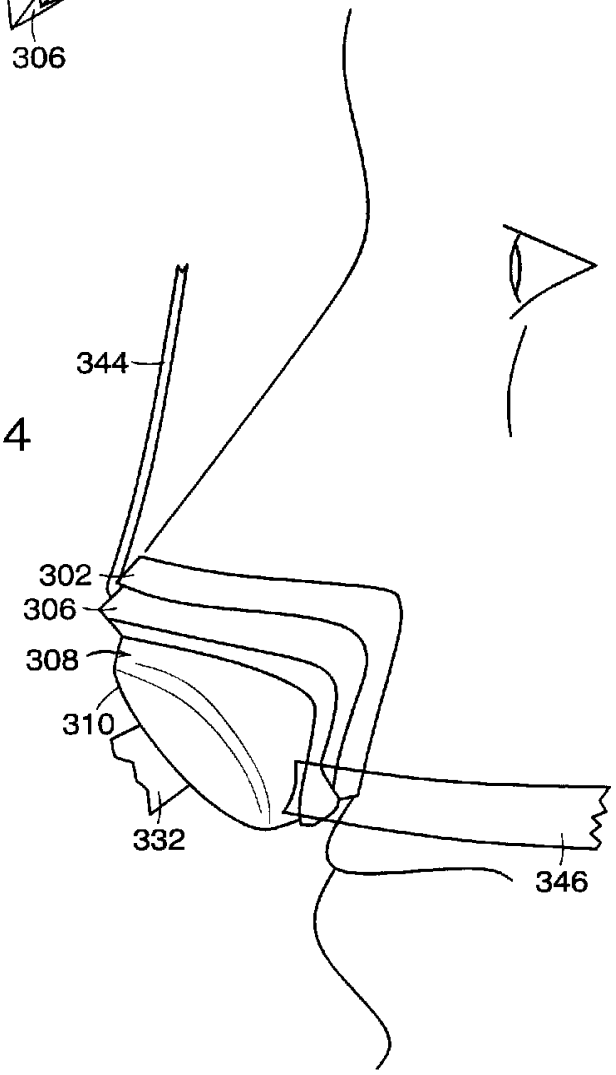

FIG. 14

INTERNATIONAL SEARCH REPORT

Int ational Application No
PCT/US 00/14524

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61M16/06

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 A61M

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 practical, search terms used)
EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 98 18514 A (SLEEPNET CORP) 7 May 1998 (1998-05-07) the whole document more specifically: page 8, line 2 -page 9, line 35 page 19, line 8 - line 16 figures 1-3	1,4-20, 24
P,X	& US 6 019 101 A (COTNER RONALD L; ASACKER THOMAS E) 1 February 2000 (2000-02-01) cited in the application	
X	FR 2 658 725 A (MEIGNAN CHRISTIAN;BARTHOU GILLES) 30 August 1991 (1991-08-30) page 6, line 4 -page 7, line 27 figures 6-8	1-3,8-18

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[X] Further documents are listed in the continuation of box C.

[X] Patent family members are listed in annex.

° Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"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)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"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

"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

"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.

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
6 September 2000	13/09/2000

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL – 2280 HV Rijswijk Tel. (+31–70) 340–2040, Tx. 31 651 epo nl, Fax: (+31–70) 340–3016	Lakkis, A

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INTERNATIONAL SEARCH REPORT

Int ational Application No
PCT/US 00/14524

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication,where appropriate, of the relevant passages	Relevant to claim No.
X	FR 2 749 176 A (MIDI OXYGENE) 5 December 1997 (1997-12-05) claim 1; figures 4,5	1-3,8-18
X	US 5 884 624 A (BARNETT SHARI S ET AL) 23 March 1999 (1999-03-23) column 4, line 33 -column 7, line 5; figures 1-4	1,5,8-20
A	EP 0 747 078 A (RESPIRONICS INC) 11 December 1996 (1996-12-11) abstract; figures 1-4	1-3,18
A	US 4 782 832 A (TRIMBLE RUSSELL L ET AL) 8 November 1988 (1988-11-08) column 5, line 6 - line 14; figure 9	2,5, 19-22
P,X	WO 99 58181 A (GOLDSTEIN JOSEPH) 18 November 1999 (1999-11-18) page 13, line 23 -page 14, line 4 figures 19,20	1-3,8-18

1

Form PCT/ISA/210 (continuation of second sheet) (July 1992)

INTERNATIONAL SEARCH REPORT

Information on patent family members

Int tional Application No
PCT/US 00/14524

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
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Form PCT/ISA/210 (patent family annex) (July 1992)

Electronic Acknowledgement Receipt

EFS ID:	4903103
Application Number:	12307993
International Application Number:	
Confirmation Number:	7084
Title of Invention:	A BREATHING ASSISTANCE APPARATUS
First Named Inventor/Applicant Name:	ALASTAIR EDWIN McAULEY
Customer Number:	00279
Filer:	Linda L. Palomar/Tiffany Lynch
Filer Authorized By:	Linda L. Palomar
Attorney Docket Number:	1171/48067/202-PCT-US
Receipt Date:	04-MAR-2009
Filing Date:	
Time Stamp:	15:33:15
Application Type:	U.S. National Stage under 35 USC 371

Payment information:

Submitted with Payment	no

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Information Disclosure Statement (IDS) Filed (SB/08)	IDS202.pdf	607764 d3b34729df23041f366f3a264dab8d0a7dc91acf	no	4

Warnings:	
Information:	

2	Foreign Reference	WO0074758.pdf	1330394 81686ef72a2f270fe382dd4c01c51b2364d10fea	no	40

Warnings:	
Information:	
Total Files Size (in bytes):	1938158

This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.

New Applications Under 35 U.S.C. 111
If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

National Stage of an International Application under 35 U.S.C. 371
If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office
If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

MULTIPLE DEPENDENT CLAIM
FEE CALCULATION SHEET
(FOR USE WITH FORM PTO-875)

SERIAL NO. 12/307993 | FILING DATE

APPLICANT(S)

CLAIMS

	AS FILED		AFTER 1ST AMENDMENT		AFTER 2ND AMENDMENT	
	IND.	DEP.	IND.	DEP.	IND.	DEP.
1	1		1			
2		1		1		
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TOTAL IND.	4		2			
TOTAL DEP.	42		30			
TOTAL CLAIMS	46		32			

	AS FILED		AFTER 1ST AMENDMENT		AFTER 2ND AMENDMENT	
	IND.	DEP.	IND.	DEP.	IND.	DEP.
51						
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99						
100						
TOTAL IND.						
TOTAL DEP.						
TOTAL CLAIMS						

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

U.S. APPLICATION NUMBER NO.	FIRST NAMED APPLICANT	ATTY. DOCKET NO.
12/307,993	ALASTAIR EDWIN McAULEY	1171/48067/202-PCT-US

279
TREXLER, BUSHNELL, GIANGIORGI,
BLACKSTONE & MARR, LTD.
105 WEST ADAMS STREET
SUITE 3600
CHICAGO, IL 60603

INTERNATIONAL APPLICATION NO.	
PCT/NZ2007/000185	
I.A. FILING DATE	PRIORITY DATE
07/13/2007	07/14/2006

CONFIRMATION NO. 7084
371 FORMALITIES LETTER

Date Mailed: 05/06/2009

NOTIFICATION OF MISSING REQUIREMENTS UNDER 35 U.S.C. 371 IN THE UNITED STATES DESIGNATED/ELECTED OFFICE (DO/EO/US)

The following items have been submitted by the applicant or the IB to the United States Patent and Trademark Office as an Elected Office (37 CFR 1.495):

- Priority Document
- Copy of the International Application filed on 01/08/2009
- Copy of the International Search Report filed on 01/08/2009
- Preliminary Amendments filed on 01/08/2009
- Information Disclosure Statements filed on 01/08/2009
- Oath or Declaration filed on 01/08/2009
- U.S. Basic National Fees filed on 01/08/2009
- Priority Documents filed on 01/08/2009
- Specification filed on 01/08/2009
- Claims filed on 01/08/2009
- Abstracts filed on 01/08/2009
- Drawings filed on 01/08/2009

The applicant needs to satisfy supplemental fees problems indicated below.

The following items **MUST** be furnished within the period set forth below in order to complete the requirements for acceptance under 35 U.S.C. 371:

- Additional claim fees of $**52** as a non-small entity, including any required multiple dependent claim fee, are required. Applicant must submit the additional claim fees or cancel the additional claims for which fees are due.
- Oath or declaration of the inventors, in compliance with 37 CFR 1.497(a) and (b), identifying the application by the International application number and international filing date. The current oath or declaration does not comply with 37 CFR 1.497(a) and (b) in that it:
  - is not executed in accordance with either 37 CFR 1.66 or 37 CFR 1.68.
- To avoid abandonment, a surcharge (for late submission of filing fee, search fee, examination fee or oath or declaration) as set forth in 37 CFR 1.492(h) of $130 for a non-small entity, must be submitted with the missing items identified in this letter.

SUMMARY OF FEES DUE:

Total additional fees required for this application is $**182** for a Large Entity:
- $**130** Surcharge.

FORM PCT/DO/EO/905 (371 Formalities Notice)

Total additional claim fee(s) for this application is $**52**

- $**52** for **12** total claims over 20.

ALL OF THE ITEMS SET FORTH ABOVE MUST BE SUBMITTED WITHIN TWO (2) MONTHS FROM THE DATE OF THIS NOTICE OR BY 32 MONTHS FROM THE PRIORITY DATE FOR THE APPLICATION, WHICHEVER IS LATER. FAILURE TO PROPERLY RESPOND WILL RESULT IN ABANDONMENT.

The time period set above may be extended by filing a petition and fee for extension of time under the provisions of 37 CFR 1.136(a).

Applicant is reminded that any communications to the United States Patent and Trademark Office must be mailed to the address given in the heading and include the U.S. application no. shown above (37 CFR 1.5)

Registered users of EFS-Web may alternatively submit their reply to this notice via EFS-Web.
https://sportal.uspto.gov/authenticate/AuthenticateUserLocalEPF.html

For more information about EFS-Web please call the USPTO Electronic Business Center at **1-866-217-9197** or visit our website at http://www.uspto.gov/ebc.

If you are not using EFS-Web to submit your reply, you must include a copy of this notice.

VONDA M WALLACE

Telephone: (703) 756-1425

FORM PCT/DO/EO/905 (371 Formalities Notice)

1171/48067/202-PCT-US

DECLARATION AND POWER OF ATTORNEY FOR PATEN

My residence, post office address and citizenship are as stated below next to my name, S89957 NJC

I believe I am the original, first and sole inventor (if only one name is listed below) or an .or (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the ... titled: BREATHING ASSISTANCE APPARATUS the specification of which

(check one) [ ] is attached hereto.
[X] was filed on July 13, 2007 as Application Serial No. PCT/NZ2007/000185 and was amended on January 8, 2009.

I hereby state that I have reviewed and understand the contents of the above identified specification, including the claims, as amended by any amendment referred to above.

I acknowledge the duty to disclose information which is material to patentability as defined in Title 37, Code of Federal Regulations, §1.56.

I hereby claim foreign priority benefits under Title 35, United States Code, §119(a)-(d) of any foreign application(s) for patent (nventor's certificate listed below and have also identified below any foreign application for patent or inventor's certificate having a filing date before that of the application on which priority is claimed:

Prior Foreign Application(s)			Priority Claimed	
548575 (Number)	New Zealand (Country)	14 July 2006 (Day/Month/Year Filed)	[X] Yes	[ ] No
551103 (Number)	New Zealand (Country)	06 November 2006 (Day/Month/Year Filed)	[X] Yes	[ ] No

Prior Provisional Application(s)

I hereby claim the benefit under Title 35, United States Code, §119(e) of any United States provisional application(s) listed below.

(Application Number) (Filing Date)

((Application Number) (Filing Date)

I hereby claim the benefit under Title 35, United States Code, §120 of any United States application(s) listed below; insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States application in the manner provided by the first paragraph of Title 35, United States Code, §112, I acknowledge the duty to disclose material information as defined in Title 37, Code of Federal Regulations, §1.56(a) which occurred between the filing date of the prior application and the national or PCT international filing date of this application:

(Application Serial No.) (Filing Date) (Status: patented, pending, abandoned)

POWER OF ATTORNEY: As a named inventor, I hereby appoint the following attorney(s) and/or agent(s) to prosecute this application and transact all business in the Patent and Trademark Office connected therewith: Richard A. Giangiorgi, Reg. 24,284; Raiford A. Blackstone, Jr., Reg. 25,156; David J. Marr, Reg. 32,915; Linda L. Palomar, Reg. 37,903; James R. Foley, Reg. 39,979; James A. O'Malley, Reg. 45,952; Timothy M. McCarthy, Reg. 42,855; and Paige A. Kitzinger, Reg. 45,219.

SEND CORRESPONDENCE TO: TREXLER, BUSHNELL, GIANGIORGI, BLACKSTONE & MARR, LTD.
105 W. ADAMS STREET, CHICAGO, IL 60603

DIRECT TELEPHONE CALLS TO: (312) 704-1890 Raiford A. Blackstone, Esq.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Full name of sole or first inventor ALASTAIR EDWIN McAULEY
Inventor's signature _____ Date 22/Jan/09
Residence City Auckland Country New Zealand
Citizenship New Zealand
Post Office Address 58A Ngapuhi Road, Remuera, Auckland, New Zealand

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Full name of second inventor OLIVER GLEESON
Inventor's signature _____ Date 20/4/09
Residence City Auckland Country New Zealand
Citizenship New Zealand
Post Office Address 19A Ropata Avenue, Point England, Auckland, New Zealand

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Full name of third inventor EVAN STUART ERSTICH
Inventor's signature _____ Date _____
Residence City Auckland Country New Zealand
Citizenship New Zealand
Post Office Address 100 Main Highway, Ellerslie, Auckland, New Zealand

POWER OF ATTORNEY: As a named inventor, I hereby appoint the following attorney(s) and/or agent(s) to prosecute this application and transact all business in the Patent and Trademark Office connected therewith: Richard A. Giangiorgi, Reg. 24,284; Raiford A. Blackstone, Jr., Reg. 25,156; David J. Marr, Reg. 32,915; Linda L. Palomar, Reg. 37,903; James R. Foley, Reg. 39,979; James A. O'Malley, Reg. 45,952; Timothy M. McCarthy, Reg. 42,855; and Paige A. Kitzinger, Reg. 45,219.

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Full name of sole or first inventor ALASTAIR EDWIN McAULEY
Inventor's signature _____ Date 22/Jan/09
Residence City Auckland Country New Zealand
Citizenship New Zealand
Post Office Address 58A Ngapuhi Road, Remuera, Auckland, New Zealand

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Full name of second inventor OLIVER GLEESON
Inventor's signature _____ Date _____
Residence City Auckland Country New Zealand
Citizenship New Zealand
Post Office Address 19A Ropata Avenue, Point England, Auckland, New Zealand

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Full name of third inventor EVAN STUART ERSTICH
Inventor's signature E. Erstich Date 9 APR 09
Residence City Auckland Country New Zealand
Citizenship New Zealand
Post Office Address 100 Main Highway, Ellerslie, Auckland, New Zealand

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Full name of fourth inventor SIMON ERIC FREEMAN
Inventor's signature _____ Date 07 April 09
Residence City Auckland Country New Zealand
Citizenship New Zealand
Post Office Address 53 Glenvar Road, Torbay, Auckland, New Zealand

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Full name of fifth inventor NEIL GLEN DAVIES
Inventor's signature _____ Date 11 March 09
Residence City Auckland Country New Zealand
Citizenship New Zealand
Post Office Address 22A Browns Avenue, Pakuranga, Auckland, New Zealand

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Full name of sixth inventor STEPHEN JOHN SCHOENBERG
Inventor's signature _____ Date 17 Feb 09
Residence City Auckland Country New Zealand
Citizenship United States of America
Post Office Address 4/78 Waiatarua Road, Remuera, Auckland, New Zealand

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Full name of seventh inventor KAMMAN LAW
Inventor's signature _____ Date 17 Feb 09
Residence City Auckland Country New Zealand
Citizenship New Zealand
Post Office Address 1616 Dominion Road Extension, Mt. Roskill, Auckland, New Zealand

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Full name of eighth inventor CRAIG ROBERT PRENTICE
Inventor's signature _____ Date 17 FEB 09
Residence City Auckland Country New Zealand
Citizenship New Zealand
Post Office Address 95 Kiwi Esplanade, Mangere Bridge, Auckland, New Zealand

Electronic Patent Application Fee Transmittal

Application Number:	12307993
Filing Date:	
Title of Invention:	A BREATHING ASSISTANCE APPARATUS
First Named Inventor/Applicant Name:	ALASTAIR EDWIN McAULEY
Filer:	Linda L. Palomar/Tiffany Lynch
Attorney Docket Number:	1171/48067/202-PCT-US

Filed as Large Entity

U.S. National Stage under 35 USC 371 Filing Fees

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Basic Filing:				
Pages:				
Claims:				
Claims in excess of 20	1615	1	52	52
Miscellaneous-Filing:				
Oath/decl > 30 months from priority date	1617	1	130	130
Petition:				
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Extension-of-Time:				
Miscellaneous:				
		Total in USD ($)		**182**

Electronic Acknowledgement Receipt	
EFS ID:	5531341
Application Number:	12307993
International Application Number:	
Confirmation Number:	7084
Title of Invention:	A BREATHING ASSISTANCE APPARATUS
First Named Inventor/Applicant Name:	ALASTAIR EDWIN McAULEY
Customer Number:	00279
Filer:	Linda L. Palomar/Tiffany Lynch
Filer Authorized By:	Linda L. Palomar
Attorney Docket Number:	1171/48067/202-PCT-US
Receipt Date:	17-JUN-2009
Filing Date:	
Time Stamp:	11:49:21
Application Type:	U.S. National Stage under 35 USC 371

Payment information:

Submitted with Payment	yes
Payment Type	Deposit Account
Payment was successfully received in RAM	$182
RAM confirmation Number	7547
Deposit Account	201495
Authorized User	
The Director of the USPTO is hereby authorized to charge indicated fees and credit any overpayment as follows: Charge any Additional Fees required under 37 C.F.R. 1.492 (National application filing, search, and examination fees) Charge any Additional Fees required under 37 C.F.R. Section 1.17 (Patent application and reexamination processing fees)	

Charge any Additional Fees required under 37 C.F.R. Section 1.19 (Document supply fees)	
Charge any Additional Fees required under 37 C.F.R. Section 1.21 (Miscellaneous fees and charges)	

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Applicant Response to Pre-Exam Formalities Notice	DOC061709-001.pdf	242913 778d3baf6416db8c10393a2ab11c7f534bf432ca	no	5
Warnings:					
Information:					
2	Fee Worksheet (PTO-875)	fee-info.pdf	32132 df575f0820e46145969f3390f7e58207728a500e	no	2
Warnings:					
Information:					
		Total Files Size (in bytes):	275045		

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PATENT APPLICATION FEE DETERMINATION RECORD

Effective December 8, 2004

Application or Docket Number: 12/307993

CLAIMS AS FILED - PART I

	(Column 1)	(Column 2)	SMALL ENTITY TYPE ☐ RATE	FEE	OR	OTHER THAN SMALL ENTITY RATE	FEE
U.S. NATIONAL STAGE FEES							
BASIC FEE	SMALL ENT. = $ 150	LARGE ENT. = $ 300	BASIC FEE		OR	BASIC FEE	330
EXAMINATION FEE	Satisfies PCT Article 33(1)-(4) = $ 50 / $ 100	All other situations = $ 100 / $ 200	EXAM. FEE			EXAM. FEE	220
SEARCH FEE	U.S. is ISA = $ 50 / $ 100 ALL other countries = $ 200 / $ 400	All other situations = $ 250 / $ 500	SEARCH FEE			SEARCH FEE	430
FEE FOR EXTRA SPEC. PGS.	minus 100 =	/ 50 =	X $ 125 =			X $ 250 =	
TOTAL CHARGEABLE CLAIMS	32 minus 20 =	* 12	X $ 25 =		OR	X $ 50 =	624
INDEPENDENT CLAIMS	2 minus 3 =	*	X $ 100 =		OR	X $ 200 =	
MULTIPLE DEPENDENT CLAIM PRESENT		☒	+ $ 180 =		OR	+ $ 360 =	360
* If the difference in column 1 is less than zero, enter "0" in column 2			TOTAL		OR	TOTAL	1964

CLAIMS AS AMENDED - PART II

		(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA	SMALL ENTITY RATE	ADDITIONAL FEE	OR	OTHER THAN SMALL ENTITY RATE	ADDITIONAL FEE
AMENDMENT A	Total	*	Minus	**	=	X $ 25 =		OR	X $ 50 =	
	Independent	*	Minus	***	=	X $ 100 =		OR	X $ 200 =	
	FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM ☐					+ $ 180 =		OR	+ $ 360 =	
						TOTAL ADDIT. FEE		OR	TOTAL ADDIT. FEE	

		(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA	RATE	ADDITIONAL FEE	OR	RATE	ADDITIONAL FEE
AMENDMENT B	Total	*	Minus	**	=	X $ 25 =		OR	X $ 50 =	
	Independent	*	Minus	***	=	X $ 100 =		OR	X $ 200 =	
	FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM ☐					+ $ 180 =		OR	+ $ 360 =	
						TOTAL ADDIT. FEE		OR	TOTAL ADDIT. FEE	

* If the entry in column 1 is less than the entry in column 2, write "0" in column 3.

** If the "Highest Number Previously Paid For" IN THIS SPACE is less than '20', enter "20".

*** If the "Highest Number Previously Paid For" IN THIS SPACE is less than '3', enter "3".

The "Highest Number Previously Paid For" (Total or Independent) is the highest number found in the appropriate box in column 1.

U.S NATIONAL STAGE WORKSHEET (DO/EO)

U.S. APPL. NO. 12/307993 INTERNATIONAL APPL. NZ07/000185

APPLICATION FILED BY: 20 MOS., ____ OR 30 MOS., X SCREENED BY

INTERNATIONAL APPLICATION PAPERS IN THE APPLICATION FILE:

- X International application
- ___ Article 19 amendments
- X Priority Document(s) No. 2
- ___ Request Form PCT/RO/101
- ___ PCT/IB/302
- ___ PCT/IB/304
- ___ PCT/IB/306
- ___ PCT/IB/308
- ___ PCT/IB/331
- ___ OTHER PCT/IB/ 237
- ___ PCT/IPEA/409 also 416
- ___ 409 annexes to IPER
- X PCT/ISA/210 (Search report)
- ___ Search report References
- ___ Other Papers filed

WIPO PUBLICATION
PUBLICATION NO. WO 08/007985
PUBLICATION DATE 17-JAN-08
PUBLICATION LANG., ENGLISH
NOT PUBLISHED
_____U.S. only _____Requested

RECEIVED FROM THE APPLICANT: (other than checked above)

- X National application basic fee paid
- X Express Processing Requested
- ___ Translation of the International Application
- X Used the IB copy of the IA
- X Description
- X Claims
- X Drawings 21
- ___ Foreign Language in drawing
- ___ Article 19 Amendments
- ___ Amendment used in application
- ___ Article 34 Amendment
- ___ Amendment used in application
- ___ DNA
- ___ 1194 transaction done
- X Preliminary Amendment(s) filed 08 JAN 2009
- ___ second submission ____
- X Information Disclosure Statement 08 JAN 2009
- X second submission 3-4-09
- X Assignment 6-17-09
- ___ Forward to Assignment Branch
- ___ Substitute Specification ____
- ___ Small Entity Statement ____
- ___ type ____
- X Oath/Declaration (date submitted 17-JAN-09
- ___ Not executed
- X Executed
- ___ Power of Attorney
- ___ Change of Address

Data Sheet

35 USC Receipt of Request (PTO – 1399 Transmittal Letter) 08 JAN 2009
Date Acceptable oath/declaration received 6-17-09
102(e) Date 6-17-09
Date complete 35 USC 371 requirements met 6-17-09

DATE NOTICE COMPLETED

DO/EO 903 Notice of Acceptance
DO/EO 905 Notice of Missing Requirements
DO/EO 917 Notice of A defective oath or declaration
DO/EO 916 Notice of defective response
DO/EO 913 Notice of defective translation
DO/EO 909 Notification of Abandonment

UNITED STATES PATENT AND TRADEMARK OFFICE

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United States Patent and Trademark Office
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P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NUMBER	FILING or 371(c) DATE	GRP ART UNIT	FIL FEE REC'D	ATTY.DOCKET.NO	TOT CLAIMS	IND CLAIMS
12/307,993	06/17/2009		2124	1171/48067/202-PCT-US	31	2

CONFIRMATION NO. 7084

279
TREXLER, BUSHNELL, GIANGIORGI,
BLACKSTONE & MARR, LTD.
105 WEST ADAMS STREET
SUITE 3600
CHICAGO, IL 60603

FILING RECEIPT

OC000000037932906

Date Mailed: 09/25/2009

Receipt is acknowledged of this non-provisional patent application. The application will be taken up for examination in due course. Applicant will be notified as to the results of the examination. Any correspondence concerning the application must include the following identification information: the U.S. APPLICATION NUMBER, FILING DATE, NAME OF APPLICANT, and TITLE OF INVENTION. Fees transmitted by check or draft are subject to collection. Please verify the accuracy of the data presented on this receipt. **If an error is noted on this Filing Receipt, please submit a written request for a Filing Receipt Correction. Please provide a copy of this Filing Receipt with the changes noted thereon. If you received a "Notice to File Missing Parts" for this application, please submit any corrections to this Filing Receipt with your reply to the Notice. When the USPTO processes the reply to the Notice, the USPTO will generate another Filing Receipt incorporating the requested corrections**

Applicant(s)

Alastair Edwin McAuley, Auckland, NEW ZEALAND;
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Craig Robert Prentice, Auckland, NEW ZEALAND;

Power of Attorney: The patent practitioners associated with Customer Number 00279

Domestic Priority data as claimed by applicant

This application is a 371 of PCT/NZ2007/000185 07/13/2007

Foreign Applications

NEW ZEALAND 548575 07/14/2006
NEW ZEALAND 551103 11/06/2006

If Required, Foreign Filing License Granted: 09/22/2009

The country code and number of your priority application, to be used for filing abroad under the Paris Convention, is **US 12/307,993**

Projected Publication Date: 01/07/2010

Non-Publication Request: No

Early Publication Request: No

Title

BREATHING ASSISTANCE APPARATUS

Preliminary Class

PROTECTING YOUR INVENTION OUTSIDE THE UNITED STATES

Since the rights granted by a U.S. patent extend only throughout the territory of the United States and have no effect in a foreign country, an inventor who wishes patent protection in another country must apply for a patent in a specific country or in regional patent offices. Applicants may wish to consider the filing of an international application under the Patent Cooperation Treaty (PCT). An international (PCT) application generally has the same effect as a regular national patent application in each PCT-member country. The PCT process **simplifies** the filing of patent applications on the same invention in member countries, but **does not result** in a grant of "an international patent" and does not eliminate the need of applicants to file additional documents and fees in countries where patent protection is desired.

Almost every country has its own patent law, and a person desiring a patent in a particular country must make an application for patent in that country in accordance with its particular laws. Since the laws of many countries differ in various respects from the patent law of the United States, applicants are advised to seek guidance from specific foreign countries to ensure that patent rights are not lost prematurely.

Applicants also are advised that in the case of inventions made in the United States, the Director of the USPTO must issue a license before applicants can apply for a patent in a foreign country. The filing of a U.S. patent application serves as a request for a foreign filing license. The application's filing receipt contains further information and guidance as to the status of applicant's license for foreign filing.

Applicants may wish to consult the USPTO booklet, "General Information Concerning Patents" (specifically, the section entitled "Treaties and Foreign Patents") for more information on timeframes and deadlines for filing foreign patent applications. The guide is available either by contacting the USPTO Contact Center at 800-786-9199, or it can be viewed on the USPTO website at http://www.uspto.gov/web/offices/pac/doc/general/index.html.

For information on preventing theft of your intellectual property (patents, trademarks and copyrights), you may wish to consult the U.S. Government website, http://www.stopfakes.gov. Part of a Department of Commerce initiative, this website includes self-help "toolkits" giving innovators guidance on how to protect intellectual property in specific countries such as China, Korea and Mexico. For questions regarding patent enforcement issues, applicants may call the U.S. Government hotline at 1-866-999-HALT (1-866-999-4158).

LICENSE FOR FOREIGN FILING UNDER

Title 35, United States Code, Section 184

Title 37, Code of Federal Regulations, 5.11 & 5.15

GRANTED

The applicant has been granted a license under 35 U.S.C. 184, if the phrase "IF REQUIRED, FOREIGN FILING LICENSE GRANTED" followed by a date appears on this form. Such licenses are issued in all applications where the conditions for issuance of a license have been met, regardless of whether or not a license may be required as set forth in 37 CFR 5.15. The scope and limitations of this license are set forth in 37 CFR 5.15(a) unless an earlier

license has been issued under 37 CFR 5.15(b). The license is subject to revocation upon written notification. The date indicated is the effective date of the license, unless an earlier license of similar scope has been granted under 37 CFR 5.13 or 5.14.

This license is to be retained by the licensee and may be used at any time on or after the effective date thereof unless it is revoked. This license is automatically transferred to any related applications(s) filed under 37 CFR 1.53(d). This license is not retroactive.

The grant of a license does not in any way lessen the responsibility of a licensee for the security of the subject matter as imposed by any Government contract or the provisions of existing laws relating to espionage and the national security or the export of technical data. Licensees should apprise themselves of current regulations especially with respect to certain countries, of other agencies, particularly the Office of Defense Trade Controls, Department of State (with respect to Arms, Munitions and Implements of War (22 CFR 121-128)); the Bureau of Industry and Security, Department of Commerce (15 CFR parts 730-774); the Office of Foreign AssetsControl, Department of Treasury (31 CFR Parts 500+) and the Department of Energy.

NOT GRANTED

No license under 35 U.S.C. 184 has been granted at this time, if the phrase "IF REQUIRED, FOREIGN FILING LICENSE GRANTED" DOES NOT appear on this form. Applicant may still petition for a license under 37 CFR 5.12, if a license is desired before the expiration of 6 months from the filing date of the application. If 6 months has lapsed from the filing date of this application and the licensee has not received any indication of a secrecy order under 35 U.S.C. 181, the licensee may foreign file the application pursuant to 37 CFR 5.15(b).

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

U.S. APPLICATION NUMBER NO.	FIRST NAMED APPLICANT	ATTY. DOCKET NO.
12/307,993	Alastair Edwin McAuley	1171/48067/202-PCT-US

279
TREXLER, BUSHNELL, GIANGIORGI,
BLACKSTONE & MARR, LTD.
105 WEST ADAMS STREET
SUITE 3600
CHICAGO, IL 60603

INTERNATIONAL APPLICATION NO.	
PCT/NZ2007/000185	
I.A. FILING DATE	PRIORITY DATE
07/13/2007	07/14/2006

CONFIRMATION NO. 7084
371 ACCEPTANCE LETTER

OC000000037932907

Date Mailed: 09/25/2009

NOTICE OF ACCEPTANCE OF APPLICATION UNDER 35 U.S.C 371 AND 37 CFR 1.495

The applicant is hereby advised that the United States Patent and Trademark Office in its capacity as a Designated / Elected Office (37 CFR 1.495), has determined that the above identified international application has met the requirements of 35 U.S.C. 371, and is ACCEPTED for national patentability examination in the United States Patent and Trademark Office.

The United States Application Number assigned to the application is shown above and the relevant dates are:

06/17/2009	06/17/2009
DATE OF RECEIPT OF 35 U.S.C. 371(c)(1), (c)(2) and (c)(4) REQUIREMENTS	DATE OF COMPLETION OF ALL 35 U.S.C. 371 REQUIREMENTS

A Filing Receipt (PTO-103X) will be issued for the present application in due course. **THE DATE APPEARING ON THE FILING RECEIPT AS THE " FILING DATE" IS THE DATE ON WHICH THE LAST OF THE 35 U.S.C. 371 (c)(1), (c)(2) and (c)(4) REQUIREMENTS HAS BEEN RECEIVED IN THE OFFICE. THIS DATE IS SHOWN ABOVE.** *The filing date of the above identified application is the international filing date of the international application (Article 11(3) and 35 U.S.C. 363).* Once the Filing Receipt has been received, send all correspondence to the Group Art Unit designated thereon.

The following items have been received:

- Copy of the International Application filed on 01/08/2009
- Copy of the International Search Report filed on 01/08/2009
- Preliminary Amendments filed on 01/08/2009
- Information Disclosure Statements filed on 01/08/2009
- Oath or Declaration filed on 06/17/2009
- U.S. Basic National Fees filed on 01/08/2009
- Assignment filed on 06/17/2009
- Priority Documents filed on 01/08/2009
- Specification filed on 01/08/2009
- Claims filed on 01/08/2009
- Abstracts filed on 01/08/2009
- Drawings filed on 01/08/2009

FORM PCT/DO/EO/903 (371 Acceptance Notice)

Applicant is reminded that any communications to the United States Patent and Trademark Office must be mailed to the address given in the heading and include the U.S. application no. shown above (37 CFR 1.5)

VONDA M WALLACE

Telephone: (703) 756-1425

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NUMBER	FILING OR 371(C) DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO./TITLE
12/307,993	06/17/2009	Alastair Edwin McAuley	1171/48067/202-PCT-US

CONFIRMATION NO. 7084

279
TREXLER, BUSHNELL, GIANGIORGI,
BLACKSTONE & MARR, LTD.
105 WEST ADAMS STREET
SUITE 3600
CHICAGO, IL 60603

PUBLICATION NOTICE

OC000000039527272

Title:BREATHING ASSISTANCE APPARATUS

Publication No.US-2010-0000537-A1
Publication Date:01/07/2010

NOTICE OF PUBLICATION OF APPLICATION

The above-identified application will be electronically published as a patent application publication pursuant to 37 CFR 1.211, et seq. The patent application publication number and publication date are set forth above.

The publication may be accessed through the USPTO's publically available Searchable Databases via the Internet at www.uspto.gov. The direct link to access the publication is currently http://www.uspto.gov/patft/.

The publication process established by the Office does not provide for mailing a copy of the publication to applicant. A copy of the publication may be obtained from the Office upon payment of the appropriate fee set forth in 37 CFR 1.19(a)(1). Orders for copies of patent application publications are handled by the USPTO's Office of Public Records. The Office of Public Records can be reached by telephone at (703) 308-9726 or (800) 972-6382, by facsimile at (703) 305-8759, by mail addressed to the United States Patent and Trademark Office, Office of Public Records, Alexandria, VA 22313-1450 or via the Internet.

In addition, information on the status of the application, including the mailing date of Office actions and the dates of receipt of correspondence filed in the Office, may also be accessed via the Internet through the Patent Electronic Business Center at www.uspto.gov using the public side of the Patent Application Information and Retrieval (PAIR) system. The direct link to access this status information is currently http://pair.uspto.gov/. Prior to publication, such status information is confidential and may only be obtained by applicant using the private side of PAIR.

Further assistance in electronically accessing the publication, or about PAIR, is available by calling the Patent Electronic Business Center at 1-866-217-9197.

Office of Data Managment, Application Assistance Unit (571) 272-4000, or (571) 272-4200, or 1-888-786-0101

Doc code: IDS
Doc description: Information Disclosure Statement (IDS) Filed

PTO/SB/08a (11-08)
Approved for use through 12/31/2008. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (**Not for submission under 37 CFR 1.99**)		
	Application Number	12307993
	Filing Date	2009-01-08
	First Named Inventor	ALASTAIR EDWIN McAULEY
	Art Unit	
	Examiner Name	
	Attorney Docket Number	1171/48067/202

U.S.PATENTS

Examiner Initial*	Cite No	Patent Number	Kind Code[1]	Issue Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1	6951218		2005-10-04	Gradon et al.	

If you wish to add additional U.S. Patent citation information please click the Add button.

U.S.PATENT APPLICATION PUBLICATIONS

Examiner Initial*	Cite No	Publication Number	Kind Code[1]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1	20040226566		2004-11-18	Gunaratnam et al.	

If you wish to add additional U.S. Published Application citation information please click the Add button.

FOREIGN PATENT DOCUMENTS

Examiner Initial*	Cite No	Foreign Document Number[3]	Country Code[2]	Kind Code[4]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear	T[5]
	1	2004/073778	WO		2004-09-02	Resmed Ltd.		☐

If you wish to add additional Foreign Patent Document citation information please click the Add button

NON-PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc), date, pages(s), volume-issue number(s), publisher, city and/or country where published.	T[5]

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	12307993
	Filing Date	2009-01-08
	First Named Inventor	ALASTAIR EDWIN McAULEY
	Art Unit	
	Examiner Name	
	Attorney Docket Number	1171/48067/202

	1		☐

If you wish to add additional non-patent literature document citation information please click the Add button

EXAMINER SIGNATURE

Examiner Signature		Date Considered	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through a citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

[1] See Kind Codes of USPTO Patent Documents at www.USPTO.GOV or MPEP 901.04. [2] Enter office that issued the document, by the two-letter code (WIPO Standard ST.3). [3] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [4] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. [5] Applicant is to place a check mark here if English language translation is attached.

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	12307993
	Filing Date	2009-01-08
	First Named Inventor	ALASTAIR EDWIN McAULEY
	Art Unit	
	Examiner Name	
	Attorney Docket Number	1171/48067/202

CERTIFICATION STATEMENT

Please see 37 CFR 1.97 and 1.98 to make the appropriate selection(s):

☐ That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(1).

OR

☐ That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(2).

☐ See attached certification statement.

☐ Fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

☒ None

SIGNATURE

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/RAIFORD A. BLACKSTONE/	Date (YYYY-MM-DD)	2010-04-26
Name/Print	RAIFORD A. BLACKSTONE, JR.	Registration Number	25156

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 1 hour to complete, including gathering, preparing and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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The Privacy Act of 1974 (P.L. 93-579) requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

The information provided by you in this form will be subject to the following routine uses:

1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C. 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether the Freedom of Information Act requires disclosure of these record s.

2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.

3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.

4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).

5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.

6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).

7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.

8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspections or an issued patent.

9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

Electronic Acknowledgement Receipt

EFS ID:	7486958
Application Number:	12307993
International Application Number:	
Confirmation Number:	7084
Title of Invention:	BREATHING ASSISTANCE APPARATUS
First Named Inventor/Applicant Name:	Alastair Edwin McAuley
Customer Number:	00279
Filer:	Linda L. Palomar/Tiffany Lynch
Filer Authorized By:	Linda L. Palomar
Attorney Docket Number:	1171/48067/202-PCT-US
Receipt Date:	26-APR-2010
Filing Date:	17-JUN-2009
Time Stamp:	15:09:29
Application Type:	U.S. National Stage under 35 USC 371

Payment information:

Submitted with Payment	no

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Foreign Reference	WO2004073778.pdf	5893082 b885063301f669ac27ab3d7d7cd2894eea8d302a	no	179

Warnings:	
Information:	

2	Information Disclosure Statement (IDS) Filed (SB/08)	DOC042610-009.pdf	183371 7439a5d553b42f2d425c31f2ad7b6b81e051f819	no	4

Warnings:	
Information:	
This is not an USPTO supplied IDS fillable form	
Total Files Size (in bytes):	6076453

This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.

New Applications Under 35 U.S.C. 111
If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

National Stage of an International Application under 35 U.S.C. 371
If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office
If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
2 September 2004 (02.09.2004)

PCT

(10) International Publication Number
WO 2004/073778 A1

(51) International Patent Classification[7]: A61M 16/06

(21) International Application Number:
PCT/AU2004/000207

(22) International Filing Date: 20 February 2004 (20.02.2004)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:

60/448,465	21 February 2003 (21.02.2003)	US
60/482,872	27 June 2003 (27.06.2003)	US
60/488,810	22 July 2003 (22.07.2003)	US
60/494,119	12 August 2003 (12.08.2003)	US
60/529,696	16 December 2003 (16.12.2003)	US

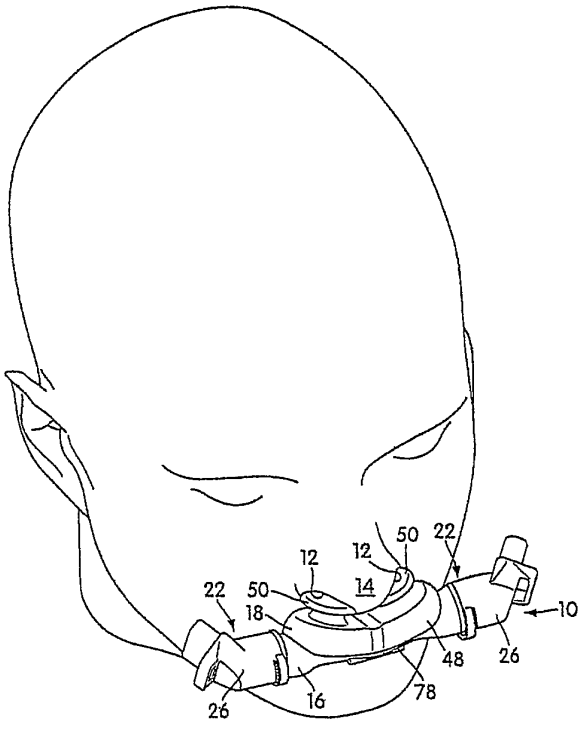
(71) Applicant *(for all designated States except US)*: **RESMED LIMITED** [AU/AU]; 97 Waterloo Road, North Ryde, New South Wales 2113 (AU).

(72) Inventors; and

(75) Inventors/Applicants *(for US only)*: **GUNARATNAM, Michael, Kassipillai** [AU/AU]; 3 Keiley Street, Marsfield, New South Wales 212 (AU). **KWOK, Philip, Rodney** [AU/AU]; 15 Davies Street, Chatswood, New South Wales 2067 (AU). **GUNEY, Memduh** [AU/AU]; 52 Eastgate Avenue, Killara, New South Wales 2071 (AU). **LITHGOW, Perry, David** [AU/AU]; 9 Staff Avenue, Glenwood, New South Wales 2768 (AU). **DARKIN, Donald** [GB/AU]; 2 Athella Place, Dural, New South Wales 2158 (AU). **LYNCH, Susan, Robyn** [GB/AU]; Unit 7/14 Forest Grove, Epping, New South Wales 2121 (AU). **HITCHCOCK, Robin, Garth** [AU/AU]; Unit 21, 9-13 Castle Street, North Parramatta, New South Wales 2151 (AU). **VELISS, Lee, James** [AU/AU]; Unit 18/1-5 Station Street, West Ryde, New South Wales 2114 (AU). **SOKOLOV, Richard** [AU/AU]; 4 Bardwell Crescent, Earlwood, New South Wales 2206 (AU).

[Continued on next page]

(54) Title: NASAL ASSEMBLY



(57) Abstract: A nasal assembly (10) for delivering breathable gas to a patient includes a frame (16) having an integrally formed first connector portion (24). A nozzle assembly (18) includes a gusset or base portion (48) and a pair of nozzles (50). At least one inlet conduit is structured to deliver breathable gas into the frame and nozzle assembly for breathing by the patient. A pair of second connector portions (26) are removably and rotatably connected to respective first connector portions of the frame and are in communication with respective inlet conduits, *e.g.*, directly or *via* angle connectors. A headgear assembly (20) is removably connected to the pair of second connector portions and/or the angle connectors so as to maintain the frame and the nozzle assembly in a desired adjusted position on the patient's face.

WO 2004/073778 A1

(74) **Agents: DAVIDSON, Geoffrey, Robert** et al.; Halford & Co., 1 Market Street, Sydney, New South Wales 2000 (AU).

(81) **Designated States** *(unless otherwise indicated, for every kind of national protection available)*: AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BW, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NA, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, YU, ZA, ZM, ZW.

(84) **Designated States** *(unless otherwise indicated, for every kind of regional protection available)*: ARIPO (BW, GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IT, LU, MC, NL, PT, RO, SE, SI, SK, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

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NASAL ASSEMBLY

FIELD OF THE INVENTION

[0001] The present invention relates to a nasal assembly used for treatment, e.g., of Sleep Disordered Breathing (SDB) with Continuous Positive Airway Pressure (CPAP) or Non-invasive Positive Pressure Ventilation (NPPV).

CROSS-REFERENCE TO PRIORITY APPLICATIONS

[0002] This application claims the benefit of U.S. provisional applications nos. 60/529,696, filed December 16, 2003, 60/494,119, filed August 12, 2003, 60/448,465, filed February 21, 2003, 60/482,872, filed June 27, 2003, and 60/488,810, filed July 22, 2003, each of which is incorporated herein in its entirety.

BACKGROUND OF THE INVENTION

[0003] Some nasal assemblies used in the treatment of SDB are designed for insertion into the nasal passages of the patient. Air or other breathable gas is supplied by a blower and passed along a flexible conduit to the nasal assembly.

[0004] The nasal assembly generally includes a relatively rigid shell, e.g., a frame, and a pair of nozzles (which may be in the form of nasal pillows, nasal prongs, cannula, or nasal puffs) that are mounted on the rigid shell and structured to be inserted into the nasal passages of the patient. The nozzles are usually held in place using a headgear assembly, the relatively rigid shell and headgear assembly being joined using some form of connector.

[0005] One form of known nasal assembly is described in U.S. Patent No. 4,782,832 (Trimble et al.). Trimble discloses a nasal puff assembly 20 that includes a nasal puff 22 adapted to be worn adjacent the nose of a patient, together with a harness assembly 24 adapted to be worn over the head of the patient. The harness assembly 24 is designed to operatively hold puff 22 adjacent and partially within the nasal passages of the patient.

[0006] The puff 22 is in the form of a generally Y-shaped rigid hollow plenum chamber 28 together with a pair of laterally spaced apart nares elements 30. Adjustability of the nares elements 30 may be provided by rotatably mounting the elements 30 to the plenum chamber 28 and mounting the elements 30 in slots permitting selective lateral positioning of the elements 30 with respect to each other. Also, the harness assembly 24 may be adjusted to adjust the fit and seal of the nares elements 30 during use. That is, the force required to

maintain a sufficient seal is directly associated with the force required to maintain a desired fit. Thus, adjustment of the fit or stability of the nasal assembly directly affects the seal, which can adversely affect patient comfort.

[0007] Other examples of nasal pillows or cannula mounted to rigid shells are disclosed in U.S. Patent Nos. 5,724,965 and 6,431,172.

[0008] A nasal mask assembly manufactured by Viasys, i.e., Spiritus, includes a plenum chamber with a pair of adjacent or laterally spaced nares elements. A harness assembly is engaged with the plenum chamber to adjust the fit and seal of the nares elements during use. Similar to Trimble, adjustment of the fit or stability of the nasal assembly directly affects the seal, which can adversely affect patient comfort.

[0009] A nasal mask assembly manufactured by InnoMed, i.e., Nasal Aire, includes a plenum chamber with a pair of adjacent or laterally spaced nares elements. The nares elements are structured to engage within the mucosal surfaces or internal passages of the patient's nose to maintain the nasal mask assembly on the patient's face and to provide a seal. See, e.g., U.S. Patent No. 5,533,506.

[0010] A nasal mask assembly manufactured by Stevenson Industries (see U.S. Patent No. 6,012,455), i.e., CPAP-Pro, includes a dental anchor, a platform, and air supply tubes having nasal pads, wherein the platform supports the air supply tubes. The dental anchor is sized to be engaged between the teeth in the patient's mouth so as to retain the assembly in place.

[0011] PCT Application Publication No. WO 00/13751 discloses a device that includes gas delivery elements positioned into engagement with the patient's nose by a mouthpiece fitted to the patient's teeth.

[0012] A common problem with known nasal assemblies, such as those discussed above, is patient comfort. For example, the prongs tend to irritate the patient's nose due to the tension applied by the headgear assembly that pulls the rigid shell and prongs towards the patient's nose.

[0013] Another problem is achievement of a sealing fit with the patient's nasal passages without sacrificing patient comfort.

[0014] Another problem is irritation of the inside of the patient's nostrils caused by contact with the prongs, e.g., an edge thereof.

[0015] Another problem is irritation of the inside of the patient's nostrils caused by air jetting (air flow irritation) from the prongs.

[0016] Another problem is adjustment of the nasal assemblies relative to the nose and/or head of the patient so as to accommodate various shapes and angles of patient's noses.

[0017] Still another problem is the direct association between sealing and stability forces that can affect patient comfort.

SUMMARY OF THE INVENTION

[0018] One aspect of the invention is directed towards a nasal assembly that provides more comfort to the patient.

[0019] Another aspect of the invention is directed towards a nasal assembly that provides an effective seal with the patient's nasal passages. Preferably, the nasal assembly is a nozzle assembly including nozzles which comfortably come into contact with the external rim of the nares and avoid the sensitive internal passages (e.g., mucosal surfaces or internal passages) of the nasal passage.

[0020] Still another aspect of the invention is directed towards a nasal assembly that does not rely on tension from the headgear assembly to provide an effective seal between the nozzles and the patient's nasal passages.

[0021] Still another aspect of the invention is directed towards a nasal assembly that is unobtrusive.

[0022] Still another aspect of the invention is directed towards a nasal assembly that is easy to use.

[0023] Still another aspect of the invention is directed towards a nasal assembly that maintains a headgear adjustment setting.

[0024] Still another aspect of the invention is directed towards a nasal assembly that helps decouple sealing and stability forces. Specifically, one aspect of the invention is directed towards a nasal assembly that is structured such that the stability forces that act to maintain the nasal assembly on the patient's face are separated or at least better distinguished from the sealing forces that act to maintain a seal between the nasal assembly and the patient's face.

[0025] Yet another aspect of the invention is directed towards a nasal assembly that provides a greater range of movement for nozzles of the nasal assembly.

[0026] Another aspect of the invention provides a nasal assembly for delivering breathable gas to a patient. The nasal assembly includes a frame having a main body and a side frame member provided on each lateral side of the main body, each side frame member including an integrally formed first connector portion. A nozzle assembly includes a gusset or base portion and a pair of nozzles. The nozzle assembly is coupled with the main body of the frame with the pair of nozzles structured to sealingly engage with nasal passages of a patient's nose in use. A pair of inlet conduits are structured to deliver breathable gas into the

frame and nozzle assembly for breathing by the patient. A pair of second connector portions are removably and rotatably connected to respective first connector portions of the frame. The second connector portions are in communication with the inlet conduits via angle connectors. A headgear assembly is removably connected to at least one of the second connector portions and the angle connectors so as to maintain the frame and the nozzle assembly in a desired adjusted position on the patient's face.

[0027] Other aspects, features and advantages of this invention will become apparent from the following detailed description when taken in conjunction with the accompanying drawings, which are a part of this disclosure and which illustrate, by way of example, principles of this invention.

BRIEF DESCRIPTION OF THE DRAWINGS

[0028] The accompanying drawings facilitate an understanding of the various embodiments of this invention. In such drawings:

[0029] Fig. 1 is a perspective view illustrating a partial nasal assembly constructed in accordance with an embodiment of the invention mounted to a patient's head and engaged with nasal passages of the patient;

[0030] Fig. 2 is a front view of a frame of the nasal assembly shown in Fig. 1 with some parts removed for clarity;

[0031] Fig. 3 is a cross-sectional view of the frame shown in Fig. 2;

[0032] Fig. 4 is a side view of the frame shown in Fig. 2;

[0033] Fig. 5 is a front view of a nozzle assembly of the nasal assembly shown in Fig. 1;

[0034] Fig. 6 is a front cross-sectional view of the nozzle assembly shown in Fig. 5;

[0035] Fig. 7 is a side view of the nozzle assembly shown in Fig. 5;

[0036] Fig. 8 is a side cross-sectional view of the nozzle assembly shown in Fig. 5;

[0037] Fig. 9 is a perspective view of an embodiment of an inlet conduit and headgear connector assembly of the nasal assembly shown in Fig. 1;

[0038] Fig. 10 is a rear perspective view of the inlet conduit and headgear connector assembly shown in Fig. 9;

[0039] Fig. 11 is a perspective view of another embodiment of an inlet conduit and headgear connector assembly adapted to be used with the nasal assembly shown in Fig. 1;

[0040] Fig. 12 is a rear perspective view of the inlet conduit and headgear connector assembly shown in Fig. 11;

[0041] Fig. 13 is a side view illustrating an over-the-head inlet conduit routing for the nasal assembly shown in Fig. 1;

[0042] Fig. 14 is a side view illustrating an under-the-chin inlet conduit routing for the nasal assembly shown in Fig. 1;

[0043] Fig. 15 is a perspective view illustrating a connector for use in routing the inlet conduits over the head of the patient;

[0044] Fig. 16 is a perspective view illustrating a connector for use in routing the inlet conduits under the chin of the patient;

[0045] Fig. 17 is a perspective view illustrating a flow generator connector for use in connecting the nasal assembly shown in Fig. 1 to a pressurized supply;

[0046] Fig. 18 is a side view illustrating an embodiment of headgear components for use with the nasal assembly shown in Fig. 1;

[0047] Fig. 19 is a schematic view illustrating a patient's nose having a substantially flat alar angle;

[0048] Fig. 20 is a schematic view illustrating a patient's nose having a substantially steep alar angle;

[0049] Fig. 21 is a schematic view illustrating an embodiment of a sealing zone of a nozzle;

[0050] Fig. 22 is a graph illustrating average nostril ratios opening/entrance;

[0051] Fig. 23 is a schematic view illustrating an embodiment for calculating a base major axis of a nozzle;

[0052] Fig. 24 is a schematic view illustrating an embodiment for calculating a base minor axis of a nozzle;

[0053] Fig. 25 is a partial perspective view illustrating another embodiment of a nasal assembly mounted to a patient's head and engaged with nasal passages of the patient;

[0054] Fig. 26 is a partial front perspective view of the nasal assembly shown in Fig. 25;

[0055] Fig. 27 is a cross-sectional view of the nasal assembly shown in Fig. 25;

[0056] Fig. 28 is a front perspective view of a frame of the nasal assembly shown in Fig. 25;

[0057] Fig. 29 is a rear perspective view of the frame shown in Fig. 28;

[0058] Fig. 30 is a partial front perspective view of a half of the nozzle assembly of the nasal assembly shown in Fig. 25;

[0059] Fig. 31 is a side cross-sectional view of the nozzle assembly shown in Fig. 30;

[0060] Fig. 32 is a perspective view illustrating an embodiment of an inlet conduit and headgear connector assembly of the nasal assembly shown in Fig. 25;

[0061] Fig. 33 is a rear perspective view of the inlet conduit and headgear connector assembly shown in Fig. 32;

[0062] Fig. 34 is a cross-sectional view of the inlet conduit and headgear connector assembly shown in Fig. 32 with the flexible arms in phantom;

[0063] Fig. 35 is a perspective view of a flow generator connector for use in connecting tubes for use with the nasal assembly shown in Fig. 25 to a pressurized supply;

[0064] Fig. 36 is a side view illustrating the routing of the inlet conduits of the nasal assembly shown in Fig. 25;

[0065] Fig. 37 is a side view illustrating the nasal assembly shown in Fig. 25 mounted to a patient's head;

[0066] Fig. 38 is a perspective view illustrating another embodiment of a nasal assembly mounted to a patient's head and engaged with nasal passages of the patient;

[0067] Fig. 38B is a perspective view illustrating an inlet conduit and an inlet conduit and headgear connector of the nasal assembly shown in Fig. 38;

[0068] Fig. 39 is a perspective view of the nasal assembly shown in Fig. 38;

[0069] Fig. 40 is a perspective view of a frame of the nasal assembly shown in Fig. 38;

[0070] Fig. 41 is a perspective view of a nozzle assembly of the nasal assembly shown in Fig. 38;

[0071] Fig. 42 is a perspective view illustrating the nozzle assembly shown in Fig. 41 mounted to the frame to shown in Fig. 40;

[0072] Fig. 43 is a cross-sectional view of the nasal assembly shown in Fig. 38;

[0073] Fig. 44 is a side cross-sectional view of the nasal assembly shown in Fig. 38;

[0074] Fig. 45 is a side view illustrating the nasal assembly shown in Fig. 38 mounted to a patient's head showing two inlet configurations;

[0075] Fig. 46 is a schematic force diagram illustrating some of the forces that are developed when the nasal assembly shown in Fig. 38 is mounted to the patient's head;

[0076] Fig. 47 is a cross-sectional view of an embodiment of an inlet conduit engaged with an embodiment of an angle connector for delivering breathable gas;

[0077] Fig. 47B is a perspective view illustrating another embodiment of an inlet conduit;

[0078] Fig. 48 is a cross-sectional view illustrating another embodiment of an inlet conduit engaged with another embodiment of a flow generator connector for delivering breathable gas;

[0079] Fig. 48B is perspective view illustrating another embodiment of an inlet conduit;

[0080] Fig. 49 is a perspective view illustrating an embodiment of an inlet conduit of the nasal assembly shown in Fig. 38;

[0081] Fig. 50 is a side view illustrating the nasal assembly shown in Fig. 38 prior to engagement with nasal passages of the patient;

[0082] Fig. 51 is a front view illustrating the nasal assembly shown in Fig. 38 (in cross-section) engaged with nasal passages of the patient;

[0083] Fig. 52 is a perspective view illustrating another embodiment of a nasal assembly mounted to a patient's head and engaged with nasal passages of the patient with two inlet configurations shown;

[0084] Fig. 53 is a perspective view illustrating the nasal assembly shown in Fig. 52;

[0085] Fig. 54 is a cross-sectional view illustrating a nozzle assembly being engaged with a frame of the nasal assembly shown in Fig. 52;

[0086] Fig. 55 is a perspective view illustrating an inlet conduit and headgear connector assembly of the nasal assembly shown in Fig. 52;

[0087] Fig. 56 is a cross-sectional view illustrating the inlet conduit and headgear connector assembly of the nasal assembly shown in Fig. 52;

[0088] Fig. 57 is a cross-sectional side view illustrating the nasal assembly shown in Fig. 52 about to be engaged with nasal passages of the patient;

[0089] Fig. 58 is a front view illustrating the nasal assembly shown in Fig. 52 (in cross-section) being engaged with nasal passages of the patient;

[0090] Fig. 59 is a perspective view illustrating another embodiment of a nasal assembly mounted to a patient's head and engaged with nasal passages of the patient;

[0091] Fig. 60 is a perspective view of the nasal assembly shown in Fig. 59 removed from a patient's head;

[0092] Fig. 61 is an exploded view of a portion of the nasal assembly shown in Fig. 59 illustrating the frame, nozzle assembly, and clip thereof;

[0093] Fig. 62 is a perspective view of a portion of the nasal assembly shown in Fig. 59 illustrating the clip being engaged with the frame and nozzle assembly;

[0094] Fig. 63 is a perspective view of a portion of the nasal assembly shown in Fig. 59 illustrating the engagement between the frame, nozzle assembly, and clip;

[0095] Fig. 64 is a partial cross-sectional view of a portion of the nasal assembly shown in Fig. 59 illustrating the engagement between the frame, nozzle assembly, and clip;

[0096] Fig. 65 is a top perspective view of a portion of the nasal assembly shown in Fig. 59;

[0097] Fig. 65A is a partial enlarged view of the cushion shown in Fig. 65;

[0098] Fig. 65B is a schematic diagram illustrating force distribution according to one aspect of the present invention;

[0099] Fig. 66 is a rear perspective view of a portion of an alternative embodiment of a nasal assembly illustrating the engagement between the frame, nozzle assembly, and clip;

[00100] Fig. 67 is a rear perspective illustrating the engagement between another embodiment of the frame, nozzle assembly, and clip;

[00101] Fig. 68 is a perspective view illustrating the nozzle assembly shown in Fig. 66 being engaged with the frame shown in Fig. 66;

[00102] Fig. 69 is a perspective view illustrating the nozzle assembly shown in Fig. 67 being engaged with the frame shown in Fig. 67;

[00103] Fig. 70 is a perspective view illustrating the clip shown in Fig. 66 being engaged with the frame and nozzle assembly shown in Fig. 66;

[00104] Fig. 71 is a perspective view illustrating the clip shown in Fig. 67 being engaged with the frame and nozzle assembly shown in Fig. 67;

[00105] Fig. 72 is a perspective view of a second connector portion of the nasal assembly shown in Fig. 59;

[00106] Fig. 73 is a cross-sectional view of a portion of the nasal assembly shown in Fig. 59 illustrating the engagement between the frame, second connector portion, and angle connector;

[00107] Fig. 74 is a perspective view of an angle connector of the nasal assembly shown in Fig. 59;

[00108] Fig. 74B is a perspective similar to Fig. 74 but at a different angle;

[00109] Fig. 75 is a side view of the angle connector shown in Fig. 74;

[00110] Fig. 76 is a cross-sectional view of the angle connector shown in Fig. 74;

[00111] Fig. 76A illustrates another embodiment of the present invention;

[00112] Fig. 76B is an exploded view of Fig. 76A;

[00113] Fig. 76C illustrates a second connector portion of the assembly of Fig. 76A;

[00114] Fig. 76D illustrates an angle connector used in the assembly of Fig. 76A;

[00115] Fig. 77 is a perspective view of a flow generator connector of the nasal assembly shown in Fig. 59;

[00116] Fig. 78 is a cross-sectional view of the flow generator connector shown in Fig. 77;

[00117] Fig. 79 is a cross-sectional view of an embodiment of an inlet conduit of the nasal assembly shown in Fig. 59;

[00118] Fig. 80 is a perspective view of headgear yoke of the headgear assembly of the nasal assembly shown in Fig. 59;

[00119] Fig. 81 is a perspective view illustrating engagement between the headgear yoke (Fig. 80) and angle connector (Fig. 74);

[00120] Fig. 82 is a cross-section through line 82-82 of Fig. 81;

[00121] Fig. 83 is a perspective view of a headgear buckle of the nasal assembly shown in Fig. 59;

[00122] Fig. 84 is a perspective view of the nasal assembly shown in Fig. 59 illustrating the routing of the headgear assembly;

[00123] Fig. 85 is another perspective view of the nasal assembly shown in Fig. 59 illustrating the routing of the headgear assembly;

[00124] Fig. 86 is a top view illustrating a nasal assembly constructed in accordance with an embodiment of the invention;

[00125] Fig. 87 is a side view of the nasal assembly shown in Fig. 86;

[00126] Fig. 88 is a bottom view of the nasal assembly shown in Fig. 86;

[00127] Fig. 89 is an exploded view of a portion of the nasal assembly shown in Fig. 86;

[00128] Fig. 90 is a perspective view of a portion of an embodiment of a nasal assembly;

[00129] Fig. 91 is a top view of a headgear connector according to an alternative embodiment of the invention;

[00130] Fig. 92 is a perspective view of an upper portion of a central conduit of the nasal assembly shown in Fig. 90;

[00131] Fig. 93 is a top view of the upper portion of the central conduit shown in Fig. 92;

[00132] Fig. 94 is a perspective view of a lower portion of a central conduit of the nasal assembly shown in Fig. 90;

[00133] Fig. 95 is a bottom view of the lower portion of the central conduit shown in Fig. 94;

[00134] Fig. 96 is a perspective view of an inlet conduit of the nasal assembly shown in Fig. 86;

[00135] Fig. 96A is a schematic view of a Y-shaped inlet connector of the nasal assembly shown in Fig. 86;

[00136] Fig. 97 is a perspective view of an inlet connector of the nasal assembly shown in Fig. 86;

[00137] Fig. 97A is a schematic view of the nasal assembly shown in Fig. 86 with the nozzles in a first position adjacent to the nasal passages of the patient;

[00138] Fig. 97B is a schematic view of the nasal assembly shown in Fig. 86 with the nozzles in a second position in sealing engagement with the nasal passages of the patient;

[00139] Fig. 98 is a perspective view of another embodiment of a nasal assembly;

[00140] Fig. 99 is an enlarged perspective view of nozzles and a gusset portion of the nasal assembly shown in Fig. 98;

[00141] Fig. 100 is an enlarged perspective view of inlet conduits of the nasal assembly shown in Fig. 98;

[00142] Fig. 101 is a front perspective view illustrating the nasal assembly shown in Fig. 98 mounted to a patient's head;

[00143] Fig. 102 is a rear perspective view illustrating the nasal assembly shown in Fig. 98 mounted to a patient's head;

[00144] Fig. 103 is a front perspective view illustrating the nasal assembly shown in Fig. 98 engaged with nasal passages of the patient;

[00145] Fig. 104 is a side perspective view illustrating the nasal assembly shown in Fig. 98 engaged with the nasal passages of the patient;

[00146] Fig. 105 is a side view illustrating the nasal assembly shown in Fig. 98 engaged with the nasal passages of the patient;

[00147] Fig. 106 is a front perspective view illustrating the nasal assembly shown in Fig. 98 engaged with nasal passages of the patient;

[00148] Fig. 107 is a perspective view of another embodiment of a nasal assembly mounted to a patient's head;

[00149] Fig. 107-1 is a perspective view of yet another embodiment of the present invention;

[00150] Fig. 107-2 is a perspective view of yet another embodiment of the present invention;

[00151] Figs. 107A-107C illustrate yet another alternative embodiment of the present invention;

[00152] Figs. 107D and 107E illustrate still another embodiment according to the present invention;

[00153] Fig. 107F illustrates another alternative embodiment of the present invention;

[00154] Figs. 107G and 107H illustrate another alternative embodiment of the present invention;

[00155] Fig. 107I illustrates still another embodiment of the present invention;

[00156] Fig. 107J illustrates yet another alternative embodiment of the present invention;

[00157] Figs. 107K and 107L illustrate yet another embodiment of the present invention;

[00158] Figs. 107M-107Q illustrate cross-sections of alternative nozzles according to the present invention;

[00159] Fig. 107R illustrates a perspective view of two nozzles like the nozzle shown in Fig. 107Q;

[00160] Fig. 108 is a perspective view of yet another embodiment of a nasal assembly;

[00161] Figs. 108A and 108B illustrate a tube retainer according to an embodiment of the present invention;

[00162] Fig. 108C illustrates another tube retainer according to an embodiment of the present invention;

[00163] Fig. 109 is an isometric view illustrating a portion of the nasal assembly shown in Fig. 108;

[00164] Fig. 110 is a cross-sectional view of a portion of a nasal assembly according to the present invention;

[00165] Figs. 110-1 and 110-2 illustrate cross-sectional views of a vent aperture according to the present invention;

[00166] Fig. 110A is a partial enlarged cross-sectional view of the left hand side of Fig. 110;

[00167] Fig. 110B is an partial enlarged cross-sectional view of the right hand side of Fig. 110;

[00168] Fig. 111 is an exploded perspective view showing the interface between seal ring and elbow swivel according to an embodiment of the present invention;

[00169] Fig. 112 is a partial cross-sectional view of a portion of the mask assembly shown in Fig. 108;

[00170] Fig. 113 illustrates still another embodiment of the present invention with an integral plug and seal assembly;

[00171] Figs. 114-126 illustrate yet another embodiment of the present invention;

[00172] Figs. 127-130 illustrate still another embodiment of the present invention;

[00173] Figs. 131-133 illustrate yet another swivel elbow according to an embodiment of the present invention; and

[00174] Figs. 134-135 illustrate further alternative embodiments of the present invention.

DETAILED DESCRIPTION OF ILLUSTRATED EMBODIMENTS

[00175] The following includes descriptions of several main illustrated embodiments of the present invention. Each illustrated main embodiment includes features that may be used with and/or in the other embodiments, as would be apparent to those of ordinary skill in the art.

FIRST ILLUSTRATED EMBODIMENT

[00176] Fig. 1 shows an embodiment of a nasal assembly 10 structured to deliver breathable gas to nasal passages 12 of a patient's nose 14. The nasal assembly 10 includes a frame 16 and a nozzle assembly 18 that may be permanently or removably connected to the frame 16. A headgear assembly 20 (see Fig. 18) is preferably removably attached to connection assembly 22 to maintain the frame 16 and nozzle assembly 18 in a desired adjusted position on the patient's face. Inlet conduits (see Fig. 49 for example) are also removably attached to the frame 16 by a connection assembly 22 to deliver breathable gas into the frame 16 and nozzle assembly 18 for breathing by the patient. The headgear assembly 20 and inlet conduits are removably attached to the frame 16 by an inlet conduit and headgear connection assembly 22. The connection assembly 22 includes first connector portions 24 (see Figs. 2 and 3) provided by the frame 16 and second connector portions 26 adapted to be removably coupled with the first connector portions 24. The second connector portions 26 are removably connected to the headgear assembly 20 and the inlet conduits, as will be further discussed.

[00177] As shown in Figs. 2-4, the frame 16 includes a main body 28 that provides a central opening 30 for accommodating the nozzle assembly 18. The frame 16 also includes side frame members 32 provided on each lateral side of the main body 28. The side frame members 32 are preferably formed in one piece with the main body 28 of the frame 16. In the illustrated embodiment, the frame 16 is a rigid or semi-rigid structure formed from a polymer material. However, the frame 16 may be semi-rigid to allow flexibility of the frame 16 with respect to the patient's face in use. The frame 16 may also be semi-rigid in certain regions for customized flex in certain regions of the frame 16.

[00178] Each side frame member 32 includes a first connector portion 24 that is integrally formed therewith. As best shown in Figs. 2 and 3, the first connector portion 24 includes a connecting section 34 and an indexing section 36. The connecting section 34 is structured to

interlock with the second connector portion 26 to prevent axial disengagement of the second connector portion 26 from the first connector portion 24. The indexing section 36 is structured to ratchet/detent with the second connector portion 26 to allow selective circumferential adjustment of the second connector portion 26 with respect to the first connector portion 24 about an axis during fit whilst remaining "locked" in adjusted position during usage.

[00179] Specifically, the connecting section 34 of each side frame member 32 includes a series of grooves or slots 37 that separates the connecting section 34 into a plurality of resiliently flexible arms 38 that are structured to flex radially inwardly and outwardly. Each arm 38 provides a rib portion 40 at the free end thereof. In use, the rib portions 40 of the plurality of arms 38 are adapted to engage with corresponding portions of the second connector portion 26 for coupling the first and second connector portions 24, 26 with one another. For example, the first and second connector portions 24, 26 interlock with one another to prevent accidental disengagement of the second connector portion 26 from the first connector portion 24 if a force is applied to the second connector portion 26 axially away from the first connector portion 24. Moreover, the first and second connector portions 24, 26 mate with one another to provide a good seal.

[00180] The indexing section 36 of each side frame member 32 includes a plurality of teeth 42. The teeth 42 are structured so as to selectively engage a tooth 44 provided on the second connector portion 26 (see Figs. 9 and 10). As a result, the second connector portion 26 can be rotated to a desired position with respect to the frame 16. In use, the tooth 44 on the second connector portion 26 engages between selective teeth 42 provided on the indexing section 36 in the desired position and rotationally locks the second connector portion 26 with respect to the first connector portion 24 and hence the frame 16. For adjustment, the user can manually change the position of the tooth 66 and the teeth 42.

[00181] In accordance with one embodiment, the teeth 42 of the indexing section 36 can be configured so that when a predetermined torque is applied to the second connector portion 26, the teeth 42 will automatically force the tooth 44 of the second connector portion 26 outwardly to allow rotation of the second connector portion 26 until the torque is removed and the teeth 42 reengage with the tooth 44 of the second connector portion 26. The second connector portion 26 can thus be rotationally adjusted or indexed with respect to the frame 16 within a predetermined angle. The angle of available rotational adjustment can be altered as desired by altering the number and positioning of the teeth 42 on the indexing section 36. The adjustment angle range allows the patient to adjust the position of the nozzle assembly

18 relative to the nose of the patient. For optimal positioning, in one preferred embodiment, nozzle assembly 18 is formed from a one part molded silicone piece that attaches to frame 16.

[00182] In the illustrated embodiment, the adjusting or indexing operation is oriented perpendicular to the connecting operation in order to minimize potential disengagement of the second connector portion 26 from the first connector portion 24.

[00183] As best shown in Fig. 4, the main body 28 includes opposing side walls 46 that define the central opening 30 for accommodating the nozzle assembly 18. The side walls 46 are adapted to engage with corresponding portions of the nozzle assembly 18 for coupling the nozzle assembly 18 and the frame 16 with one another, as will be further discussed.

[00184] As shown in Figs. 5-8, the nozzle assembly 18 includes a base portion 48 and a pair of nozzles 50 attached thereto. The base portion 48 has side walls 52 adapted to sealingly engage with the side walls 46 of the frame 16 and a central wall 54. The pair of nozzles 50 each have a first portion 56 and a second portion 58. The first portion 56 is attached to the central wall 54 of the base portion 48 in communication with respective outlet openings provided in the central wall 54. The second portion 58 is structured to sealingly engage with nasal passages 12 of the patient's nose 14 in use and to provide a seal between the nasal assembly 10 and the patient's nasal passages 12. When the nozzle assembly 18 is attached to the frame 16, the nozzle assembly 18 and the frame 16 together form a conduit for directing breathable gas to the patient's nose through the pair of nozzles 50.

[00185] In the illustrated embodiment, the nozzle assembly 18 is removably attached to the frame 16 with a snap, e.g., snap-fit, push-pin fit, or stretch over fit, which allows for simple assembly. For example, the side walls 52 of the base portion 48 may include a rib or groove/recess that is structured to interlock with a recess/rib provided on respective side walls 46 of the frame 16 with a snap-fit. However, the nozzle assembly 18 may be removably attached to the frame 16 in any other suitable manner, e.g., friction or interference fit and/or a tongue and groove arrangement, as is known in the art. Alternatively, the nozzle assembly 18 may be rigidly coupled to the frame 16 by an adhesive or fasteners, for example. Also, the nozzle assembly 18 may be formed in one piece with the frame 16, or over-molded. That is, the nozzle assembly and frame may be a one-piece structure with different thicknesses and hardnesses to add rigidity.

[00186] Preferably, the nozzle assembly 18 is flexible, to thereby allow relative movement between the nozzle assembly 18 and the frame 16, for increased comfort and accommodation of variations in patient facial features. Moreover, the base portion 48 is structured such that it can expand and contract to alter a distance between the frame 16 and the pair of nozzles 50,

as will be further discussed below. That is, the central wall 54 is preferably made of a resilient and/or flexible material structured to deform, e.g., inflate upon introduction of pressurized gas, from a generally flat configuration to a generally curved configuration in use to thereby move the nozzles 50 towards the patient's nose. Other portions of the base portion 48, e.g., side walls 52, may be structured to deform/inflate as well.

[00187] In the illustrated embodiment, the base portion 48 has a generally dog-bone shape. However, the base portion 48 may have any suitable shape, including shapes to avoid contact with sensitive regions of the patient's face, e.g., notched base shape, to prevent contact with the patient's septum or otherwise minimize contact pressure in these sensitive regions.

[00188] As best shown in Figs. 1, 5, and 6, the second portion 58 of the nasal assembly is contoured (e.g., tapered, cone-shaped, truncated hollow cone, etc.) with a portion that seals on the underside of the nostrils (e.g., an area about the rim of the nostril openings) and another portion that enters into the nasal passage of the patient's nose in use. However, the nozzles 50 may be in the form of nasal prongs, cannula, or nasal puffs, for example, and may sealingly engage with the nasal passages 12 in any suitable manner. For example, the nozzles 50 may seal within the nasal passages 12, against the nasal passages 12, around the nasal passages 12, or combinations thereof. The nozzles 50 may be contoured to match the interior anatomical profile of the patient's nose. Moreover, different size and/or shape nozzles, e.g., small, medium, and large, may be provided to accommodate a range of patient's noses.

[00189] In the illustrated embodiment, the first portion 56 of the nozzles 50 have a reduced cross-section with respect to the second portion 58 to allow the nozzles 50 to move relative to the base portion 48, and hence the frame 16, for increased comfort and accommodation of variations in patient facial features.

[00190] In one embodiment, the nasal assembly 10 uses patient-customized nozzles which may be removably mounted to the base portion 48 or the frame 16. In a preferred form, the nozzles are constructed from a substantially flexible polymer material, such as a silicone elastomer. A unique nozzle can be made match each patient's nose by first scanning their nose, either in situ or remotely, and then using the data for manufacture of the interface, for example, a mold maker. Scanning can be done using either non-contact or contact methods. Non-contact, for example photographically, or by physical contact with a probe or by collecting an impression of the inside of the nares of the desired contact interface. Once a pair of suitable nozzles are made, they are sent to the customer to be fitted to a patient. Advantage of the pre-formed or customized shape is that cross-sectional area may be maximized to reduce flow impedance. Also, the use of pre-formed shapes improves comfort

and increased stiffness materials such as semi-rigid plastics may be used that have greater resistance to distorting, thus minimizing nozzle distortion of the patient's nares. Further, rigid plastics may be used that allows thin wall sections and allows flexibility of the nozzle due to its connection to the base portion 48, e.g., the base portion 48 is soft and compliant.

[00191] In the illustrated embodiment, the nozzles 50 are molded in one piece with the base portion 48 from deformable and inflatable materials. The nozzles 50 and base portion 48 may be constructed from a soft, flexible, skin-compatible material such as silicone. The nozzles 50 and base portion 48 may be formed, for example, in an injection, compression, and/or transfer molding process as is known in the art.

[00192] However, the nozzles 50 and base portion 48 may be formed with any suitable material and may be formed by any suitable process. For example, the base portion 48 and nozzles 50 may be formed separately and permanently attached to one another with an adhesive and/or mechanical fasteners, for example. Alternatively, the base portion 48 and nozzles 50 may be formed separately and removably attached to one another.

[00193] As aforesaid, second connector portions 26 are provided to removably connect the headgear assembly 20 and the inlet conduits with the frame 16. As shown in Figs. 9 and 10, each second connector portion 26 is a unitary polymeric piece (e.g., silicone) formed by injection molding, compression molding, or blow-molding, for example. Each second connector portion 26 includes a main body having a front portion 60 and a rear portion 62. The front portion 60 is interlocked with the first connector portion 24 provided on the frame 16 and the rear portion 62 is removably connected to the headgear assembly 20 and the inlet conduits. The front and rear portions 60, 62 are angled with respect to one another such that the second connector portions 26 follow the contour of the patient's face in use, as shown in Fig. 1.

[00194] Specifically, the front portion 60 provides a generally cylindrical conduit 64 having a recess 66 on an inner surface thereof. The recess 66 is adapted to receive the rib portions 40 of the plurality of arms 38 on the first connector portion 24. That is, the plurality of arms 38 are forced towards one another as the first connector portion 24 is inserted into the conduit 64 of the second connector portion 26. Once the rib portions 40 of the arms 38 reach the recess 66, the arms 38 can spring outwardly into the recess 66 to provide an interlocking engagement between the first and second connector portions 24, 26. To disengage the second connector portion 26 from the frame 16, the patient simply pulls the second connector portion 26 axially outwardly from the frame 16 with sufficient force to release the rib portions 40 from the recess 66.

[00195] The front portion 60 also provides a cross-bar 68 that provides the tooth 44 of the second connector portion 26. As discussed above, the tooth 44 engages the plurality of teeth 42 provided by the first connector portion 24 to allow selective rotational adjustment of the second connector portion 26 with respect to the first connector portion 24 and hence the frame 16. The cross bar 68 acts as a leaf spring to resiliently bias the tooth 44 into engagement with the teeth 42 of the first connector portion 24.

[00196] As shown in Figs. 9 and 10, the rear portion 62 of the second connector portion 26 includes a cross-bar 70 that forms an opening through which a strap of the headgear assembly 20 may pass and be removably connected. However, the cross-bar 70 may be configured to provide more than one opening for connection to the headgear assembly 20. For example, as shown in Figs. 11 and 12, the second connector portion 26` includes a cross-bar 71 that provides a pair of openings through which a pair of straps of the headgear assembly 20 may pass and be removably connected.

[00197] The rear portion 62 also provides an elongated conduit 72 adapted to be connected to an inlet conduit that delivers breathable gas to the frame 16 and nozzle assembly 18. In the illustrated embodiment, the conduit 72 of the rear portion 62 has a different cross-sectional shape than the conduit 64 of the front portion 60 to facilitate connection to the inlet conduit. However, the conduits 72, 64 of the rear and front portions 62, 60, respectively, may have similar cross-sectional areas.

[00198] Figs. 13 and 14 schematically illustrate the routing of on of the first pair of inlet conduits 74 and one of the second pair of inlet conduits 76 of the nasal assembly 10. First ends of the first pair of conduits 74 are connected to respective conduits 72 of the second connector portions 26. Second ends of the first pair of conduits 74 are connected to respective first ends of the second pair of inlet conduits 76. Second ends of the second pair of inlet conduits are connected to a pressurized supply that supplies pressurized breathable gas. As a result, pressurized gas can pass through the first and second pairs of inlet conduits 74, 76 into the frame 16 and base portion 48, and through the nozzles 50 for breathing by the patient. As shown in Fig. 1, the frame 16 includes an exhaust vent 78 that protrudes slightly outwardly from the frame 16 and includes a series of openings for CO_2 washout.

[00199] As schematically shown in Fig. 13, the first and second pairs of inlet conduits 74, 76 may be routed to extend upwardly over the head of the patient. For example, in Fig. 13, the first pair of inlet conduits 74 may have a length of about 120-160 mm, preferably about 140 mm and the second pair of inlet conduits 76 may have a length of about 160-200 mm, preferably about 180 mm. However, other length dimensions may be used as well. In the

illustrated embodiment, the first pair of inlet conduits 74 are angled about 30° from horizontal and the second pair of inlet conduits 76 are angled about 90° from horizontal, or about 60° from the first pair of inlet conduits 74. However, the first and second pairs of inlet conduits 74, 76 may have any suitable length and may be routed in any suitable manner to extend upwardly over the head of the patient.

[00200] Alternatively, as schematically shown in Fig. 14, the first and second pairs of inlet conduits 74, 76 may be routed to extend downwardly under the chin of the patient. For example, in Fig. 14, the first pair of inlet conduits 74 may have a length of about 40-80 mm, preferably about 60 mm and the second pair of inlet conduits 76 may have a length of about 180-220 mm, preferably about 200 mm. In the illustrated embodiment, the first pair of inlet conduits are angled about -20° to 40° from horizontal, preferably about 30° from horizontal and the second pair of inlet conduits 76 are angled about -90° from horizontal, or about -120° from the first pair of inlet conduits 74. However, the first and second pairs of inlet conduits may have any suitable length and may be routed in any suitable manner to extend upwardly over the head of the patient.

[00201] Figs. 15 and 16 illustrate embodiments of connectors structured to interconnect the second ends of the first pair of conduits 74 with respective first ends of the second pair of inlet conduits 76. The connector 80 shown in Fig. 15 is suitably angled to route the conduits 74, 76 upwardly over the head of the patient. The connector 82 shown in Fig. 16 is suitably angled to route the conduits 74, 76 downwardly under the chin of the patient.

[00202] Fig. 17 illustrates a flow generator connector 84 structured to interconnect the second ends of the second pair of inlet conduits 76 with a pressurized supply. Specifically, the flow generator connector 84 includes a first conduit 86 structured to connect to one of the second pair of inlet conduits 76 and a second conduit 88 structured to connect to the other of the second pair of inlet conduits 76 . The flow generator connector 84 includes a third conduit 90 structured to connect to a conduit that is connected to the pressurized supply. The third connector 90 may include a swivel mechanism or flexible joint to allow relative movement between the flow generator connector 84 and the conduit associated with the pressurized supply.

[00203] In the illustrated embodiment, the inlet conduits 74, 76 provide a single air flow channel. However, the conduits 74, 76 , connector portions 24, 26, and connectors 80, 82, 84 may be structured to provide more than one air flow channel.

[00204] The inlet conduits 74, 76 may be manufactured in any suitable manner. For example, the conduits 74, 76 may be extruded or the conduits may be injection molded. Also, the inlet conduits 74, 76 may be structured from any suitable polymeric material such as silicone or a thermoplastic elastomer, such as Krayton®, for example.

[00205] Also, the inlet conduits 74, 76 may be formed of crush-resistant, anti-crush or anti-kinking tubing such as that disclosed in U.S. Patent No. 6,044,844, the entirety of which is incorporated herein by reference.

[00206] The inlet conduits 74, 76 and respective connector portions 24, 26 and/or connectors 80, 82, 84 may be retained with a friction-type fit, mechanical fasteners, adhesive, co-molded, insert molded, or any other suitable means.

[00207] In use, pressurized gas enters through connector 90 of the flow generator connector 84 and proceeds through the second set of inlet conduits 76 into the first set of inlet conduits 74 and into both side frame members 32 of the frame 16. Air passes through the frame 16, into the base portion 48 and nozzles 50, and into the nasal passages 12 of the patient. Exhaust gasses from the patient's nose can exit through the exhaust vent 78 provided in the frame 16.

[00208] The headgear assembly 20 is removably attached to second connector portion 26 attached to the frame 16 to maintain the frame 16 and nozzle assembly 18 in a desired adjusted position on the patient's face. As shown in Fig. 18, the headgear assembly 20 includes two side portions 92 with a rear portion 94 connecting the side portions 92. Each side portion 92 comprises a side strap 96. The rear portion 94, which interconnects the two side portions 92, includes an upper strap 98 that passes over the top of the patient's head and a rear strap 100 that passes around the rear portion of the patient's head. However, the headgear assembly may be permanently attached to the frame.

[00209] Each side strap 96 is removably connected to the second connector portion 26. Specifically, the end portion of each side strap 96 has a reduced width that enables the side strap 96 to be wrapped around the cross-bar 70 provided on the second connector portion 26. Fastening of the side straps 96 to respective cross-bars 70 may be assisted by use of a hook and loop material, such as Velcro®. Thus, the side straps 96 may be adjusted with respect to the second connector portion 26 for proper fit.

[00210] The upper strap 98 and rear strap 100 are removably connected to the side straps 96 by buckles 102 provided on the side straps 96. The buckles 102 can be attached to the side straps 96 with adhesives, stitching and/or other known manners. In the illustrated

embodiment, the buckles 102 includes a single cross-bar to enable the upper and rear straps 98, 100 to be coupled therewith. However, any other suitable buckle arrangement may be provided to interconnect the side straps 96 with the upper and rear straps 98, 100.

[00211] The straps 96, 98, 100 of the headgear assembly 20 may be constructed from a soft, flexible composite material. For example, the straps 96,98, 100 may include two layers of material with one of the layers made of a fabric material and the other of the layers made of a polymeric material. Also, the headgear assembly 20 may include one or more stiffeners attached thereto in order to add to the rigidity of the headgear assembly 20 in certain planes and directions, which would assist in stabilizing the nasal assembly 10 on the head of the patient during use.

[00212] Further, the headgear assembly 20 may include any number of straps to support the nasal assembly 10 on the patient's head. For example, each of the side straps 96 may include a pair of straps to be used with the second connector portion 26` shown in Figs. 11 and 12. Alternatively, the headgear assembly 20 may be constructed as a one piece structure.

[00213] As best shown in Fig. 1, the base portion 48 extends outwardly from the frame 16 to provide additional surface area or footprint area. As air under pressure enters the frame 16, the base portion 48 inflates, which moves the nozzles 50 into sealing engagement with the nasal passages 12 of the patient. For example, expansion of the base portion in the direction of the nostrils causes the nozzles to move into sealing engagement with the nasal passages.

[00214] Also, a portion of the sealing force may be provided by the first portion 56, which may be pre-loaded, like a spring, against the patient's nostril.

[00215] That is, the base portion 48 is structured such that it can expand and contract to alter a distance between the frame 16 and the nozzles 50. The base portion 48 moves the nozzles 50 between a first position in which the nozzles 50 are adjacent to the nasal passages 12 of the patient and a second position in which the nozzles 50 are moved into sealing engagement with the nasal passages 12 of the patient. Specifically, in an un-inflated condition, the nozzles 50 are spaced from the nasal passages 12 of the patient or in light contact therewith. When the nasal assembly 10 is pressurized by a gas, the base portion 48 is inflated and moves the nozzles 50 into sealing engagement with the nasal passages 12 of the patient to form a seal between the nasal assembly 10 and the patient's nasal passages 12. As the gas pressure is increased, the force applied to the underside of the nasal passages is increased through the base portion 48.

[00216] The base portion 48 provides additional surface area or footprint area to the frame 16, which in turn provides an additional force on the nozzles 50 which increases the sealing

efficiency of the nozzles 50. That is, the base portion 48 is configured and positioned to force the nozzles 50 into contact with the patient's nose. The force or pressure on the patient's nose is proportional to: (a) the pressure in the frame 16 and nozzle assembly 18; (b) additional surface area of the base portion 48; and/or (c) the preload from materials and geometry of nozzles 50 or base portion 48, including central wall 54 and first portion 56 of the base portion 48. Thus, the surface area of the base portion 48 may be varied, e.g., to vary the force or pressure applied to the patient's nose.

[00217] The side walls 52 of the base portion 48 may act as a spring structure to provide a component of force on the patient's face through the nozzles 50. The force may be tailored by adjusting the thickness of the side walls 52. Moreover, the thickness of the side walls 52 may be varied in conjunction with the additional surface area provided by the base portion 48. Thus, the force provided by the base portion 48 along with the air pressure provides an effective sealing force against the nasal passages 12 of the patient.

[00218] The base portion 48 reduces the headgear assembly tension required to achieve a suitable seal. That is, the sealing force applied to the patient's nose may be provided by the base portion 48, preload and/or air pressure, and not by the tension from the headgear assembly 20. This improves patient comfort as well as sealing properties.

[00219] Accordingly, it is desirable when adjusting the headgear assembly 20 to bring the nozzles 50 only near or in very light contact with the patient's nose. In this way, the base portion 48 is not compressed substantially. In use, contact will need to be sufficient for seal.

[00220] The base portion 48 also provides a decoupling joint between the frame 16 and the nozzles 50, thus allowing some relative movement between the nasal assembly 10 and the user's face. As a result, the nozzles 50 can accommodate small variations in the shape of the patient's nasal features without undue force, and can account for small movement of the nasal assembly 10 relative to the patient's nose during use, while maintaining an effective seal.

[00221] Moreover, the connection assembly 22 including the first and second connector portions 24, 26 enables the position of the nozzles 50 to be easily adjusted with respect to the patient's nose. Specifically, the patient can rotate the frame 16 with respect to the headgear assembly 20 to adjust the positioning of the nozzles 50.

[00222] Also, the base portion 48 need not be a single base form discussed above, but can have alternative configurations. For example, the base portion 48 may be in the form of two or more base portions provided in series.

[00223] As shown in Figs. 5 and 6, end portions of the base portion 48 are angled with respect to one another so as to angle the nozzles 50 attached thereto with respect to one

another. This angle, also referred to as an alar angle, can be adjusted to accommodate different shaped noses of patients. For example, the nozzle assembly 10 shown in Figs. 5 and 6 has an alar angle in the range of 135-155°, preferably about 145°, to accommodate a substantially flat nose (see Fig. 19). Alternatively, the alar angle may be in the range of 70-90°, preferably about 80°, to accommodate a substantially pointed or steep nose (see Fig. 20). However, the alar angle may have any suitable size to accommodate any shape nose. Movement of the nozzles helps accommodate steeper noses.

[00224] As shown in Fig. 21, the sealing zone of the nozzle 50 may extend at an angle from about half the height of the nozzle 50. In the illustrated embodiment, the nozzle 50 has a height of about 9 mm. However, the nozzle 50 may have any suitable height and may provide any suitable sealing zone. (Please advise if you would like to remove Fig. 21 from the application.)

[00225] The nozzles 50 are appropriately spaced with respect to one another on the base portion 48. The spacing is based on the size of the nozzles 50 and the available space on the base portion 48.

[00226] The size of the nozzles 50 is based on the patient's nostril circumference. In one embodiment, ellipse ratios may be used to determine nozzle geometry (see Fig. 22). For example, an ellipse ratio of 0.7 (Average + 1 Standard Deviation) may be used to determine nozzle geometry. As shown in Fig. 23, the base major axis of the nozzle may be defined by measurement from the center of a nostril to the upper lip. As shown in Fig. 24, the base minor axis of the nozzle may be defined by the maximum space available between nozzles. However, any other suitable method may be used to determine the size of the nozzles. (Please advise if you would like to remove Figs. 22-24 from the application.)

[00227] The above-noted alar angle, sealing zone, spacing between nozzles, and size of the nozzles may be determined so that a wide range of patients can be accommodated. Also, different size nasal assemblies, e.g., small, medium, and large, may be provided to accommodate different size patients. However, any other suitable measurements and methods may be used to provide a nasal assembly that fits the widest range of patients.

[00228] One aspect of the invention relates to a nasal assembly that provides separate sealing and stability forces. That is, the nasal assemblies are structured such that the stability forces that act to maintain the nasal assembly on the patient's face are separated or at least better distinguished from the sealing forces that act to maintain a seal between the nasal assembly and the patient's face. In use, the sealing forces act on more sensitive regions of the patient's face, e.g., nose, and the stability forces act on less sensitive regions of the

patient's face, e.g., upper lip, cheeks and back of the patient's head. Moreover, the stability forces tend to be higher than the sealing forces. Thus, the nasal assembly is structured such that the higher stability forces are substantially separated from the lower sealing forces to improve patient comfort.

[00229] Specifically, the nasal assembly is structured such that stability forces applied by the headgear assembly are distributed to the back of the patient's head, the patient's cheeks, and the patient's upper lip to maintain the nasal assembly on the patient's face in use. The nasal assembly includes the nozzle assembly structured to apply sealing forces to nasal passages of the patient's nose in use. Features of the headgear have been designed to achieve substantially independent adjustment of sealing and stability forces. Thus, the higher stability forces do not effect the more sensitive regions of the patient's face, e.g., nose, as much.

[00230] Another aspect of the invention relates to the association between the nozzles and the base portion to apply a force to the patient's face. Specifically, the base portion is structured to apply a component of force to the patient's face and the nozzles are structured to apply a component of force to the patient's face.

[00231] As shown in Fig. 1, for example, the base portion may have a substantially rigid structure such that it applies a relatively small component of force on the patient's face. That is, the base portion may not be substantially inflatable or expandable when pressurized by a gas. In contrast, the nozzles may have a flexible structure such that they provide a relatively larger component of force on the patient's face. That is, the first portion 56 of the nozzles 50 may act as a spring structure, e.g., spring-loaded or resilient, to provide a component of force on the patient's face through the nozzles 50. By spring-loaded, it is meant that the nozzles apply a predetermined force against the user's nasal sealing area, for sealing purposes. Preferably, nozzles are preloaded before introducing pressurized gas to provide a sealing force with the user. As a result, the base portion and nozzles together provide a force to provide a seal between the nasal assembly and the patient's nasal passages.

[00232] Alternatively, the base portion may have a flexible structure such that it applies a relatively large component of force on the patient's face when inflated. In contrast, the nozzles may have a more rigid structure such that they apply a relatively smaller component of force on the patient's face. As a result, the base portion and nozzles together provide a force to provide a seal between the nasal assembly and the patient's nasal passages.

[00233] Thus, the nozzle assembly may be structured such that the nozzles are spring-loaded or resilient to apply a sufficient component of force for sealing. Thus, the base portion can be structured more rigidly to apply a smaller component of force for sealing.

Alternatively, the nozzle assembly may be structured such that the base portion is sufficiently expandable to apply a sufficient component of force for sealing and the nozzles can be structured more rigidly to apply a smaller component of force for sealing. Alternatively, the nozzles may be substantially rigid, e.g., where the nozzles are tailored for a particular user. This alternative can be combined with the earlier embodiment (relating rigid base portions and spring-loaded (e.g. preloaded) nozzles). In this event, the base of the nozzle may be structured to provide a variable amount of preload, and the sealing portion of the nozzle, preferably tailored to the user, may be relatively more rigid. Also, the nozzle assembly may be structured such that the base portion and nozzles provide substantially similar components of force for sealing.

SECOND ILLUSTRATED EMBODIMENT

[00234] Figs. 25-37 illustrate another embodiment of a nasal assembly, indicated as 210. As best shown in Figs. 25-27, the nasal assembly 210 includes a frame 216 and a nozzle assembly 218 that is removably connected to the frame 216. A headgear assembly 220 (see Fig. 37) is removably attached to the frame 216 to maintain the frame 216 and nozzle assembly 218 in a desired adjusted position on the patient's face. Inlet conduits 274 (see Figs. 36 and 37) are also removably attached to the frame 216 to deliver breathable gas into the frame 216 and nozzle assembly 218 for breathing by the patient. The headgear assembly 220 and inlet conduits 274 are removably attached to the frame 216 by an inlet conduit and headgear connection assembly 222. The connection assembly 222 includes first connector portions 224 (see Figs. 28 and 29) provided by the frame 216 and second connector portions 226 adapted to be removably coupled with the first connector portions 224. The second connector portions 226 are removably connected to the headgear assembly 220 and the inlet conduits 274, as will be further discussed.

[00235] As shown in Figs. 28 and 29, the frame 216 includes a main body 228 that provides a central opening 230 for accommodating the nozzle assembly 218. The frame 216 also includes side frame members 232 provided on each lateral side of the main body 228. Each side frame member 232 includes a first connector portion 224 that is integrally formed therewith. The first connector portion 224 is in the form of a conduit 264 having a recess 266 on an inner surface thereof. The frame 216 also includes a series of openings 278 for CO_2 washout.

[00236] As shown in Figs. 25-27 and 30-31, the nozzle assembly 218 forms a conduit that includes a main body 219 and opposing end portions 221 (only half of the nozzle assembly 218 is shown in the figures). As best shown in Fig. 27, the end portions 221 are stretched over the side frame members 232 of the frame 216 with the main body 219 in covering relation to the main body 228 and central opening 230 of the frame 216. When the nozzle assembly 218 is attached to the frame 216, the frame 216 adds rigidity to the relatively flexible nozzle assembly 218.

[00237] The main body 219 of the nozzle assembly 218 includes a gusset portion 248 and a pair of nozzles 250 attached thereto. The nozzles 250 may be designed and structured in a similar manner to the nozzles 50 described above. The main body 219 of the nozzle assembly also includes a series openings 223 that align with the series of openings 278 provided on the frame 216 for CO_2 washout.

[00238] As shown in Figs. 32-34, the second connector portion 226 includes a main body having a front portion 260 and a rear portion 262. The front portion 260 includes a plurality of resiliently flexible arms 238 that are structured to flex radially inwardly and outwardly. Each arm 238 provides a rib portion 240 at the free end thereof. In use, the rib portions 240 of the plurality of arms 238 are adapted to engage within the recess 266 of the first connector portion 224 for coupling the first and second connector portions 224, 226 with one another. In contrast to the connection assembly 22 described above, the connection assembly 222 does not provide an indexing section. Thus, the second connector portion 226 may rotate with respect to the first connector portion 224 for an infinite amount of settings for alignment of the nozzles 250 with respect to the nasal passages of the patient. The settings may be locked by way of friction, for example.

[00239] The rear portion 262 of the second connector portion 226 includes a cross-bar 270 that forms an opening through which a strap of the headgear assembly 220 may pass and be removably connected. The rear portion 262 also provides a pair of conduits 272 adapted to be connected to an inlet conduit that delivers breathable gas to the frame 216 and nozzle assembly 218.

[00240] As shown in Fig. 36, the nasal assembly 210 includes a pair of inlet conduits 274 (only one of the inlet conduits 274 being visible in Fig. 36). First ends of the pair of conduits 274 are connected to respective second connector portions 226 connected to the frame 216. Second ends of the pair of conduits 274 are connected to a pressurized supply that supplies pressurized breathable gas. As shown in Figs. 36 and 37, the pair of inlet conduits 274 are routed to extend upwardly over the head of the patient. However, the pair of inlet conduits

274 may be routed in any suitable manner, e.g., routed to extend downwardly under the chin of the patient.

[00241] As a result, pressurized gas can pass through the pair of inlet conduits 274 into the frame 216 and nozzle assembly 218, and through the nozzles 250 for breathing by the patient.

[00242] Fig. 35 illustrates a flow generator connector 284 structured to interconnect the second ends of the pair of inlet conduits 274 with a pressurized supply. Specifically, the flow generator connector 284 includes a pair of first conduits 286 structured to connect to one of the pair of inlet conduits 274 and a pair of second conduits 288 structured to connect to the other of the pair of inlet conduits 274. The flow generator connector 284 includes a third conduit 290 structured to connect to a conduit that is connected to the pressurized gas, air, or fluid supply. The third connector 290 may include a swivel or flexible joint mechanism to allow relative movement between the flow generator connector 284 and the conduit associated with the pressurized supply. Also, the third connector 290 may include a ball and socket joint so that when the third connector 290 is on top of the patient's head in an over the head configuration, the tube pull is minimized.

[00243] In the illustrated embodiment, the inlet conduits 274 provide a dual air flow channel with a central support wall to prevent kinking and occlusion. However, the conduits 274, connector portions 224, 226, and connector 284 may be structured to provide one air flow channel or more than two air flow channels.

[00244] The headgear assembly 220 is removably or fixedly attached to second connector portion 226 attached to the frame 216 to maintain the frame 216 and nozzle assembly 218 in a desired adjusted position on the patient's face. As shown in Fig. 37, the headgear assembly 220 includes two side portions 292 (only one of the side portions 292 being visible in Fig. 37) with a rear portion 294 connecting the side portions 292. Each side portion 292 comprises a side strap 296. The rear portion 294, which interconnects the two side portions 292, includes an upper strap 298 that passes over the top of the patient's head and a rear strap 299 that passes around the rear portion of the patient's head. Upper and rear strap 298, 299 can be adjusted for fit and can be a single strap or loop. Also, the headgear assembly may be permanently attached to the frame.

[00245] Each side strap 296 has a reduced width that enables the side strap 296 to be wrapped around the cross-bar 270 provided on the second connector portion 226. Fastening of the side straps 296 to respective cross-bars 270 may be assisted by use of a hook and loop

material, such as Velcro®. Thus, the side straps 296 may be adjusted with respect to the second connector portion 226 for proper fit.

[00246] Openings or buckles are provided on the side straps 296 to enable the upper and rear straps 298, 299 to be coupled therewith. However, the headgear assembly 220 may include any number of straps to support the nasal assembly 210 on the patient's head. Alternatively, the headgear assembly 220 may be constructed as a one piece structure.

[00247] As shown in Fig. 37, the headgear assembly 220 includes a retaining strap 291 to hold the flow generator connector 284 and the inlet conduits 274 in a position over the head of the patient. The headgear assembly 220 also includes retaining prongs 293 to hold the inlet conduits 274 adjacent to the headgear assembly 220 as they extend upwardly over the head of the patient.

[00248] Similar to the nasal assembly 10 described above, the force provided by the gusset portion 248 along with the air pressure provides an effective sealing force against the nasal passages 12 of the patient. Thus, the gusset portion 248 reduces the headgear assembly tension required to achieve a suitable seal. Also, the position of the nozzles 250 may be adjusted with respect to the user's nose to improve patient comfort.

[00249] As shown in Fig. 25, for example, the gusset portion 248 has a flexible structure such that it applies a relatively large component of force on the patient's face when inflated. In contrast, the nozzles have a more rigid structure such that they apply a relatively smaller component of force on the patient's face. That is, the first portion of the nozzles may have less of a spring-load to provide a relatively small component of force on the patient's face through the nozzles. As a result, the gusset portion and nozzles together provide a force to provide a seal between the nasal assembly and the patient's nasal passages.

THIRD ILLUSTRATED EMBODIMENT

[00250] Figs. 38-51 illustrate another embodiment of a nasal assembly, indicated as 310. As best shown in Figs. 38, 39, and 43, the nasal assembly 310 includes a frame 316 and a nozzle assembly 318 that is removably connected to the frame 316. A headgear assembly 320 is removably attached to the frame 316 to maintain the frame 316 and nozzle assembly 318 in a desired adjusted position relative to the patient's face. Inlet conduits 374 are also removably attached to the frame 316 to deliver breathable gas into the frame 316 and nozzle assembly 318 for breathing by the patient. The headgear assembly 320 and inlet conduits 374

are removably attached to the frame 316 by an inlet conduit and headgear connection assembly 322. The connection assembly 322 includes first connector portions 324 (see Figs. 40 and 43) provided by the frame 316 and second connector portions 326 adapted to be removably coupled with the first connector portions 324. The second connector portions 326 are removably connected to the headgear assembly 320 and the inlet conduits 374, as will be further discussed.

[00251] As shown in Fig. 40, the frame 316 includes a main body 328 that provides a central opening 330 for accommodating the nozzle assembly 318. The frame 316 also includes side frame members 332 provided on each lateral side of the main body 328. Each side frame member 332 includes a first connector portion 324 that is integrally formed therewith. The first connector portion 324 is in the form of a conduit 364 having a recess 366 (see Fig. 43) on an inner surface thereof.

[00252] As shown in Fig. 41, the nozzle assembly 318 forms a conduit that includes a main body 319 and opposing end portions 321. As best shown in Figs. 42, 43, and 44, the end portions 321 are stretched over the side frame members 332 of the frame 316 with the main body 319 in covering relation to the main body 328 and central opening 330 of the frame 316. When the nozzle assembly 318 is attached to the frame 316, the frame 316 and nozzle assembly 318 form a conduit for delivering breathable gas to the patient's nose. Also, the frame 316 adds rigidity or structural integrity to the relatively flexible nozzle assembly 318.

[00253] As shown in Figs. 43 and 44, the main body 319 of the nozzle assembly 318 includes a base portion 348 and a pair of nozzles 350 attached thereto. The nozzles 350 may be designed and structured in a similar manner to the nozzles 50 described above. The main body 319 of the nozzle assembly 318 also includes one or more openings 323 (e.g., see Figs. 39 and 41) for CO_2 washout.

[00254] As shown in Figs. 38B and 43, the second connector portion 326 includes a main body having a front portion 360 and a rear portion 362. The front portion 360 includes a rib portion 340. In use, the rib portion 340 is adapted to engage within the recess 366 of the first connector portion 324 for coupling the first and second connector portions 324, 326 with one another. Similar to the connection assembly 222 described above, the second connector portion 326 may rotate with respect to the first connector portion 324 for an infinite amount of settings for alignment of the nozzles 350 with respect to the nasal passages of the patient. The setting may be optionally locked by friction, for example.

[00255] As shown in Figs. 38 and 38B, the rear portion 362 of the second connector portion 326 includes an opening 370 through which a strap of the headgear assembly 320 may pass and be removably connected. As shown in Fig. 38B, the rear portion 362 also provides a pair of conduits 372 adapted to be connected to an inlet conduit that delivers breathable gas to the frame 316 and nozzle assembly 318.

[00256] As shown in Figs. 38, 39, and 45, the nasal assembly 310 includes a pair of inlet conduits 374. First ends of the pair of conduits 374 are connected to respective second connector portions 326 connected to the frame 316. Second ends of the pair of conduits 374 are connected to a pressurized supply that supplies pressurized breathable gas. As shown in Fig. 45, the second connector portions 326 may be rotated with respect to the first connector portions 324 to route the pair of inlet conduits 374 upwardly over the head of the patient or downwardly under the chin of the patient, for example.

[00257] As a result, pressurized gas can pass through the pair of inlet conduits 374 into the frame 316 and nozzle assembly 318, and through the nozzles 350 for breathing by the patient.

[00258] Figs. 45, 47, and 48 illustrate an angle connector 384 structured to interconnect the second ends of the pair of inlet conduits 374 with a pressurized supply. As shown in Fig. 47, the connector 384 may include a pair of double-conduits 386 to connect to respective inlet conduits 374. Alternatively, as shown in Fig. 48, the flow generator connector 384 may include a pair of single-conduits 386 to connect to respective inlet conduits 374. The end of the dual air flow channel inlet conduit 374 may be amended, as shown in Fig. 48, to facilitate connection with the connector 384 having a pair of single-conduits 386. Also, the ends of the inlet conduit 374 may include a series of ridges that interlock with a series of ridges provided on the connector 384 to reliably connect the inlet conduits 374 with the connector 384, as shown in Figs. 47 and 48.

[00259] As shown in Fig. 49, the inlet conduits 374 provide a dual air flow channel with a central support wall to prevent kinking or occlusion, e.g., anti-crush, and facilitate connection. Also, the inlet conduits may be constructed from a harder material, e.g., harder durometer silicone, to prevent kinking or occlusion. However, the conduits 374, connector portions 324, 326, and connector 384 may be structured to provide one air flow channel or more than two air flow channels. As shown in Fig. 47B, the inlet conduits 374 may be extruded or otherwise manufactured in one piece. Alternatively, as shown in Fig. 48B, the inlet conduits 374 may include a plurality of conduits formed by injection molding, co-molding, or insert molding, and connected to one another in any suitable manner, e.g., by

connectors and/or other fasteners such as adhesive, or the entire assembly could be molded in one piece, thereby reducing components and complexity.

[00260] The headgear assembly 320 is removably attached to second connector portion 326 attached to the frame 316 to maintain the frame 316 and nozzle assembly 318 in a desired adjusted position on the patient's face. As shown in Figs. 38, 39, and 45, the headgear assembly 320 includes two side portions 392 with a rear portion 394 connecting the side portions 392. Each side portion 392 comprises a side strap 396. The rear portion 394, which interconnects the two side portions 392, includes an upper strap 398 that passes over the top of the patient's head and a rear strap 399 that passes around the rear portion of the patient's head. As shown in Fig. 45, the rear portion 394 may include a second rear strap 387 to add additional stability.

[00261] Each side strap 396 has a reduced width that enables the side strap 396 to be wrapped around the opening 370 provided on the second connector portion 326. Fastening of the side straps 396 to respective openings 370 may be assisted by use of a hook and loop material, such as Velcro®. Thus, the side straps 396 may be adjusted with respect to the second connector portion 326 for proper fit.

[00262] In the illustrated embodiment, the headgear assembly 320 is constructed as a one piece structure. However, the headgear assembly 320 may include a plurality of straps suitably arranged to support the nasal assembly 310 on the patient's head. As shown in Fig. 45, the headgear assembly 320 may include retaining straps 393 to hold the inlet conduits 374 upwardly over the head of the patient.

[00263] Fig. 50 illustrates the nasal assembly 310 about to be engaged with nasal passages 12 of a patient's nose 14. Fig. 51 illustrates the nasal assembly 310 engaged with nasal passages 12 of a patient's nose. The patient's upper lip contacts the silicone outer surface of the nozzle assembly 318 to help maintain the nasal assembly 310 in position on the patient's face.

[00264] Similar to the nasal assembly 10 described above, the force provided by the base portion 348 along with the air pressure provides an effective sealing force against the nasal passages 12 of the patient. Thus, the base portion 348 reduces the headgear assembly tension required to achieve a suitable seal. Also, the position of the nozzles 350 may be adjusted with respect to the user's nose to improve patient comfort.

[00265] As shown in Fig. 43, for example, the base portion 348 has a flexible structure such that it applies a relatively large component of force on the patient's face when inflated.

In contrast, the nozzles have a more rigid structure such that they apply a relatively smaller component of force on the patient's face. That is, the first portion of the nozzles may have less of a spring-load to provide a relatively small component of force on the patient's face through the nozzles. As a result, the base portion and nozzles together provide a force to provide a seal between the nasal assembly and the patient's nasal passages.

[00266] Further, the base portion 348 may be structured to provide customized forces in desired directions, e.g., inwardly directed force to assist with sealing. The base portion 348 may offer greater displacement in some areas that would provide additional forces.

[00267] Fig. 46 is a force diagram that illustrates some of the forces that are developed when the nasal assembly 310 is attached to the patient's head. For example, the headgear tension provides a force on the patient's face and the patient's nose and lip provide forces on the nasal assembly 310. (Please advise if you would like to remove this figure).

FOURTH ILLUSTRATED EMBODIMENT

[00268] Figs. 52-58 illustrate another embodiment of a nasal assembly, indicated as 410. As best shown in Figs. 52 and 53, the nasal assembly 410 includes a frame 416 and a nozzle assembly 418 that is removably connected to the frame 416. A headgear assembly 420 is removably attached to the frame 416 to maintain the frame 416 and nozzle assembly 418 in a desired adjusted position on the patient's face. Inlet conduits 474 are also removably attached to the frame 416 to deliver breathable gas into the frame 416 and nozzle assembly 418 for breathing by the patient. The headgear assembly 420 and inlet conduits 474 are removably attached to the frame 416 by an inlet conduit and headgear connection assembly 422. The connection assembly 422 includes first connector portions 424 (see Figs. 55 and 56) provided by the frame 416 and second connector portions 426 adapted to be removably coupled with the first connector portions 424. The second connector portions 426 are removably or fixedly connected to the headgear assembly 420 and the inlet conduits 474, as will be further discussed.

[00269] As shown in Figs. 52 and 54, the frame 416 includes a main body 428 that provides a central opening 430 for accommodating the nozzle assembly 418. The frame 416 also includes side frame members 432 provided on each lateral side of the main body 428. Each side frame member 432 includes a first connector portion 424 that is integrally formed therewith. The first connector portion 424 is in the form of cross-bar 466 (see Figs. 55 and

56). As best shown in Fig. 54, the main body 428 includes rim 446 that define the central opening 430.

[00270] As shown in Fig. 54, the nozzle assembly 418 includes a gusset portion 448 and a pair of nozzles 450 attached thereto. The gusset portion 448 has side walls 452 adapted to sealingly engage with the rim 446 surrounding opening 430 of the frame 416. For example, the side walls 452 of the gusset portion 448 may include a recess that is structured to interlock with a respective tab provided on the rim 446 of the frame 416 with a snap-fit. However, the nozzle assembly 418 may be removably attached to the frame 416 in any other suitable manner, such as a friction fit, for example. When the nozzle assembly 418 is attached to the frame 416, the nozzle assembly 418 and the frame 416 together form a conduit for directing breathable gas to the patient's nose through the pair of nozzles 450.

[00271] The nozzles 450 may be designed and structured in a similar manner to the nozzles 50 described above. The frame 416 may include one or more openings (not shown) for exhaled CO_2 washout.

[00272] As shown in Fig. 55, the second connector portion 426 includes a main body having a front portion 460 and a rear portion 462. The front portion 460 includes a pair of arm members 461 having an integral lug 463 at a distal end thereof. In use, the arm members 461 are flexed inwardly by the cross-bar 466 of the first connector portion 424 until the arm members 461 reach an operative position in which the arm members 461 flex back outwardly such that the shoulder of the lug 463 is positioned to interlock the second connector portion 426 with the first connector portion 424 (see Fig. 56).

[00273] The arm members 461 of the second connector portion 426 may rotate with respect to the cross-bar 466 of the first connector portion 424. As shown in Fig. 55, a protrusion 465 may be provided on the arm members 461 that selectively engages within a series of recesses provided on an inner surface of the cross-bar 466 so as to provide a predetermined number of settings for alignment of the nozzles 450 with respect to the nasal passages of the patient.

[00274] As shown in Fig. 55, the rear portion 462 provides a pair of conduits 472 adapted to be connected to an inlet conduit that delivers breathable gas to the frame 416 and nozzle assembly 418. The rear portion 462 of the second connector portion 426 also includes a cross-bar or opening (not shown) through which a strap of the headgear assembly 420 may pass and be removably connected.

[00275] As shown in Figs. 52 and 53, the nasal assembly 410 includes a pair of inlet conduits 474. First ends of the pair of conduits 474 are connected to respective second

connector portions 426 connected to the frame 416. Second ends of the pair of conduits 474 are connected to a pressurized supply that supplies pressurized breathable gas. As shown in Fig. 52, the second connector portions 426 may be rotated with respect to the first connector portions 424 to route the pair of inlet conduits 474 upwardly over the head of the patient or downwardly under the chin of the patient, for example.

[00276] As a result, pressurized gas can pass through the pair of inlet conduits 474 into the frame 416 and nozzle assembly 418, and through the nozzles 450 for breathing by the patient.

[00277] Fig. 53 illustrates a flow generator connector 484 structured to interconnect the second ends of the pair of inlet conduits 474 with a pressurized supply.

[00278] As shown in Fig. 52, the inlet conduits 474 provide a dual air flow channel to prevent kinking and facilitate connection. However, the conduits 474, connector portions 424, 426, and connector 484 may be structured to provide one air flow channel or more than two air flow channels.

[00279] The headgear assembly 420 is removably attached to second connector portion 426 attached to the frame 416 to maintain the frame 416 and nozzle assembly 418 in a desired adjusted position on the patient's face. As shown in Figs. 52 and 53, the headgear assembly 420 includes two side portions 492 with a rear portion 494 connecting the side portions 492. Each side portion 492 comprises a side strap 496. The rear portion 494, which interconnects the two side portions 492, includes an upper strap 498 that passes over the top of the patient's head and a rear strap 499 that passes around the rear portion of the patient's head. However, the headgear assembly may be permanently attached to the frame.

[00280] Each side strap 496 has a reduced width that enables the side strap 496 to be wrapped around the cross-bar or opening provided on the second connector portion 426. Fastening of the side straps 496 to respective cross-bars or openings may be assisted by use of a hook and loop material, such as Velcro®. Thus, the side straps 496 may be adjusted with respect to the second connector portion 426 for proper fit.

[00281] In the illustrated embodiment, the headgear assembly 420 is constructed as a one piece structure. However, the headgear assembly 420 may include a plurality of straps suitably arranged to support the nasal assembly 410 on the patient's head. As shown in Figs. 52 and 53, the headgear assembly 420 may include retaining straps 493 to hold the inlet conduits 474 upwardly over the head of the patient.

[00282] Fig. 57 and 58 illustrate the nasal assembly 410 being engaged with nasal passages 12 of a patient's nose. Similar to the nasal assembly 10 described above, the force

provided by the gusset portion 448 along with the air pressure provides an effective sealing force against the nasal passages 12 of the patient. Thus, the gusset portion 448 reduces the headgear assembly tension required to achieve a suitable seal. Also, the position of the nozzles 450 may be adjusted with respect to the user's nose to improve patient comfort.

[00283] As shown in Fig. 58, for example, the gusset portion has a substantially rigid structure such that it applies a relatively small component of force on the patient's face when inflated. In contrast, the nozzles have a flexible structure such that they provide a relatively larger component of force on the patient's face. That is, the first portion of the nozzles may have a relatively large spring-load to provide a component of force on the patient's face through the nozzles. As a result, the gusset portion and nozzles together provide a force to provide a seal between the nasal assembly and the patient's nasal passages.

FIFTH ILLUSTRATED EMBODIMENT

[00284] Figs. 59-85 illustrate another embodiment of a nasal assembly, indicated as 510. The nasal assembly 510 includes a frame 516 and a nozzle assembly 518 that is removably coupled to the frame 516. As best seen in Fig. 61, the frame 516 includes a pair of first connector portions 524. Referring back to Fig. 59, a pair of inlet conduits 574 are structured to deliver breathable gas into the frame 516 and nozzle assembly 518 for breathing by the patient. The breathable gas is transported from the inlet conduits 574 to the frame 516 and nozzle assembly 518, e.g., via a pair of second connector portions 526 and a pair of angle connectors 542. The second connector portions 526 are removably and rotatably connected to respective first connector portions 524 (Fig. 61) of the frame 516. The angle connectors 542 are connected or positioned between the second connector portions 526 and respective inlet conduits 574. A headgear assembly 520 is removably connected to (a) the pair of second connector portions 526 and/or (b) the angle connectors 542, so as to maintain the frame 516 and the nozzle assembly 518 in a desired adjusted position on the patient's face, as will be further discussed.

[00285] As shown in Fig. 61, the frame 516 includes a main body 528 and a side frame member 532 provided on each lateral side of the main body 528. Each side frame member 532 includes an integrally formed first connector portion 524. The first connector portion 524 is in the form of a conduit 564 having an annular recess 566 on an outer surface thereof. Also, the main body 528 includes an elongated channel 565 on opposing sides thereof and

each side frame member 532 includes an annular channel 567. The channels 565, 567 are structured to receive the ends of the nozzle assembly 518, as will be further discussed.

[00286] As shown in Figs. 61-65, the nozzle assembly 518 includes a gusset or base portion 548 and a pair of nozzles 550 attached thereto. The nozzle assembly 518 is coupled with the frame 516 with the pair of nozzles 550 structured to sealingly engage with nasal passages of a patient's nose in use and provide a seal between the nasal assembly 510 and the patient's nasal passages. The nozzles 550 may be designed and structured in a similar manner to the nozzles 50 described above. Also, the nozzle assembly 518 includes one or more openings 549 for exhaled CO_2 washout.

[00287] Fig. 65A is an enlarged view of the nozzle assembly 518 shown in Fig. 65. The nozzle assembly preferably includes an upper contour portion 519 that maintains generally the same cross-sectional area through the assembly. Therefore, the assembly generally follows the line of the face so as not to protrude from the face thereby keeping a low profile. Similarly, Fig. 119 shows a nozzle or cushion assembly 604 that generally follows the contour of the face, from the top view.

[00288] The nozzle assembly 518 in Fig. 65A also includes a lower contour portion 521 that generally matches the contour of the face. Further, the nozzle assembly 518 is asymmetric about an axis A to provide a better fit in comparison with symmetric prior art masks, which may be subject to creasing or buckling upon distribution to fit the face. The lower contour 521 is also useful for patients with moustaches.

[00289] Forces from the patient interface retainer, e.g., headgear, are transferred to the face via nozzles 550 as well as lower contour portion 521. The increased overall area reduces the force per unit area, to spread the load. The increased overall area also helps to better anchor the patient interface. The shape of lower contour portion 521 is customizable. The lower contour portion 521 may be rigid, semi-rigid, elastic or some combination thereof. The maxilla region of the face can withstand more pressure without being uncomfortable.

[00290] Fig. 65B schematically illustrates the force distribution due to the increased area. In particular, the region immediately under the nose is only soft tissue and cartilage.

[00291] If the only contact region is the immediate underside of the nose (i.e., not including maxilla) then to hold a nozzle in place with the least amount of force would require a resultant force in direction F1. This might distort the nose and cause discomfort. If such a strap is tightened, it might slip off the front of the head. However, when some of the load is taken by the maxilla (i.e., some force under the nose and some on the maxilla), the direction of the resultant force can be changed to F2, the load is spread. Since the maxilla does not

move, F2 could be higher without causing discomfort. Such an arrangement may be more tolerant of overtightening. There is also greater ability to cup the occiput.

[00292] In the illustrated embodiment, the nozzle assembly 518 wraps around the main body 528 and each side frame member 532 of the frame 516 and is secured to the frame 516 with a clip 530. In another embodiment, the cushion can be pulled over the frame like a sock. An annular channel 567 is formed in each side frame member 532 and side portions 536 of nozzle assembly 518 wrap into channels 567. Specifically, as shown in Fig. 61, the nozzle assembly 518 has a generally open-ended tubular configuration with a longitudinal opening. This configuration provides the nozzle assembly 518 with a pair of opposing spaced apart end portions 534 and side portions 536. When the nozzle assembly 518 is coupled to the frame 516, the side portions 536 engage within respective annular channels 567 and the end portions 534 engage within respective elongated channels 565 on opposing sides of the main body 528, as best shown in Figs. 64 and 68.

[00293] As best shown in Figs. 62-64 and 66, the end portions 534 are secured between the frame 516 and the clip 530. That is, the end portions 534 are secured between respective flanges of opposing channels 565 and flanges of the clip 530. When the nozzle assembly 518 is attached to the frame 516, the nozzle assembly 518 and the frame 516 together form a conduit for directing breathable gas to the patient's nose through the pair of nozzles 550.

[00294] The clip 530 may be engaged with the frame 516 and nozzle assembly 518 in any suitable manner. For example, as shown in Figs. 62 and 70, the clip 530 may be slid onto the frame 516. Alternatively, the clip 530 may be engaged with the frame 516 with a snap-fit.

[00295] As shown in Fig. 59, the frame 516 is secured to the nozzle assembly 518 such that the frame 516 is angled away from an upper lip of the patient in use. This positions the clip 530 away from the patient such that it does not irritate the patient's face. Also, the nozzle assembly 518 may be contoured to accommodate a patient's septum in use.

[00296] The above-described coupling of the frame 516 and nozzle assembly 518 allows the nozzle assembly 518 to be easily removable from the frame 516 to facilitate cleaning of the nozzle assembly 518. Moreover, the configuration of the nozzle assembly 518 allows interior portions of the nozzle assembly 518 to be accessible for cleaning. The nozzle assembly's configuration also facilitates manufacturing.

[00297] However, the nozzle assembly 518 may be removably attached to the frame 516 in any other suitable manner. For example, Figs. 67, 69, and 71 illustrate another method of attaching the nozzle assembly to the frame. As illustrated, the frame 616 is structured without channels in the main body such that the nozzle assembly 618 wraps around the main

body and the clip 630 is secured between the side frame members of the frame 616 to hold the end portions of the nozzle assembly 618.

[00298] As shown in Fig. 72, the second connector portion 526 includes a main body having a front portion 560 and a rear portion 562. A groove 561 is provided adjacent the front portion 560. The front portion 560 includes an annular rib portion 540 (Fig. 73). The front portion 560 of the second connector portions 526 are stretched over the respective first connector portion 524 to provide an interference fit. Also, the rib portion 540 is adapted to engage within the recess 566 of the first connector portion 524 for coupling the first and second connector portions 524, 526 with one another, as shown in Fig. 73. The second connector portion 526 may rotate with respect to the first connector portion 524 for an infinite amount of settings for alignment of the nozzles 550 with respect to the nasal passages of the patient. The setting may be optionally locked by friction, for example. That is, the rotatable coupling allows the frame 516 to be rotated with respect to the second connector portions 526 so as to adjust the position of the nozzles 550 with respect to the patient's nose in use.

[00299] The second connector portions 526 may be formed of silicone with a hardness of about 50-60 Shore A hardness. This hardness facilitates assembly, swiveling movement, and seal with the frame 516. However, the second connector portions 526 may be formed of any other suitable material and may have any suitable hardness.

[00300] Each second connector portion 526 is also formed with a feature that allows relative movement between the angle connector 542 and the frame 516 for different facial widths. In the illustrated embodiment, the feature is a corrugation 538 in the second angle connector 542. This feature isolates the connection between the second connector portion 526 and the frame 516 to prevent detachment. This feature also allows the second connector portions 526 to be flexible so as to dampen tube drag forces. Moreover, the second connector portions 526 are flexible without obstructing airflow. However, the feature may have any other suitable structure to provide flexibility.

[00301] In the illustrated embodiment, each of the second connector portions 526 is provided with or connected to the angle connector 542 (see Figs. 74-76) that connects with the respective inlet conduit 574. The second connector portions 526 and the angle connectors 542 may be formed in an integral one piece unit. The rear portion 562 of each second connector portion 526 includes an interlock in the form of an undercut 544 (Fig. 73) for engagement with the angle connector 542. The angle connector 542 includes a conduit 545 with a shoulder portion 546 that engages the undercut 544 to secure the angle connector 542

to the second connector portion 526, as can be determined from Fig. 73, an exploded view prior to connection.

[00302] The angle connector 542 includes elongated connectors 552 structured to engage the respective inlet conduit 574. In the illustrated embodiment, the elongated connectors 552 have a tapered configuration to facilitate connection. Also, the connectors 552 are arranged to wedge the inlet conduit 574 therebetween to secure the inlet conduit 574 thereto. As shown in Fig. 76, the conduit 545 and elongated connectors 552 of the angle connector 542 are angled about 80° from one another. However, the angle between the conduit 545 and elongated connectors 552 may have any other suitable dimension.

[00303] Fig. 76A illustrates another embodiment of a mask assembly similar to that shown in Fig. 60. Fig. 76B is an exploded view of the mask assembly in Fig. 76A. A yoke 580' in Figs. 76A and 76B is somewhat different from the yoke 580 shown in Fig. 60 in that the yoke 580' in Figs. 76A and 76B has dimensions that are more streamlined, styled and/or optimized for use with the headgear straps. In addition, a second connector portion 526' and elbow connector 542' in Fig. 76A are structured to facilitate alignment (or prevent misalignment) therebetween. In particular, as best shown in Fig. 76C, the second connector portion 526' includes a tab 526a which is intended to be received within a key way or recess 542a of elbow connector 542'. The elbow connector 542' also includes a ridge 542b which receives a tip portion of the tab 526A.

[00304] Returning to Fig. 59, first ends of the pair of conduits 574 are connected to respective angle connectors 542. Second ends of the pair of conduits 574 are connected to a flow generator connector 584 coupled or provided to a swivel 590, which in turn is in communication with a pressurized supply that supplies pressurized breathable gas. As illustrated, the angle connectors 542 route the pair of inlet conduits 574 downwardly under the chin of the patient.

[00305] As a result, pressurized gas can pass through the pair of inlet conduits 574, angle connectors 542, second connector portions 526, frame 516 and nozzle assembly 518, and through the nozzles 550 for breathing by the patient.

[00306] Figs. 77 and 78 illustrate the flow generator connector 584 structured to interconnect the second ends of the pair of inlet conduits 574 with the swivel 590 which is in communication with a pressurized supply. The flow generator connector 584 includes first elongated connectors 586 structured to engage one of the inlet conduits 574 and second elongated connectors 588 structured to engage the other of the inlet conduits 574. In the illustrated embodiment, the first and second elongated connectors 586, 588 have a tapered

configuration, e.g., the tops are formed at an angle, to facilitate connection. Also, the first and second elongated connectors 586, 588 are arranged to wedge the respective inlet conduit 574 therebetween to secure the respective inlet conduit 574 thereto, e.g., by friction. Moreover, the flow generator connector 584 has a general Y-shape with the first elongated connectors 586 angled with respect to the second elongated connectors 588. The Y-shape of the flow generator connector 584 prevents incorrect assembly with the inlet conduits 574 and assists in merging the air paths. As shown in Fig. 59, a swivel 590 may be attached to the flow generator connector 584 to allow relative movement with respect to the pressurized supply.

[00307] As shown in Fig. 79, each inlet conduit 574 includes a plurality of channels. In the illustrated embodiment, each inlet conduit 574 is constructed with tubing that provides a dual air flow channel to prevent or at least reduce kinking and crushing and facilitate connection. However, the conduits 574, angle connectors 542, and connector 584 may be structured to provide one air flow channel or more than two air flow channels. The inlet conduits 574 may be formed with silicone and have a hardness of about 50 shore A hardness. However, the inlet conduits 574 may be formed of any other suitable material and have any suitable hardness.

[00308] The inlet conduits 574 are structured to provide low impedance. In one embodiment, the inlet conduits 574 provide impedance less than about 3 cmH_2O, for a given flow rate. Also, the inlet conduits 574 have a low profile. As shown in Fig. 79, each inlet conduit 574 has a width of about 20 mm and a height of about 9.5 mm. However, the inlet conduits 574 may have any other suitable shape, size and structure. For example, the inlet conduits 574 may have a substantially D-shaped cross section. The width dimension of 20 mm can be adjusted to change the impedance. For example, if the width is decreased while the height and pressure remain constant, the impedance will be increased, as the cross-sectional area decreases. Conversely, if the width is increased, keeping the height and pressure constant, the impedance can be lowered. The result is that impedance can be lowered without increasing the height, thereby maintaining a low profile of the inlet conduits 574, such that they are less obtrusive to the patient and/or do not uncomfortably dig into the patient's face or skin. Other components of the air delivery path, e.g., the angle connectors 542, have been designed with a view towards decreasing impedance. By contrast, impedance of an inlet conduit or angle connector with a round cross section can be similarly lowered by increasing the diameter of the conduit, but the profile also increases with commensurate discomfort to the patient since the conduit may assume a position further outward from the

patient's face, and/or the conduit may be pressed against the patient's face, which decreases comfort and compliance.

[00309] The headgear assembly 520 is removably attached to second connector portions 526 and angle connectors 542 to retain the second connector portions 526 on the frame 516. Also, the headgear assembly 520 is structured to transfer a tube pulling force to the headgear assembly 520 or the frame 516, to thereby avoid or reduce the chances that the tube pulling force is applied to the nozzle assembly, which may compromise the seal between the nozzles and the patient's airways.

[00310] As shown in Figs. 59 and 60, the headgear assembly 520 includes two side portions 592 with a rear portion 594 connecting the side portions 592. The side portions include side straps and a headgear yoke 580 is attached to each side strap. The headgear yoke 580 acts as a stiffener to add rigidity to the headgear assembly 520. Figs. 59 and 60 show slightly different yoke configurations. In Fig. 59, the yoke is shown as a member which covers at least a portion of flexible straps 598, 599, to add stiffness or rigidity thereto. In Figure 60, the yoke 580 is a semi-rigid layer, such as plastic, which is provided to, e.g., sewn onto, the headgear straps 598 and/or 599. The yoke in Fig. 60 may be more or less co-extensive with the straps 598 and/or 599, depending on the desired stiffness. The yoke 580 in Fig. 60 is also shown in Figs.80-82. The rear portion 594 includes upper straps 598 that pass over the top of the patient's head and rear straps 599 that pass around the rear portion of the patient's head. The upper straps 598 are structured to adjust the sealing force because they pull the frame 516 up into the patient's nose. The rear straps 599 are structured to adjust the stability of the nasal assembly 510 because they pull the frame 516 back into the patient's face on the top lip of the patient.

[00311] The upper straps 598 are coupled to one another by a headgear buckle 570. The headgear buckle 570 is structured to allow symmetrical adjustment of the headgear assembly 520. Specifically, as shown in Fig. 83, the headgear buckle 570 includes a first locking portion 571 and a second locking portion 572. The first locking portion 571 is adapted to be removably and adjustably coupled with one of the upper straps 598 extending from one of the headgear yokes 580 and the second locking portion 572 is adapted to be removably and adjustably coupled with the other of the upper straps 598 extending from the other of the headgear yokes 580. Each of the upper straps 598 may be wrapped around the cross-bar of the associated locking portion 571, 572 of the buckle 570, as best shown in Fig. 59. A tab 576 is provided on each locking portion 571, 572 to facilitate the patient in adjusting headgear tension. Also, the headgear buckle 570 includes a curved surface 578 that prevents

contact of the buckle 570 with the patient's head. The rear straps 599 may be coupled to one another by a buckle (as upper straps 598 are) or in any other suitable manner.

[00312] The headgear yokes 580 of the headgear assembly 520 include retaining members 581 engaged with respective second connector portions 526 so as to retain the second connector portions 526 on the frame 516. In the illustrated embodiment, the retaining members 581 are ring-shaped and enclose the respective second connector portions 526. As shown in Fig. 73, the ring-shaped retaining members 581 have an annular protrusion that engages within the annular groove 561 in a respective second connector portion 526 so as to securely retain the second connector portions 526 on the frame 516.

[00313] Also, the pair of retaining members 581 are engaged with respective grooves 561 (Fig. 72) provided in second connector portions 526 so as to transfer the headgear force to the frame 516. This allows a more accurate adjustment of the force applied by the headgear assembly 520 to the frame 516. Moreover, the headgear buckle 570 is centrally located on the patient's head to allow symmetrical adjustment of the headgear assembly 520 and hence adjust the headgear force applied to the frame 516.

[00314] The angle connectors 542 of the second connector portions 526 are releasably interlockable with the headgear assembly 520. Specifically, the angle connectors 542 include first locking members 554 (see Fig. 74B) that are interlockable with second locking members 556 (see Fig. 80) provided on the headgear yoke 580 of the headgear assembly 520. In the illustrated embodiment, the first locking members 554 are hook-shaped members that interlock with a cross-bar provided by the second locking members 556, as shown in Figs. 81 and 82. The locking members are tapered and designed to keep a low profile.

[00315] Fig. 84 and 85 illustrate the nasal assembly 510 engaged with nasal passages of a wearer's nose. As shown in Fig. 84, the nasal assembly 510 is structured such that the angle connectors are angled about 10° below the horizontal so that the nasal assembly 510 avoids contact with the patient's cheekbone. Also, Fig. 84 shows that the clip 530 which holds the split ends of the nozzle assembly is angled upwardly and outwardly away from the lips of the patient, to prevent inadvertent contact with the patient. The angle may be in the range of 10-90 degrees, and preferably 20-60 degrees or about 30 degrees. As shown in Fig. 85, the second connector portions 526 are angled about 55° from the frame 516. The corrugation 538 (Fig. 73) may be provided to flex (inward and outward) so as to accommodate patients with faces varying in width. However, the angles noted above are only exemplary and the nasal assembly 510 may be structured to provide any suitable angle with the patient's face.

[00316] Similar to the nasal assemblies described above, the inflation of the gusset or base portion 548 along with the headgear tension provides an effective sealing force against the nasal passages of the patient. Also, the springiness of the nozzles 550 provides an additional sealing force.

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[00317] Figs. 86-88 show another embodiment of a nasal assembly 10 structured to deliver breathable gas to the nasal passages 12 of the patient's nose 14 (see Figs 97A and 97B). The nasal assembly 10 includes a flexible conduit 16, a gusset portion 18, a pair of nozzles 20, 22, and a headgear connector 25. The flexible conduit 16 has a portion adapted to receive a supply of pressurized breathable gas and a patient side 24. The gusset portion 18 has a first side 26 (see Fig. 89) attached to the patient side 24 of the flexible conduit 16 and a second side 28. The pair of nozzles 20, 22 each have a first portion 30 attached to the second side 28 of the gusset portion 18 and a second portion 32 structured to sealingly engage with nasal passages 12 of the patient's nose 14 in use and provide a seal between the nasal assembly 10 and the patient's nasal passages 12 (see Fig. 90). The headgear connector 25 attaches the flexible conduit 16 to a headgear assembly positioned on the patient's head. The gusset portion 18 is structured such that it can expand and contract to alter a distance between the conduit 16 and the pair of nozzles 20, 22, as will be further discussed below.

[00318] Alternatively, the gusset portion can be eliminated in favor of a more rigid construction that does not allow significant, if any, expansion or contraction. Instead, as described above in relation to the other main illustrated embodiments, the nozzles may be structured to engage that patient's nares with some degree of pretension (before the mask is in use, e.g., pressurized), which pretension can be achieved by compressing the nozzles in an axial or longitudinal sense.

[00319] In the illustrated embodiment, the flexible conduit 16 includes a central conduit 34, a pair of inlet conduits 36, 38 connected to the central conduit 34 by respective inlet connectors 40, 42, and a Y-shaped inlet connector 44 that interconnects the inlet conduits 36, 38. The Y-shaped inlet connector 44 is structured to be connected to a conduit that is connected to a pressurized supply. The pressurized supply supplies pressurized breathable gas through the inlet conduits 36, 38 and central conduit 34, into the gusset portion 18, and into the nozzles 20, 22 for breathing by the patient.

[00320] As shown in Fig. 89, the central conduit 34 includes an upper portion 46 and a lower portion 48 that are coupled to one another. Each of the upper and lower portions 46, 48 includes an arcuate transverse cross-section such that the upper and lower portions 46, 48 form a conduit when coupled together at respective edges. In the illustrated embodiment, the upper and lower portions 46, 48 are rigidly coupled to one another by an adhesive, such as glue, for example. However, the upper and lower portions 46, 48 may be rigidly coupled to one another by any other suitable means, such as fasteners. Alternatively, the upper and lower portions 46, 48 may be removably coupled to one another, or they may be formed in a single unitary piece.

[00321] As shown in Figs. 86, 88, 90 and 92-95, the upper and lower portions 46, 48 have a generally C-shape when viewed from above. Specifically, each of the upper and lower portions 46, 48 includes an elongated central section 50 and curved end sections 52, 54. However, the upper and lower portions 46, 48 may have any other suitable shape, such as an elongated shape, as shown in Fig. 89.

[00322] The curved end sections 52, 54 each include a groove 56, as shown in Fig. 94 for example. When the upper and lower portions 46, 48 are coupled to one another, the grooves 56 retain respective inlet connectors 40, 42, as will be further discussed. At least one of the upper and lower portions 46, 48 includes an anti-crush rib 58 that prevents the central conduit 34 from deformation that can prevent the flow of air therethrough. In Fig. 89, the groove 56 is provided on opposing ends thereof.

[00323] As shown in Fig. 89, the upper portion 46 of the central conduit 34 includes an opening 60. The gusset portion 18, which is in the form of an expandable and contractible pillow, includes a first side or sidewall 26 and a second side or sidewall 28 that define a space therebetween. The first sidewall 26 is attached to the upper portion 46. The first sidewall 26 includes an inlet opening that is communicated with the opening 60 in the upper portion 46. The second sidewall 28 has a pair of outlet openings. The connection between the gusset portion 18 and the upper portion 46 of the central conduit 34 is a flexible connection that allows relative movement between the gusset portion 18 and the central conduit 34, for increased comfort and accommodation of variations in patient facial features.

[00324] In the illustrated embodiment, the gusset portion 18 has a generally rectangular shape. However, the gusset portion 18 may have a generally circular or round cross-section, or any other suitable shape, including shapes to avoid sensitive regions of the patient's face, e.g. notched gusset shape to prevent contact with the patient's septum.

[00325] The pair of nozzles 20, 22 each has a first portion 30 attached the second sidewall 28 of the gusset portion 18 in communication with a respective outlet opening of the gusset portion 18. The second portion 32 of each of the nozzles 20, 22 is structured to sealingly engage with nasal passages 12 of the patient's nose 14 in use and provide a seal between the nasal assembly 10 and the patient's nasal passages 12. In the illustrated embodiment, the nozzles 20, 22 are in the form of nasal pillows wherein the second portion 32 is contoured (e.g., tapered, cone-shaped, truncated hollow cone, etc.) with a portion that seals on the underside of the nostrils and another portion that enters into the nasal passage of the patient's nose in use. However, the nozzles 20, 22 may be in the form of nasal prongs, cannula, or nasal puffs, for example, and may sealingly engage with the nasal passages in any suitable manner. For example, the nozzles 20, 22 may seal within the nasal passages, against the nasal passages, around the nasal passages, or combinations thereof. The nozzles 20, 22 may include a corrugated or flexible portion that allows the nozzles 20, 22 to move relative to the gusset portion 18 and the central conduit 34. The nozzles 20, 22 may be contoured to match the interior profile of the patient's nose 14.

[00326] In one embodiment, the nasal assembly uses patient-customized nozzles which may be removably mounted to the gusset portion. In a preferred form, the nozzles are constructed from a substantially flexible polymer material, such as a silicone elastomer. A unique nozzle can be made to match each patient's nose by first scanning their nose, either in situ or remotely, and then using the data for manufacture of the interface, for example, a mold maker. Scanning can be done using either non-contact or contact methods. Non-contact, for example photographically, or by physical contact with a probe or by collecting an impression of the inside of the nares or the desired contact interface. Once a pair of suitable nozzles are made, they are sent to the customer to be fitted to a patient. Advantages of the preformed or customized shape is that cross-sectional area may be maximized to reduce flow impedance.

[00327] Also, the use of preformed shapes improves comfort and increased stiffness materials such as semi-rigid plastics may be used that have greater resistance to distorting, thus minimizing nozzle distortion of the patient nares. Further, rigid plastics may be used that allows thin wall sections and allows flexibility of the nozzle due to its connection to the gusset portion, e.g., the gusset portion is soft and compliant.

[00328] In the illustrated embodiment, the upper portion 46 of the central conduit 34 is molded in one piece with the gusset portion 18 and nozzles or nasal pillows 20, 22 from deformable and inflatable materials. The central conduit 34, nasal pillows 20, 22, and gusset portion 18 may be constructed from a soft, flexible skin-compatible material such as silicone.

The central conduit 34, nasal pillows 20, 22, and gusset portion 18 may be formed, for example, in an injection molding process as is known in the art.

[00329] However, the central conduit 34, nasal pillows 20, 22, and gusset portion 18 may be formed with any suitable material and may be formed by any suitable process. For example, the central conduit 34, gusset portion 18, and nasal pillows 20, 22 may be formed separately and permanently attached to one another with an adhesive, welding, and/or mechanical fasteners, for example. Alternatively, the central conduit 34, gusset portion 18, and nasal pillows 20, 22 may be formed separately and removably attached to one another.

[00330] The lower portion 48 of the central conduit 34 includes an exhaust vent 62 and a pair of tapered or barbed protrusions 64 structured to retain the headgear connector 25 to the central conduit 34. The exhaust vent 62 is aligned with the opening 60 in the upper portion 46. The exhaust vent 62 protrudes slightly outwardly from the central conduit 34 and includes a series of openings 66 for CO_2 washout.

[00331] As shown in Fig. 89, the headgear connector 25 is in the form of an elongated strap that includes a pair of openings 68 adapted to receive respective protrusions 64 of the lower portion 48 therethrough and a central opening 70 adapted to receive the exhaust vent 62 therethrough. Specifically, the openings 68 press over the tapered or barbed protrusions 64 to retain and locate the headgear connector 25 to the central conduit 34.

[00332] Further, the headgear connector 25 includes connection structures 72 on free ends thereof for connection to a headgear assembly (not shown). The headgear assembly can be removably connected to the connection structures 72 to maintain the nasal assembly 10 in a desired position on the patient's face. For example, the headgear assembly may include straps removably connected to respective connection structures 72.

[00333] As shown in Fig. 91, the connection structures 72 may have rounded edges. Moreover, the openings 68, 70 may have any suitable shape (e.g. oval, circular, rectangular, etc.). For example, Fig. 91 illustrates openings 68, 70 with a generally oval shape and Fig. 89 illustrates openings 68 with a generally circular shape and opening 70 with a generally rectangular shape.

[00334] The headgear connector 25 is constructed of a deformable and resilient material so that it can deform in at least one bending plane, e.g., around the face of the patient in use. For example, the headgear connector 25 may be constructed of polypropylene or any other suitable polymer. Also, the headgear connector 25 may be constructed of a natural or synthetic fabric material, or a combination of materials such as a laminate combination. The headgear connector 25 is deformable such that it can conform to the contour of the patient's

face when the nasal assembly 10 is mounted to the patient's head. Further, the headgear connector 25 bears the tension applied by the headgear assembly which prevents any tension from pulling on, and subsequently distorting, the flexible central conduit 16.

[00335] However, the headgear connector 25 may have any suitable structure for connection to a headgear assembly. For example, the headgear connector 25 may be the protrusions 64 provided on the central conduit 34 and the headgear assembly may attach directly to the protrusions 64. Alternatively, the headgear connector may be in the form of a locking clip receiver assembly structured to connect to a respective locking clip provided on the headgear assembly. Details of a locking clip receiver assembly and locking clips are provided in U.S. Provisional Applications of Moore et al., Serial Nos. 60/377,254, 60/397,195, and 60/402,509, all of which are hereby incorporated into the present application by reference in their entireties.

[00336] The central conduit 34 is connected to the pair of inlet conduits 36, 38 by inlet connectors 40, 42. As shown in Fig. 97, each inlet connector 40, 42 includes a first conduit portion 74 that branches into a pair of second conduit portions 76. The first conduit portion 74 includes a radially expanded flange 78 that is received within a respective groove 56 provided by the central conduit 34 on opposing end sections 52, 54 thereof. Thus, a first inlet connector 40 is retained to one end section 52 of the central conduit 34 and a second inlet connector 42 is retained to the opposite end section 54 of the central conduit 34.

[00337] The inlet conduits 36, 38 each may have a first end connected to respective inlet connectors 40, 42 and a second end connected to the Y-shaped inlet connector 44. As shown in Fig. 96, each of the inlet conduits 36, 38 include first and second passageways 80, 82. The pair of second conduit portions 76 of the inlet connector 40, 42 are inserted through the first and second passageways 80, 82 of the first end of the inlet conduit 36, 38 to couple the inlet connectors 40, 42 with respective first ends of the inlet conduits 36, 38. The inlet connectors 40, 42 and inlet conduits 36, 38 may retained with a friction-type fit, mechanical fasteners, adhesive, co-molded, insert-molded, or any other suitable means.

[00338] As shown in Fig. 96A, the Y-shaped connector 44 includes a first connector 84 that is connected with the second end of one of the inlet conduits 36, a second connector 86 that is connected with the second end of other of the inlet conduits 38, and a third connector 88 that is connected to a pressurized supply for delivering pressurized gas to the nasal assembly 10. Each of the first and second connectors 84, 86 includes a pair of conduit portions 90 that are inserted through the first and second passageways 80, 82 of the inlet conduit 36, 38 to couple the Y-shaped connector 44 with respective inlet conduits 36, 38.

The third connector 88 may include a swivel mechanism to allow relative movement between the Y-shaped connector 44 and the delivery conduit connected to the pressurized supply. The Y-shaped connector 44 and inlet conduits 36, 38 may retained with a friction-type fit, mechanical fasteners, adhesive, welding, insert molding or any other suitable means.

[00339] As shown in Fig. 98, the central conduit 34 and inlet conduits 36, 38 may be formed of crush-resistant, anti-crush, or anti-kinking tubing such as that disclosed in U.S. Patent No. 6,044,844, the entirety of which is incorporated herein by reference.

[00340] Pressurized gas enters through connector 88 of the Y-shaped connector 44 and proceeds through the first and second inlet conduits 36, 38 into both end sections of the central conduit 34. Air passes though the central conduit 34, into the gusset portion 18 and nasal pillows 20, 22, and into the nasal passages 12 of the patient. Exhaust gases from the patient's nose can exit through the exhaust vent 62 provided in the central conduit 34.

[00341] As best shown in Figs. 86 and 89, the gusset portion 18 extends outwardly from the central conduit 34 to provide additional surface area or footprint area. As air under pressure enters the central conduit 34, both the central conduit 34 and gusset portion 18 inflate, which moves the nasal pillows 20, 22 into sealing engagement with the nasal passages 12 of the patient. However, the central conduit 34 may not be inflatable along with the gusset portion 18. That is, the gusset portion 18 is structured such that it can expand and contract to alter a distance between the central conduit 34 and the nasal pillows 20, 22. The gusset portion 18 moves the nasal pillows 20, 22 between a first position (as shown in Fig. 97A) in which the nasal pillows 20, 22 are adjacent to the nasal passages 12 of the patient and a second position (as shown in Fig. 97B) in which the nasal pillows 20, 22 are moved into sealing engagement with the nasal passages 12 of the patient. Specifically, the gusset portion 18 is uninflated or generally flat when not pressurized by a gas. However, the gusset portion 18 may not have a generally flat structure when uninflated. In the uninflated condition, the nasal pillows 20, 22 are spaced from the nasal passages 12 of the patient or in light contact therewith. When the nasal assembly 10 is pressurized by a gas, the gusset portion 18 is inflated and moves the nasal pillows 20, 22 into sealing engagement with the nasal passages 12 of the patient to form a seal between the nasal assembly 10 and the patient's nasal passages 12. As the gas pressure is increased, the force applied to the underside of the nasal passages 12 is increased through the gusset portion 18.

[00342] The gusset portion 18 provides additional surface area or footprint area to the central conduit 34, which in turn provides an additional force on the nasal pillows 20, 22 which increases the sealing efficiency of the nasal pillows 20, 22. That is, the gusset portion

18 is configured and positioned to force the nasal pillows 20, 22 into contact with the patient's nose. The force or pressure on the patient's nose is proportional to the pressure in the central conduit 34 and the additional surface area of the gusset portion 18. Thus, the surface area of the gusset portion 18 may be varied, e.g., to vary the force or pressure applied to the patient's nose.

[00343] The gusset portion 18 reduces the headgear assembly tension required to achieve a suitable seal. That is, the pressure applied to the patient's nose is provided by the gusset portion 18 and not relied on by the tension from the headgear assembly. This improves patient comfort as well as sealing properties.

[00344] Accordingly, it is desirable when adjusting the headgear assembly to bring the nasal pillows 20, 22 only near or in very light contact with the patient's nose. In this way, the gusset portion 18 is not compressed substantially.

[00345] The gusset portion 18 may include a connecting wall between the side walls 26, 28 thereof. The connecting wall may act as a spring structure to provide a component of force on the patient's face through the nasal pillows 20, 22. The force may be tailored by adjusting a thickness of the connecting wall. Moreover, the thickness of the connecting wall may be varied in conjunction with the surface area provided by the gusset portion 18.

[00346] The gusset portion 18 also provides a decoupling joint between the central conduit 34 and the nasal pillows 20, 22, thus allowing some relative movement between the nasal assembly 10 and the user's face. As a result, the nasal pillows 20, 22 can accommodate small variations in the shape of the patient's nasal features without undue force, and can account for small movement of the nasal assembly 10 relative to the patient's nose during use, while maintaining an effective seal.

[00347] Also, the gusset portion 18 need not be a single gusset form discussed above, but can have alternative configurations. For example, the gusset portion 18 may be in the form of a two or more gusset portions provided in series.

[00348] Figs. 98-106 illustrate another embodiment of a nasal assembly, indicated as 210. As best shown in Figs. 98-100, the nasal assembly 210 includes a central conduit 234, a pair of inlet conduits 236, 238 connected to the central conduit 234 (e.g., by an adhesive), and an inlet connector 244 that interconnects the inlet conduits 236, 238. The inlet connector 244 is structured to be connected to a conduit that is connected to a pressurized supply. The inlet connector 244 may be axially swivelable to maximize stability by reducing kinking of the conduits.

[00349] A gusset portion 218 is provided that includes first and second side walls 226, 228 that define a space therebetween. The first side wall 226 includes an inlet opening that is communicated with an opening in the central conduit 234. The second side wall 228 has a pair of outlet openings. In the illustrated embodiment, the gusset portion 218 has a general bow-tie shape. However, the gusset portion 218 may have any other suitable shape.

[00350] A pair of nozzles 220, 222 in the form of nasal pillows are provided. Each nasal pillow 220, 222 has a first portion 230 attached the second side wall 228 of the gusset portion 218 in communication with a respective outlet opening of the gusset portion 218. The second portion 232 of each of the nasal pillows 220, 222 is structured to sealingly engage with the nasal passages 12 of the patient's nose 14 in use and provide a seal between the nasal assembly 210 and the patient's nasal passages 12.

[00351] In the illustrated embodiment, the central conduit 234, inlet conduits 236, 238, gusset portion 218, and nasal pillows 220, 222 are constructed from flexible materials, such as silicone, and attached to one another with an adhesive. However, the central conduit 234, inlet conduits 236, 238, gusset portion 218, and nasal pillows 220, 222 may be molded in one piece, or formed with any other suitable material in any suitable process.

[00352] The central conduit 234 includes exhaust vents 262 (Figs. 100 and 101) that protrude slightly outwardly therefrom for CO_2 washout. Also, a headgear connector 225 in the form of a pair of clips 272, are attached to the conduits 234, 236, 238 (e.g., by an adhesive) for connection to a headgear assembly 206. The headgear assembly 206 includes straps 207 removably connected to respective clips 272 by a hook and loop fastener, for example. As shown in Figs. 101 and 102, the straps 207 pass over the ears of the patient and engage a head cloth 208 that sits on the upper portion of the patient's head to cup the occipital portion of the patient's head. However, the headgear assembly 206 may have any suitable structure for maintaining the nasal assembly 210 on the patient's head.

[00353] Figs. 103-106 illustrate the nasal assembly 210 engaged with outer edges of the nasal passages 12 of the patient's nose 14. Similar to the nasal assembly 10 described above, as air enters the central conduit 234, both the central conduit 234 and gusset portion 218 inflate, which moves the nasal pillows 220, 222 into sealing engagement with the nasal passages 12 of the patient. However, the central conduit 234 may not be inflatable along with the gusset portion 218. That is, the gusset portion 218 moves the nasal pillows 220, 222 between a first position in which the nasal pillows 220, 222 are adjacent to the nasal passages 12 of the patient and a second position in which the nasal pillows 220, 222 are moved into sealing engagement with the nasal passages 12 of the patient.

[00354] In the embodiments of nasal assemblies 10, 210, the inlet conduits 36, 38, 236, 238 extend downwardly from the nasal pillows 20, 22, 220, 222 away from the patient's head. However, as shown in Fig. 107, the nasal assembly, indicated as 310, may be an over-the-head type assembly in which the inlet conduit(s) 336 extends upwardly from the nasal pillows 320, 322 over the head of the patient.

[00355] Fig. 107-1 illustrates an embodiment like that shown in Fig. 107, but which includes an adjustable forehead support 411. The forehead support 411 includes a first portion 413 provided to a tube support 415. Connection between the first portion 413 and the tube support 415 allows adjustment of a second portion 417 of the forehead support 411 relative to the patient's forehead, to achieve the best possible fit. The second portion 417 includes a bridge 419 to support one or more forehead cushions or pads 421, as described in U.S. Patent No. 6,119,693 or in U.S. Patent Application No. 10/655,595 (each incorporated herein by reference in its entirety) and headgear connector portions 423 for releasable connector to headgear straps 425. The headgear connector portions may take the form of those shown in U.S. Patent No. 6,374,826, incorporated herein by reference in its entirety, or in U.S. Provisional application No. 60/467,570, incorporated herein by reference in its entirety. The bridge 419 may include a central portion 427 structured to accommodate, guide and/or hold an upper portion of air delivery tube as it is guided over the head of the patient. Adjustment may be achieved via bending, flexing and/or pivoting of the first portion 413 relative to the support 415. For example, support 415 may include a pivot pin 429 which is introduced into an aperture on the first portion 413. Support 415 and first portion 413 may include a plurality of locking members 431 (e.g., protrusions and recesses), to allow locking of the forehead support 411 in a number (e.g., 3-5, preferably 4) of predetermined positions.

[00356] Fig. 107-2 illustrates another embodiment of an adjustable forehead support that operates like that disclosed in U.S. Patent No. 6,532,961, incorporated herein by reference in its entirety.

[00357] Figs. 107A-107C illustrate yet another alternative embodiment of the present invention. Fig. 107A is a perspective view of a mask assembly 650, while Fig. 107B is a side view of the mask assembly shown in Fig. 107A. The mask assembly 650 includes a headgear assembly 652 and a nasal cushion assembly 654. The headgear assembly includes a coronal strap 654 and an occipital strap 656.

[00358] A flexible tube 658 includes a first end 660 which may include a swivel connector. The tube 658 is provided with a suitable source of pressurized gas. The tube includes a second end 662 which is provided to the cushion assembly 654. The tube 658 is

supported by a support frame 664. The support frame includes a lower portion 666 which supports a cushion 668 of the cushion assembly 654. The support frame also includes a central portion 670 and an upper portion 672. The upper portion 672 may include flexible arms separated by a gap. The arms may be resiliently deformed to allow insertion and removal of the tube between the two arms. The support frame 664 may include lateral support arms 674 which are configured to rest against the patient's forehead in use. Each lateral support arm 674 includes first and second connector slots 676 and 678 which provide a connection point for coronal strap 654 and occipital strap 656, respectively.

[00359] Fig. 107B is a side view of the mask assembly. Fig. 107C is an enlarged side view of a portion of the assembly 650 shown in Figs. 107A and 107B. The lower portion 666 of the support frame 664 is adapted to support the cushion 668 as shown therein. The cushion 668 includes a pair of nozzles 680 (one shown) which are formed in an integral piece with a plenum chamber 682.

[00360] Figs. 107D and 107E illustrate yet another embodiment of the present invention. A mask assembly 690 includes a headgear assembly 692 which includes an occipital strap 694, a coronal strap 696 and depending arm straps 698 each of which extends from a junction between the occipital and coronal straps 694 and 696 and forwardly of the ear along the user's face. The top portion of the coronal strap 696 may include a suitable connector 700 such as the flexible arms shown in Fig. 107A. Alternatively, the connector 700 may take the form of a VELCRO® loop which helps to fasten a tube 702. The tube 702 includes a first end 704 which may be provided with a swivel connector which in turn is connected to a suitable source of pressurized gas via an air delivery tube. The tube 702 is routed over the top of the forehead and is generally aligned with but spaced from the nose and bridge of the patient. A support frame 708 includes an upper portion 710 which helps to maintain the tube 702 in the desired position. The upper portion 710 may include flexible arms, like the upper portion 672 in Fig. 107A.

[00361] The support 708 may include a pair of lateral arms 714, best illustrated in the side view of Fig. 107E. Each lateral support arm 714 includes a connector slot 715 which is adapted to receive an end of the depending arm strap 698.

[00362] Fig. 107F illustrates an alternative embodiment of a mask assembly 720 including a headgear assembly 722 having the configuration generally corresponding to that of the letter "X", including a first cross strap 724 and a second cross strap 726. The first and second cross strap 724 and 726 meet at a junction or intersection 728. The forward end of second cross strap 726 is provided with a connector element 730, which may take the form of a

VELCRO® loop. The connector element 730 may be adapted to support and/or hold a transitional tubing piece which includes a first end for connecting with relatively large bore tubing 732 and a second end for accommodating relatively small bore tubing 734. A support frame 736 is provided to support the tube 734 and a cushion 738 in the position shown in Fig. 107F.

[00363] Fig. 107G illustrates a mask assembly 750 according to yet another embodiment of the present invention. The mask assembly 750 includes a headgear assembly 752 including a rear strap 754 and a forehead strap 756. A depending arm strap 758 extends from a junction between the rear strap 754 and the forehead strap 756. One or more of the straps may include a yoke member 759 which helps to reinforce and maintain the position of the straps relative to one another. As shown in Fig. 107G, the mask assembly 750 includes a tube 760 including a first end 762 that may include a swivel connector, which can be connected to an air delivery tube 764, which is in turn provided to a source of pressurized air.

[00364] As shown in Fig. 107H, each strap 758 includes a first connector portion 766 having one or more arms 767 which can be resiliently flexed toward one another to insert and remove the connector portion 766 from a suitable recess in frame 768. The frame 768 is provided with a connector portion 770 which receives and/or connects to the tube 760. As shown in Fig. 107H, only a portion of one of the nozzles 772 is visible.

[00365] Fig. 107I illustrates another embodiment of the present invention. A mask assembly 780 includes a headgear assembly 782 including a rear strap 784 and a forward strap 786. A tube 788 is connected to a junction connector 790 which in turn is connected to one or more soft flexible tubes 792 that follow and/or are connected to rear strap 784 on each side of the user's head. The headgear assembly 782 may include depending arm straps 783 that are positioned forward of the ear and along the cheek of the user. Each tube 792 may be suitably attached to the depending arm strap 783. Each tube 792 is suitably connected to a cushion assembly 794.

[00366] Fig. 107J illustrates still another embodiment of the present invention. A mask assembly 800 may include a headgear assembly, only a portion of which is shown in the drawing. The headgear assembly may include depending arm straps 802 which support lateral support arms 804 which are connected or provided to a cushion assembly 812. Each depending arm strap 802 may also support an interchange 806, which may take the form of a U-shape coupling member having a first end connected to an air delivery tube 808 and a second end connected to tube 810 which is connected to the cushion assembly 812.

[00367] Figs. 107K and 107L illustrate yet another embodiment of the present invention. As shown in Fig. 107K, a cushion assembly includes a frame 820, a plenum or bellows chamber 824 and a pair of nozzles 826 mounted on the plenum chamber 824. The cushion assembly may be supported by one or more lateral support arms 822, as shown in Fig. 107K. Alternatively, the cushion assembly can be supported by a support frame as shown, for example, in Fig. 107A. As shown in Fig. 107K, the nozzle 826 has a relatively low profile because it is engaged with a patient's nares. However, as shown in Fig. 107L, the nozzle 826 may extend from the low profile position shown in Fig. 107K to the higher profile position shown in Fig. 107L, by virtue of its resiliency.

[00368] Figs. 107M-107Q illustrate cross-sections of various nozzles 832, 834, 836, 840 and 844 according to the present invention. As shown in Fig. 107O, the nozzle may include a ledge 838 which is intended to rest on the nostril edge while the middle portion 839 is received by the nare. As shown in Fig. 107P, the nozzle 840 includes a cut away 842 which may be advantageous to avoid or reduce the chances of rubbing on the center of the nose. As seen in Fig. 107Q, the nozzle 844 may include a protrusion 846 to deflect air away from nostril walls. Fig. 107R shows the position of the protrusions 846 on the nozzles in perspective view.

SEVENTH ILLUSTRATED EMBODIMENT

[00369] Figs. 108-113 illustrate yet another preferred embodiment of the present invention. As shown in Fig. 108, a mask assembly 600 includes headgear 602 and a cushion assembly 604, each of which is substantially similar to the headgear and cushion assembly shown, e.g., in Figs. 60 and 61, respectively. Headgear 602 is designed to capture the crown of the patient's head. Adjustment of strap tension can be accomplished by pulling loose tabs on the top of the head in opposite directions. The pulley direction is not aligned with the force the nozzle assembly applies to the patient. Therefore, the patient is more isolated from the strap adjustment forces. Yokes provide stability to the sides. Yokes retain at least a partial portion of the basic shape of headgear, which facilitates donning of the headgear. Headgear need not include adjustability toward front of the face, as all adjustment of headgear can be effected at the back or top of the head.

[00370] In the embodiment of Fig. 108, one end of the cushion assembly 604 is provided with a plug 622 and the other end is provided with a swivel elbow 612. The positions of the swivel elbow 612 and the plug 622 may be interchanged, according to preference, e.g., the typical sleeping position of the patient. An air delivery tube 606 is joined to the swivel elbow 612. The air delivery tube 606 may include a swivel connector 607 and includes an end 609 which also may be provided with a swivel connector. The end 609 is provided with a source of pressurized gas.

[00371] As shown in Fig. 108, the elbow 612 is angled about 120' from the cushion assembly 604. This helps to keep the tube out of line of sight, to minimize pressure drop and to maintain the flexion point of tube as close to the face as possible. However, the elbow may have a typical 90° bend as shown, e.g., in Figs. 109 and 110.

[00372] Fig. 109 is a schematic perspective view of the mask assembly 600 shown in Fig. 108, but only yokes 608 of headgear 602 are shown without straps. As with the fifth main illustrated embodiment, the yoke 608 may include a yoke ring 610. As shown in Fig. 109, the cushion assembly may be adjustably rotated with respect to headgear, to a position which best fits the patient. In Fig. 109, the ring 610 of the yoke 608 of the headgear includes an alignment marker 611a and the cushion includes a plurality of alignment markers 611b that can be selectively aligned with marker 611a.

[00373] Fig. 110 is a cross-sectional view of a portion of the cushion assembly 604. In particular, the cushion assembly 604 includes a frame 616 which supports a cushion 617. The frame 616 includes a first connector portion 618 provided to each end of the frame 616 and/or cushion 617. Each first connector portion 618 is provided with or to a seal ring 614. Both seal ring and plug are examples of second connector portions that are connected or otherwise provided to the first connector portions 618. As seen in Fig. 110, the left hand side of the mask assembly includes the plug 622 while the right hand side of the mask assembly includes the swivel elbow 612, i.e., the reverse arrangement view shown in Figs. 108 and 109.

[00374] Fig. 110 shows that the cushion 617 includes a plurality of vent apertures 619, each of which is designed to reduce noise. Cross-sections of two possible aperture profiles are shown in Figs. 110-1 and 110-2. In Fig. 110-2, the end 617a displaces any potential noise creating flash (i.e., a molding seam) out of main air path through bore of vent. Stated differently, the molding seam is moved from a position from where it could potentially create noise, to a position where it is less likely to create noise.

[00375] Fig. 110A is a partial cross-sectional view showing the interaction between the seal ring 614, first connector portion 618 and the plug 622. In particular, the seal ring 614 may be provided with first and second protrusions 624, 626, respectively. The first protrusion 624 may interact with a groove 618a provided in the first connector portion 618, for sealing and/or locking purposes. The second protrusion 626 may interact with a groove 628 provided in the plug 622, the sealing and/or locking purposes. As shown in Fig. 110A, each seal ring 614 includes a groove 630 to receive a respective one of the rings 610 of the yoke 608. In Fig. 110A, the yoke 608 is not shown.

[00376] Fig. 110B is an enlarged partial cross-sectional view of the mask assembly 600 on the right hand side of Fig. 110. A first end 612a of the swivel elbow 612 is inserted in and received within the first connector portion 618. The first end 612a may include an enlarged head portion which prevents inadvertent dislodgment of the swivel elbow 612 from the assembly. The front end 612a may include at least one slot 613 to allow the enlarged head portion to reduce its diameter upon insertion by resiliently flexing. Preferably, there are a plurality of such slots, e.g., four slots. The seal ring 614 may include first and second protrusions 624, 626, as described above. In this case, the second protrusion 626 may interact by friction with the outer circumference of the swivel elbow 612, and provide a seal. Moreover, the swivel elbow 612 may be provided with a groove or other structure to receive the second protrusion 626.

[00377] Fig. 110B also schematically shows that the swivel elbow 612 and the seal ring 614 may include a swivel stop 631. For example, the swivel stop 631 may be formed as part of the yoke 608.

[00378] Alternatively or in addition, as shown in Fig. 111, the swivel elbow 612 may be provided with a ring 633 including a protrusion 634. The seal ring 614 may be modified to include swivel stops 632. Accordingly, the protrusion 634 may rotate along with swivel elbow 612 until the protrusion 634 abuts against the swivel stop 632. Therefore, movement of the air delivery tube 606 can be confined with a predetermined range of movement, e.g., about 220°-300°, and preferably 250°-270°, thus minimizing or avoiding undesirable contact between the air delivery tube and the patient.

[00379] Fig. 112 is a partial cross-sectional view of the assembly of the frame, first connector portion 618, yoke 608, seal ring 614 and plug 622. Fig. 112 shows the plug 622 to be inserted in the right hand side of the cushion assembly 604, as shown in Fig. 108.

[00380] Fig. 113 shows an alternative embodiment of the invention in which the plug and seal ring are formed of a single integral piece. As shown in Fig. 113, the seal ring 636

includes a flange portion 638 which generally follows along a contour of the yoke 608. This is best shown in the cross-sectional view of Fig. 110 where the seal ring 614 and the yoke 608 are positioned closely adjacent one another.

[00381] The seventh main illustrated embodiment may provide for improved decoupling of the air delivery tube 606 and/or swivel elbow 612 from the cushion assembly 604. In addition, this embodiment provides a choice of tube routing, which can be either up or down or on the left or right hand sides of the cushion assembly 604. As such, this embodiment may be perceived as less obtrusive and is significantly lighter. It also includes less parts than previous embodiments and can be easier to manufacture, assemble and clean.

[00382] The swivel elbow 612 may be provided with a quick release mechanism (not shown). The swivel elbow 612, as shown in Fig. 110B, is able to fit and snap into the mask frame 616. This construction allows free swiveling within the frame 616, between a range of defined angles, thereby ensuring that the tube does not get into an uncomfortable position with respect to the head and pillow.

[00383] The seal ring 614 is structured such that it cooperates with the geometry of the elbow swivel 612. In addition, the seal ring 614 may be connected to the ring 610 of the yoke 608. The seal ring 614 may be permanently connected to the ring 610, e.g., via co-molding. For example, the swivel stop 631 in Fig. 110B may be formed as part of the ring 610. The first connector portion 618 on each side of the frame 616 may be rotated with respect to the seal ring 614, to thereby position the cushion assembly 604 accordingly. The seal ring 614 seals the swivel elbow 612 preferably with minimum friction. Each seal ring 614 may accommodate either the plug 622 or the swivel elbow 612. The seal ring 614 is large enough for patients to handle, especially patients with reduced manual dexterity.

[00384] The plug 622 may be press fit into the seal ring 614. The plug 622 can also be designed to be press fit into the frame. The plug 622 may be made from hard polymer, for example, polypropylene. A recess (not shown) may be provided to remove the plug 622. The plug functions to seal the frame and cushion assembly on the side opposing the air delivery tube. The plug 622 is large enough for patients to handle, even with reduced manual dexterity.

[00385] The tubing 606 may be permanently attached to the end of the swivel elbow 612. However, a push-on friction connection may also be suitable. The tube length may be between 200mm and 400mm, preferably 250 and 350 mm, for example, or any other length which will not interfere with the patient's face.

[00386] As shown in Figs. 110B and 111, respectively, the yokes 608 and seal ring 614 may be provided with structure to limit the angular or rotational movement of the swivel elbow 612 with respect to the first connector portion 618. Further, the headgear and/or yoke may be provided with a tube retention feature to control the tube position. For example, simple VELCRO® straps may be provided along some portion of the headgear to restrain movement of the air delivery tube.

[00387] In another example shown in Figs. 108A and 108B, a tube retainer 900 includes a first portion 902 to be connected or attached to one of the straps of headgear. For example, the first portion 902 can be in the form of a loop that is attached to a portion 904 of headgear strap shown in Fig. 108. Attachment can be accomplished by threading the headgear strap 904 though the first portion 902 before the headgear strap 904 is threaded through the headgear buckle 906. The retainer 900 includes a second portion 908 provided or attached to the first portion 902. The second portion 908 may be made of a resilient plastic that retains the shape shown in Fig. 108A, with a gap 910 defined between two ends 912 of the second portion 908. The gap 910 is sized to be smaller than the diameter of the air delivery tube 606, so as to reliably hold the tube 606. Alternatively, the second portion 908 can be a VELCRO® loop, with the ends 912 including the mating hooks and loops. As shown in Figs. 108A and 108B, the second portion may include one or more slots 914 to receive ribs 916 (Fig. 108) of the air delivery tube 606, to thereby prevent axial sliding of the tube 606. With this arrangement, the tube 606 can be reliably held in a position over the patient's head.

[00388] Fig. 108C illustrates a plan view of a tube retainer, wherein like reference numbers relate to like parts. In Fig. 108C, exemplary dimensions of the tube retainer are shown. It is to be noted that these dimensions are examples only, and the dimensions can be changed up to about $\pm$ 20% of the values shown therein.

[00389] The nasal assemblies 10, 210, 310, 410, 510, 600 described above and below have several advantages. For example, the nasal assemblies 10, 210, 310, 410, 510 are unobtrusive due to their small overall size and weight. The nasal assemblies 10, 210, 310, 410, 510, 600 provide a high level of comfort due to the minimal force applied to the patient's nose – and contact with the bridge can be eliminated. The nasal assemblies 10, 210, 310, 410, 510, 600 are easy to use and include minimal parts and adjustments, e.g., the inlet conduits can be easily adjusted to extend upwardly over the head of the patient or downwardly below the chin of the patient. The pressurized supply can be easily connected to and disconnected from the connectors without altering the headgear setting. Also, the nasal assemblies 10, 210, 310, 410, 510, 600 allow for greater nozzle range of motion to accommodate a wide range of

patients. That is, the nozzles can be rotated with respect to the patient's face by rotating the frame relative to the headgear assembly. Further, strap tension need not be as high as the area of contact with the face is less. The headgear provides stability, e.g., the yokes help maintain the mask assembly's position on the face. The adjustment of the headgear is designed such that the force required to tighten the straps is not applied to the patient's face, e.g., the straps can be pulled in opposite directions above the head to counteract one another. It is relatively easy to find balance between performance and comfort. In addition, the weight, noise level, and/or number of parts of the mask assembly is reduced.

[00390] An Appendix including additional drawings and depictions of various aspects of preferred embodiments of the invention is included in U.S. Provisional Application no. 60/529,696, filed December 16, 2003 and incorporated herein by reference in its entirety. To the extent that any drawing in the labeled Figures or the Appendix includes dimensions, those dimensions are exemplary only and may be changed without departing from the scope of the disclosure.

[00391] Fig. 114 illustrates an exploded view of another embodiment of the present invention. In this embodiment, the cushion assembly 604 is similar to that shown in Figs. 108-109, and swivel elbow 612 is as described in relation to Figs. 108, 110B and 111. Yoke 608 includes a widened portion 608a intended to engage with a corresponding widened portion 630a adjacent or formed as part of groove 630. In addition, yoke 608 includes a recess 608b intended to receive ear 638 of seal ring 614. In a further embodiment, yoke and seal ring may be formed in one piece. Also, the yoke and headgear could be formed of one piece, instead of using stitching. As can be seen in Fig. 115, the yoke 608 and seal ring 614 can be snap fit relative to one another, e.g., via shoulder 621. By this structure, the yoke and ring are prevented from rotating relative to one another. Fig. 115 also shows the general position of yoke flex point P, which allows a good fit with the patient.

[00392] Figs. 116 to 126 illustrate further views of the embodiment shown in Figs. 114 and 115. Another aspect of the arrangement is that the ring 610 of the yoke 608 is angularly offset with respect to the main body 609 of the yoke 608. Compare Fig. 116 with Fig. 110, e.g., where the main body 609 in Fig. 116 is twisted. For example, front side 609a in Fig. 116 is positioned laterally outward in comparison to rear side 609b in Fig. 116. This structure helps to bias the bottom portion of the yoke 608 towards the patient's face, so that the yoke more closely follows the contours of the patient's face.

[00393] Figs. 127-130 illustrate a further embodiment of the present invention. This embodiment is similar to that shown and described in Figs. 114-126. However, there are two

main differences. First, the elbow 612 is free to rotate 360° within seal ring 614. As shown in the partial exploded view of Fig. 128, seal ring 614 does not include stops 632 and elbow 612 does not include protrusion 634, as compared to what is shown in Fig. 114.

[00394] Second, as shown in Fig. 129, seal ring 614 includes a selectively removable and insertable cap 614a. In other words, the plug 622 in Fig. 119 is made in two parts rather than one. The cap 614a may also include a vent, instead of or supplemental to the vent provided on the cushion. Fig. 130 shows a partial exploded view of cap 614a. Because seal rings 614 on both sides of nozzle assembly are identical, the cap 614a and elbow 612can be removed and swapped, if the patient opts to have the elbow 612 routed over the left or right side. This can be done while the mask assembly is in use on the patient. Also, the elbow 612 can be removed to allow for patient mobility.

[00395] Figs. 131-133 illustrate an elbow 612 according to yet another embodiment. As compared to elbow 612 shown in Fig. 114, elbow 612 in Figs. 131-133 includes one and preferably a pair of key-shaped apertures 613. The elbow may be made of polypropylene, e.g., "Borealis," or polyester. The shape of the apertures allows for improved retention and removal forces, when the elbow is in place and when it is removed.

[00396] Further, the nozzle assembly and/or its associated cushion could be replaced with a nasal mask and/or nasal cushion. See, e.g., Figs. 134 and 135. Fig. 134 shows an arrangement in which the frame includes opposite apertures or first connector portions (e.g., tubular extensions), each of which is provided with a seal ring as described above. A seal ring 500 is adapted to include a separate or integral plug to close one aperture or first connector portion of the frame, while another seal ring is adapted to engage with the other frame aperture/first connector portion, and to receive the swivel elbow. Of course, the positions of the elbow and plug may be interchanged, depending on patient preference. In Fig. 135, the elbow is provided to the front of the mask frame, like ReMed's VISTA mask, while both apertures/first connector portions are provided with plugged seal rings. Of course, in each embodiment, frame, elbow, and/or seal ring(s) may be provided with appropriate vents to exhaust exhaled gas from the breathing chamber.

[00397] It can thus be appreciated that the aspects of the present invention have been fully and effectively accomplished. The foregoing specific embodiments have been provided to illustrate the 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.

CLAIMS:

1. A nasal assembly for delivering breathable gas to a patient, comprising:

a frame having a main body and a side frame member provided on each lateral side of the main body, each side frame member including an integrally formed first connector portion;

a nozzle assembly including a gusset or base portion and a pair of nozzles, the nozzle assembly being coupled with the main body of the frame with the pair of nozzles structured to sealingly engage with nasal passages of a patient's nose in use;

at least one inlet conduit structured to deliver breathable gas into the frame and nozzle assembly for breathing by the patient;

a pair of second connector portions provided to a respective first connector portion of the frame, at least one of said second connector portions being in communication with said at least one inlet conduit; and

a headgear assembly removably connected to at least one of the pair of second connector portions so as to maintain the frame and the nozzle assembly in a desired adjusted position on the patient's face.

2. The nasal assembly according to claim 1, wherein the frame may be rotated with respect to the pair of second connector portions so as to adjust a position of the nozzles with respect to the patient's nose in use, without detaching the first and second connector portions.

3. The nasal assembly according to claim 1, wherein the pair of second connector portions are releasably interlockable with the headgear assembly.

4. The nasal assembly according to claim 3, wherein the pair of second connector portions include respective grooves that are engagable with retaining members provided on yokes of the headgear assembly.

5. The nasal assembly according to claim 4, wherein the retaining members are ring shaped members.

6. The nasal assembly according to claim 5, further comprising an angle connector provided to each said second connector portion, each said angle connector including a first locking member and the headgear includes a second locking member.

7. The nasal assembly according to claim 1, wherein each of the second connector portions includes an interlock for engagement with an angle connector.

8. The nasal assembly according to claim 7, wherein the interlock is an undercut.

9. The nasal assembly according to claim 1, wherein the at least one inlet conduit includes a plurality of channels.

10. The nasal assembly according to claim 9, further comprising an angle connector provided to each said second connector portion, each said angle connector including elongated connectors structured to engage each of the channels of the respective inlet conduit.

11. The nasal assembly according to claim 10, wherein the elongated connectors have a tapered configuration to facilitate connection.

12. The nasal assembly according to claim 1, wherein the headgear assembly helps retain the second connector portions on the frame.

13. The nasal assembly according to claim 12, wherein the headgear assembly includes a pair of retaining members engaged with respective second connector portions so as to transfer headgear force to the frame and thereby help prevent inadvertent detachment of the second connector portions from the frame.

14. The nasal assembly according to claim 1, wherein the headgear assembly is connected to both the second connector portions and associated angle connectors.

15. The nasal assembly according to claim 1, wherein the headgear assembly is structured to transfer a tube force to the headgear assembly or the frame, to avoid application of the tube force to the nozzle assembly.

16. The nasal assembly according to claim 15, wherein the headgear assembly includes a pair of retaining or locking members engaged with respective second connector portions and/or angle connectors, so as to transfer the headgear force to the frame.

17. The nasal assembly according to claim 1, wherein the headgear assembly allows symmetrical adjustment.

18. The nasal assembly according to claim 17, wherein the headgear assembly includes a pair of headgear yokes coupled to one another by a headgear buckle, the headgear buckle structured to allow symmetrical adjustment of the headgear assembly.

19. The nasal assembly according to claim 18, wherein the headgear buckle includes a first locking portion adapted to be removably and adjustably coupled with one of the pair of headgear yokes and a second locking portion adapted to be removably and adjustably coupled with the other of the pair of headgear yokes.

20. The nasal assembly according to claim 1, wherein each second connector portion is formed with an adjustment portion that allows relative movement between the second connector portion and an angle connector.

21. The nasal assembly according to claim 20, wherein the adjustment portion comprises a flexible corrugation in the second connector portion.

22. The nasal assembly according to claim 1, further comprising a flow generator connector structured to interconnect the at least one inlet conduit with a pressurized supply.

23. The nasal assembly according to claim 22, wherein the flow generator connector includes a first elongated connector structured to engage the at least one inlet conduit and a second elongated connector structured to engage the another said at least one inlet conduit.

24. The nasal assembly according to claim 23, wherein the flow generator connector has a general Y-shape with the first elongated connectors angled with respect to the second elongated connectors.

25. The nasal assembly according to claim 23, wherein the first and second elongated connectors have a tapered configuration to facilitate connection.

26. The nasal assembly according to claim 1, wherein the nozzle assembly wraps around the main body of the frame.

27. The nasal assembly according to claim 1, wherein the nozzle assembly is secured to the frame with a clip.

28. The nasal assembly according to claim 27, wherein the nozzle assembly includes a pair of opposing spaced apart end portions, the end portions being secured between the frame and the clip.

29. The nasal assembly according to claim 1, wherein the frame is secured to the nozzle or nasal assembly such that the frame is angled away from an upper lip of the patient in use.

30. The nasal assembly according to claim 1, wherein the nozzle assembly is easily removable from the frame to facilitate cleaning of the nozzle assembly.

31. The nasal assembly according to claim 1, wherein the nozzle assembly is accessible for cleaning.

32. The nasal assembly according to claim 31, wherein the nozzle assembly has a generally tubular configuration with a longitudinal opening.

33. The nasal assembly according to claim 1, wherein the nozzle assembly has a generally tubular configuration with a longitudinal opening to facilitate manufacturing.

34. The nasal assembly according to claim 1, wherein the inlet conduits provide low impedance.

35. The nasal assembly according to claim 34, wherein the inlet conduits provide impedance less than about 3 cmH_2O, for a given flow rate.

36. The nasal assembly according to claim 1, wherein the second connector portions are flexible to dampen tube drag forces.

37. The nasal assembly according to claim 1, wherein the inlet conduits have a low profile.

38. The nasal assembly according to claim 1, wherein the second connector portions are flexible without obstructing airflow.

39. The nasal assembly according to claim 1, wherein the nozzle assembly is contoured to accommodate a patient's septum.

40. The nasal assembly according to claim 1, wherein the headgear assembly includes stiffeners to add rigidity to the headgear assembly.

41. The nasal assembly according to claim 1, wherein the at least one inlet conduit is constructed with kink and/or occlusion resistant tubing.

42. The nasal assembly according to claim 1, wherein the second connector portions include a seal ring provided to one said first connector portion and a plug provided to another said first connector portion, said at least one inlet conduit being provided to the seal ring.

43. The nasal assembly according to claim 42, wherein the plug and the seal ring are non-rotatably mounted on the headgear.

44. The nasal assembly according to claim 43, wherein the headgear includes a yoke arranged to non-rotatably mate with respect to at least one of the plug and the seal ring.

45. The nasal assembly according to claim 1, further comprising a tube retainer including a first portion provided to a portion of the headgear, and a second portion constructed to receive the at least one inlet conduit.

46. The nasal assembly according to claim 45, wherein the second portion includes at least one slot to receive a ribbed portion of the inlet conduit.

47. The nasal assembly according to claim 1, wherein the at least one conduit is rotatably provided to one of the second connector portions, wherein rotation is limited to a predetermined angular extent.

48. The nasal assembly according to claim 47, wherein one said second connector portion is a seal ring provided with at least one stop to define said angular extent.

49. The nasal assembly according to claim 1, wherein said at least one inlet conduit includes an elbow connector provided to one of said second connector portions, said elbow connector having first and second legs that are angled at more than 90 degrees from one another.

50. The nasal assembly according to claim 1, wherein the frame and nozzle assembly are rotatable with respect to the second connector portions so as to adjust the nozzle relative to the patient in use.

51. The nasal assembly according to claim 50, wherein the nozzle assembly includes a plurality of visual indicators which can be selectively matched with a reference indicator provided adjacent the visual indicators.

52. The nasal assembly according to claim 51, wherein the reference indicator is provided on a yoke of the headgear.

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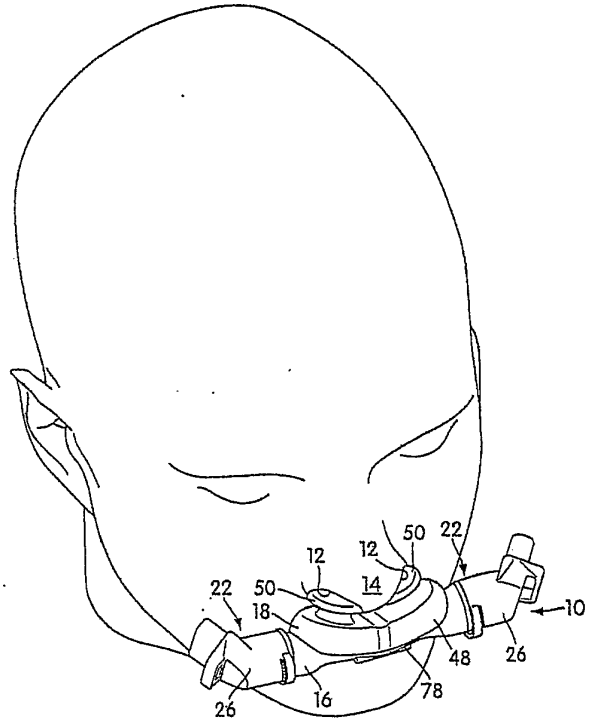


FIG. 1

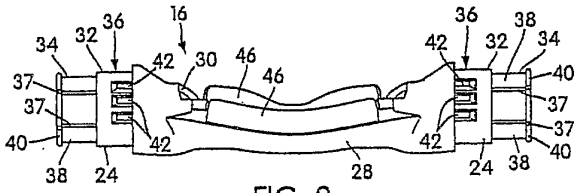


FIG. 2

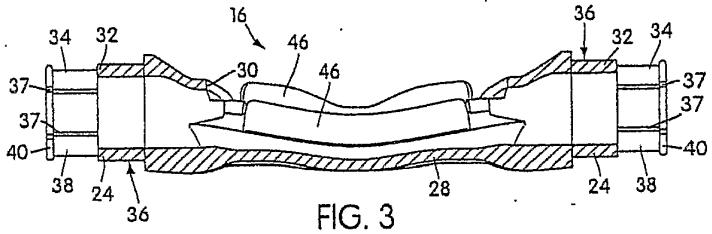


FIG. 3

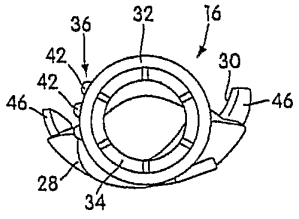


FIG. 4

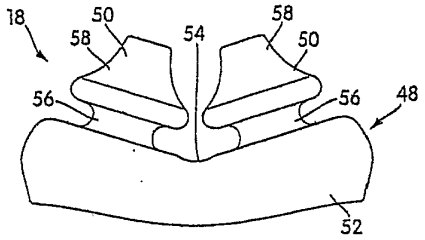


FIG. 5

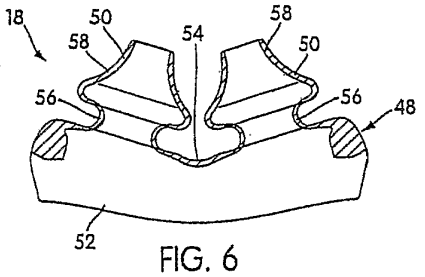


FIG. 6

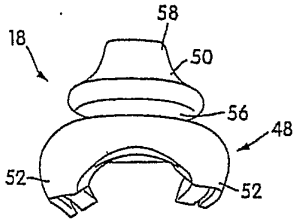


FIG. 7

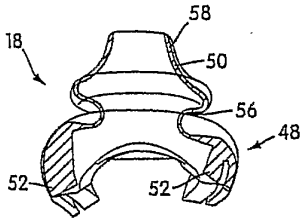


FIG. 8

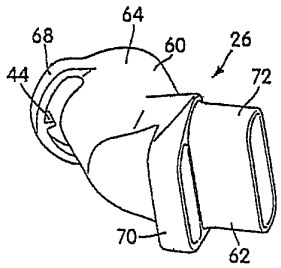


FIG. 9

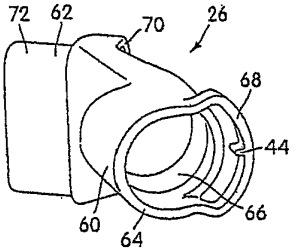


FIG. 10

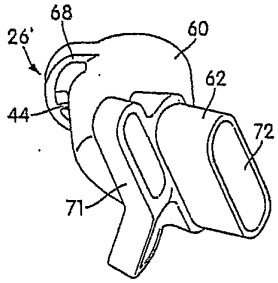


FIG. 11

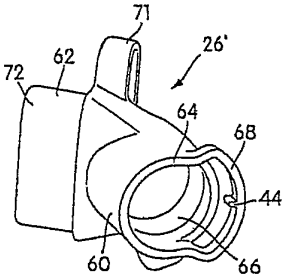


FIG. 12

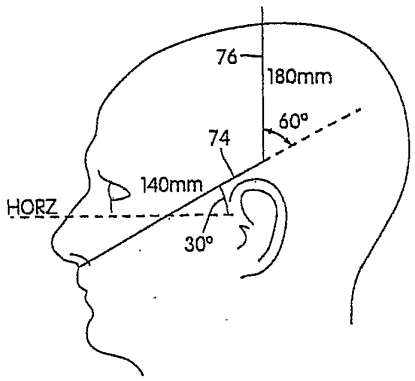


FIG. 13

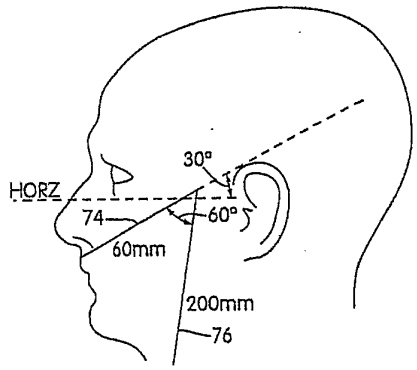


FIG. 14

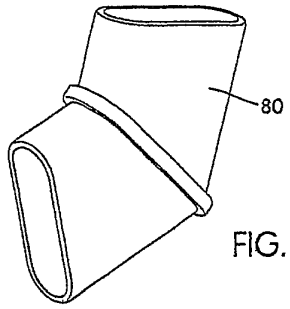


FIG. 15

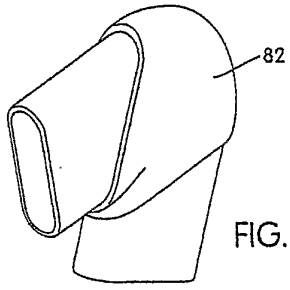


FIG. 16

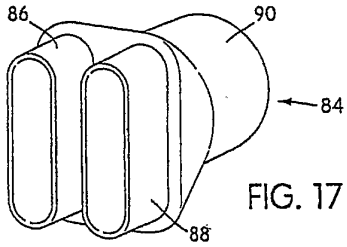


FIG. 17

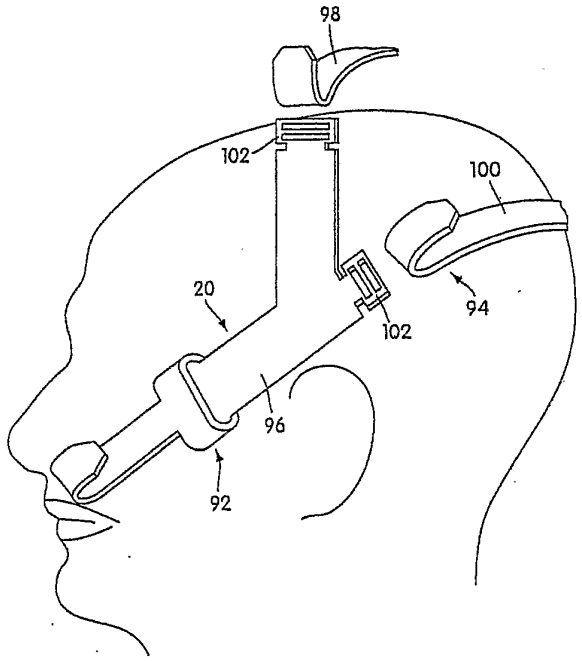


FIG. 18

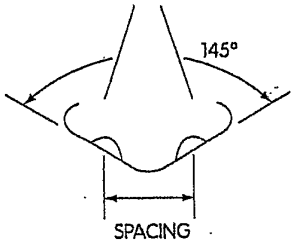


FIG. 19

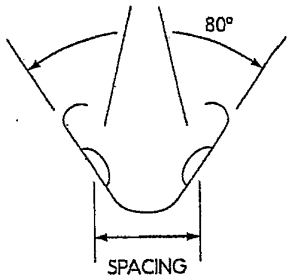


FIG. 20

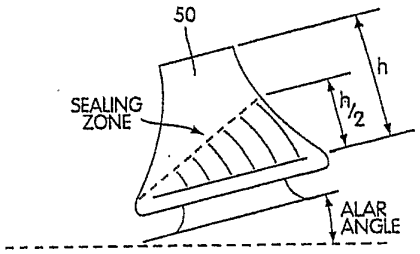


FIG. 21

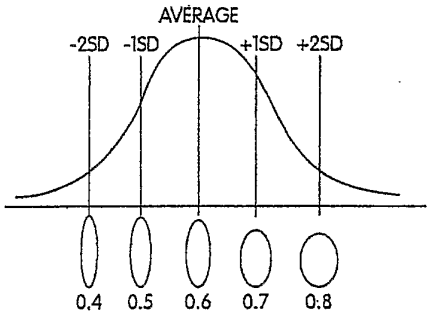


FIG. 22

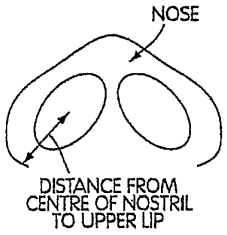


FIG. 23

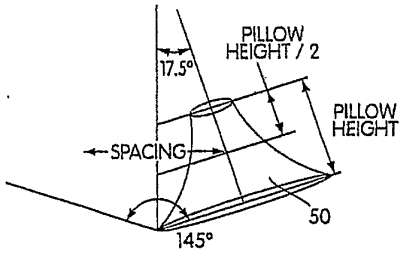


FIG. 24

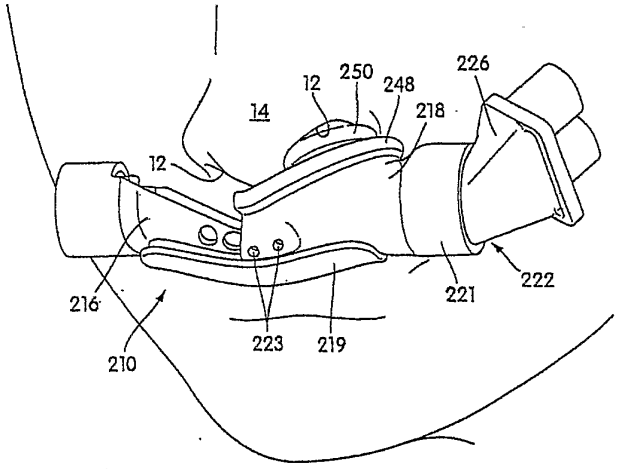


FIG. 25

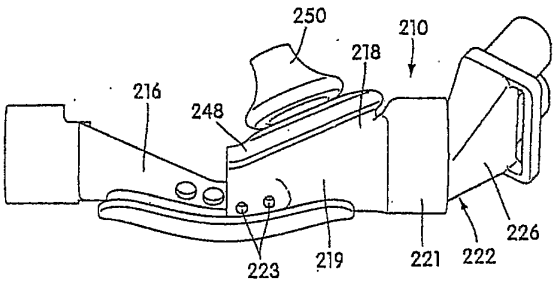

250
210
218
216
248
226
223
219
221
222

FIG. 26

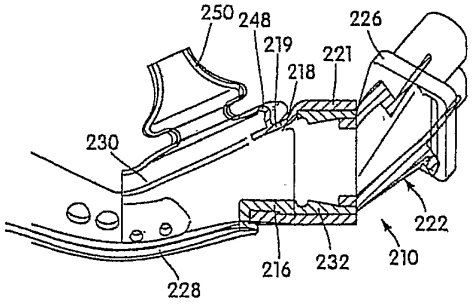

250
248
219
226
221
218
230
222
216
232
210
228

FIG. 27

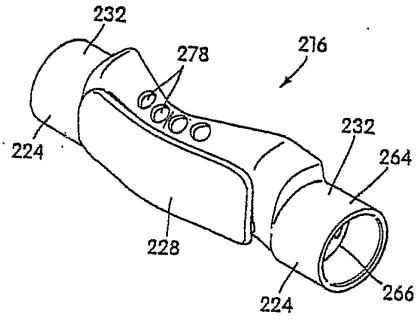

232
278
216
224
232
264
228
224
266

FIG. 28

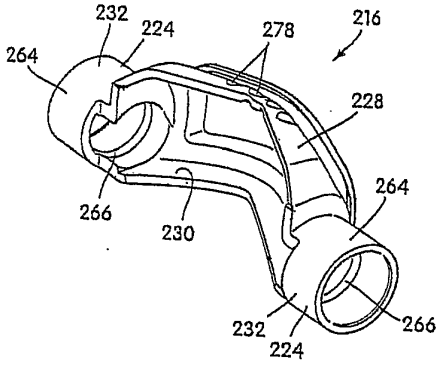

232
224
278
216
264
228
266
230
264
232
224
266

FIG. 29

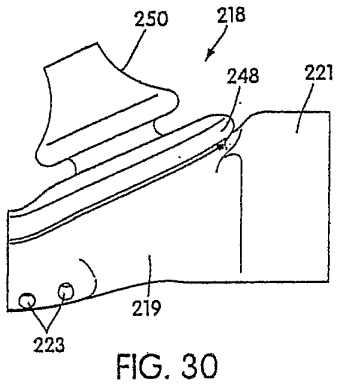


FIG. 30

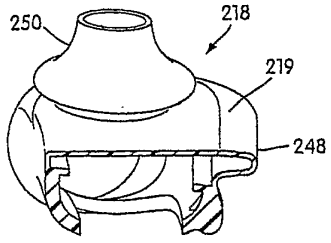


FIG. 31

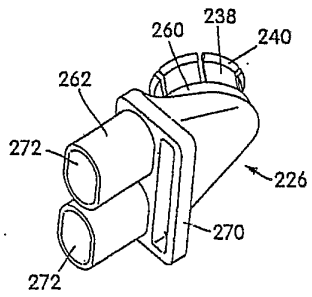


FIG. 32

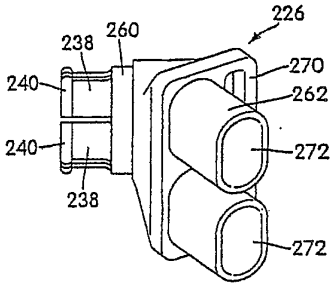


FIG. 33

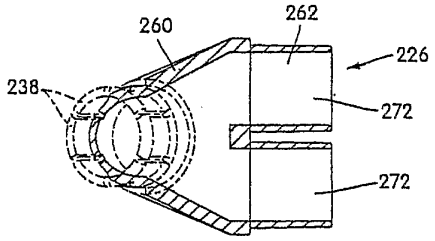


FIG. 34

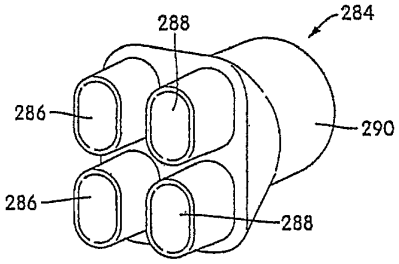


FIG. 35

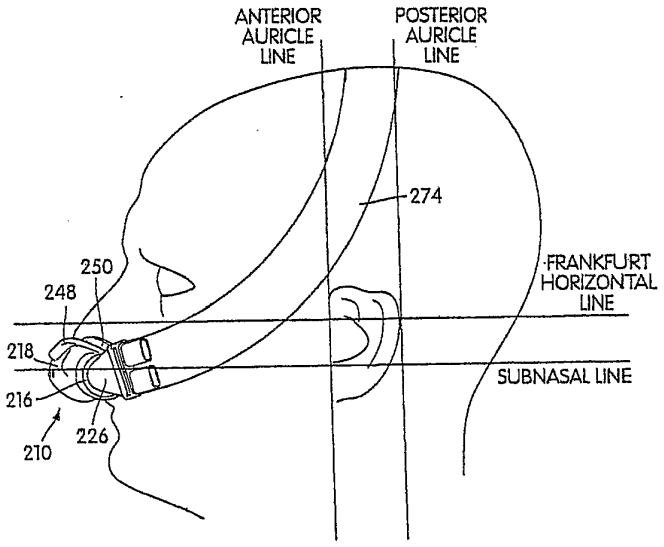

ANTERIOR AURICLE LINE
POSTERIOR AURICLE LINE
274
250
248
218
216
210
226
FRANKFURT HORIZONTAL LINE
SUBNASAL LINE

FIG. 36

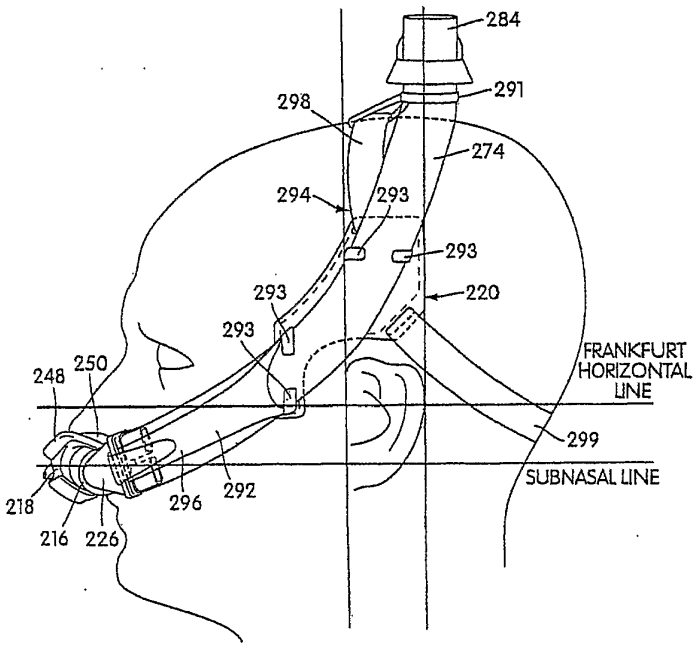

284
291
298
274
294
293
293
293
220
293
248
250
FRANKFURT
HORIZONTAL
LINE
299
SUBNASAL LINE
218
216
226
296
292

FIG. 37

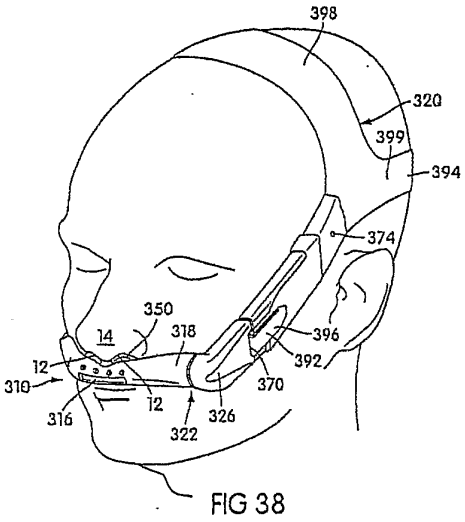


FIG 38

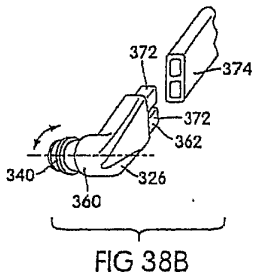


FIG 38B

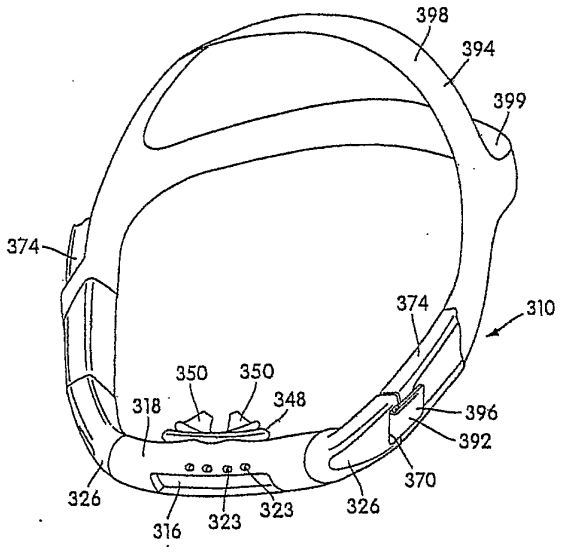

398
394
399
374
374
310
350
350
348
318
396
392
370
326
326
316
323
323

FIG. 39

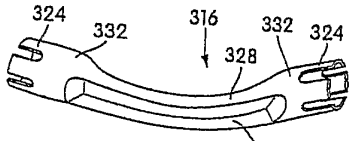


FIG. 40

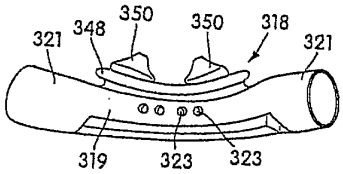


FIG. 41

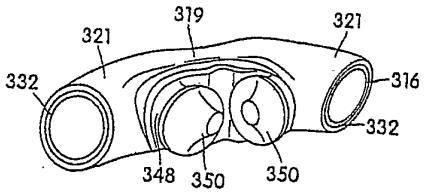
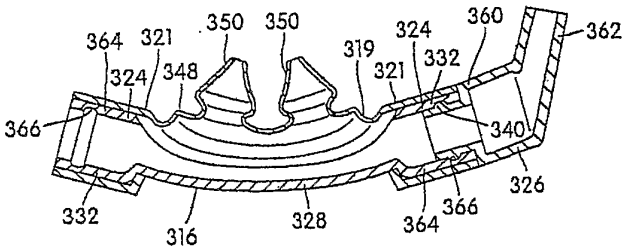


FIG. 42


364
321
350
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319
324
360
362
324
348
321
332
366
340
326
332
316
328
364
366

FIG. 43

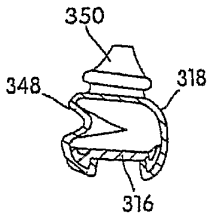

350
348
318
316

FIG. 44

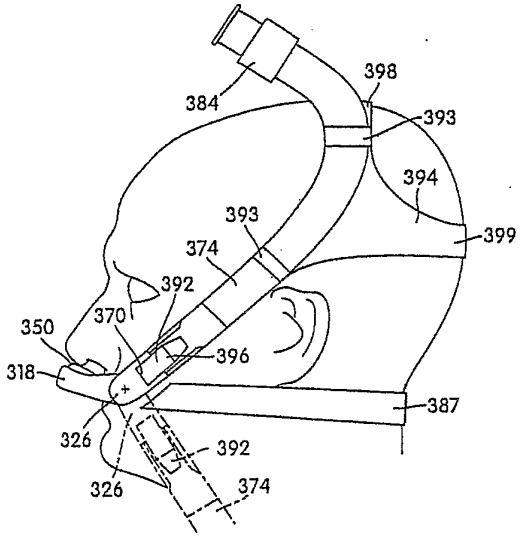

398
384
393
394
393
399
374
392
370
350
396
318
387
326
392
326
374

FIG. 45

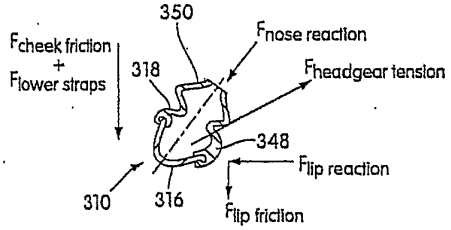

350
Fcheek friction
+
Flower straps
318
Fnose reaction
Fheadgear tension
348
Flip reaction
310
316
Flip friction

FIG. 46

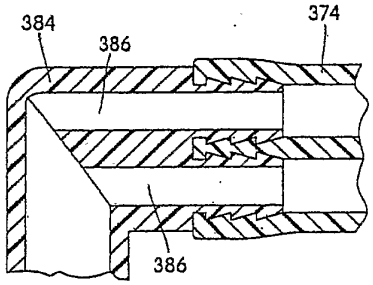


FIG. 47

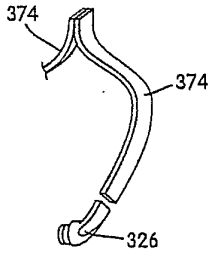


FIG. 47B

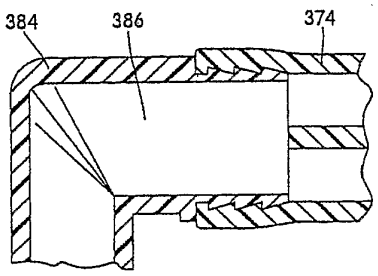


FIG. 48

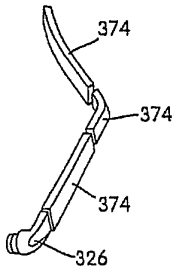


FIG. 48B

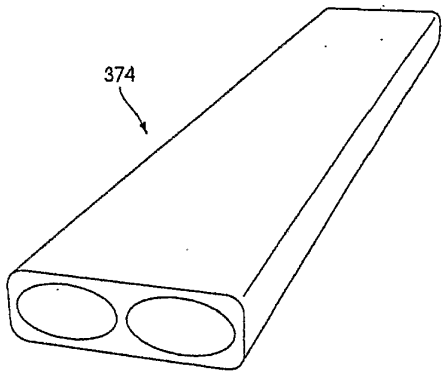


FIG. 49

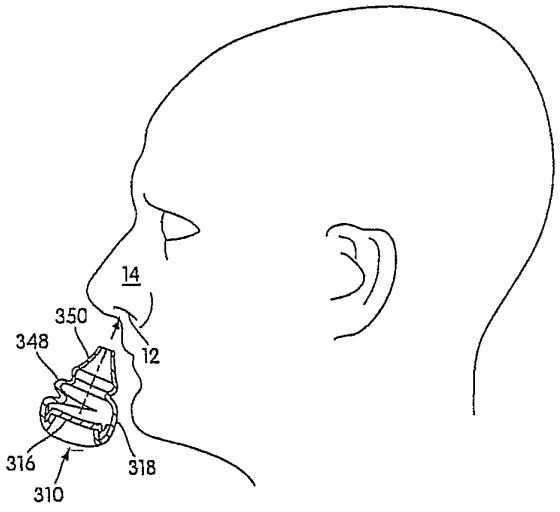


FIG. 50

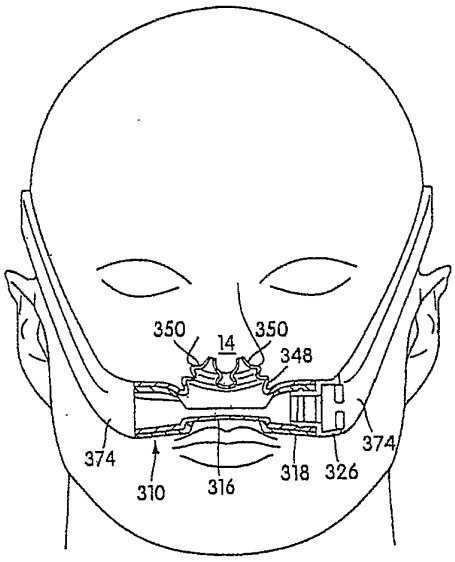
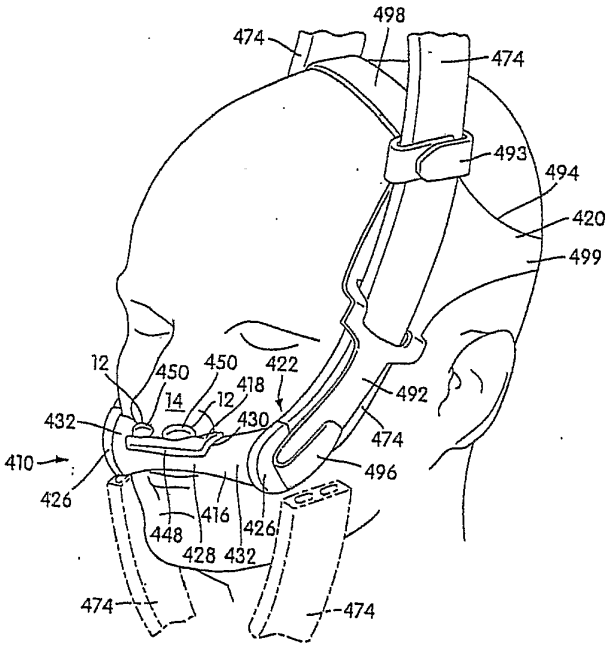


FIG. 51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474
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416
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474
474

FIG 52

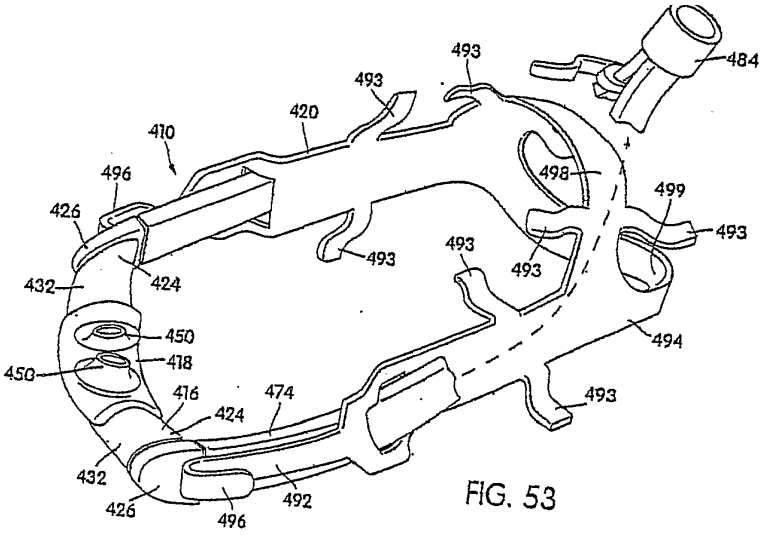
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FIG. 53

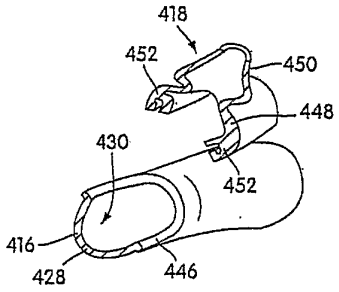

FIG. 54

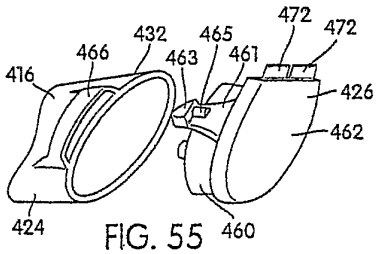

FIG. 55

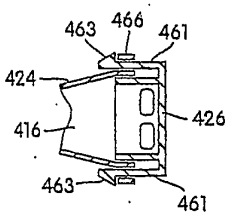

FIG. 56

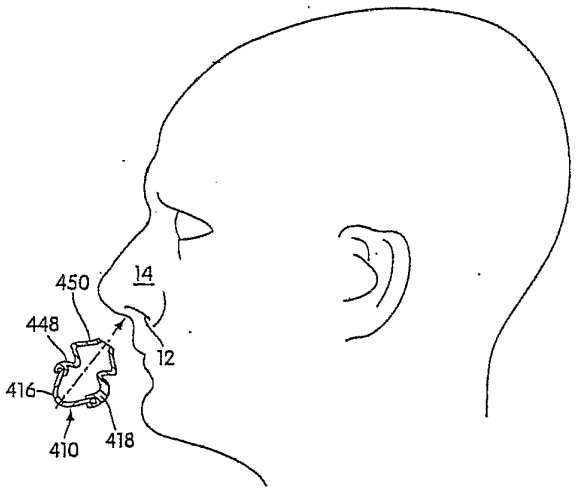

FIG. 57

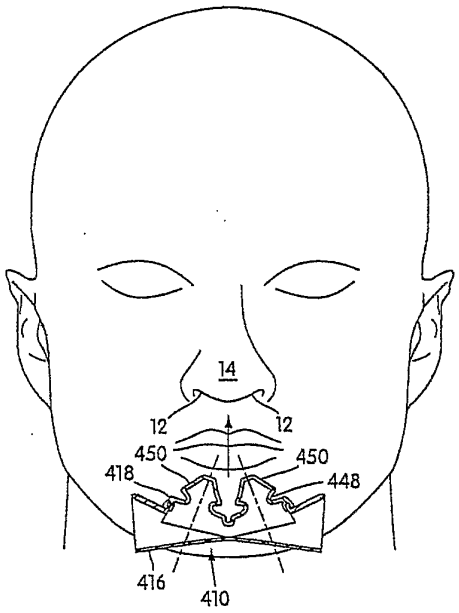

FIG. 58

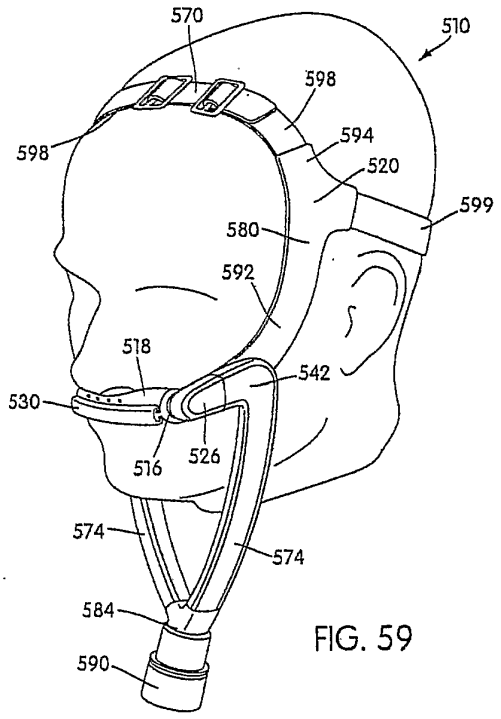
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FIG. 59

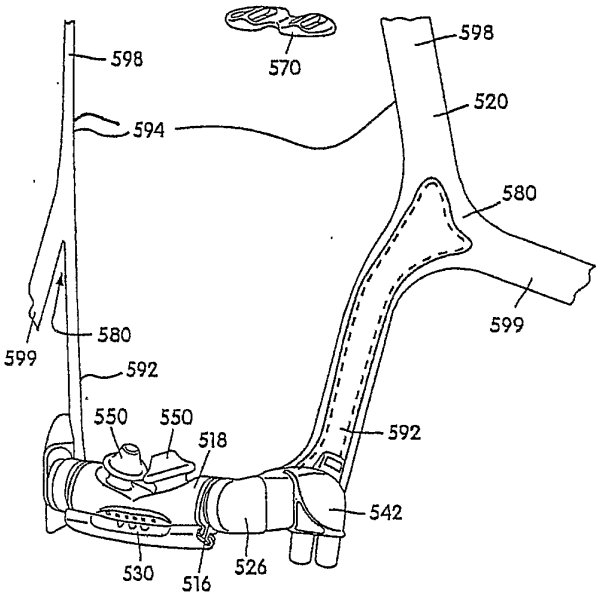
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FIG. 60

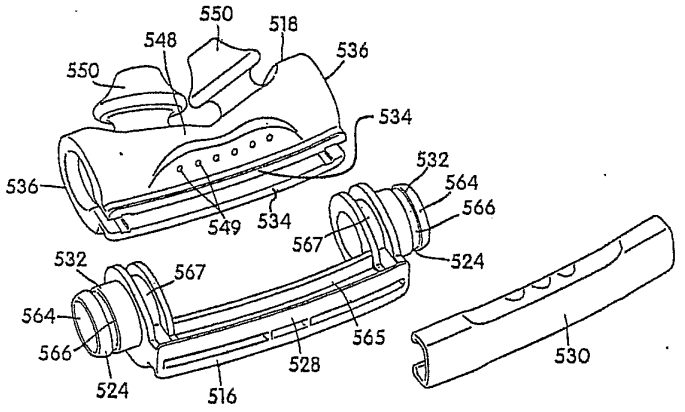
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FIG. 61

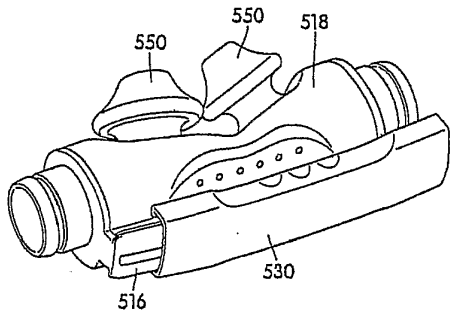

FIG. 62

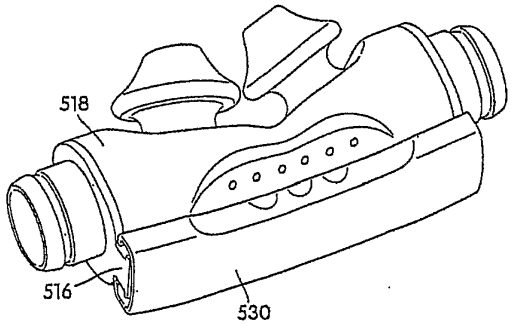

FIG. 63

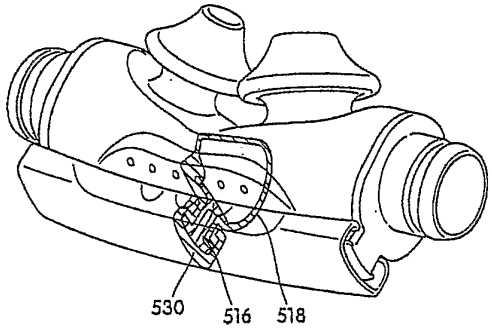

FIG. 64

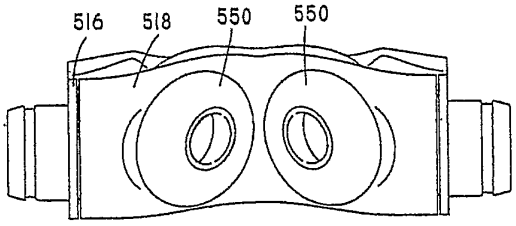

FIG. 65

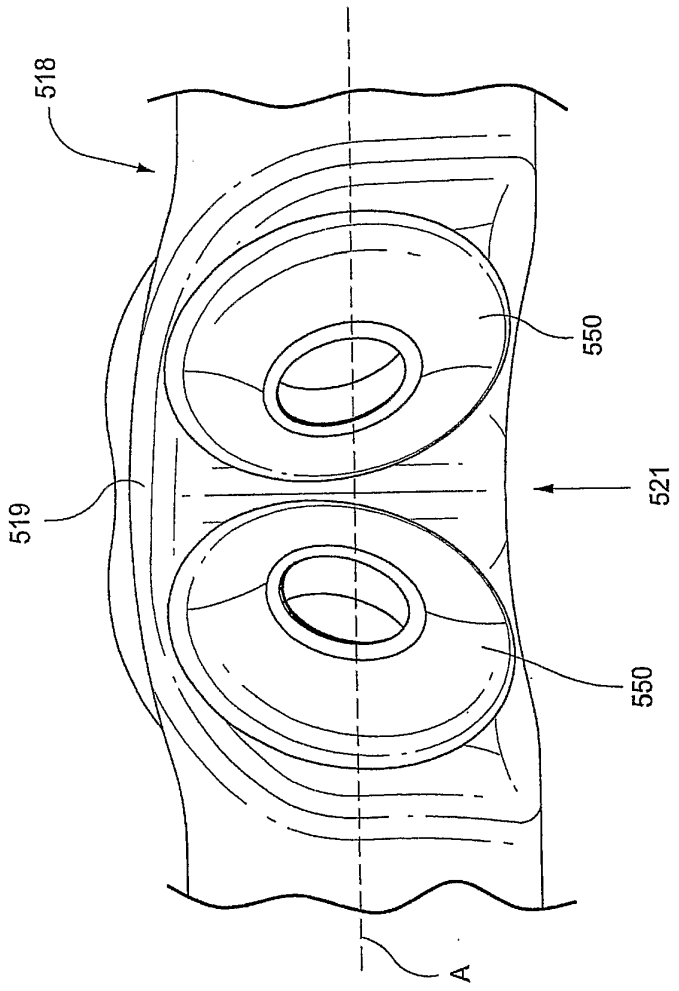

FIG. 65A

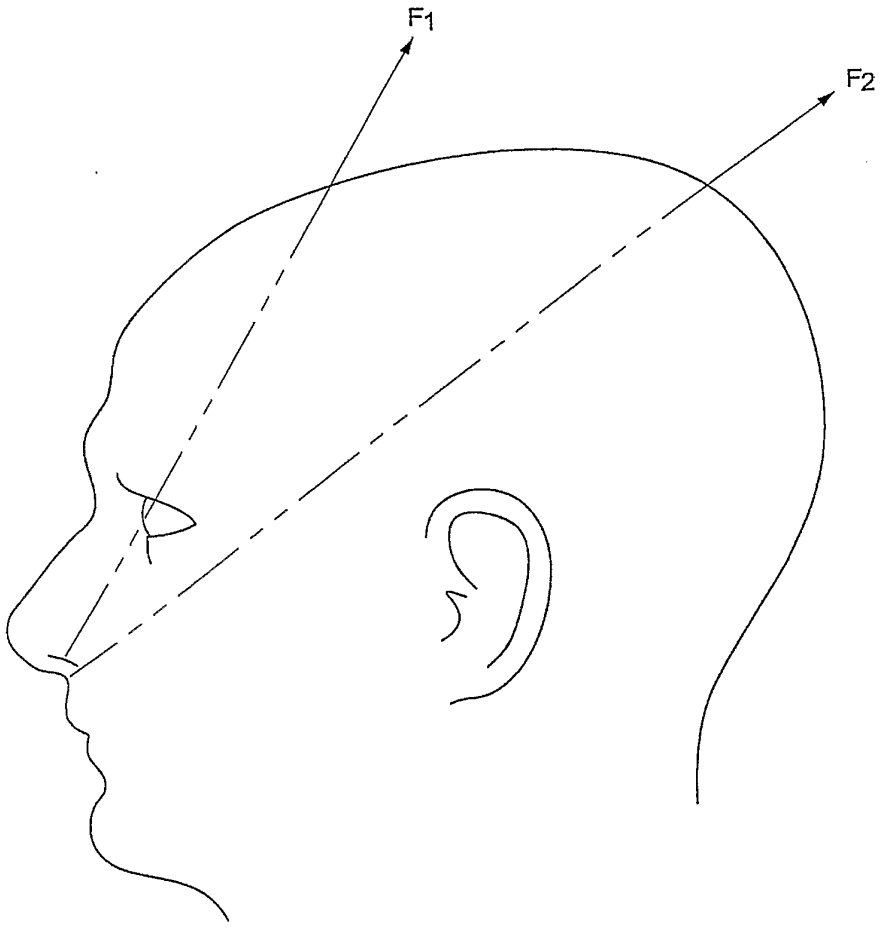

FIG. 65B

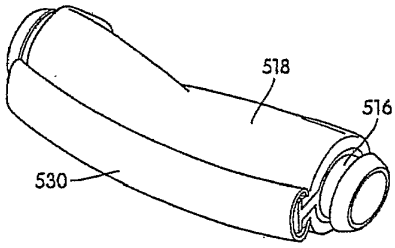

FIG. 66

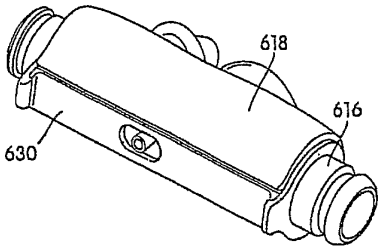

FIG. 67

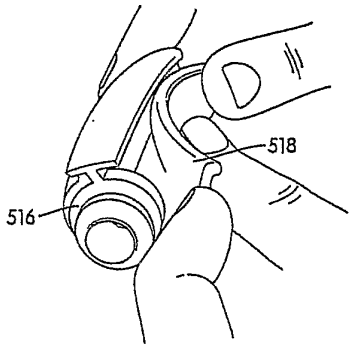

FIG. 68

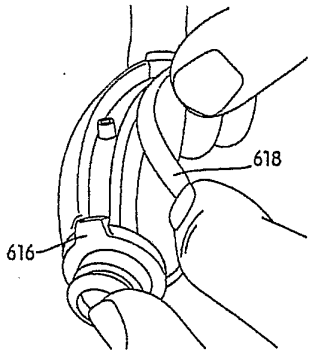

FIG. 69

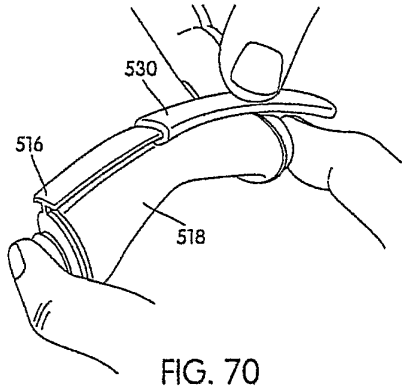

FIG. 70

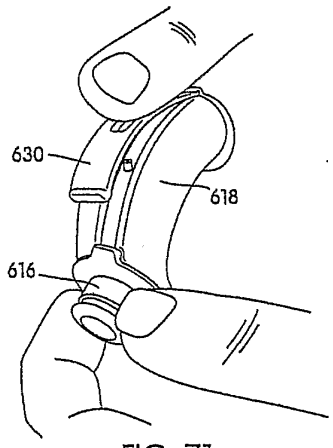

FIG. 71

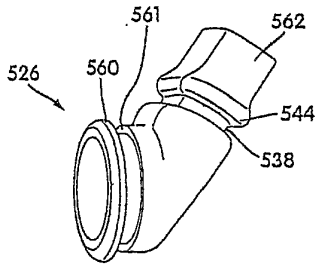

FIG. 72

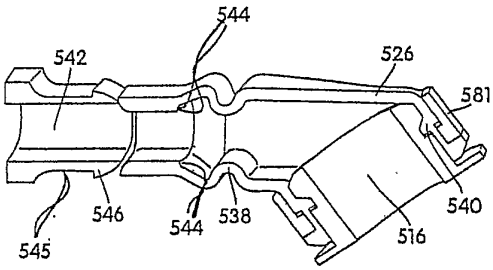

FIG. 73

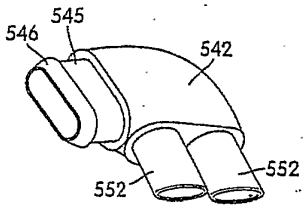

FIG. 74

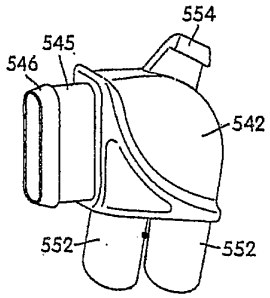

FIG. 74B

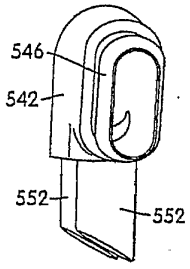

FIG. 75

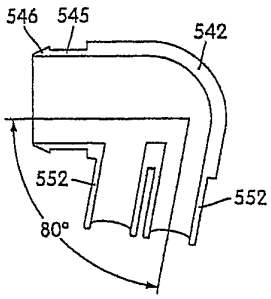

FIG. 76

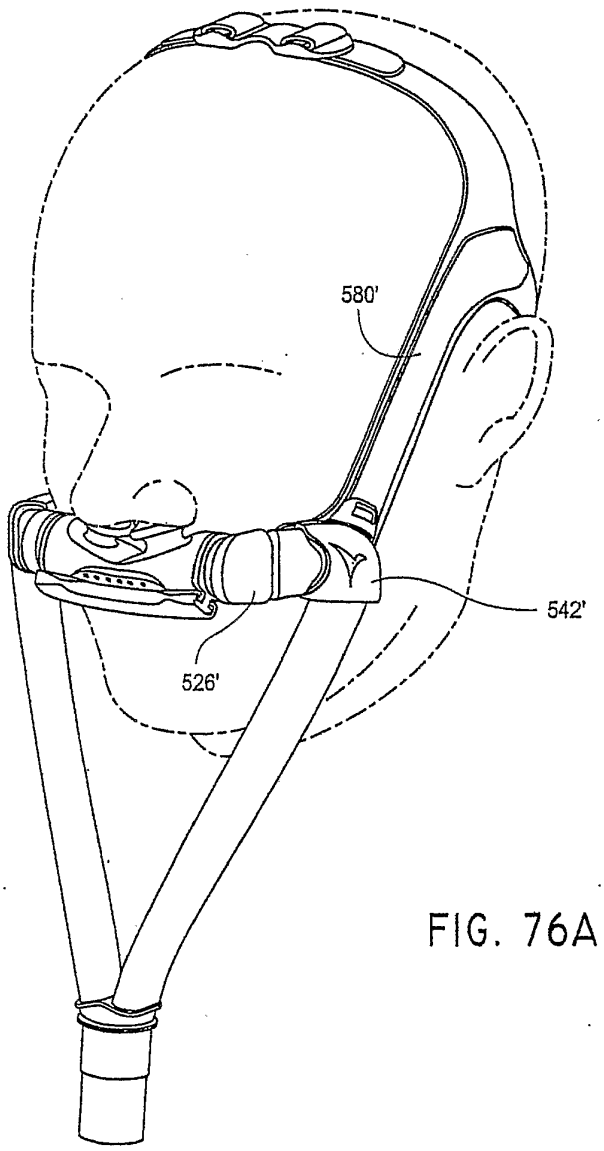

FIG. 76A

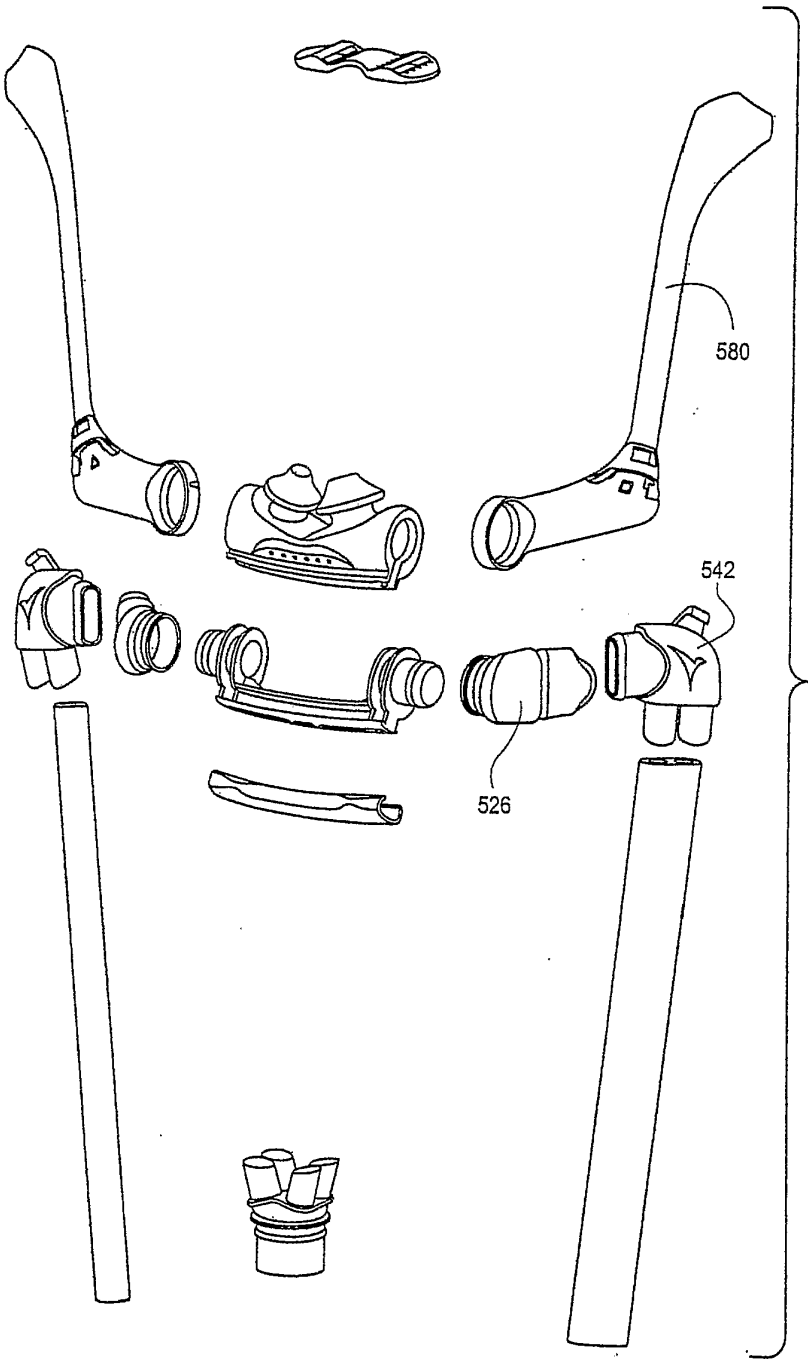

FIG. 76B

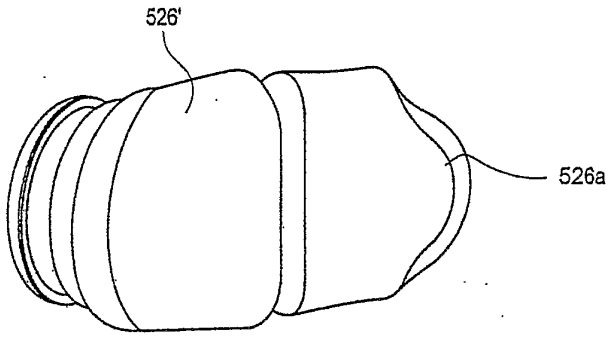

FIG. 76C

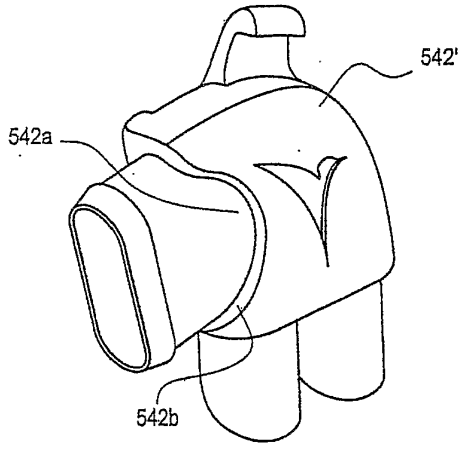

FIG. 76D

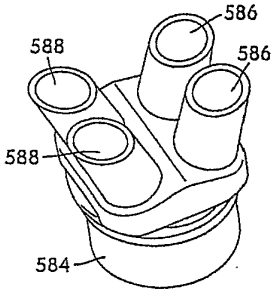

FIG. 77

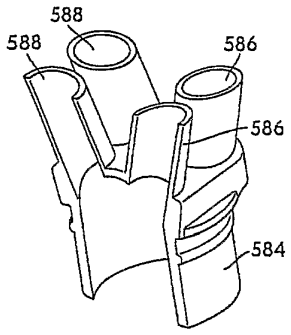

FIG. 78

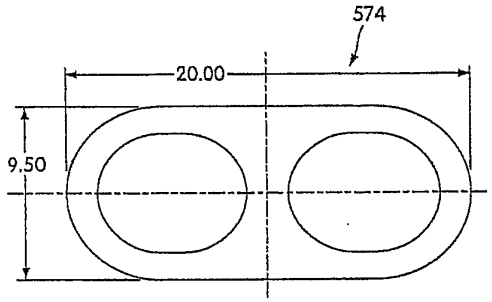

FIG. 79

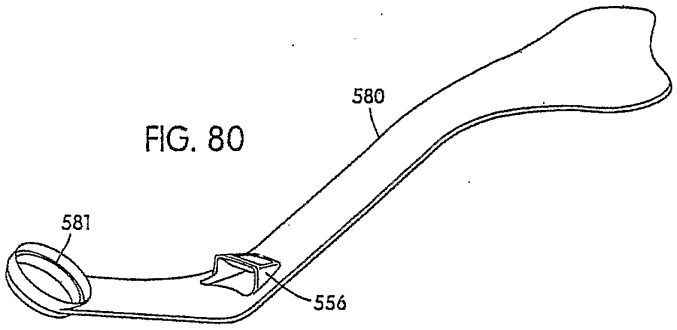

FIG. 80

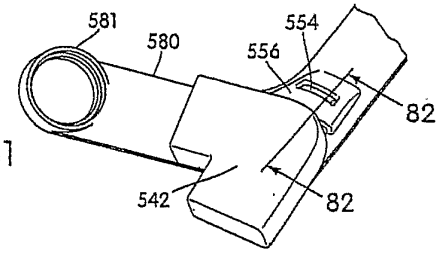

FIG. 81

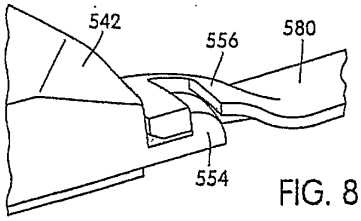

FIG. 82

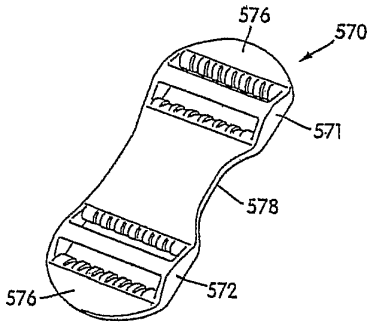

FIG. 83

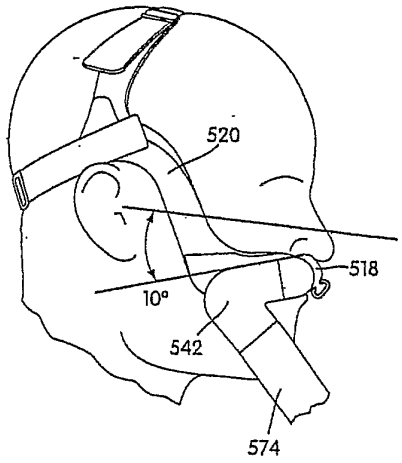

FIG. 84

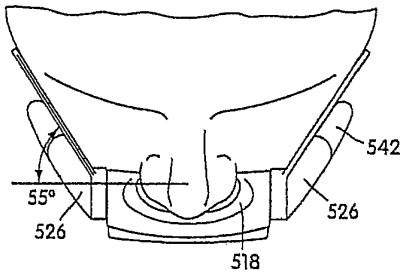

FIG. 85

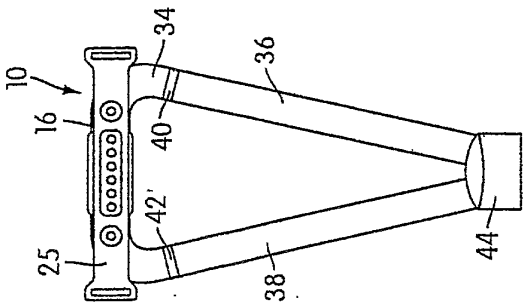

FIG. 88

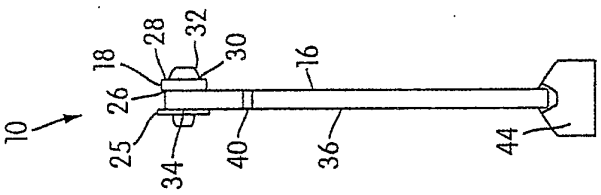

FIG. 87

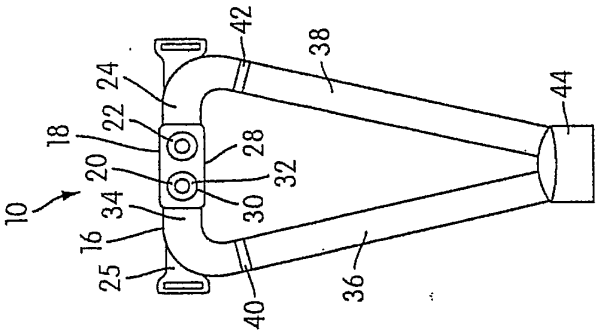

FIG. 86

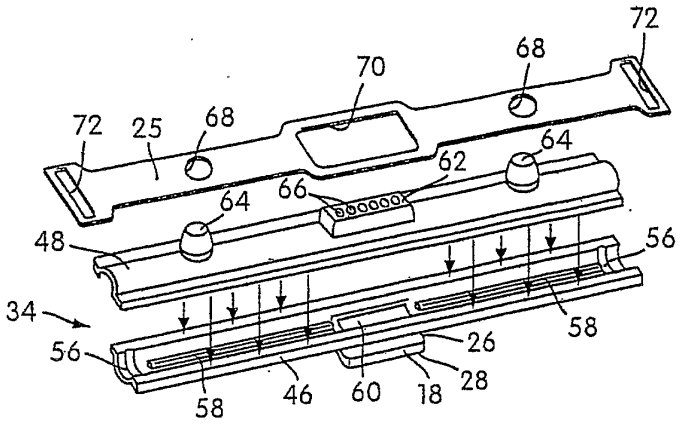

FIG. 89

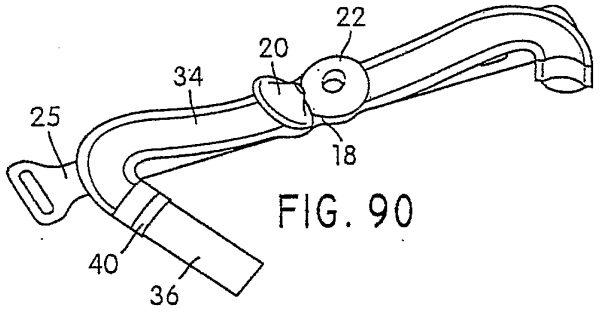

FIG. 90

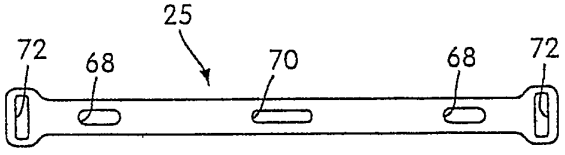

FIG. 91

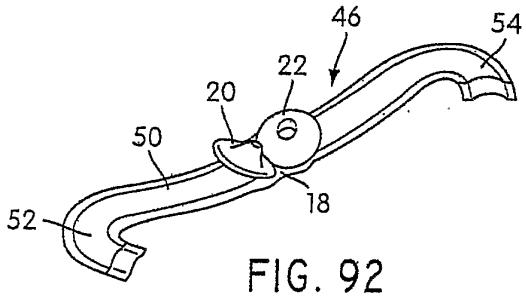

FIG. 92

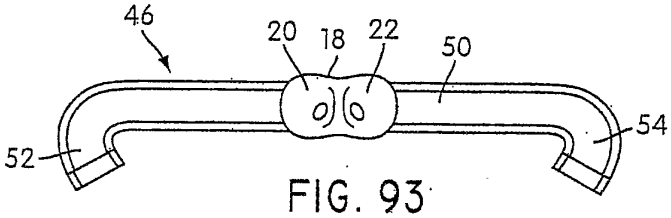

FIG. 93

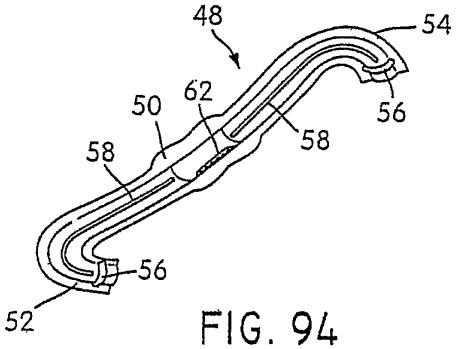

FIG. 94

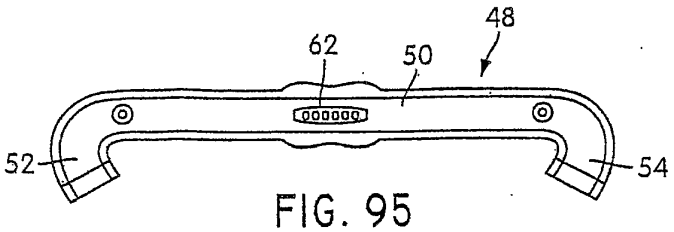

FIG. 95

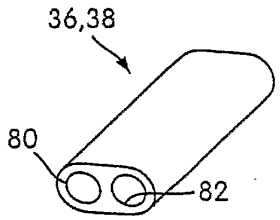

FIG. 96

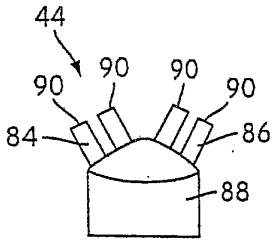

FIG. 96A

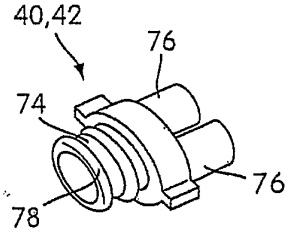

FIG. 97

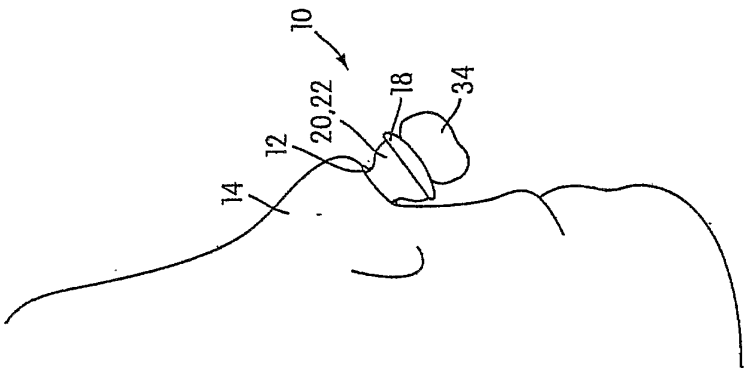

FIG. 97B

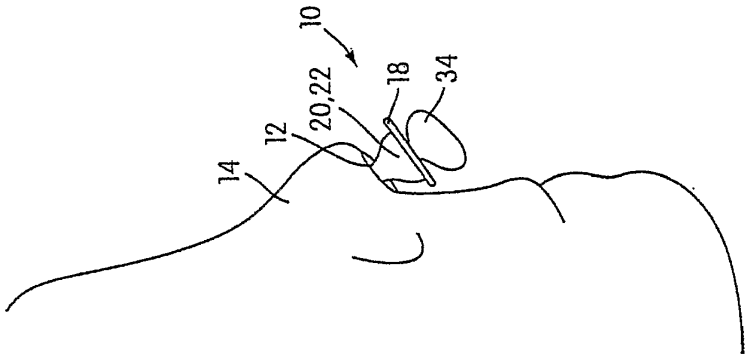

FIG. 97A

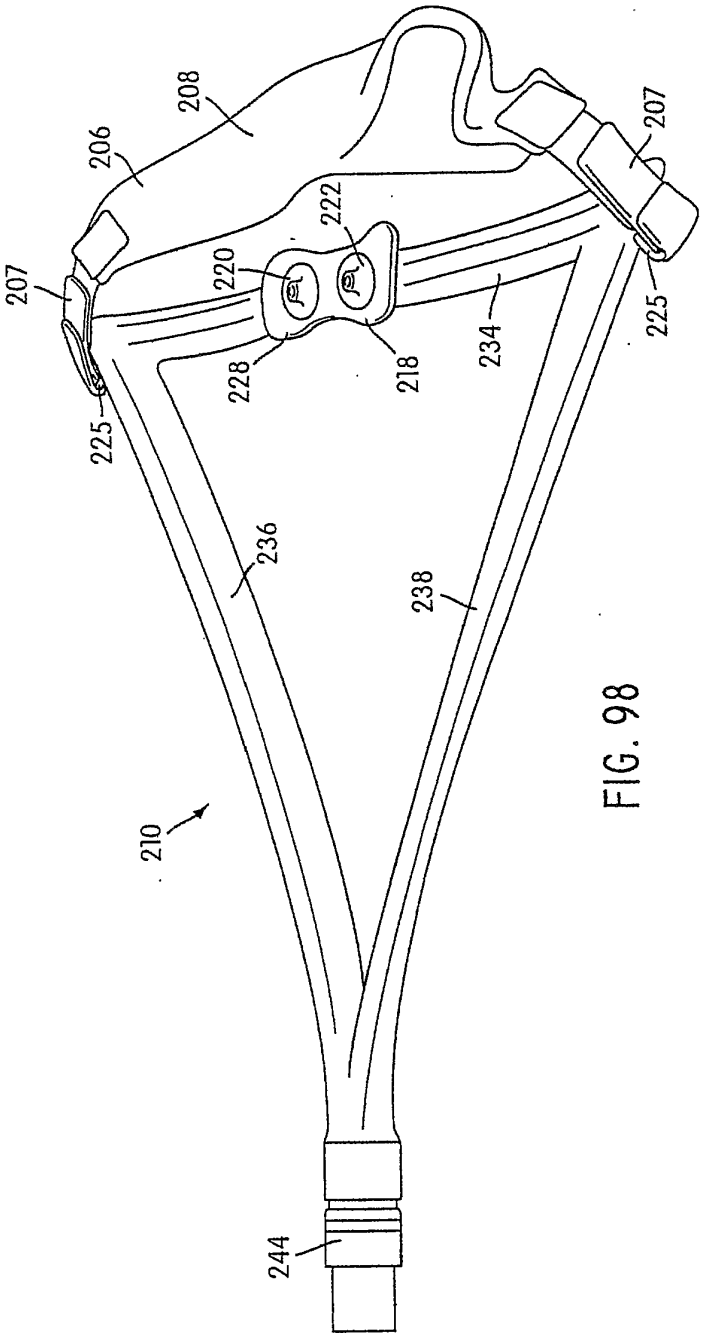

FIG. 98

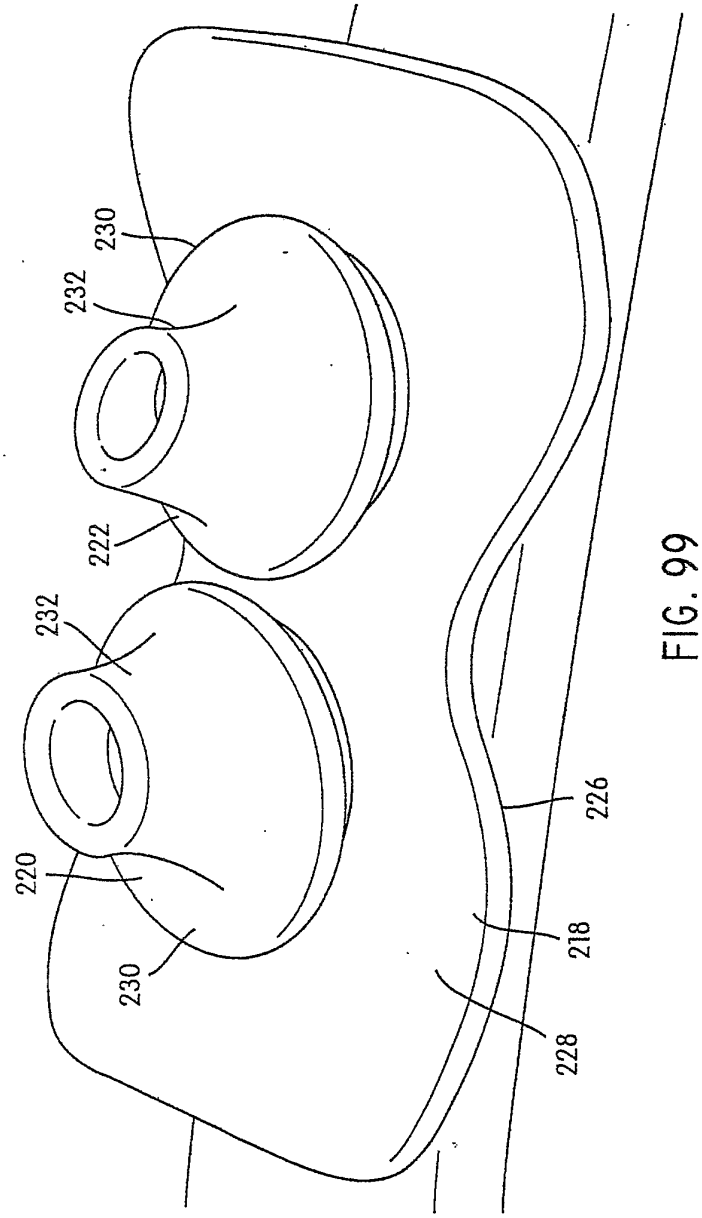

FIG. 99

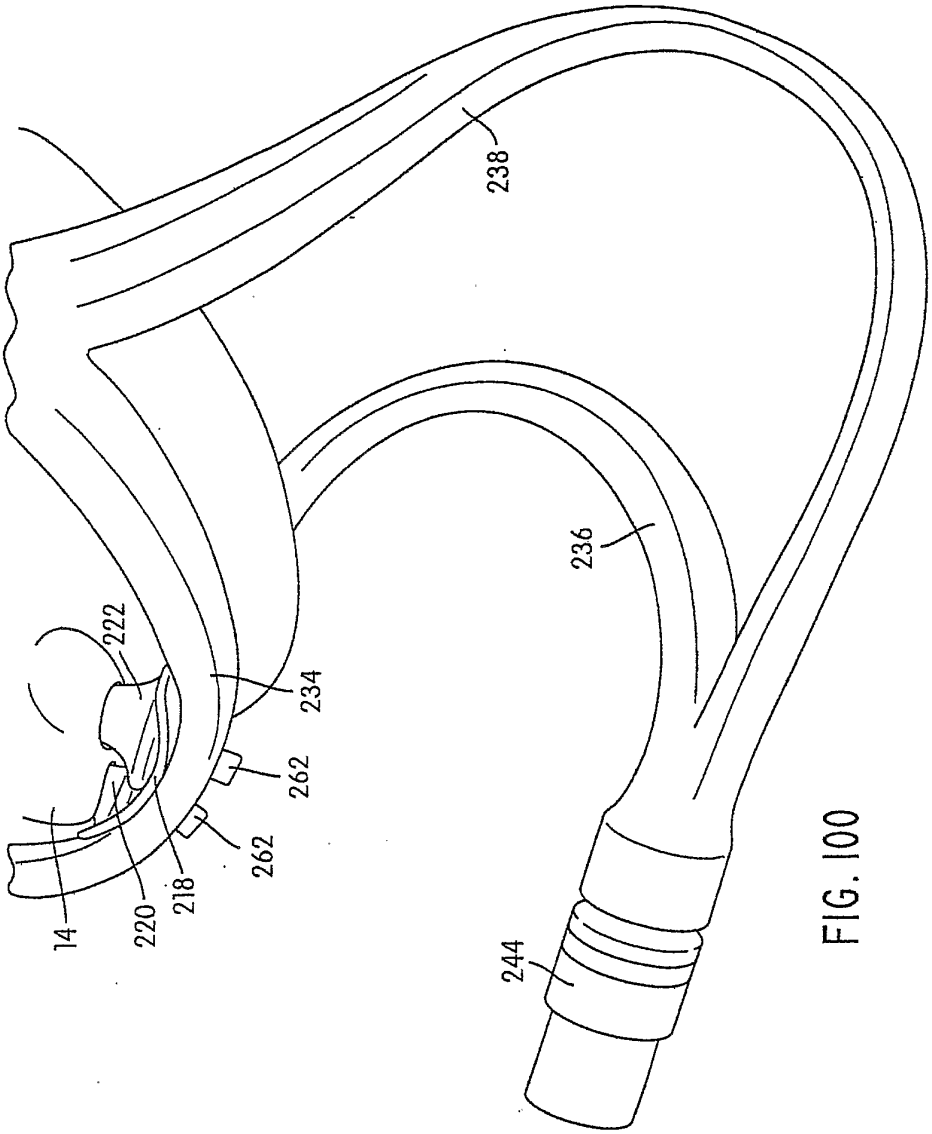

FIG. 100

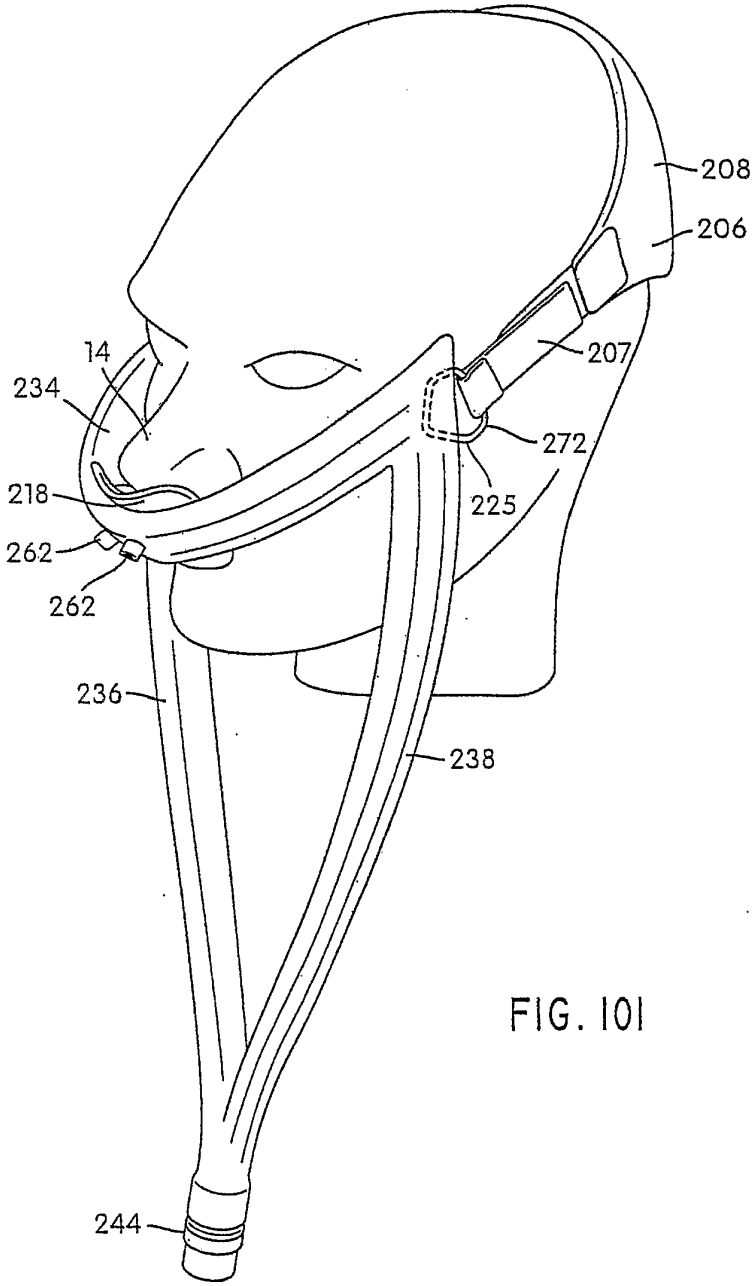

FIG. 101

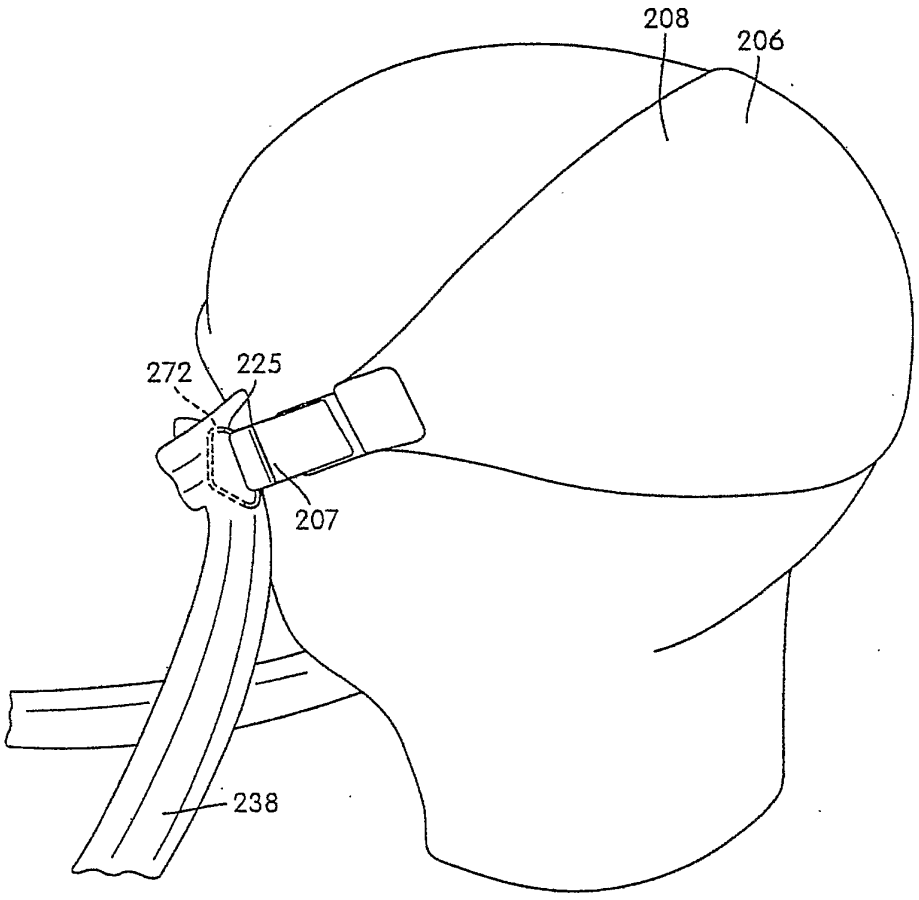

FIG. 102

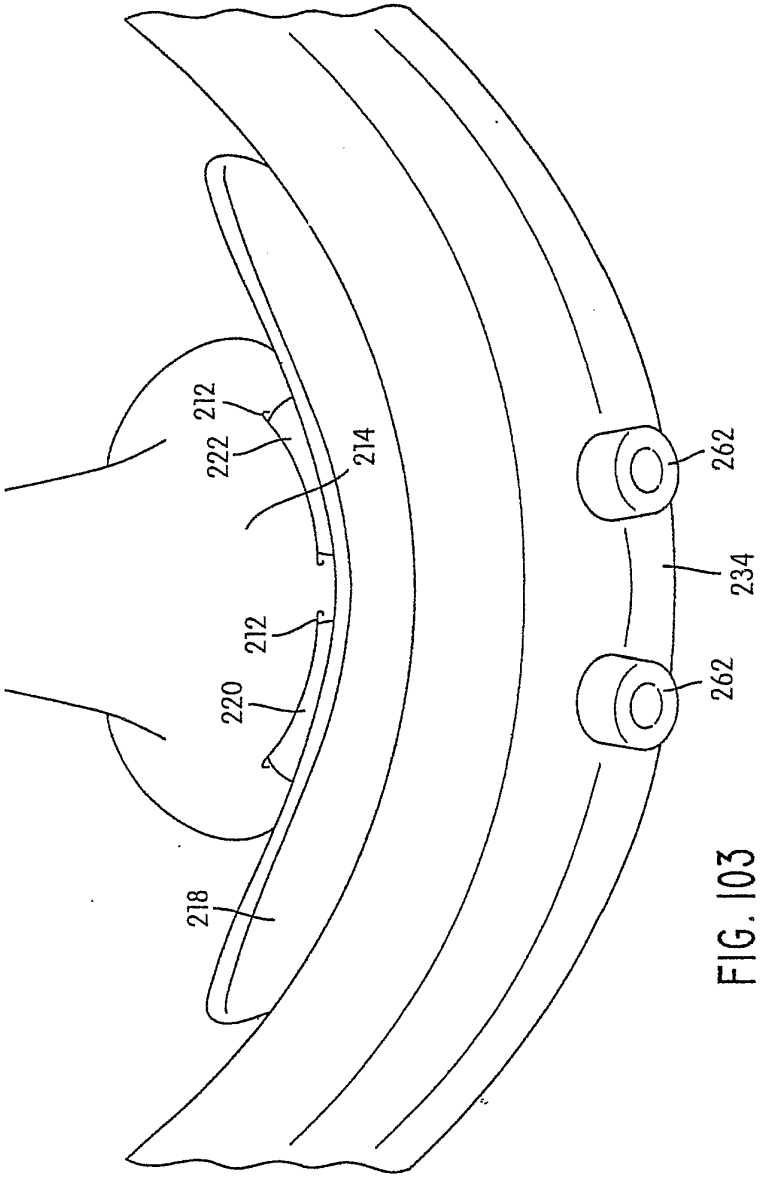

FIG. 103

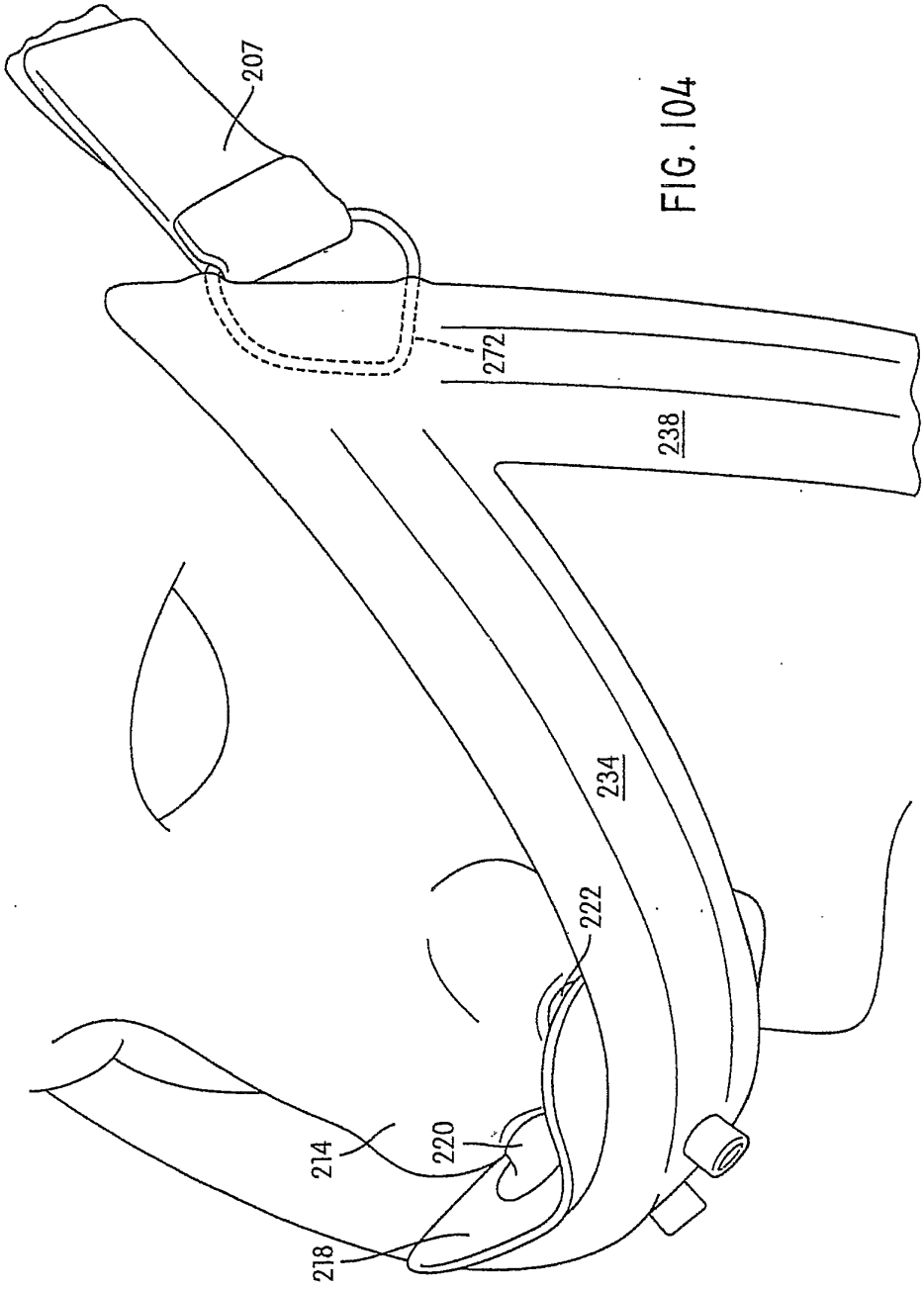

FIG. 104

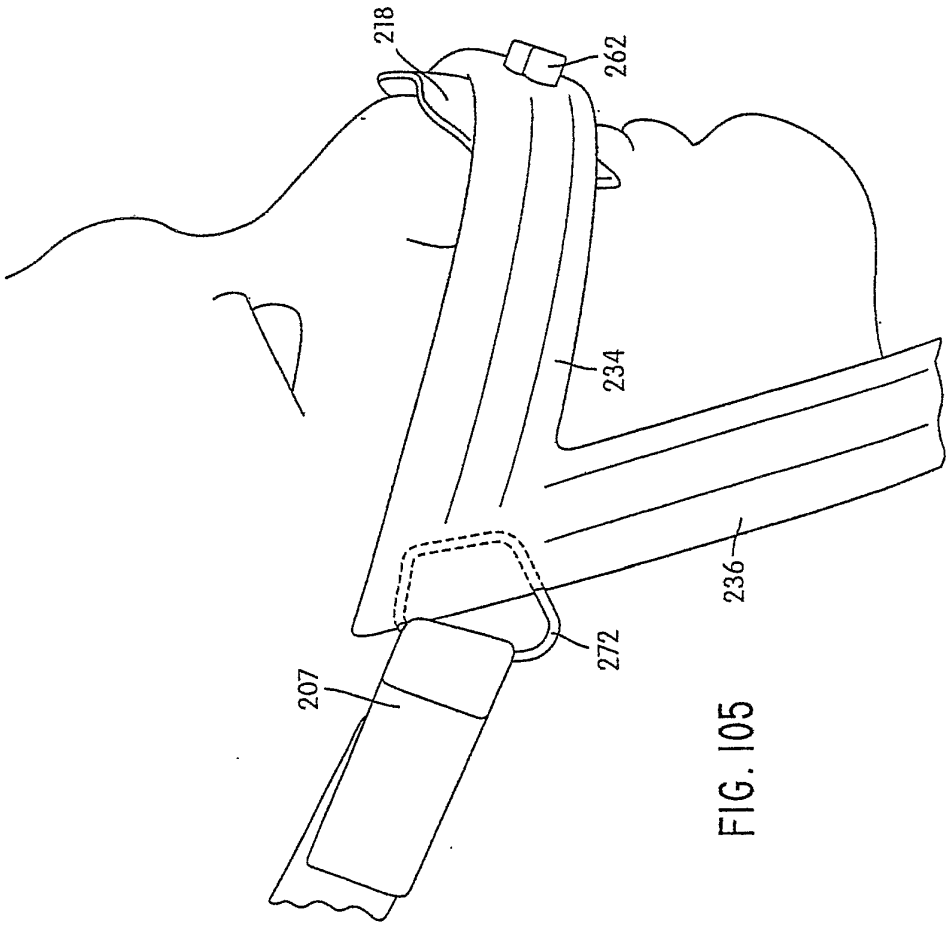

FIG. 105

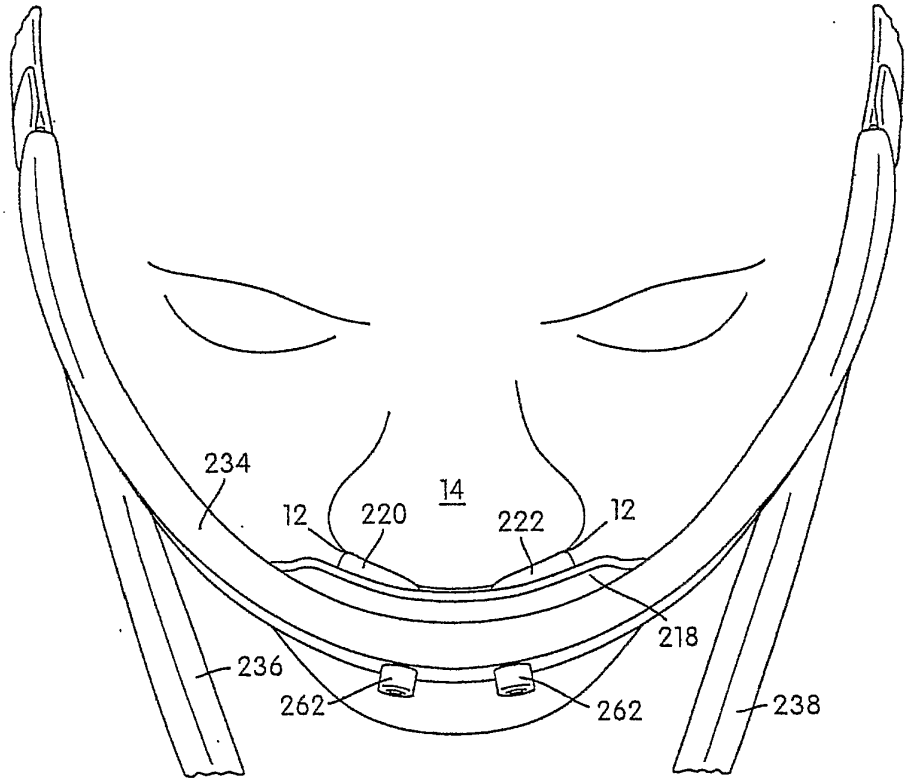

FIG. 106

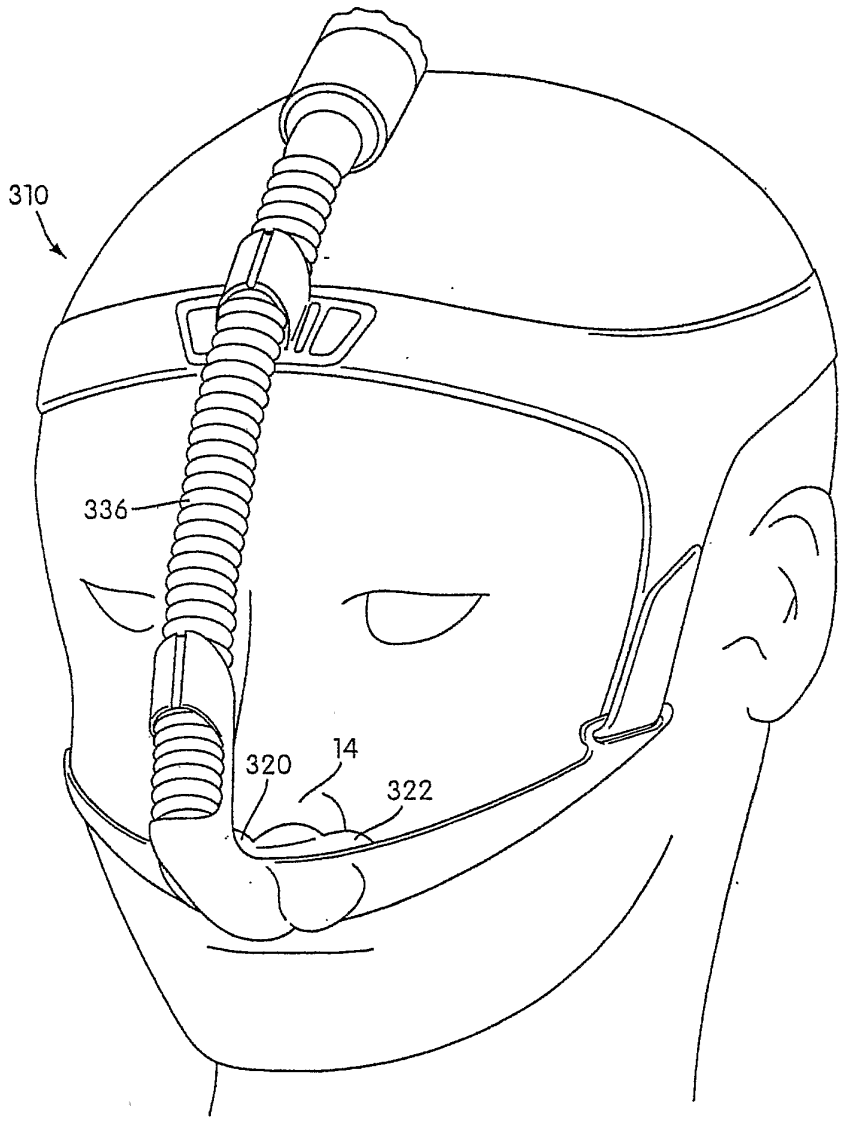

FIG. 107

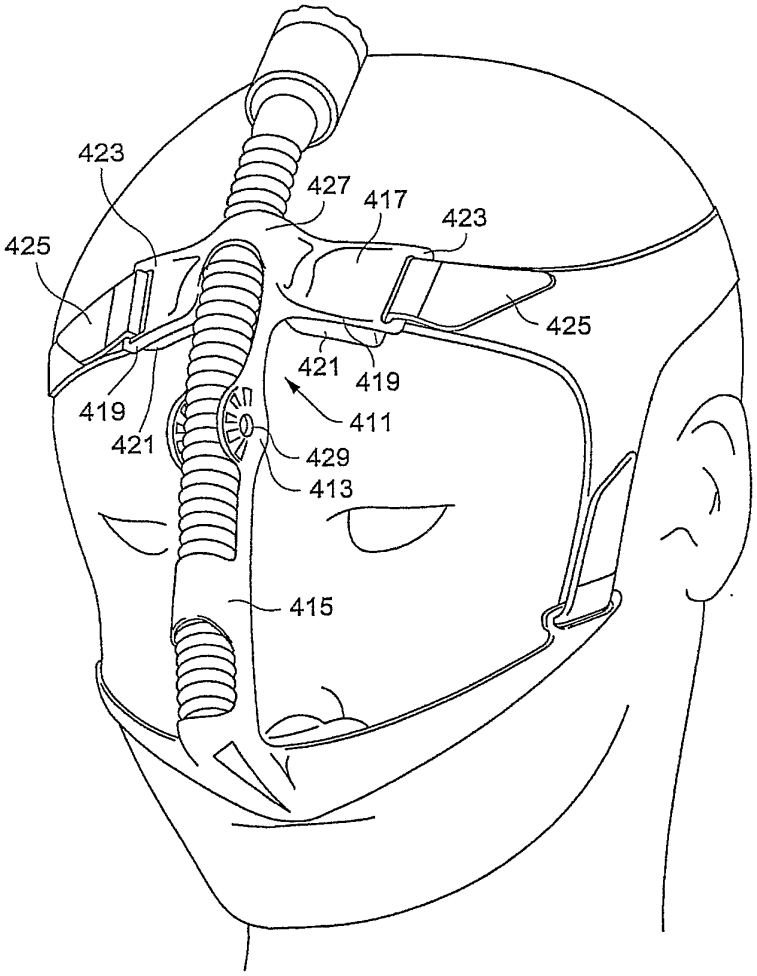

FIG. 107-I

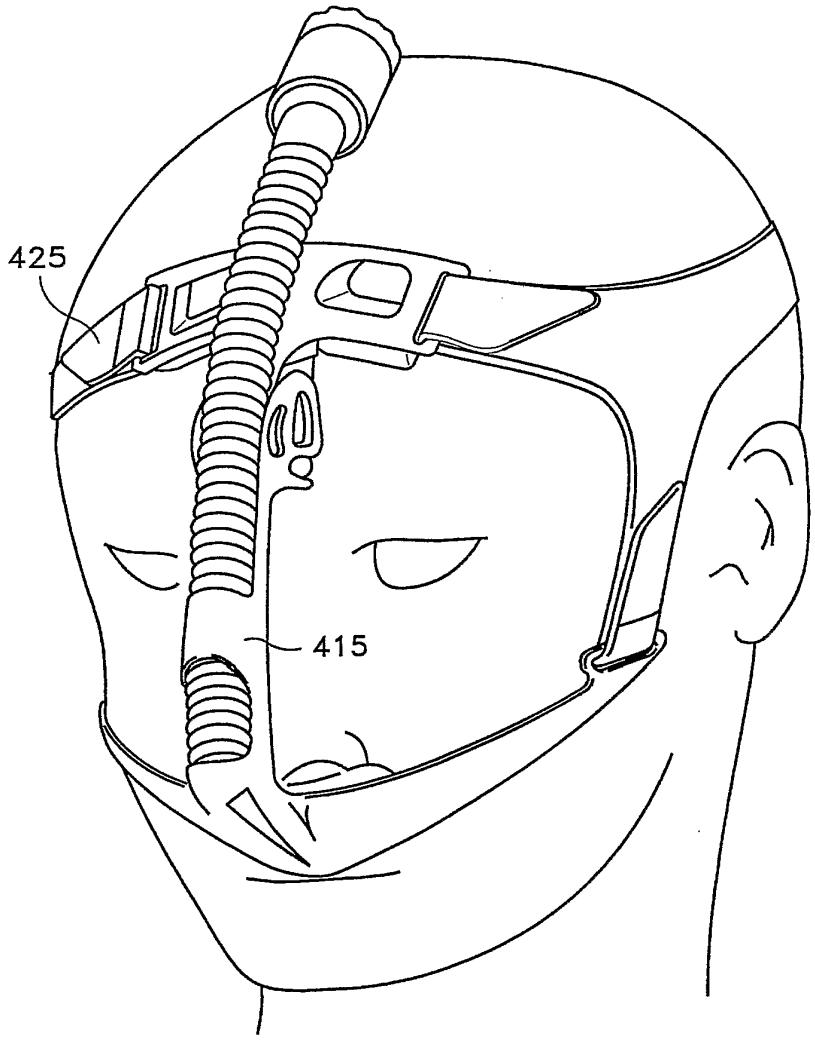

FIG. 107-2

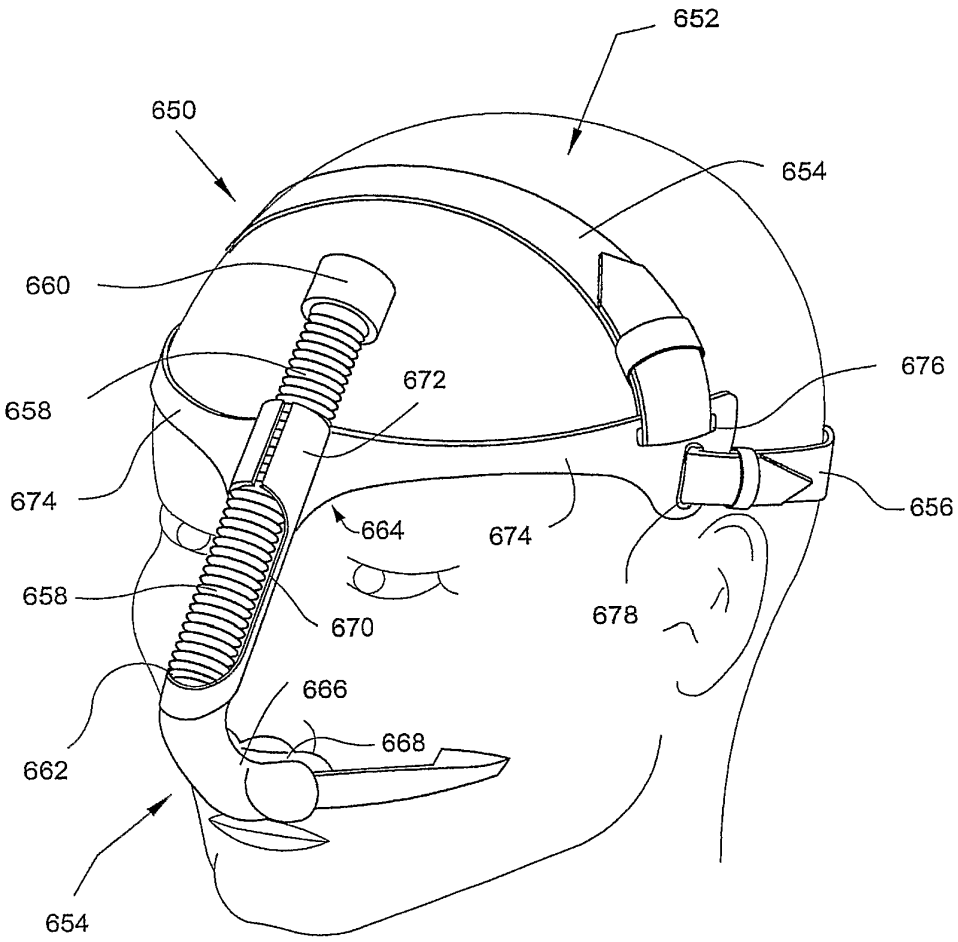
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FIG. 107A

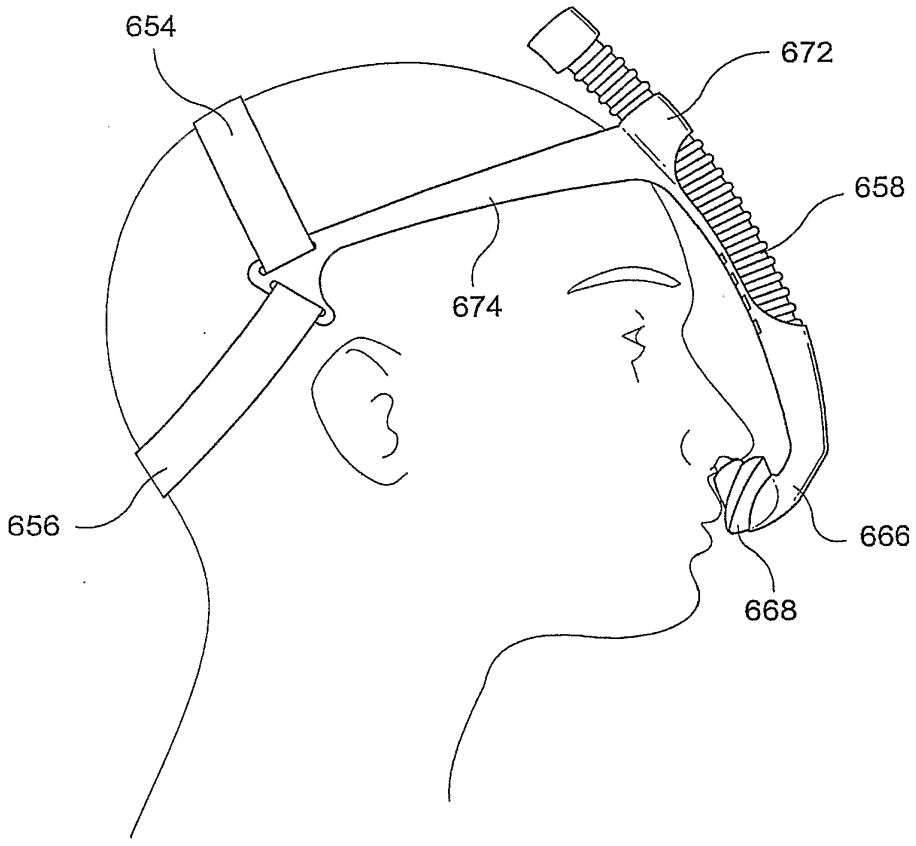


FIG. 107B

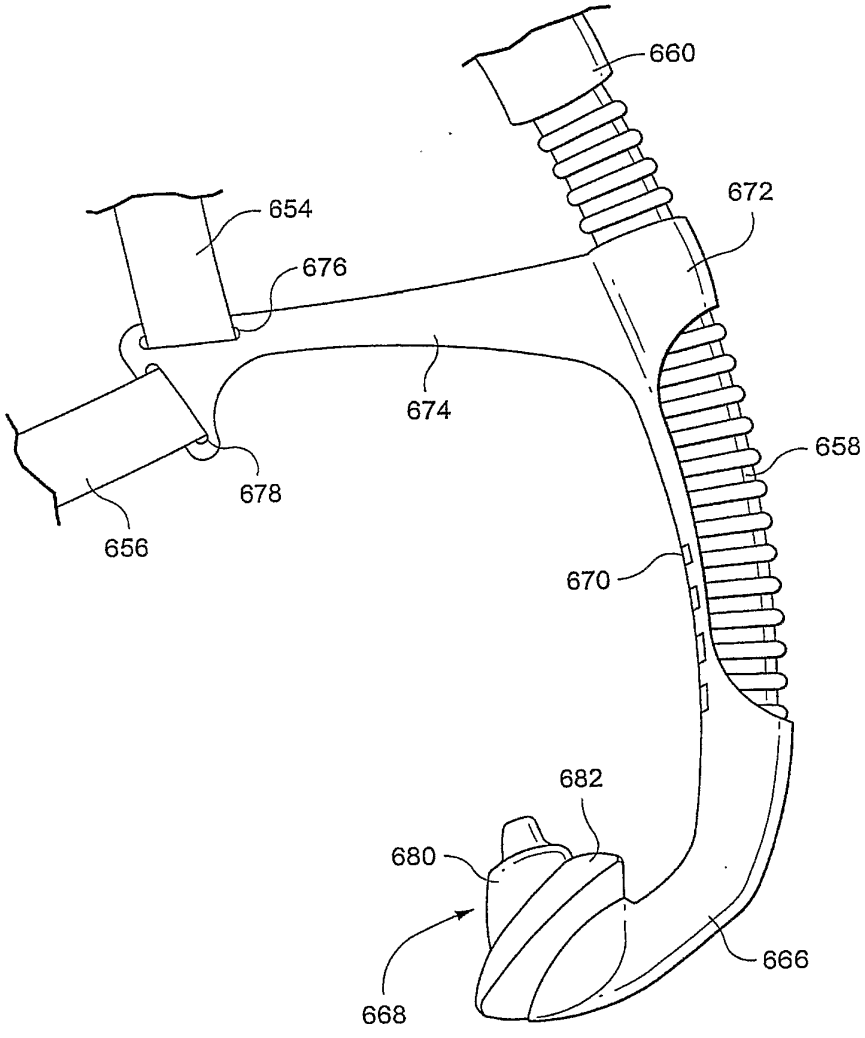


FIG. 107C

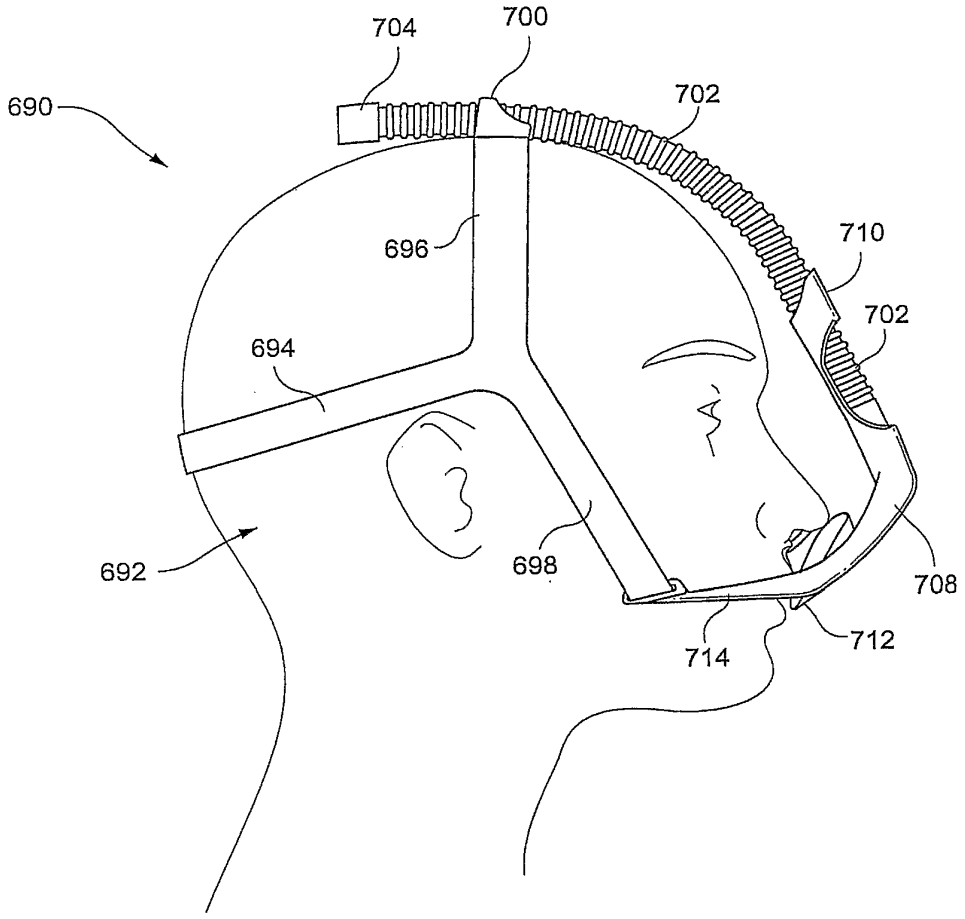


FIG. 107D

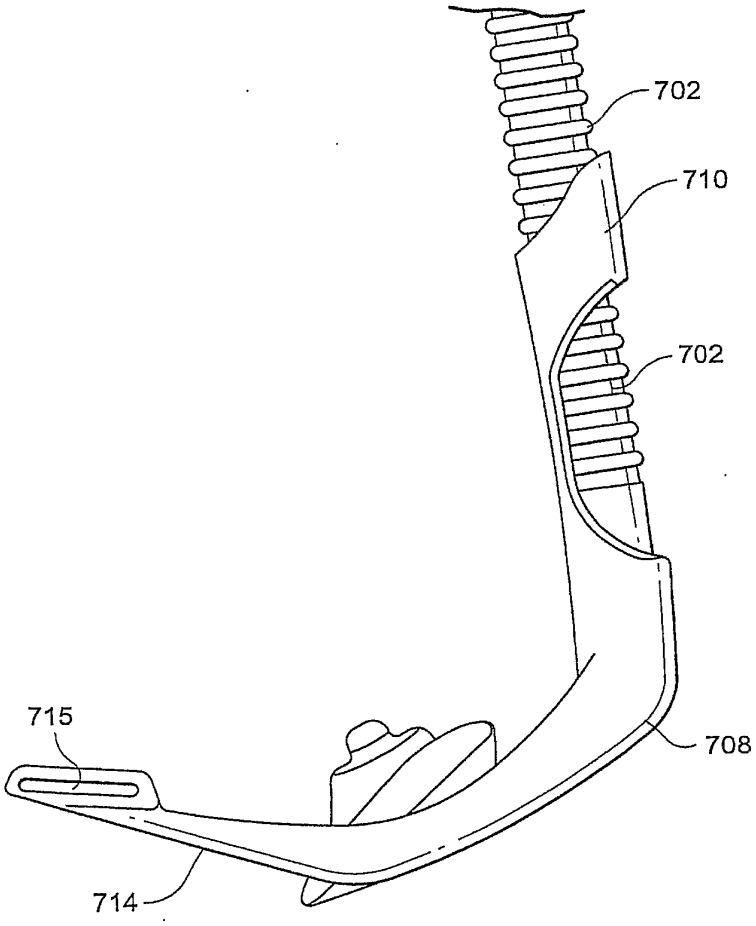


FIG. 107E

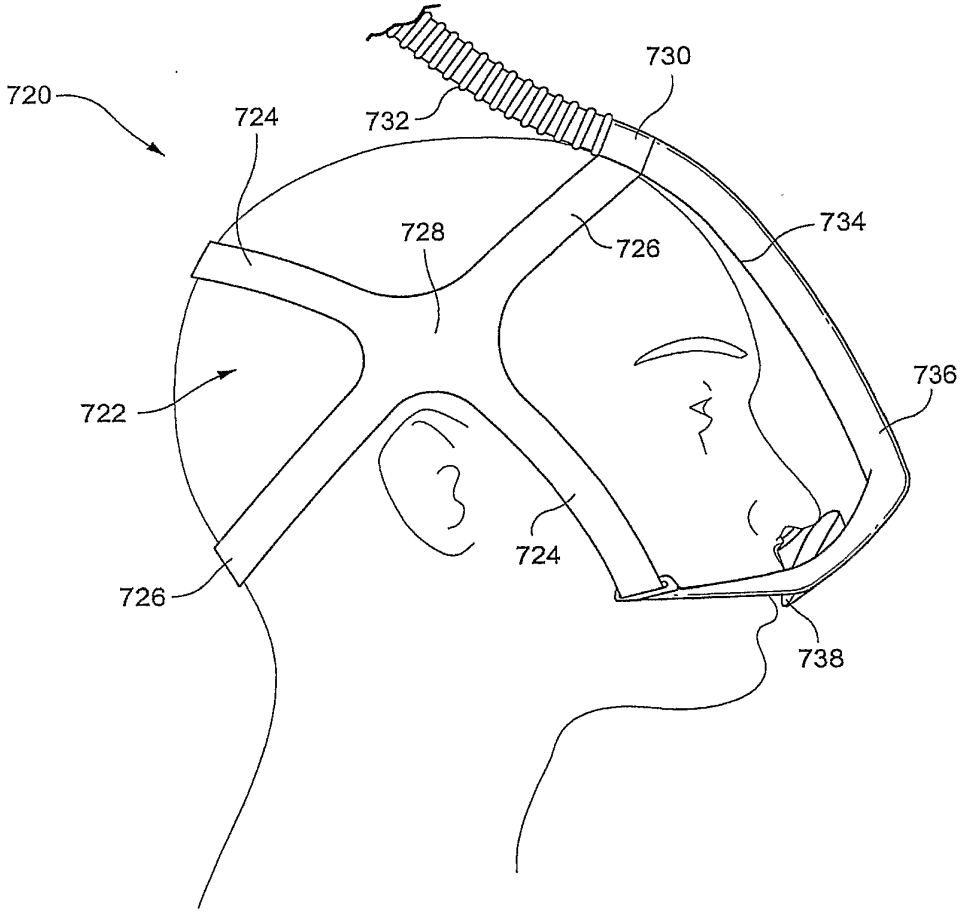


FIG. 107F

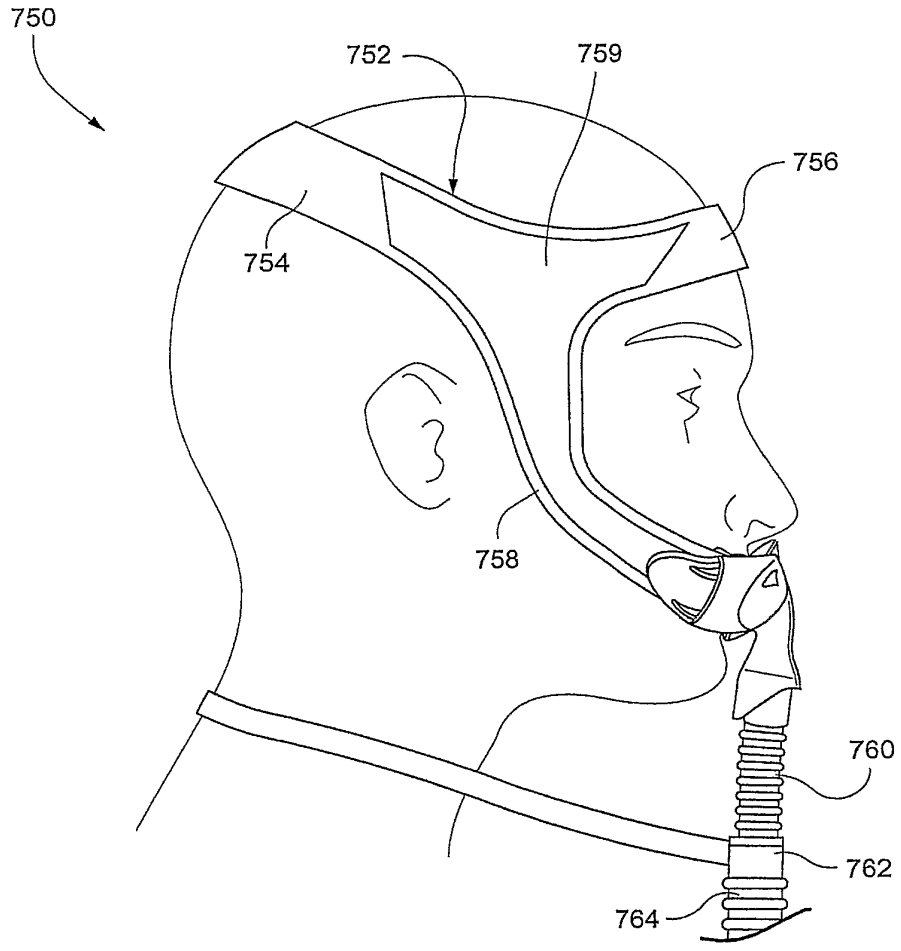


FIG. 107G

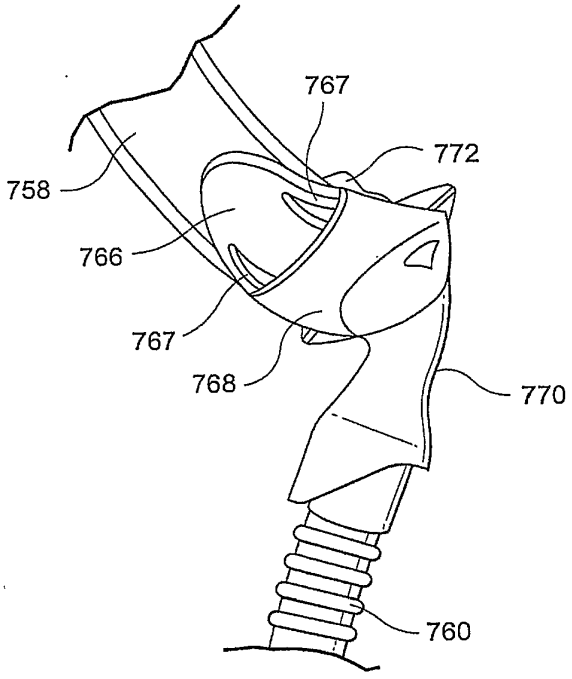


FIG. 107H

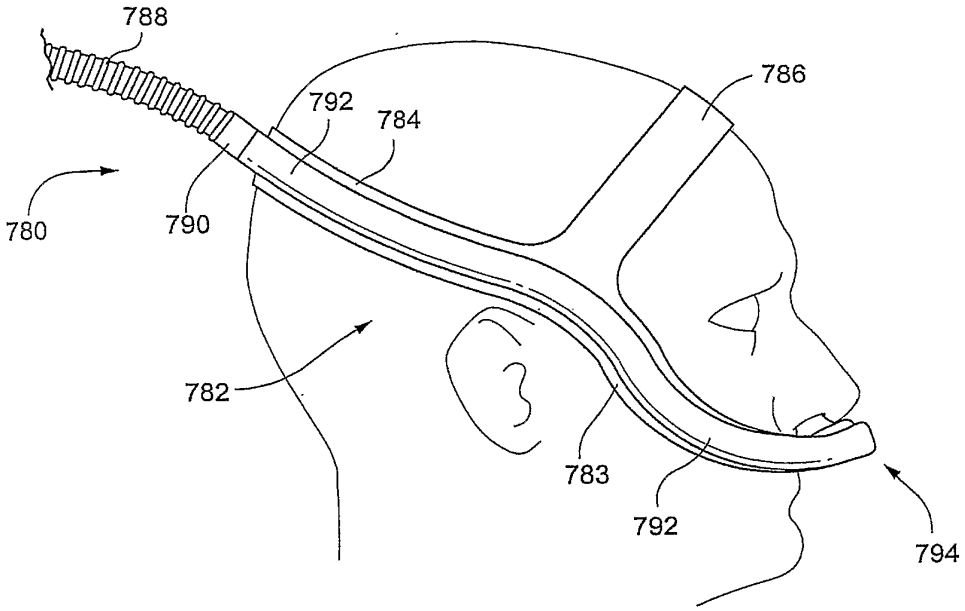


FIG. 107I

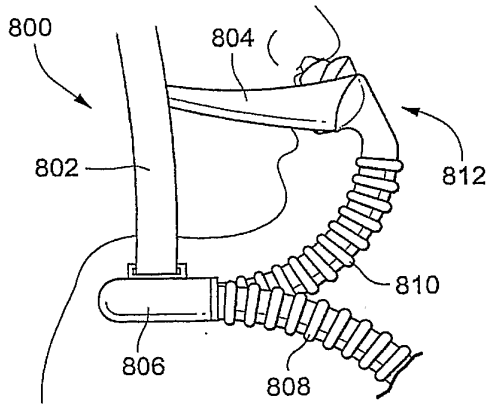


FIG. 107J

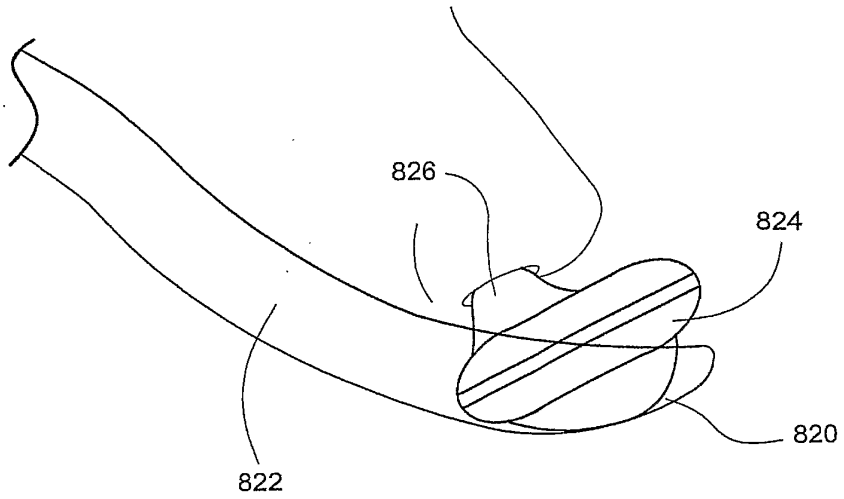


FIG. 107K

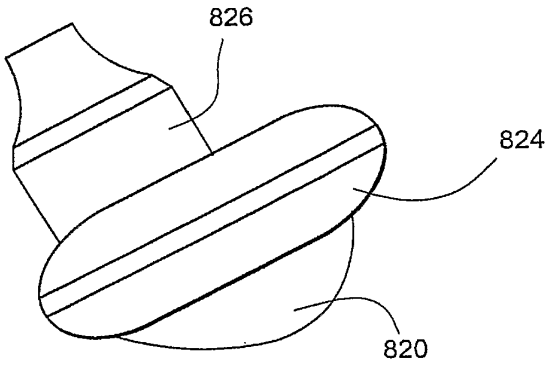


FIG. 107L

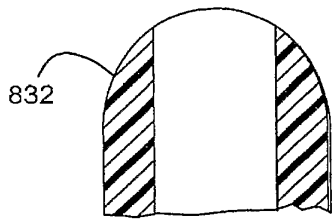


FIG. 107M

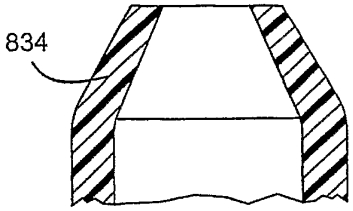


FIG. 107N

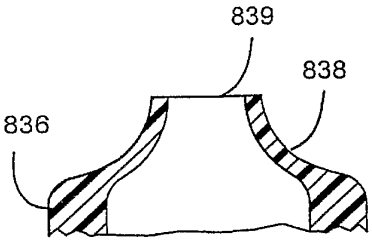


FIG. 107O

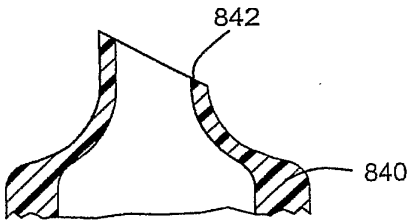


FIG. 107P

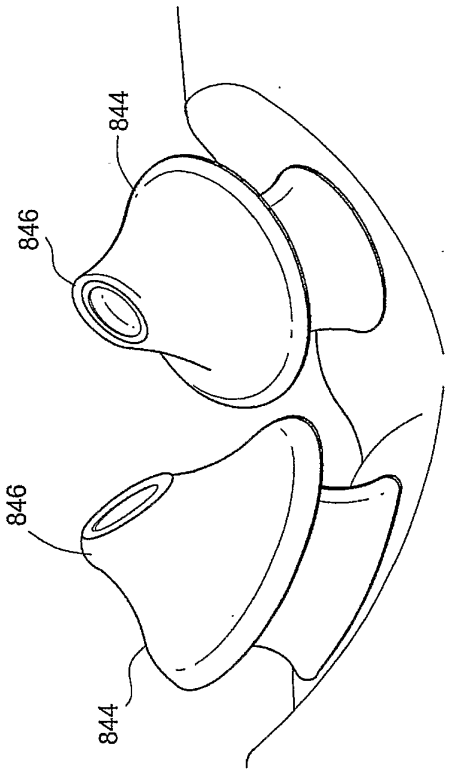


FIG. 107R

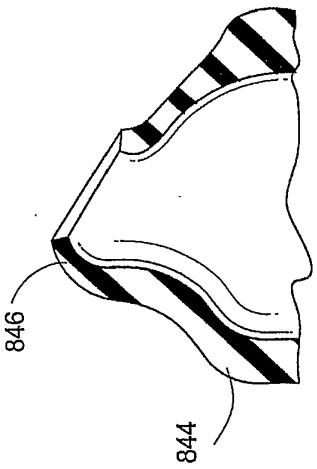


FIG. 107Q

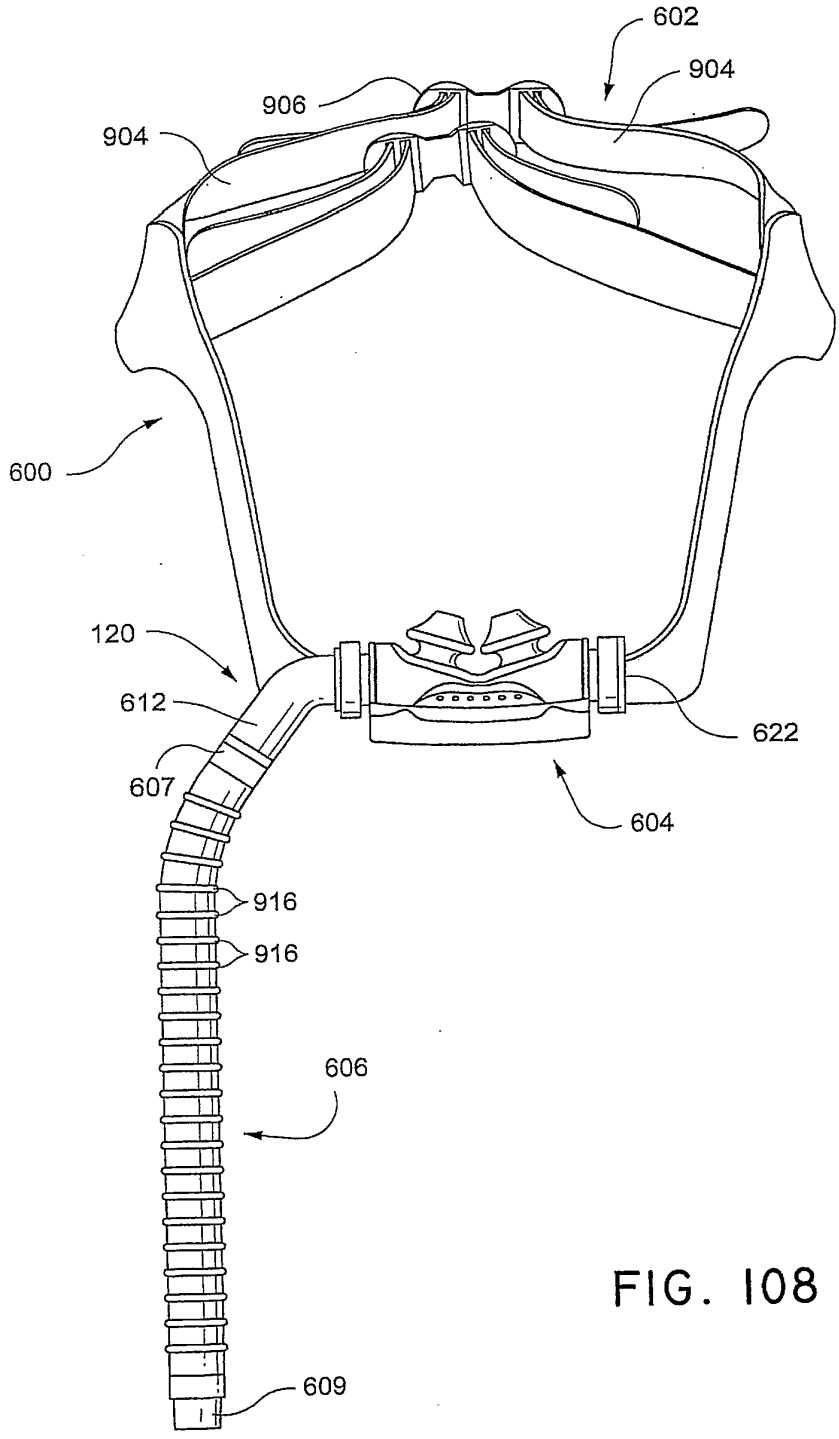


FIG. 108

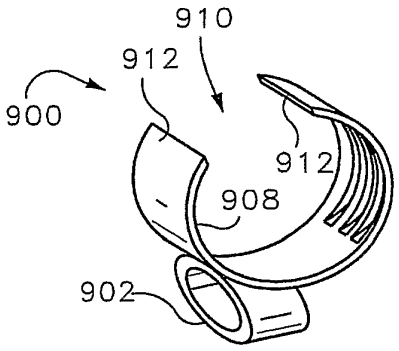


FIG. 108A

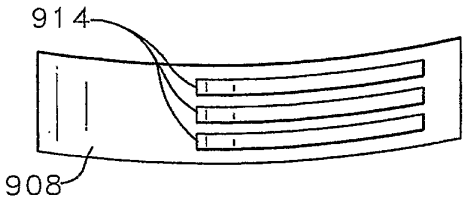


FIG. 108B

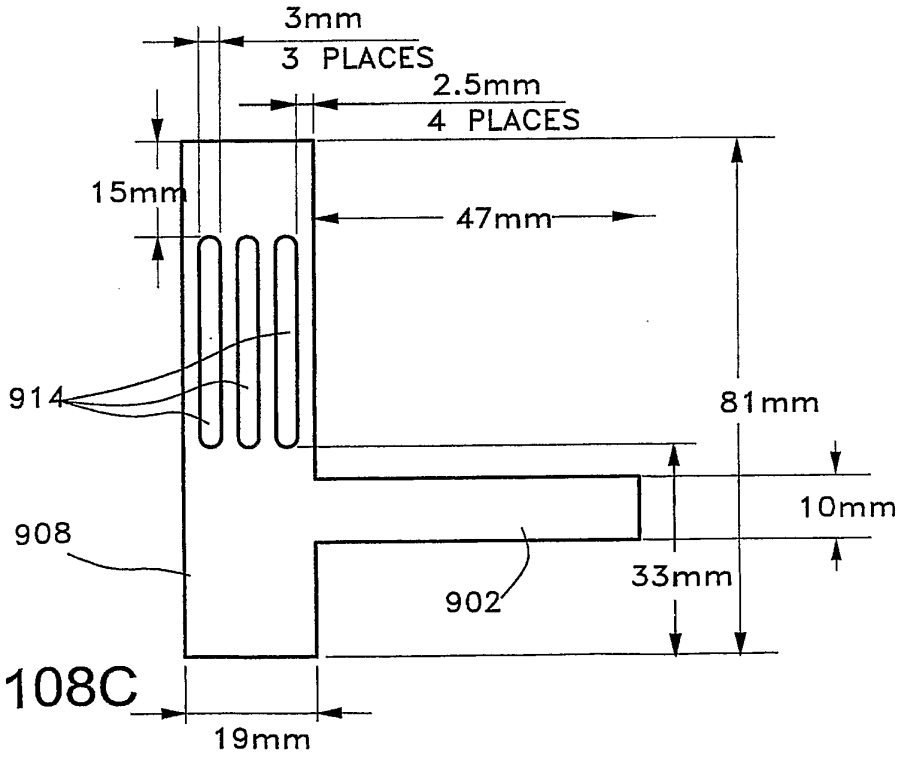


FIG. 108C

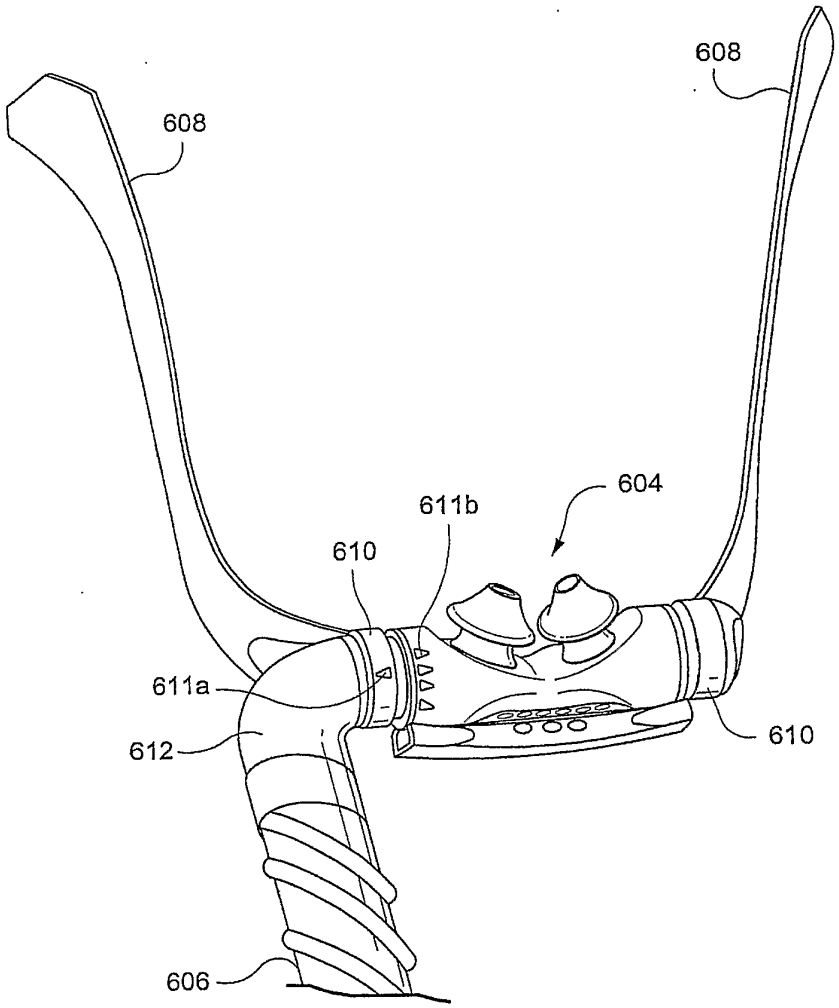


FIG. 109

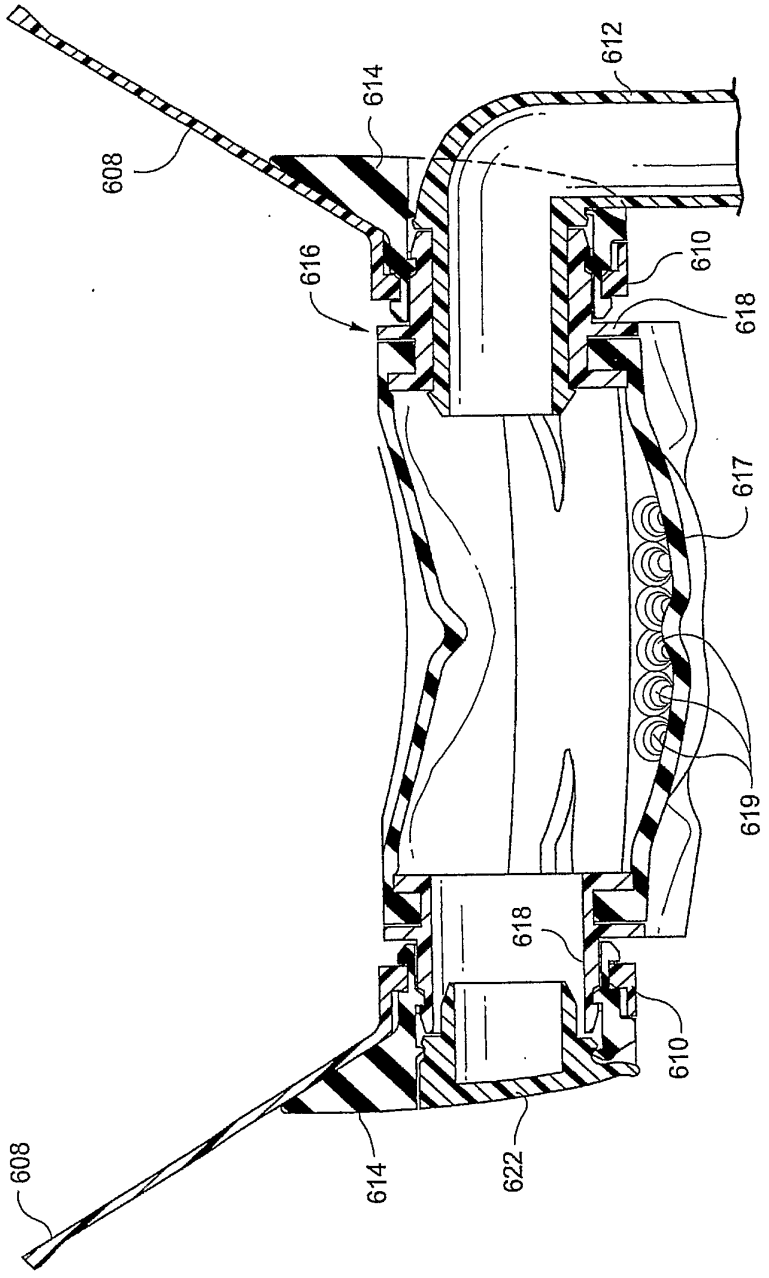


FIG. 110

FIG. 110-1

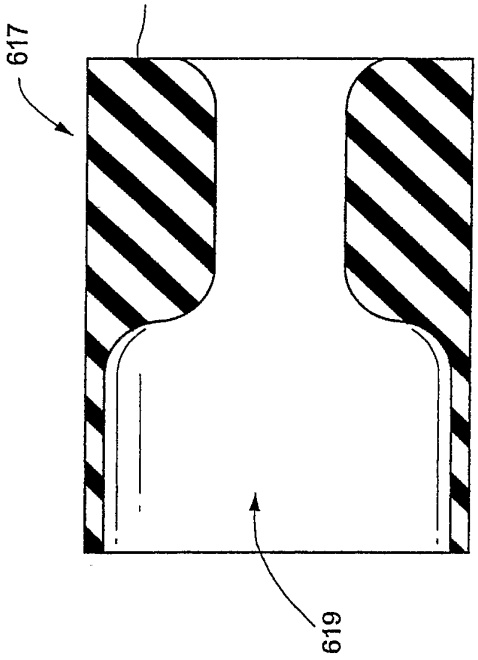
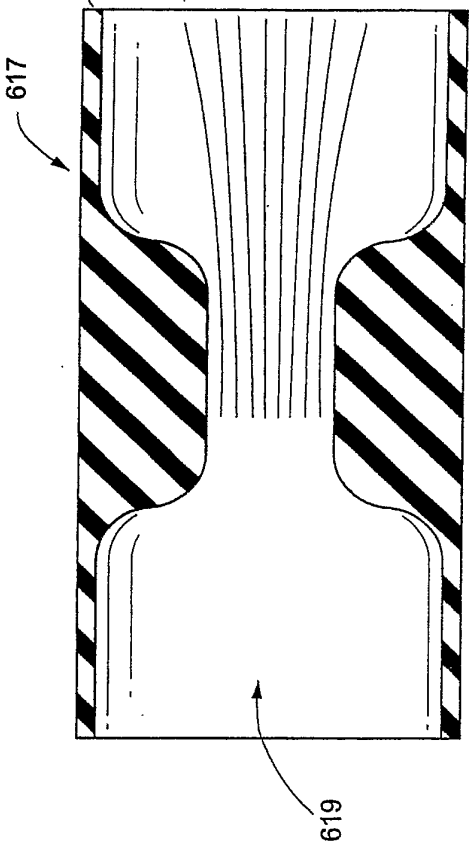


FIG. 110-2



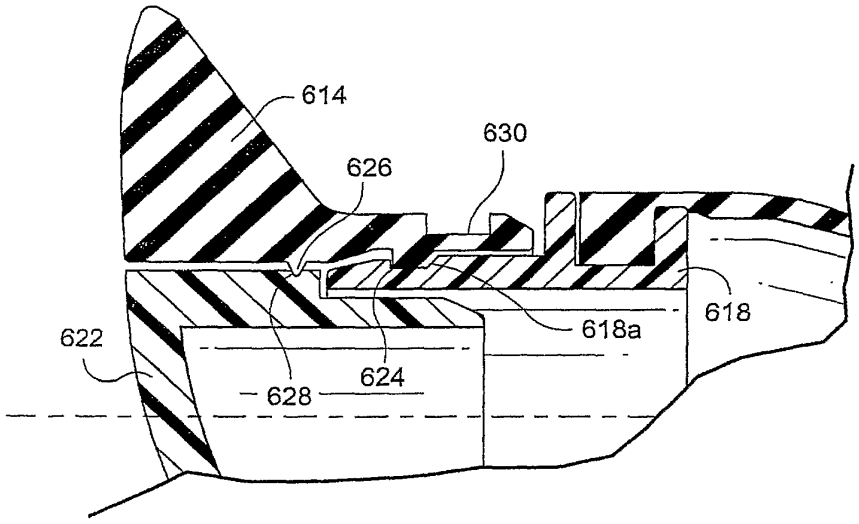


FIG. 110A

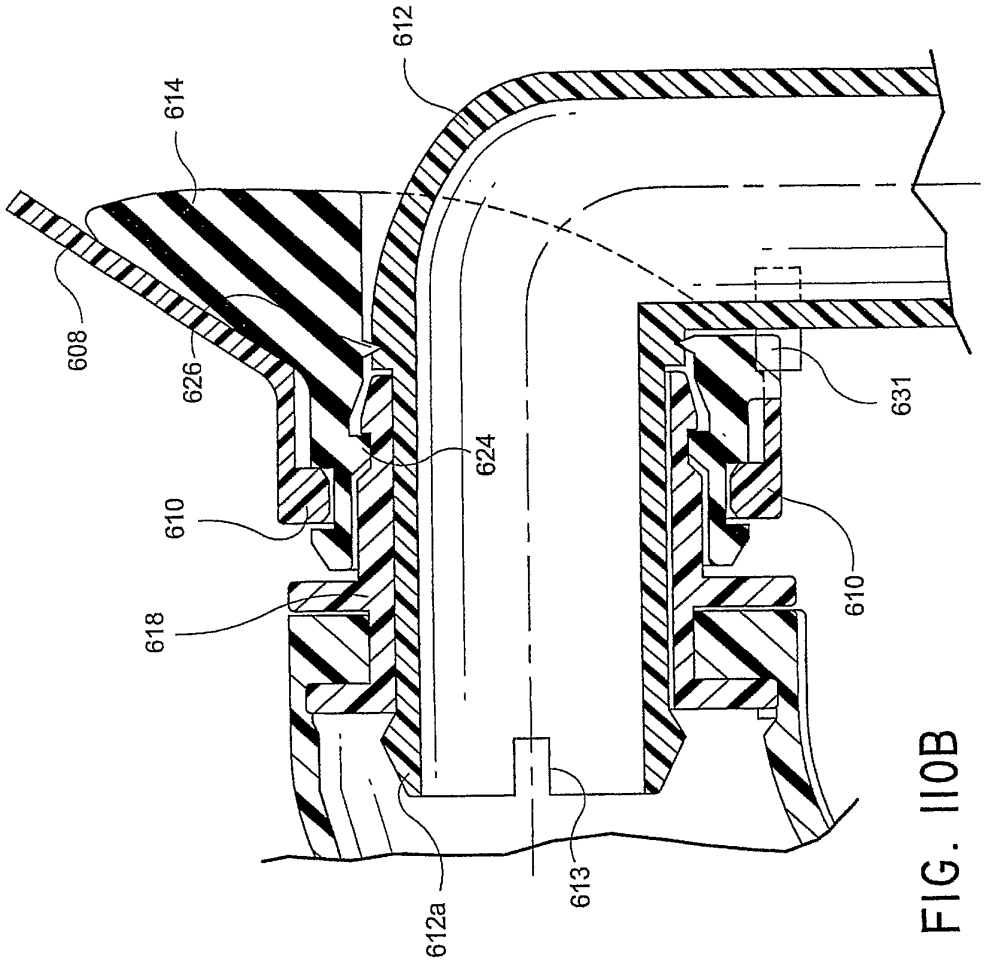


FIG. 110B

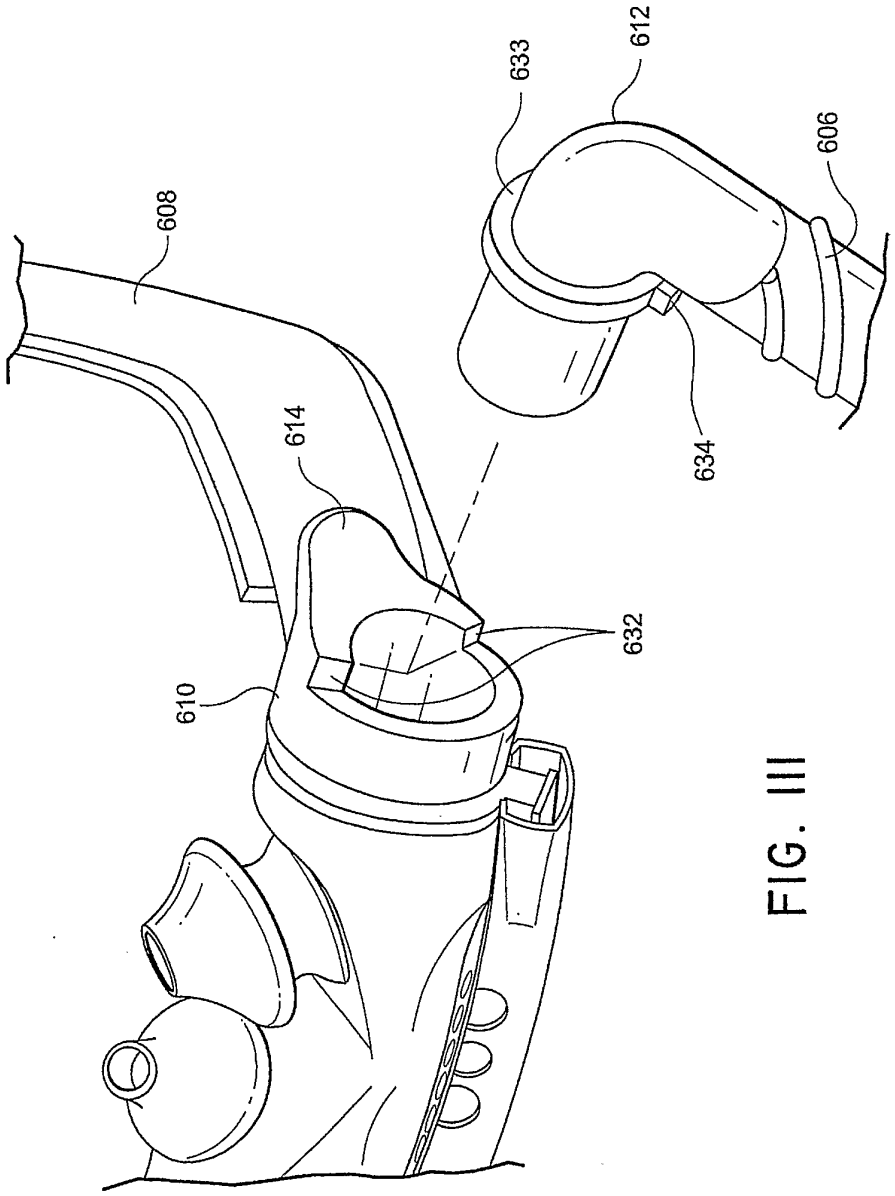


FIG. III

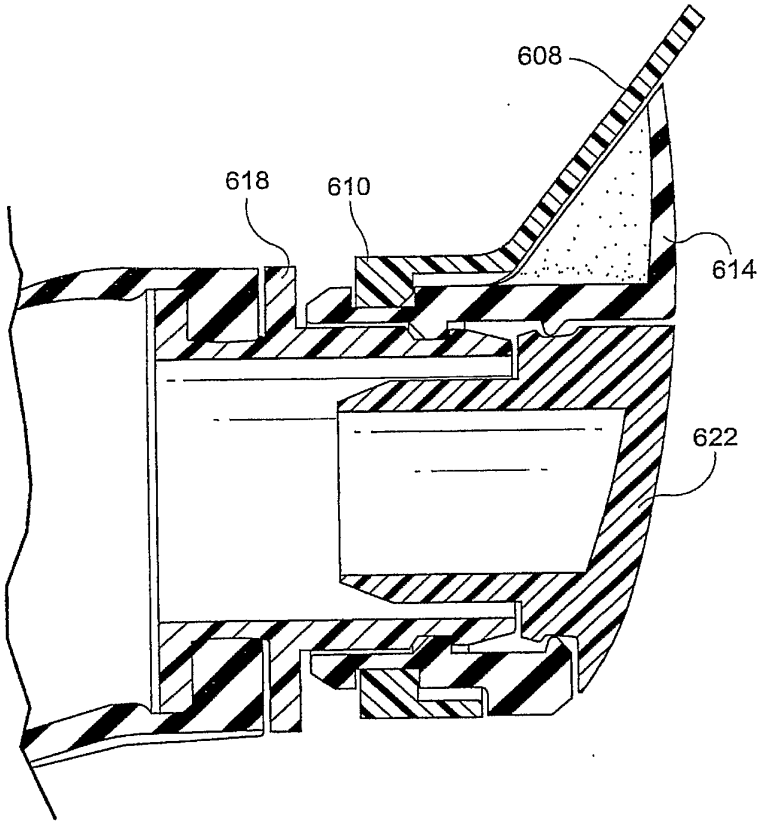


FIG. 112

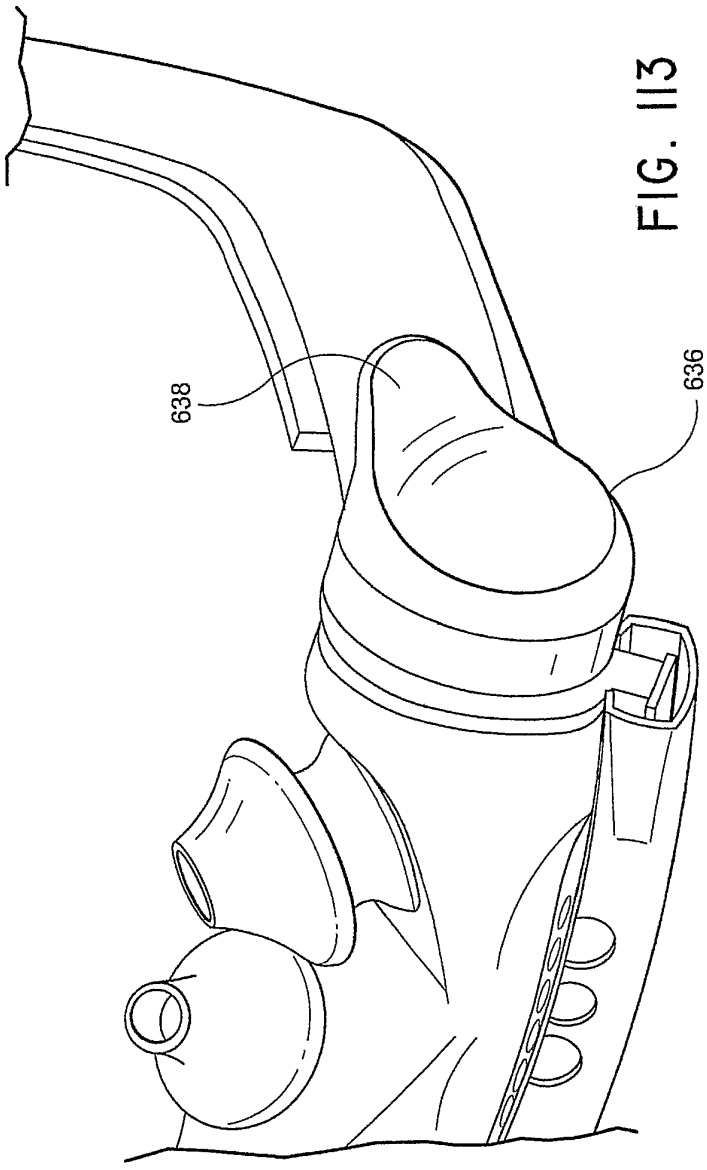


FIG. 113

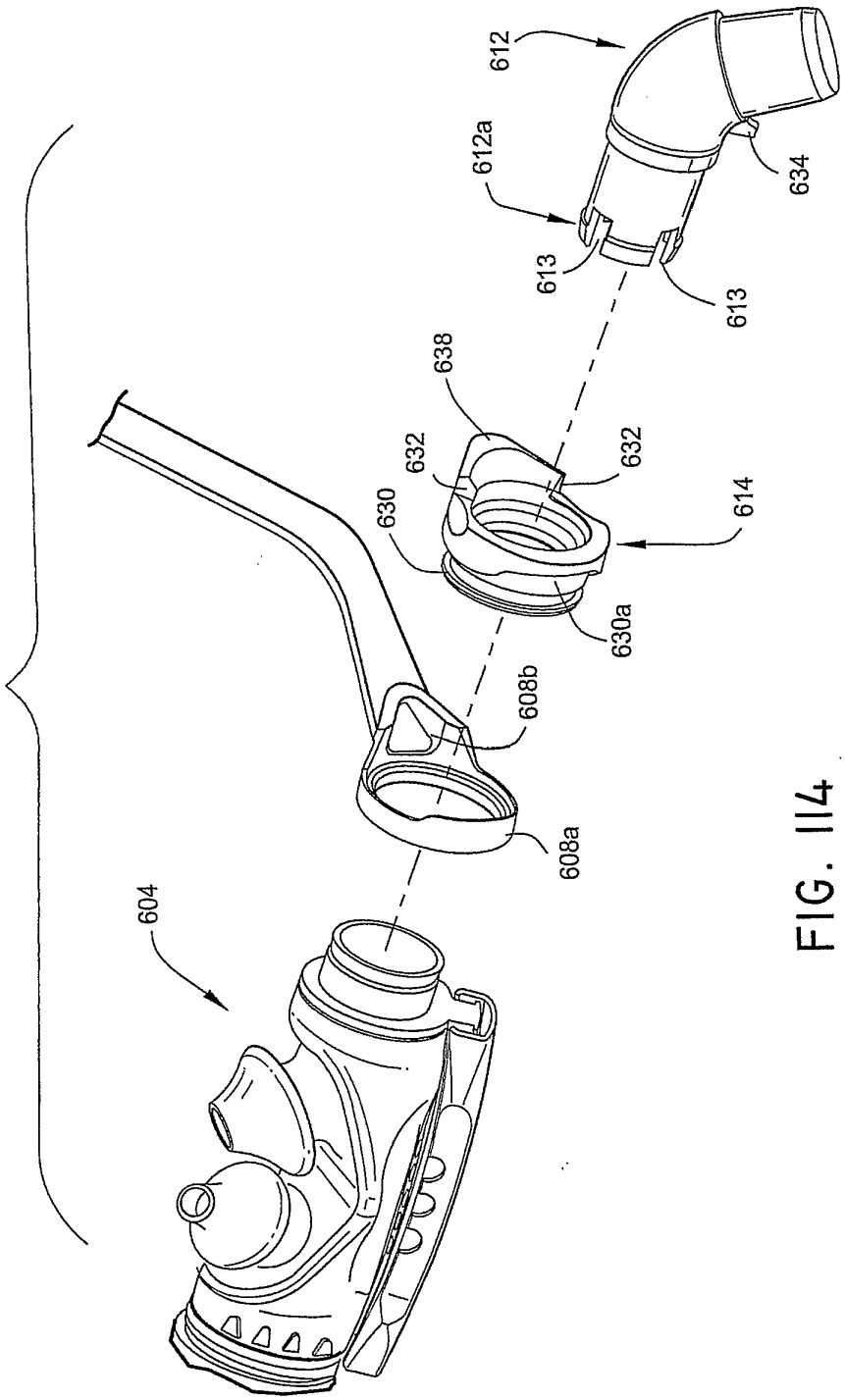


FIG. 114

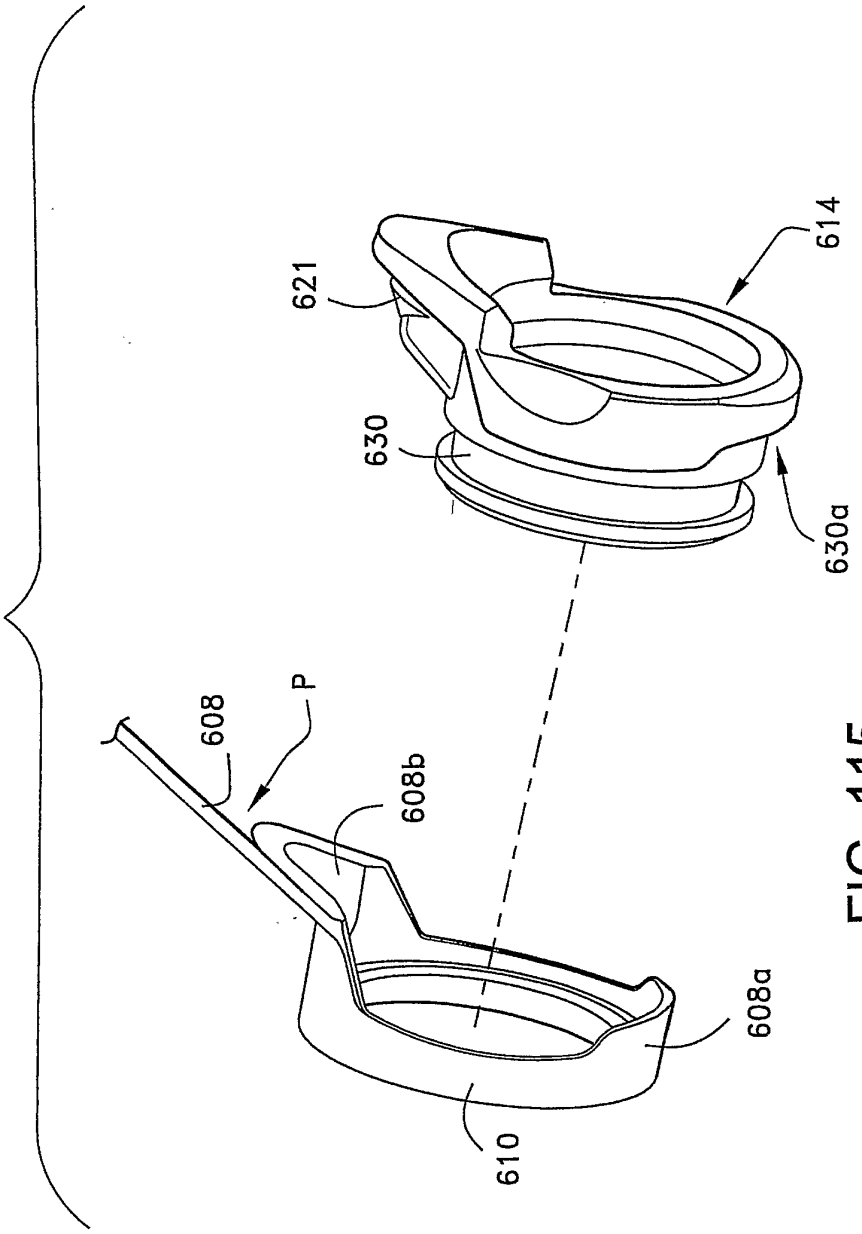


FIG. 115

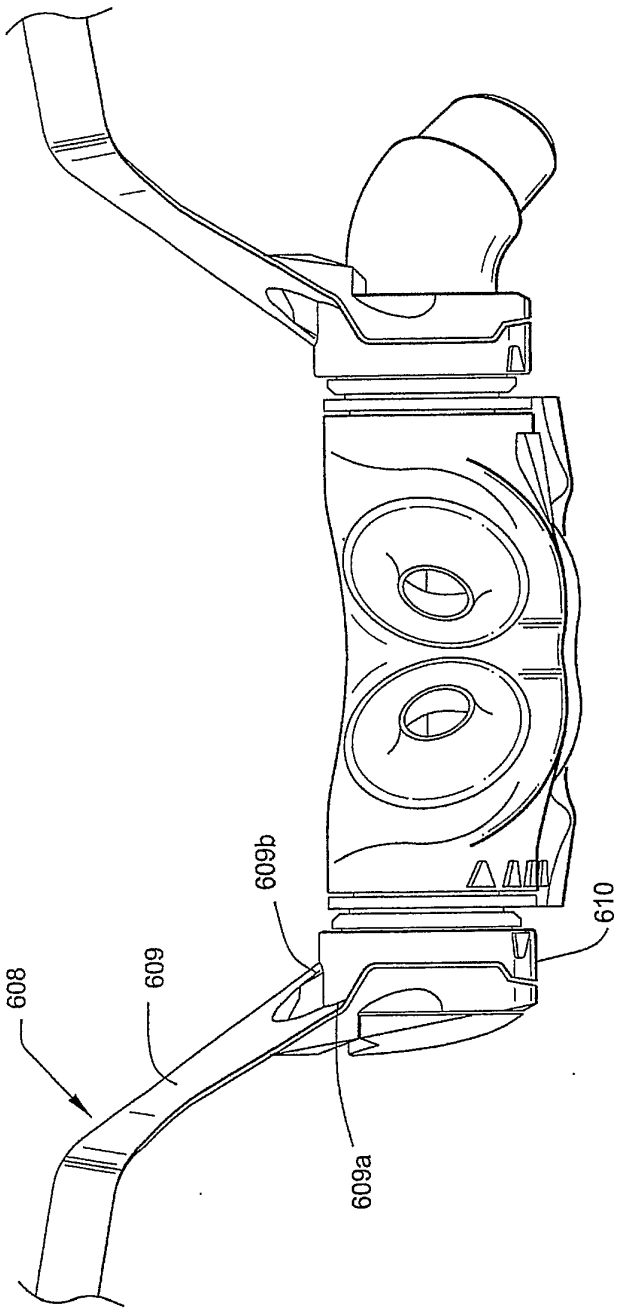


FIG. 116

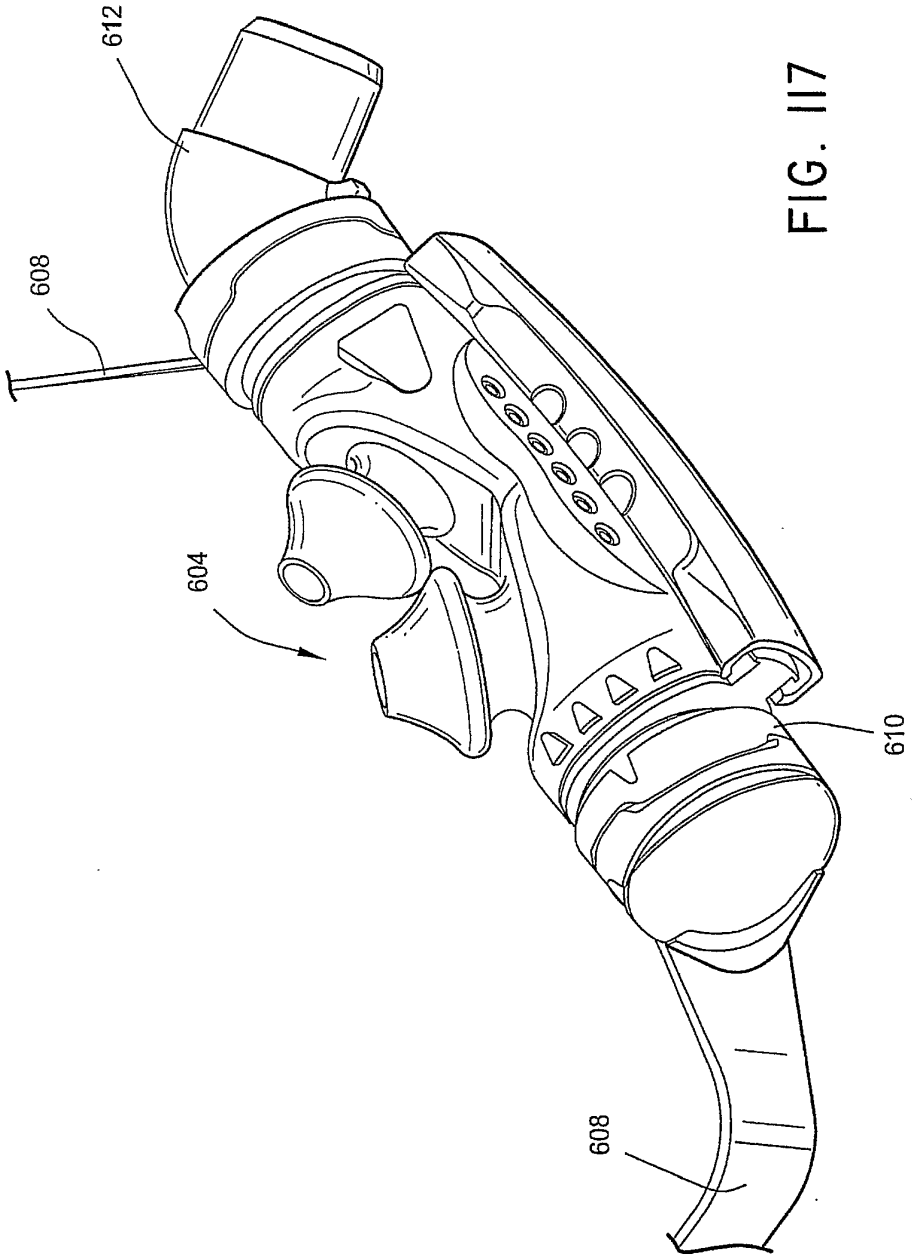


FIG. 117

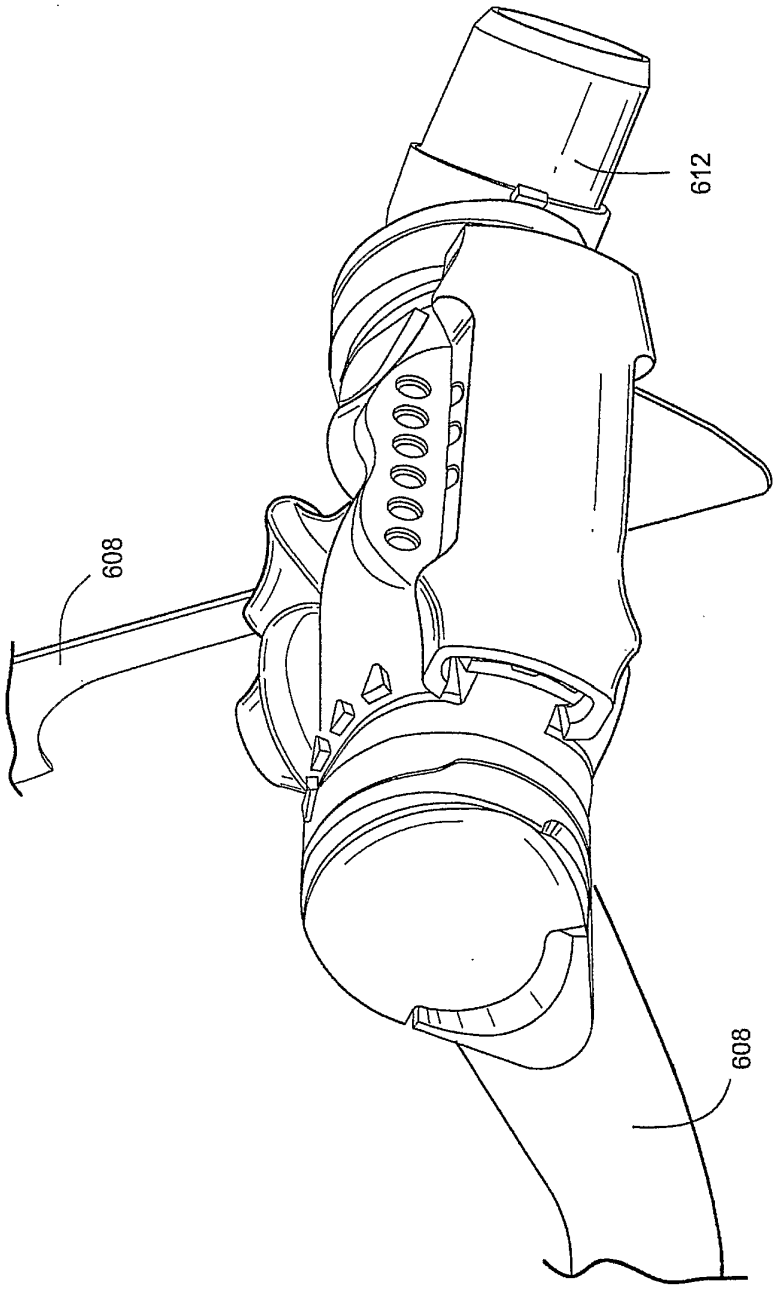


FIG. 118

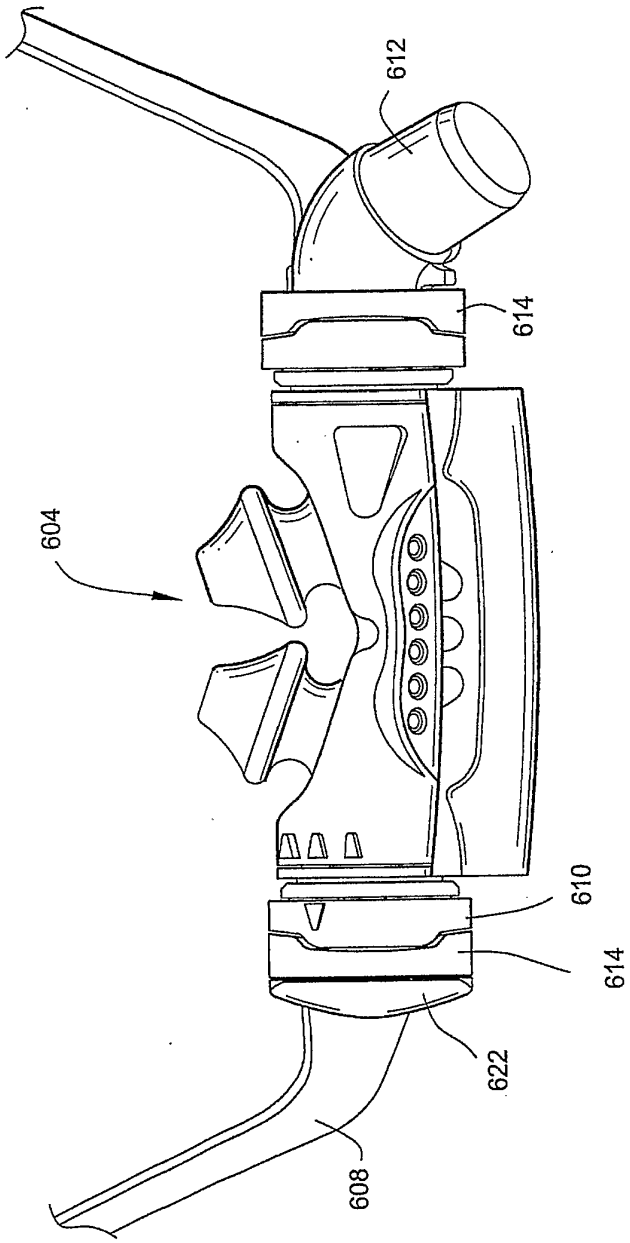


FIG. 119

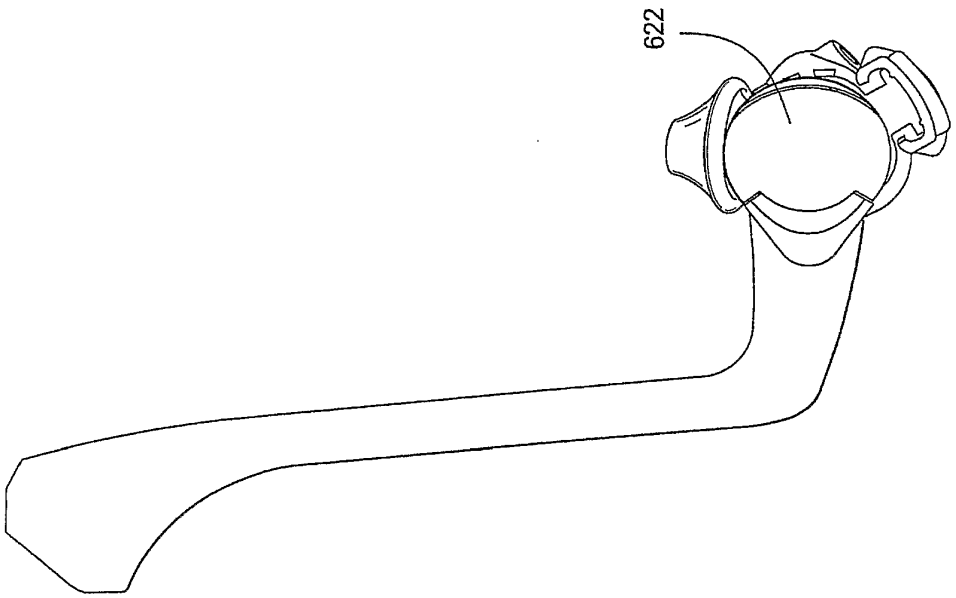


FIG. 120

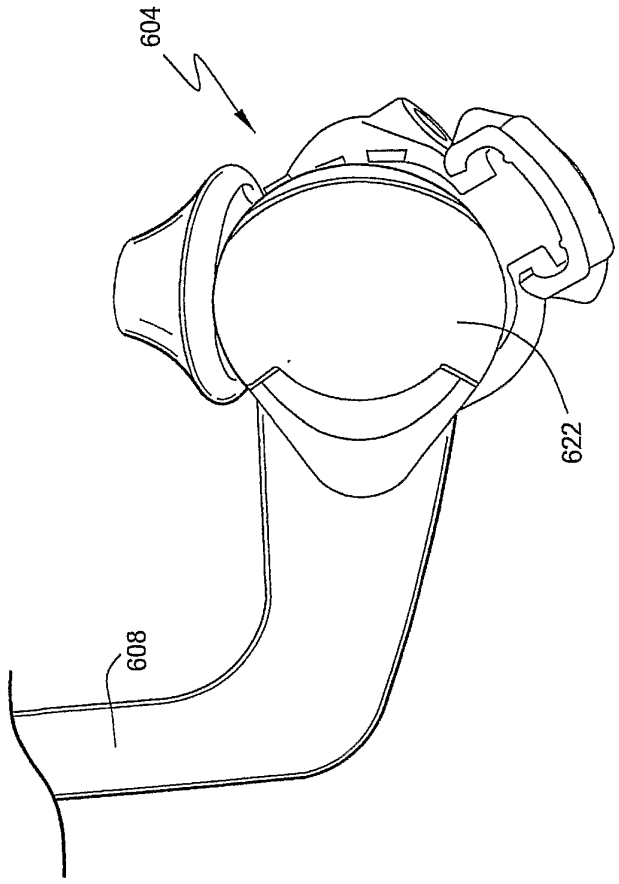
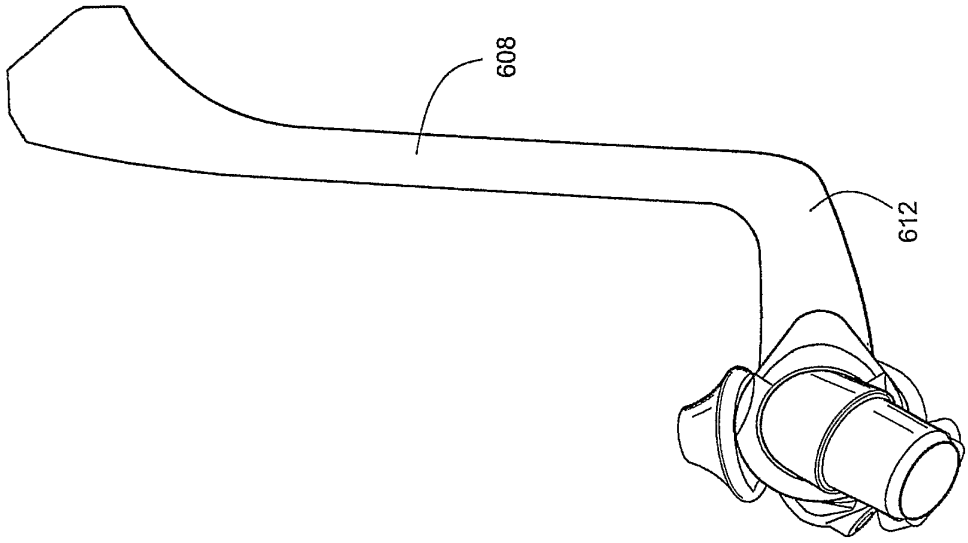


FIG. 121

FIG. 122



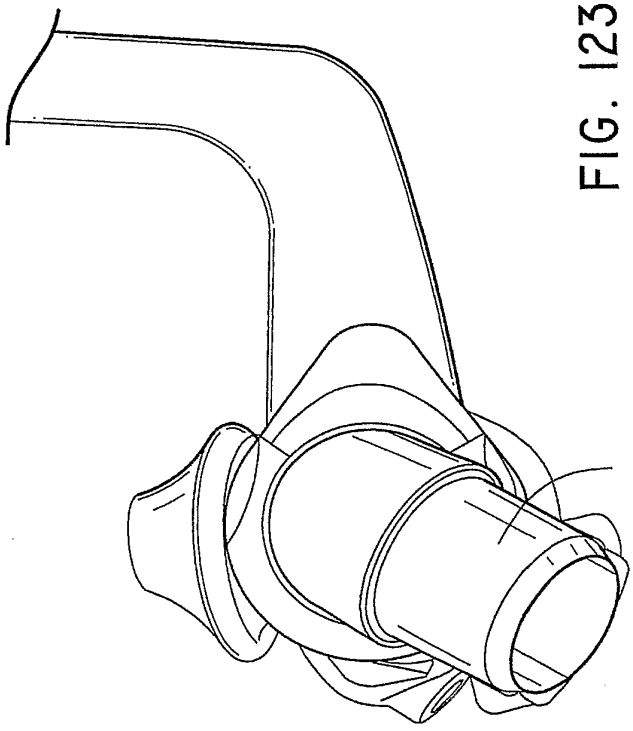


FIG. 123

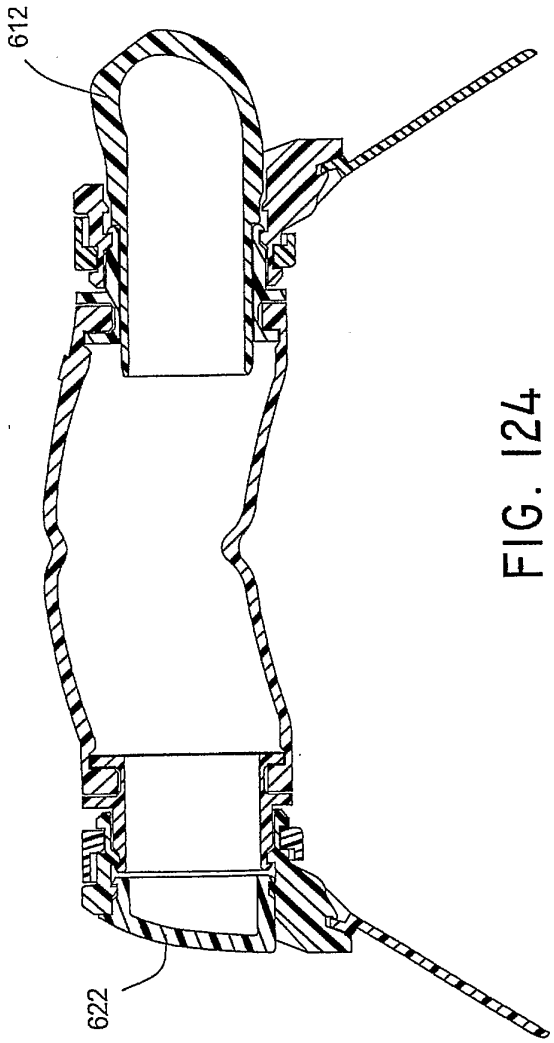


FIG. 124

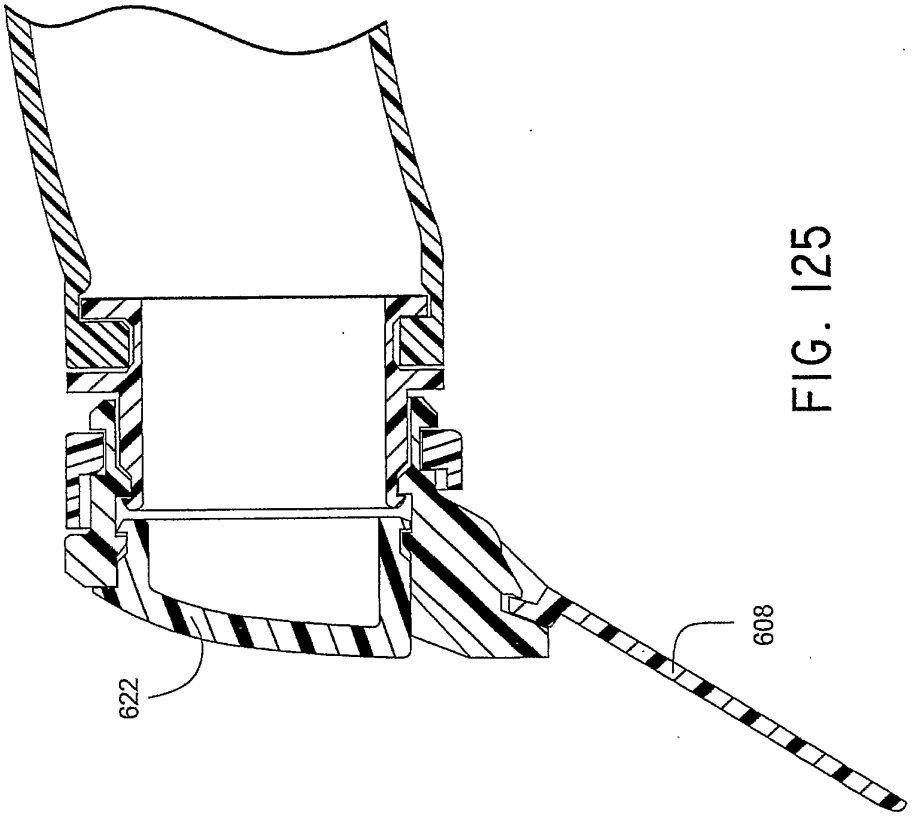


FIG. 125

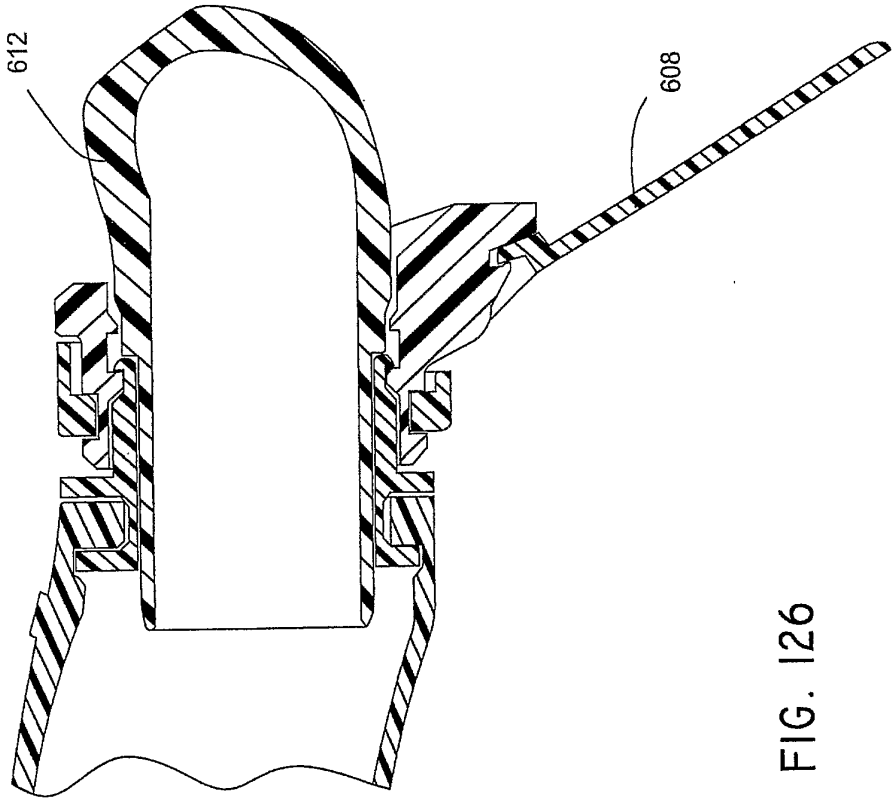


FIG. 126

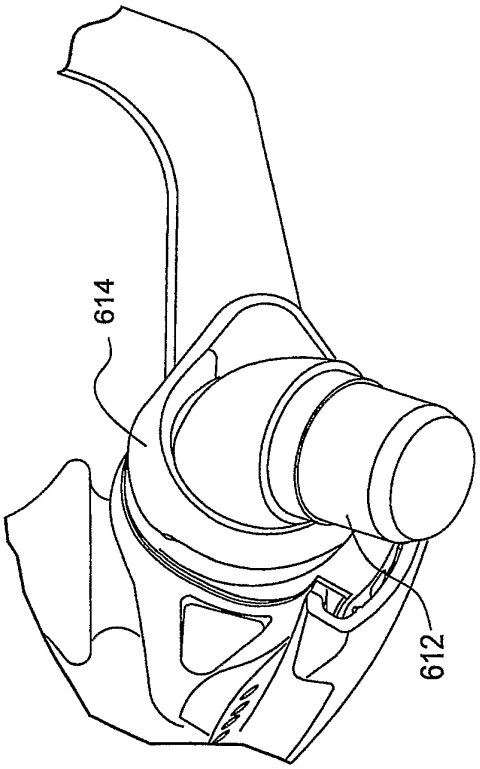


Fig.127

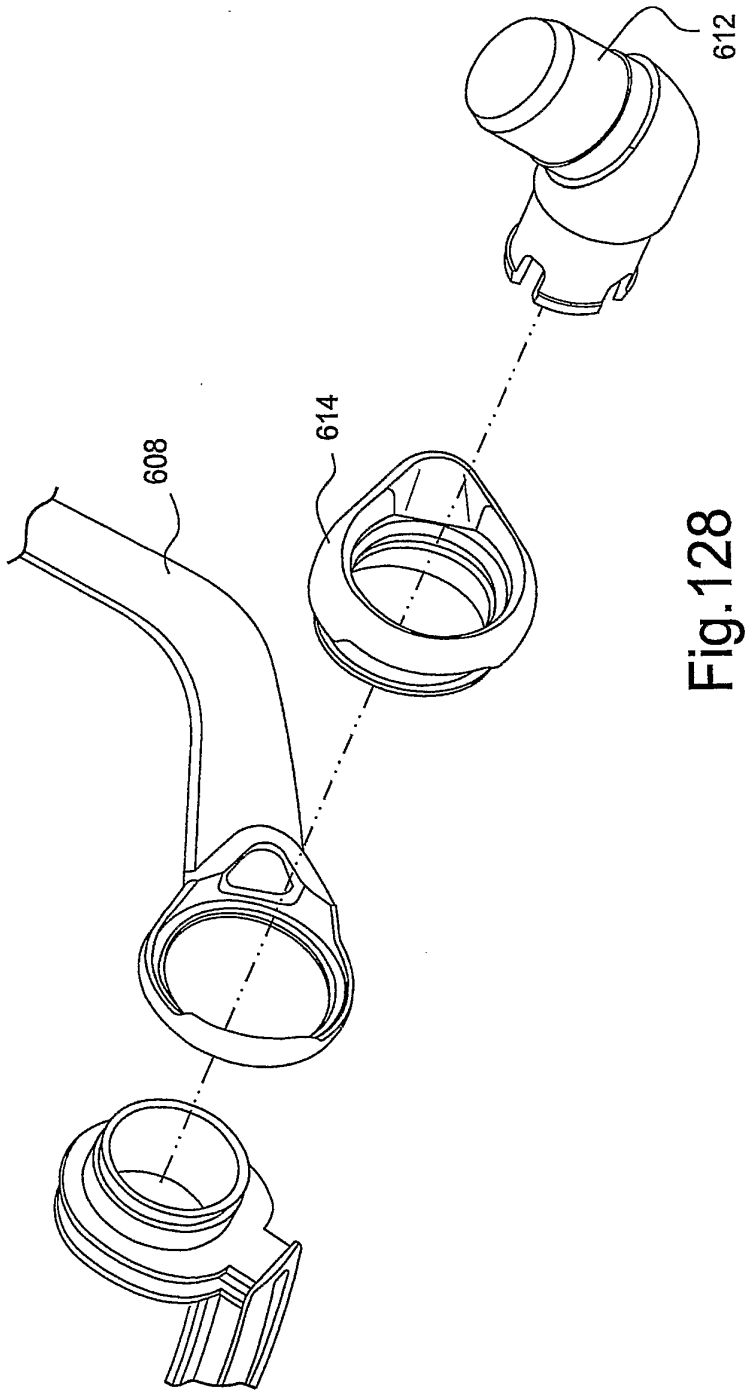


Fig.128

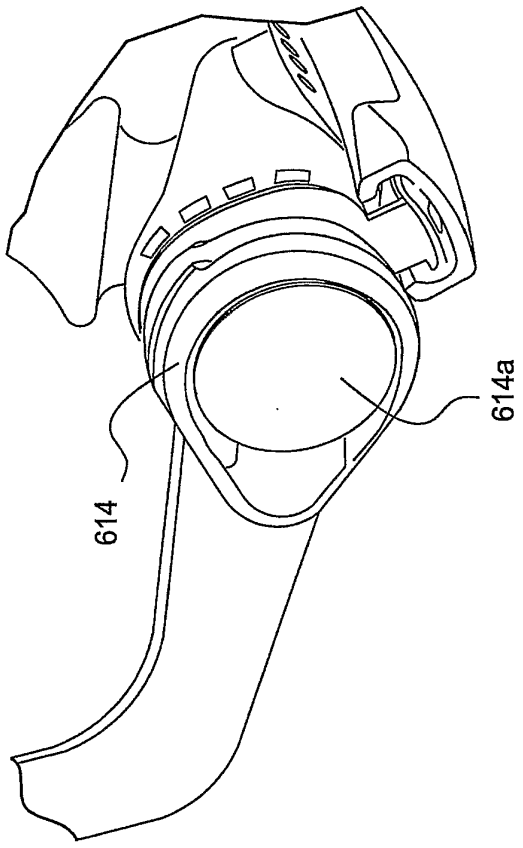


Fig.129

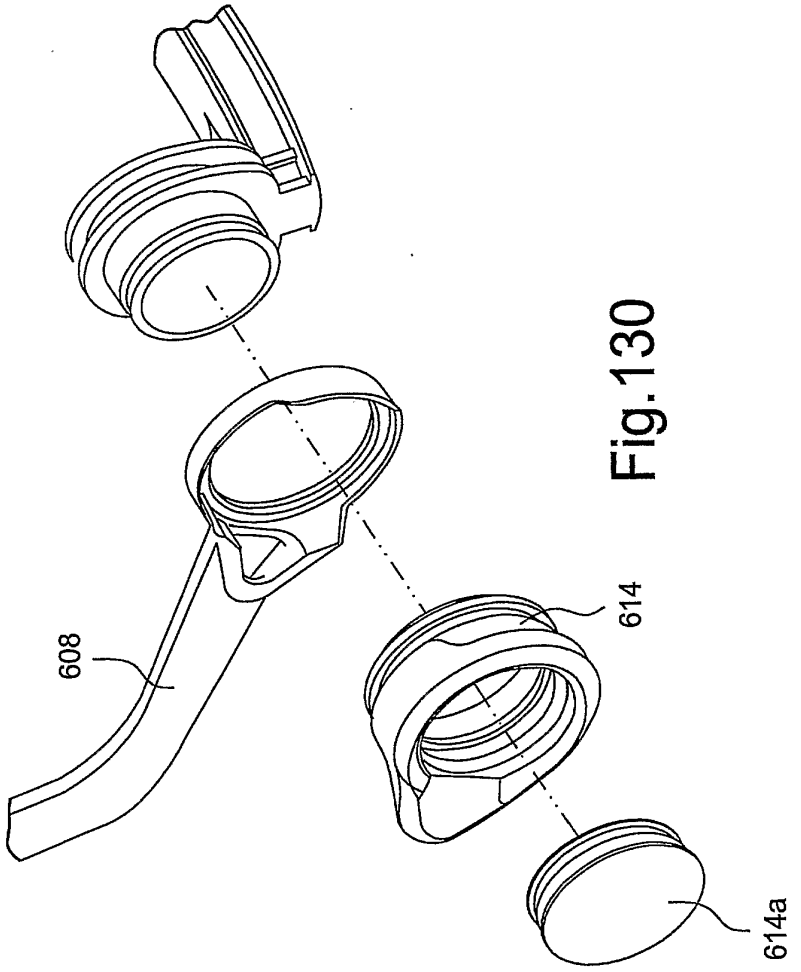
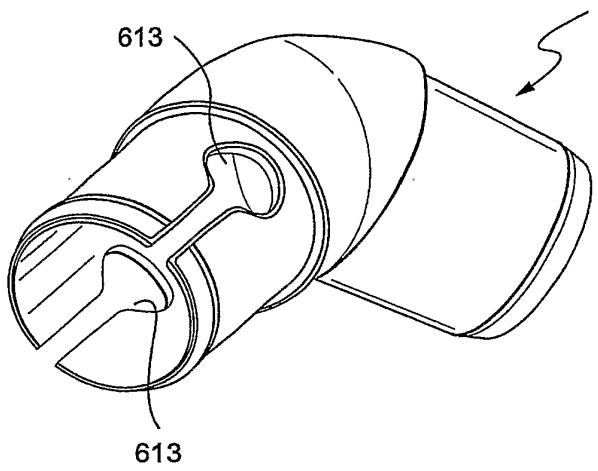


Fig.130

FIG. 131



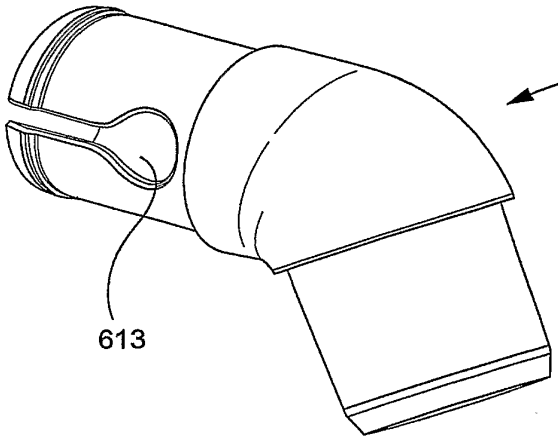


FIG. 132

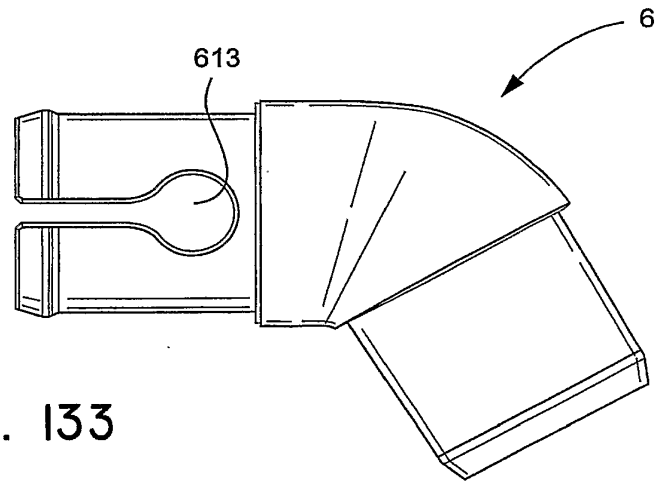


FIG. 133

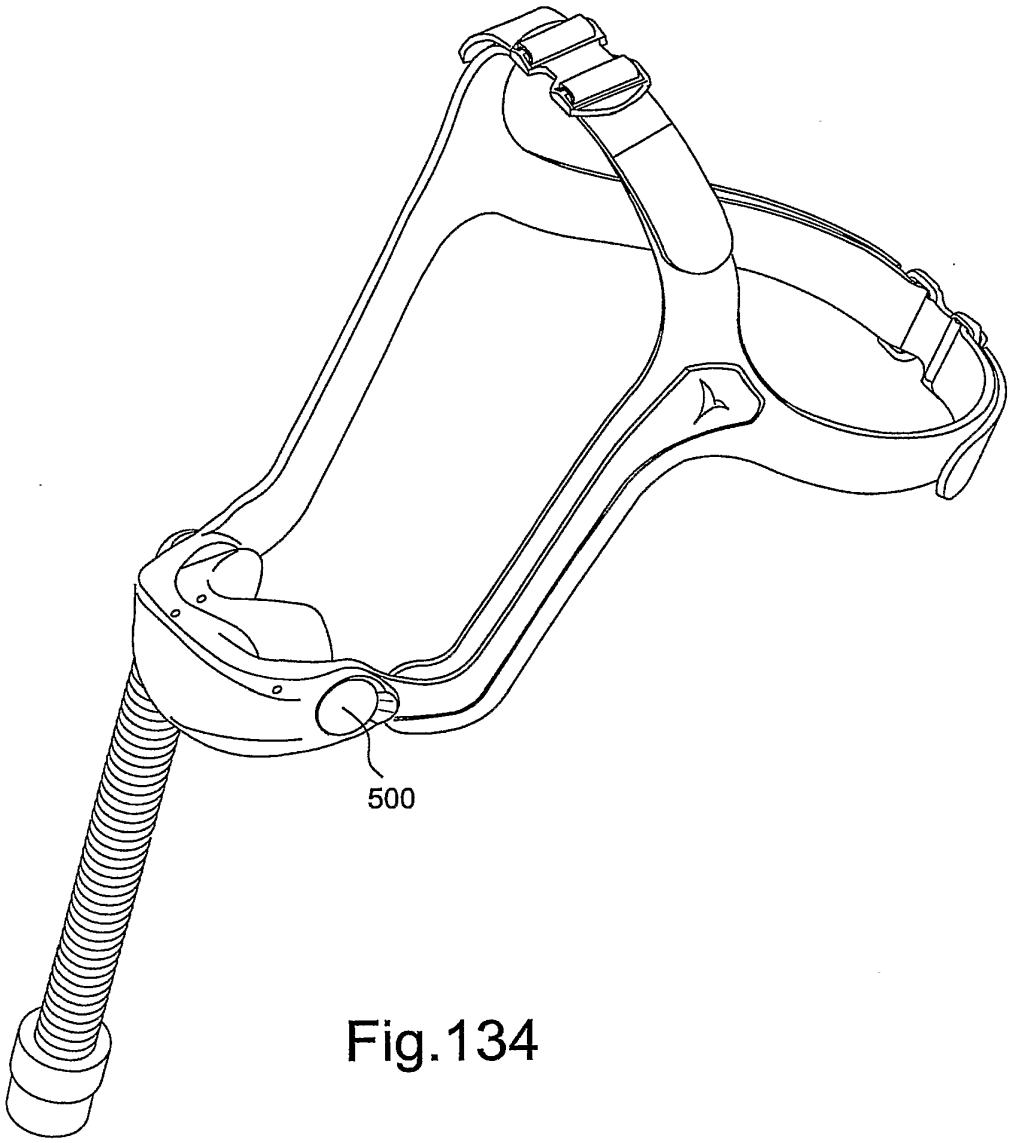


Fig.134

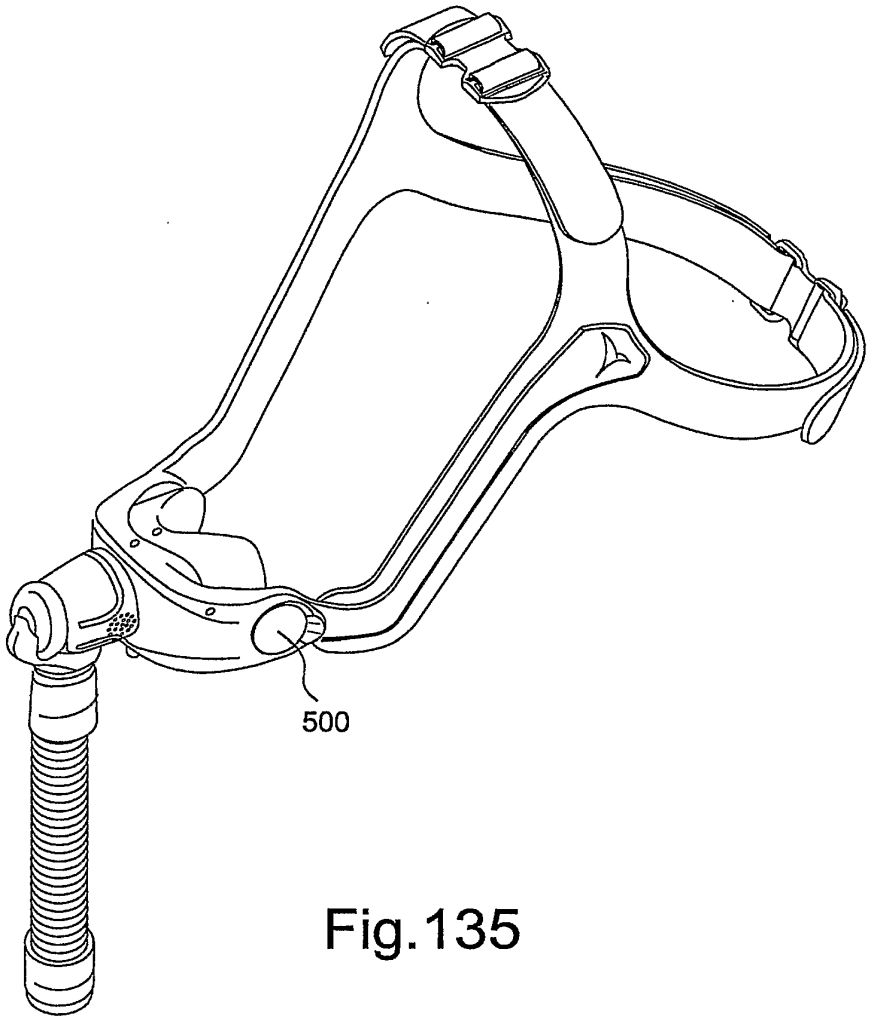


Fig.135

INTERNATIONAL SEARCH REPORT

International application No.
PCT/AU2004/000207

A. CLASSIFICATION OF SUBJECT MATTER

Int. Cl. [7]: A61M 16/06

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
SEE ELECTRONIC DATABASES CONSULTED

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)
DWPI JAPIO: A61M A62B B63C nasal nares nose nostril rhino naso vestibul gusset seal boot diaphragm internal inside within insert

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 4774946 A (ACKERMAN) 4 October 1988 Figures 1, 3, 7, column 3 line 9 to column 6 line 7	
A	WO 1984/001293 A1 (PHILLIPS et al) 12 April 1984 Figures 1, 3 and 7	
A	WO 1999/004842 A1 (RESPIRONICS GEORGIA, INC.) 4 February 1999 Figures 1 and 4	
A	US 6478026 B1 (WOOD) 12 November 2002 Figure 2, column 4 line 32 to column 6 line 11	

[X] Further documents are listed in the continuation of Box C [X] See patent family annex

* Special categories of cited documents:

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier application or patent but published on or after the international filing date

"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)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"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

"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

"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

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
28 April 2004	- 6 MAY 2004
Name and mailing address of the ISA/AU AUSTRALIAN PATENT OFFICE PO BOX 200, WODEN ACT 2606, AUSTRALIA E-mail address: pct@ipaustralia.gov.au Facsimile No. (02) 6285 3929	Authorized officer **MATTHEW FORWARD** Telephone No : (02) 6283 2606

Form PCT/ISA/210 (second sheet) (January 2004)

INTERNATIONAL SEARCH REPORT

International application No.
PCT/AU2004/000207

C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	WO 2001097892 A1 (AUSTRALIAN CENTRE FOR ADVANCED MEDICAL TECHNOLOGY LTD) 27 December 2001 Figures 1, 3 and 6	
A	US 2002/0162558 A1 (NOBLE) 7 November 2002 Figures 2 to 5b	
A	US 4782832 A (TRIMBLE) 8 November 1988 Figures	
A	US 5533506 A (WOOD) 9 July 1996 Entire document	
A	EP 0658356 A2 (LANDIS) 21 June 1995 Figures 1 and 2, column 7 line 37 to column 9 line 30	

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No.
PCT/AU2004/000207

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 Search Report		Patent Family Member					
US	4774946	NO	FAMILY				
WO	1984/001293	AU	21204/83	AU	21244/83	CA	1222178
		DK	269984	EP	120926	EP	120941
		GB	2142545	NL	8320328	SE	8402954
		US	4535767	WO	84/01295		
WO	1999/004842	AU	85962/98	EP	998319	US	6119694
US	6478026	CA	2364183	CA	2368825	CA	2416410
		EP	1317940	EP	1317941	US	6595214
		US	2002059935	US	2002092527	US	2003116163
		US	2004020493				
WO	2001097892	AU	65690/01	EP	1292350	US	2003172936
US	2002162558	US	6561193	US	6637434	US	2003172936
US	4782832	NO	FAMILY				
US	5533506	NO	FAMILY				
EP	0658356	EP	2110450	US	5269296	US	5477852
		US	5687715				

Due to data integration issues this family listing may not include 10 digit Australian applications filed since May 2001.

END OF ANNEX

Docket No.: FPHCR.000GEN **Customer No. 20,995**

REVOCATION & GENERAL POWER OF ATTORNEY
and
CHANGE IN CORRESPONDENCE ADDRESS

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

The undersigned are empowered representatives of the Assignee and hereby appoint the registrants of Knobbe, Martens, Olson & Bear, LLP, **Customer No. 20,995**, as attorneys and agents to represent the Assignee before the United States Patent and Trademark Office (USPTO) in connection with any and all patent applications assigned to the Assignee according to the USPTO assignment records or assignment documents supplied with an accompanying Statement Under 37 CFR § 3.73(b). This appointment is to be to the exclusion of the inventor(s) and his attorney(s) in accordance with the provisions of 37 CFR § 3.71.

Submission of this paper in connection with any matter of the below named assignee, together with a statement under 37 CFR 3.73(b), shall serve to revoke any previous powers of attorney in that matter.

Attached is a Statement Under 37 CFR § 3.73(b), signed by a registrant of Knobbe, Martens, Olson & Bear, LLP, setting forth a full chain of title for the subject application owned by the Assignee named below.

Please recognize or change the correspondence address for the application identified in the attached Statement to **Customer No. 20,995.**

By: _____ Date: 28 September 2010

Name: Michael Daniell Title: Chief Executive Officer / Director

By: _____ Date: 28 September 2010

Name: Lewis Gradon Title: Snr VP Products & Technology / Director

Assignee: Fisher & Paykel Healthcare Limited
15 Maurice Paykel Place
East Tamaki, Auckland 2013
Address: New Zealand

9666820:ah
091410

Electronic Acknowledgement Receipt

EFS ID:	8803140
Application Number:	12307993
International Application Number:	
Confirmation Number:	7084
Title of Invention:	BREATHING ASSISTANCE APPARATUS
First Named Inventor/Applicant Name:	Alastair Edwin McAuley
Customer Number:	00279
Filer:	Robert J. Roby/Valerie Jones
Filer Authorized By:	Robert J. Roby
Attorney Docket Number:	1171/48067/202-PCT-US
Receipt Date:	09-NOV-2010
Filing Date:	17-JUN-2009
Time Stamp:	18:57:18
Application Type:	U.S. National Stage under 35 USC 371

Payment information:

Submitted with Payment	no

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1		FPHCR-131NP_Statement373_POA.pdf	75648 f5347bb03486efc3f65f937662db355e5bc1f808	yes	2

	Multipart Description/PDF files in .zip description		
	Document Description	**Start**	**End**
	Assignee showing of ownership per 37 CFR 3.73(b).	1	1
	Power of Attorney	2	2
Warnings:			
Information:			
	Total Files Size (in bytes):	75648	

This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.

New Applications Under 35 U.S.C. 111
If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

National Stage of an International Application under 35 U.S.C. 371
If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office
If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

Docket No.: FPHCR.131NP **Customer No. 20995**

STATEMENT UNDER 37 CFR § 3.73(b)
ESTABLISHMENT OF ASSIGNEE

Applicant	:	McAuley et al.
App. No.	:	12/307,993
Filed	:	June 17, 2009
For	:	BREATHING ASSISTANCE APPARATUS
Examiner	:	Justine Romang Yu
Group Art Unit	:	3771

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

This document is being filed with a copy of a Power of Attorney signed by the Assignee. This Statement sets forth the chain of title of the above-identified application.

Fisher & Paykel Healthcare Limited, is the Assignee of the entire right, title, and interest of the above-referenced application by virtue of:

> The Assignment from the inventor(s) to the Assignee recorded in the United States Patent and Trademark Office on June 17, 2009, at Reel 022836, and Frame 0553.

The undersigned is an agent of Customer Number 20995 and is authorized to act on behalf of the Assignee. Please recognize or change the correspondence address for the above-identified application to **Customer No. 20995.**

Respectfully submitted,
KNOBBE, MARTENS, OLSON & BEAR, LLP

Dated: 11.9.2010

By: _____
Robert J. Roby
Registration No. 44,304
Attorney of Record
Customer No. 20995
(949) 760-0404

9965250:ah
110510

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NUMBER	FILING OR 371(C) DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO./TITLE
12/307,993	06/17/2009	Alastair Edwin McAuley	1171/48067/202-PCT-US

CONFIRMATION NO. 7084

279
CLARK HILL PLC
150 NORTH MICHIGAN AVENUE
SUITE 2700
CHICAGO, IL 60601

POWER OF ATTORNEY NOTICE

Date Mailed: 11/18/2010

NOTICE REGARDING CHANGE OF POWER OF ATTORNEY

This is in response to the Power of Attorney filed 11/09/2010.

- The Power of Attorney to you in this application has been revoked by the assignee who has intervened as provided by 37 CFR 3.71. Future correspondence will be mailed to the new address of record(37 CFR 1.33).

/fstephanos/

Office of Data Management, Application Assistance Unit (571) 272-4000, or (571) 272-4200, or 1-888-786-0101

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NUMBER	FILING OR 371(C) DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO./TITLE
12/307,993	06/17/2009	Alastair Edwin McAuley	FPHCR.000GEN

CONFIRMATION NO. 7084

20995
KNOBBE MARTENS OLSON & BEAR LLP
2040 MAIN STREET
FOURTEENTH FLOOR
IRVINE, CA 92614

POA ACCEPTANCE LETTER

OC000000044514917

Date Mailed: 11/18/2010

NOTICE OF ACCEPTANCE OF POWER OF ATTORNEY

This is in response to the Power of Attorney filed 11/09/2010.

The Power of Attorney in this application is accepted. Correspondence in this application will be mailed to the above address as provided by 37 CFR 1.33.

/fstephanos/

Office of Data Management, Application Assistance Unit (571) 272-4000, or (571) 272-4200, or 1-888-786-0101

PTO/SB/08 Equivalent

INFORMATION DISCLOSURE STATEMENT BY APPLICANT	Application No.	12/307993
	Filing Date	June 17, 2009
	First Named Inventor	Alastair Edwin McAuley
	Art Unit	3771
(Multiple sheets used when necessary)	Examiner	Yu, Justine Romang
SHEET 1 OF 1	Attorney Docket No.	FPHCR.131NP

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials	Cite No.	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T[1]
	1	English Translation of Chinese Examination Report; 5 pages	

12036919:ah
100411

Examiner Signature	Date Considered
***Examiner:** Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.	

T[1] - Place a check mark in this area when an English language Translation is attached.

Electronic Acknowledgement Receipt

EFS ID:	11115536
Application Number:	12307993
International Application Number:	
Confirmation Number:	7084
Title of Invention:	BREATHING ASSISTANCE APPARATUS
First Named Inventor/Applicant Name:	Alastair Edwin McAuley
Customer Number:	20995
Filer:	Robert J. Roby/ThuyQuyen Nguyen
Filer Authorized By:	Robert J. Roby
Attorney Docket Number:	FPHCR.131NP
Receipt Date:	05-OCT-2011
Filing Date:	17-JUN-2009
Time Stamp:	14:14:19
Application Type:	U.S. National Stage under 35 USC 371

Payment information:

Submitted with Payment	no

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1		FPHCR-131NP_IDS.pdf	60080 af6586fcd979e4eddd740edc64d439448f92b237	yes	2

	Multipart Description/PDF files in .zip description				
	Document Description		Start	End	
	Transmittal Letter		1	1	
	Information Disclosure Statement (IDS) Form (SB08)		2	2	
Warnings:					
Information:					
2	Non Patent Literature	Chinese_Examination_Report.pdf	348841 b9522380b3fcfdb215c2fd41ad4eab6ce9b40518	no	5
Warnings:					
Information:					
		Total Files Size (in bytes):	408921		

This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.

New Applications Under 35 U.S.C. 111
If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

National Stage of an International Application under 35 U.S.C. 371
If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office
If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

INFORMATION DISCLOSURE STATEMENT

Applicant	:	McAuley et al.
App. No	:	12/307993
Filed	:	June 17, 2009
For	:	BREATHING ASSISTANCE APPARATUS
Examiner	:	Yu, Justine Romang
Art Unit	:	3771
Conf No.	:	7084

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

Enclosed for filing in the above-identified application is a PTO/SB/08 Equivalent listing one (1) reference, of which one (1) are enclosed/submitted.

This Information Disclosure Statement is being filed before the receipt of a first Office Action on the merits, and presumably no fee is required. If a first Office Action on the merits was mailed before the mailing date of this Statement, the Commissioner is authorized to charge the fee set forth in 37 C.F.R. § 1.17(p) to Deposit Account No. 11-1410.

Respectfully submitted,
KNOBBE, MARTENS, OLSON & BEAR, LLP

Dated: 10.5.2011

By: _____
Robert J. Roby
Registration No. 44,304
Attorney of Record
Customer No. 20995
(949) 760-0404

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant	:	McAuley et al.
App. No.	:	12/307,993
Filed	:	June 17, 2009
For	:	BREATHING ASSISTANCE APPARATUS
Examiner	:	Catharine L. Anderson
Art Unit	:	3764
Conf No.	:	7084

SUPPLEMENTAL PRELIMINARY AMENDMENT

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

Further to the Preliminary Amendment submitted on Prior to examination on the merits, please enter the below preliminary amendment:

Amendments to the Claims are reflected in the listing of claims which begins on page 2 of this paper.

Remarks/Arguments begin on page 5 of this paper.

AMENDMENTS TO THE CLAIMS

The following listing of claims replaces all prior versions and listings of claims.

Claims 1-37 (Canceled).

38. (**New**) A patient interface comprising:

a mask body including two nasal pillows extending from it, which in use rest in a substantially sealed manner against the nares of a user;

a ring engaged with the mask body;

an elbow rotatably engaged with the ring,

a tube or conduit extending from the elbow; and

side straps that pass down the cheeks of the user to secure the mask body to a face of the user.

39. (**New**) A patient interface as claimed in claim 38, wherein the mask body includes a lip and the ring includes a channel receiving the lip of the mask body.

40. (**New**) A patient interface as claimed in claim 39, wherein the mask body comprises a molded elastomeric material.

41. (**New**) A patient interface as claimed in claim 38, wherein the elbow is able to swivel in the ring such that the tubing is available to be adjacent to either side strap.

42. (**New**) A patient interface as claimed in claim 38, wherein the ring comprises a hard plastic material.

43. (**New**) A patient interface as claimed in claim 42, wherein the elbow includes a vent.

44. (**New**) A patient interface as claimed in claim 43, wherein the vent comprises a plurality of holes in the wall of the elbow.

45. (**New**) A patient interface as claimed in claim 38 further comprising molded side arms extending away from the ring to connect with the side strap, the molded side arms connecting to the side straps that pass down the cheeks of the user.

46. (**New**) A patient interface as claimed in claim 38, wherein, in use, gases flow from the tube or conduit, through the elbow, through the ring, through the mask body and through the pillows.

47. (**New**) A patient interface comprising:

a mask body comprising a substantially flexible elastomeric material, the mask body comprising a first nasal pillow and a second nasal pillow, the first nasal pillow and the second nasal pillow being angled toward one another, the first nasal pillow comprising a first generally conical portion and a first generally cylindrical portion, the second nasal pillow comprising a second generally conical portion and a second generally cylindrical portion, the first nasal pillow comprising a first outlet opening and the second nasal pillow comprising a second outlet opening, the mask body also comprising a mask body inlet opening, the mask body inlet opening being spaced apart form the first outlet opening and the second outlet opening, the mask body inlet opening comprising a generally circular opening into the mask body;

a tube assembly configured to deliver airflow to the mask body, the tube assembly comprising a flexible conduit, the flexible conduit comprising a first end and a second end, the first end of the flexible conduit comprising a connector, the second end of the flexible conduit comprising an elbow, the elbow comprising a wall, the wall comprising a vent, the vent comprising a plurality of holes extending through the wall of the elbow, a connector end being secured to a portion of the elbow, the connector end being ring-like, the elbow and the mask body being connected at least in part by the ring-like connector end such that airflow from the tube assembly can be directed from the elbow through the generally circular opening of the mask body and into the mask body, the elbow and the mask body being capable of rotating relative to each other; and

a headgear assembly configured to secure the mask body to a face of a user, the headgear assembly comprising a first side strap and a second side strap, and a top strap being connected to the first side strap and the second side strap.

48. (**New**) A patient interface comprising:

a mask body comprising a molded elastomeric material, the mask body comprising two nasal pillows and a lip, the two nasal pillows, in use, resting in a substantially sealed manner against corresponding nares of a user;

a ring of a hard plastic material engaged with the lip of the mask body;

an elbow rotatably engaged with the ring, the elbow comprising a wall, a vent comprising a plurality of holes in the wall of the elbow;

a tube or conduit extending from the elbow; and

side straps adapted to pass down the cheeks of the user, the elbow being able to swivel in the ring such that the tubing can be positioned adjacent to either side strap or can fall freely.

49. (**New**) A patient interface as claimed in claim 48, wherein the ring comprises a channel receiving the lip of the mask body.

50. (**New**) A patient interface as claimed in claim 48, wherein the two nasal pillows are angled toward one another.

51. (**New**) A patient interface as claimed in claim 48 further comprising two molded side arms that extend away from the mask body to connect with the two side straps.

52. (**New**) A patient interface as claimed in claim 51, wherein the two side arms overlap a portion of the two side straps.

53. (**New**) A patient interface as claimed in claim 48, wherein, in use, gases flow from the tube or conduit, through the elbow, through the ring, through the mask body and through the pillows.

54. (**New**) A patient interface as claimed in claim 48, wherein each of the two nasal pillows comprises an inner profile and an outer profile, the inner profile defining an outlet of the nasal pillow, and the inner profile being offset inward relative to the outer profile.

55. (**New**) A patient interface as claimed in claim 48, wherein each of the two nasal pillows comprises an inner profile and an outer profile, the inner profile defining an outlet of the nasal pillow, and the inner profile being offset downward relative to the outer profile such that, in use, the inner profile is offset toward the user's lip relative to the outer profile.

REMARKS

Following this Supplemental Preliminary Amendment, Claims 38-55 are pending. Claims 1-31, originally pending, have now been cancelled. Claims 32-37, previously cancelled by the Preliminary Amendment filed on January 8, 2008, remain cancelled. Claims 38-55 have been added. No new matter is added. Applicants respectfully request that the preliminary amendments, including the amendment to the specification contained in the Preliminary Amendment filed on January 8, 2008, be entered prior to examination on the merits.

Co-Pending Applications of Assignee

Applicant wishes to draw the Examiner's attention to the following co-pending applications of the present application's assignee.

Docket No.	Serial No.	Title	Filed
FPHCR.131C1	12/353,640	BREATHING ASSISTANCE APPARATUS	01/14/09
FPHCR.131C2	12/633,135	BREATHING ASSISTANCE APPARATUS	12/08/09

Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

KNOBBE, MARTENS, OLSON & BEAR, LLP

Dated: November 29, 2011

By: _____
Robert J. Roby
Registration No. 44,304
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Electronic Acknowledgement Receipt

EFS ID:	11498442
Application Number:	12307993
International Application Number:	
Confirmation Number:	7084
Title of Invention:	BREATHING ASSISTANCE APPARATUS
First Named Inventor/Applicant Name:	Alastair Edwin McAuley
Customer Number:	20995
Filer:	Robert J. Roby/Heide Young
Filer Authorized By:	Robert J. Roby
Attorney Docket Number:	FPHCR.131NP
Receipt Date:	29-NOV-2011
Filing Date:	17-JUN-2009
Time Stamp:	17:40:25
Application Type:	U.S. National Stage under 35 USC 371

Payment information:

Submitted with Payment	no

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1		FPHCR-131NP_Supplemental_Preliminary_Amendment.pdf	201077 5c0f55babf0fe251fb6224109d402dea13c69337	yes	5

	Multipart Description/PDF files in .zip description		
	Document Description	**Start**	**End**
	Preliminary Amendment	1	1
	Claims	2	4
	Applicant Arguments/Remarks Made in an Amendment	5	5
Warnings:			
Information:			
	Total Files Size (in bytes):	201077	

This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.

New Applications Under 35 U.S.C. 111
If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

National Stage of an International Application under 35 U.S.C. 371
If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office
If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

PTO/SB/06 (07-06)
Approved for use through 1/31/2007. OMB 0651-0032
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
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PATENT APPLICATION FEE DETERMINATION RECORD Substitute for Form PTO-875	Application or Docket Number 12/307,993	Filing Date 06/17/2009	☐ To be Mailed

APPLICATION AS FILED – PART I

	(Column 1)	(Column 2)	SMALL ENTITY ☐		OR	OTHER THAN SMALL ENTITY	
FOR	NUMBER FILED	NUMBER EXTRA	RATE ($)	FEE ($)		RATE ($)	FEE ($)
☐ BASIC FEE (37 CFR 1.16(a), (b), or (c))	N/A	N/A	N/A			N/A	
☐ SEARCH FEE (37 CFR 1.16(k), (i), or (m))	N/A	N/A	N/A			N/A	
☐ EXAMINATION FEE (37 CFR 1.16(o), (p), or (q))	N/A	N/A	N/A			N/A	
TOTAL CLAIMS (37 CFR 1.16(i))	minus 20 =	*	X $ =		OR	X $ =	
INDEPENDENT CLAIMS (37 CFR 1.16(h))	minus 3 =	*	X $ =			X $ =	
☐ APPLICATION SIZE FEE (37 CFR 1.16(s))	If the specification and drawings exceed 100 sheets of paper, the application size fee due is $250 ($125 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).						
☐ MULTIPLE DEPENDENT CLAIM PRESENT (37 CFR 1.16(j))							
* If the difference in column 1 is less than zero, enter "0" in column 2.			TOTAL			TOTAL	

APPLICATION AS AMENDED – PART II

AMENDMENT	11/29/2011	(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA	SMALL ENTITY RATE ($)	ADDITIONAL FEE ($)	OR	OTHER THAN SMALL ENTITY RATE ($)	ADDITIONAL FEE ($)
	Total (37 CFR 1.16(i))	* 18	Minus	** 32	= 0	X $ =		OR	X $60=	0
	Independent (37 CFR 1.16(h))	* 3	Minus	***3	= 0	X $ =		OR	X $250=	0
	☐ Application Size Fee (37 CFR 1.16(s))									
	☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))							OR		
						TOTAL ADD'L FEE		OR	TOTAL ADD'L FEE	**0**

AMENDMENT		(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA	RATE ($)	ADDITIONAL FEE ($)	OR	RATE ($)	ADDITIONAL FEE ($)
	Total (37 CFR 1.16(i))	*	Minus	**	=	X $ =		OR	X $ =	
	Independent (37 CFR 1.16(h))	*	Minus	***	=	X $ =		OR	X $ =	
	☐ Application Size Fee (37 CFR 1.16(s))									
	☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))							OR		
						TOTAL ADD'L FEE		OR	TOTAL ADD'L FEE	

* If the entry in column 1 is less than the entry in column 2, write "0" in column 3.

** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, enter "20".

*** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 3, enter "3".

The "Highest Number Previously Paid For" (Total or Independent) is the highest number found in the appropriate box in column 1.

Legal Instrument Examiner:
/DENISE HOPKINS/

This collection of information is required by 37 CFR 1.16. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

PTO/SB/08 Equivalent

INFORMATION DISCLOSURE STATEMENT BY APPLICANT	Application No.	12/307993
	Filing Date	June 17, 2009
	First Named Inventor	Alastair Edwin McAuley
	Art Unit	3771
(Multiple sheets used when necessary)	Examiner	Steven O. Douglas
SHEET 1 OF 1	Attorney Docket No.	FPHCR.131NP

U.S. PATENT DOCUMENTS					
Examiner Initials	Cite No.	Document Number *Number - Kind Code (if known)* Example: 1,234,567 B1	Publication Date MM-DD-YYYY	Name of Patentee or Applicant	Pages, Columns, Lines Where Relevant Passages or Relevant Figures Appear
	1	6,581,594	06-24-2003	Drew et al.	
	2	2005/0076913	04-14-2005	Ho et al.	
	3	2007/0125385	06-07-2007	Ho et al.	

FOREIGN PATENT DOCUMENTS						
Examiner Initials	Cite No.	Foreign Patent Document *Country Code-Number-Kind Code* Example: JP 1234567 A1	Publication Date MM-DD-YYYY	Name of Patentee or Applicant	Pages, Columns, Lines Where Relevant Passages or Relevant Figures Appear	T[1]
	4	WO 2005/051468	06-09-2005	Resmed Limited		

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials	Cite No.	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T[1]
	5	Examination Report; Australian Application No. 2007273324; dated May 22, 2012; 3 pages	

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Examiner Signature	Date Considered
***Examiner:** Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.	

T[1] - Place a check mark in this area when an English language Translation is attached.

(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

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(71) Applicant *(for all designated States except US)*: **RESMED LIMITED** [AU/AU]; 97 Waterloo Road, North Ryde, New South Wales 2113 (AU).

(72) Inventors; and

(75) Inventors/Applicants *(for US only)*: **DARKIN, Donald** [GB/AU]; c/-ResMed Limited, 97 Waterloo Road, North Ryde, New South Wales 2113 (AU). **MCAULIFFE, Patrick, John** [AU/AU]; c/- ResMed Limited, 97 Waterloo Road, North Ryde, New South Wales 2113 (AU).

(74) Agents: **DAVIDSON, Geoffrey, Robert** et al.; Halford & Co., 1 Market Street, Sydney, New South Wales 2000 (AU).

(81) Designated States *(unless otherwise indicated, for every kind of national protection available)*: AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BW, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NA, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, YU, ZA, ZM, ZW.

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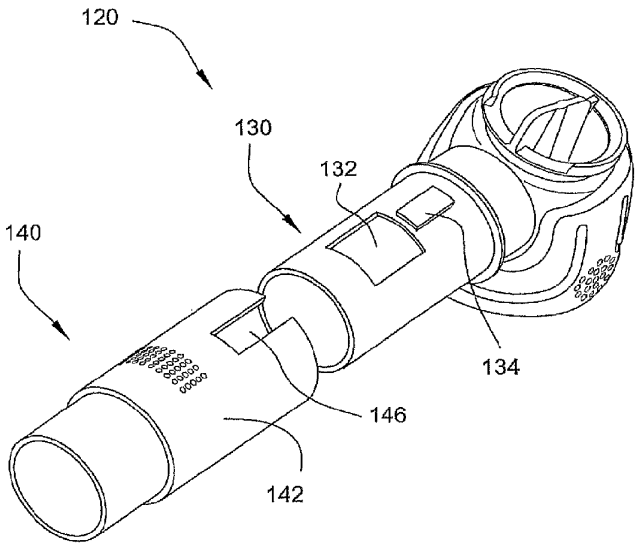
[Continued on next page]

(54) Title: VENT SYSTEM FOR CPAP PATIENT INTERFACE USED IN TREATMENT OF SLEEP DISORDERED BREATHING



(57) Abstract: A vent assembly for use with a mask assembly includes a first vent, a second vent and a selector to switch the flow of exhaled gas from a patient between the first and second vents.

WO 2005/051468 A1

Published:
— *with international search report*

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

VENT SYSTEM FOR CPAP PATIENT INTERFACE USED IN TREATMENT OF SLEEP DISORDERED BREATHING

CROSS REFERENCE TO PRIORITY APPLICATIONS

[0001] This application claims priority to U.S. Provisional Applications Nos. 60/524,728, filed November 25, 2003, 60/538,507, filed January 26, 2004 and 60/550,319, filed March 8, 2004, each incorporated by reference in its entirety.

FIELD OF THE INVENTION

[0002] The invention relates to a vent system for use with a Continuous Positive Airway Pressure (CPAP) patient interface, e.g. a mask, used in treatment of Sleep Disordered Breathing.

BACKGROUND

[0003] The use of nasal CPAP apparatus to treat "snoring sickness" was pioneered by Sullivan and taught in US Patent 4,944,310. Nasal CPAP apparatus typically comprises a blower, an air delivery conduit and a patient interface. The blower provides a supply of air or breathable gas at positive pressure. The conduit interconnects the blower and the patient interface. A variety of nasal masks, nose & mouth masks, full face masks, nasal prongs and nasal pillows are used to provide an interface with the patient.

[0004] A typical mask comprises:

(i) a rigid or semi-rigid portion, termed a shell or frame, which defines a nose-receiving cavity; and

(ii) a soft patient contacting portion, termed a cushion or membrane.

Cushions have been constructed from silicone, foam, gel and combinations of these materials.

[0005] Since a patient typically exhales into the same mask cavity wherefrom they inhale, the possibility of rebreathing of carbon dioxide (CO_2) exists. In conjunction with a sufficient continuous flow of fresh air or breathable gas, a vent can allow a controlled leak from the mask cavity and hence provide for the washout of CO_2. Unfortunately, the noise of air or breathable gas from the vent can disrupt anyone within earshot attempting to sleep. Hence there is an advantage in providing a low-noise vent.

[0006] One form of known vent is described in US Patents 6,561,190 (Kwok) and 6,561,191 (Kwok). These patents describe the use of grommet in a mask frame. The contents of these patents are hereby incorporated by cross-reference. A vent in accordance with embodiments of these inventions is found in the MIRAGE™ mask, manufactured by ResMed Limited.

[0007] Another known form of vent is described in International Patent Application PCT/AU00/00636 (Drew et al.) published as WO 00/78381. This patent application describes the use of a connector for a mask having a vent along a smooth continuing surface. The contents of this patent application are hereby incorporated by cross-reference. A vent in accordance with an embodiment of this invention is found in the ULTRA MIRAGE™ mask, manufactured by ResMed Limited.

[0008] Another known form of vent is described in US Patent 6,581,594 (Drew et al.). This patent describes the use of a vent which, in one form, comprises a thin air permeable membrane. The contents of this patent application are hereby incorporated by cross-reference.

[0009] Another known form of vent is described in International Patent Application PCT/AU01/01658 (Dantanarayana et al.) published as WO 02/051486. This patent application describes the use of a flow regulation vent. The contents of this patent application are hereby incorporated by cross-reference.

[0010] US Patent 6,557,555 (Hollis) describes a vent valve apparatus. The contents of this patent application are hereby incorporated by cross-reference.

[0011] Another known vent is the Respironics WHISPER swivel.

[0012] European Patent No. 0 697 225 discloses a vent formed from a porous sintered material.

[0013] A known vent, manufactured by Gottleib Weinmann Geräte Für 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.

[0014] 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.

[0015] Typically vents are designed with sufficient porosity to provide enough vent flow at a low pressure (e.g. 4 cmH_2O) to ensure adequate washout of CO_2.

[0016] Reducing the pore size of a vent can make the vent quieter, but can also increase the chances that the vent will clog.

[0017] Problems with prior art vents include that they can be too noisy, that they clog with dirt and moisture (particularly when used with humidifiers), that they are awkward or difficult to clean or assemble and that they have designs which are sensitive to very small changes in the manufacturing process which can lead to variation in the pressure flow relationship.

SUMMARY OF THE INVENTION

[0018] In accordance with a first aspect of the invention there is provided a vent for a CPAP patient interface.

[0019] In accordance with a second aspect of the invention there is provided a vent assembly comprising at least two alternative vents each having substantially the same pressure-flow characteristics.

[0020] In accordance with a third aspect of the invention there is provided a vent assembly comprising at least two alternative vents each having different pressure-flow characteristics.

[0021] In accordance with another aspect of the invention there is provided a vent assembly comprising at least two alternative vents and a mount adapted to support at least one vent in a venting position.

[0022] In accordance with another aspect of the invention there is provided a vent assembly comprising at least two alternative vents and a mount adapted to support at least one vent in a venting position and a locking mechanism adapted to retain said at least one vent in a venting position.

[0023] In accordance with still another aspect, there is provided a mask assembly for a patient comprising a frame, a cushion provided to the frame, and a vent assembly including a first vent, a second vent, and a selector to switch the flow of exhaled gas from the patient between the first and second vents.

BRIEF DESCRIPTION OF THE DRAWINGS

[0024] Fig. 1 shows a schematic diagram of a prior art blower, air delivery conduit and patient interface.

[0025] Fig. 2 shows a related art mask with swivel elbow.

[0026] Fig. 3 shows a cross-section of a related art patient interface in position on a patient's face with swivel elbow.

[0027] Fig. 4a-c show side views, a cross section and a detail of a swivel in accordance with a first embodiment of the invention.

[0028] Fig. 5a-c shows a swivel in accordance with a first embodiment of the invention in three positions.

[0029] Fig. 6 shows an exploded perspective view of a swivel elbow in accordance with a second embodiment of the invention.

[0030] Fig. 7 shows a swivel elbow assembly in accordance with a second embodiment of the invention with the vent in a "coarse" hole position.

[0031] Fig. 8 shows a swivel elbow assembly in accordance with a second embodiment of the invention with the vent in a "fine" hole position.

[0032] Fig. 9 shows a swivel elbow sleeve in accordance with a second embodiment of the invention.

[0033] Fig. 10 shows a swivel elbow assembly in accordance with another embodiment of the invention, suitable for use with a RESMED ULTRA MIRAGE mask.

[0034] Figs. 11a and 11b show a sliding vent assembly in accordance with an embodiment of the invention.

[0035] Fig. 12 shows a further view of the vent assembly of Fig. 11a.

[0036] Fig. 13 shows a drawing of the vent assembly of Fig. 11a.

[0037] Fig. 14 shows an alternative view of the vent assembly of Fig. 11a.

[0038] Fig. 15 shows a front view of a swivel elbow with vent assembly in accordance with a first embodiment of the invention.

[0039] Fig. 16 shows a side view of a swivel elbow with vent assembly in accordance with a first embodiment of the invention.

[0040] Fig. 17 shows a front view of an assembly including mask frame and swivel elbow with vent assembly in accordance with a first embodiment of the invention.

[0041] Fig. 18 shows a side view of the assembly of Fig. 17.

[0042] Fig. 19 shows a perspective view of the assembly of Fig. 17.

[0043] Fig. 20 shows an embodiment of the invention which incorporates visual, tactile and aural feedback of vent position.

[0044] Fig. 21 shows an embodiment of the invention which incorporates an electrical resistance sensor.

[0045] Fig. 22 shows an embodiment of the invention with a slidable vent cover exposing a set of larger holes.

[0046] Fig. 23 shows an embodiment of the invention with a slidable vent cover exposing a set of smaller holes.

[0047] Figs. 23a-23c illustrate still another embodiment of the present invention.

[0048] Fig. 24 shows an embodiment of the invention with a hinged vent cover.

[0049] Figs. 25a and 25b show an alternative embodiment of the invention incorporating a rotating vent cover.

[0050] Figs 25c-25e illustrates another alternative embodiment of the present invention.

[0051] Figs. 25f-25g illustrate yet another embodiment of the present invention.

[0052] Fig. 26 shows a cartridge-style embodiment of the invention in exploded view.

[0053] Figs. 27a and 27b show the cartridge-style embodiment of the invention in two different positions.

[0054] Figs. 28a and 28b illustrate yet another embodiment of the present invention.

DETAILED DESCRIPTION OF PREFERRED EMBODIMENTS

[0055] Fig. 1 shows a blower 10 connected to an air delivery conduit 20 and the air delivery conduit 20 connected to a patient interface 30. In the view shown in Fig. 1, the patient interface 30 is a nasal mask. The patient interface 30 includes a vent 40. The vent 40 includes one or more holes, e.g., six holes 50.

[0056] Fig. 2 shows an alternative nasal mask, the MIRAGE® ACTIVA™ nasal mask. This mask includes a swivel elbow 60. The swivel elbow is described in further detail in the Applicant's co-pending International Patent Application PCT/AU03/01162, the contents of which are hereby incorporated by cross-reference. The swivel elbow 60 includes a vent cover 70 having a number of holes 50 therethrough.

[0057] Fig. 3 shows a cross-section of a patient interface 30 in position on a face of a patient 80. A swivel elbow 60 is shown detached and in front of the patient interface 30.The cavity 90 into which the patient 80 can exhale nasally can accumulate carbon dioxide unless it is washed out through the vent 40 included in the elbow 60.

[0058] In a first embodiment of the invention, a vent assembly is provided with two alternative vents, vent a and vent b as shown in Fig. 4a-5c. Both vent a and vent b provide approximately the same total flow. Vent a provides relatively fewer large vent holes, whereas vent b provides a matrix of relatively smaller holes (e.g. below 0.5mm diameter, preferably approximately 0.1mm in diameter). Selection between vent a and vent b is made by rotating or sliding a cover so that either the small or large holes are lined up with an orifice on a mating surface.

[0059] As shown in Fig. 4a and 4b in exploded views, a vent assembly 90 in accordance with an embodiment of the invention comprises a generally cylindrical first portion 100 and a generally cylindrical sleeve portion 110. The first portion 100 includes an orifice or window 102. The sleeve portion 110 includes, in one embodiment, two alternative sets of holes corresponding to vents a and b respectively. Vent a uses three large holes. Vent b uses a series of smaller holes. In use the sleeve portion 110 rotatingly fits over an end of the first portion 100. In the embodiment of the invention shown in Fig. 4a, the sleeve is free to rotate through 180° degrees as shown by the arrows in Fig. 5a-5c, although in other embodiments the sleeve may rotate through fewer degrees. As shown in Fig. 4a-4b, both the first portion 100 and sleeve portion 110 are hollow which allows air to pass between the interior of the first portion 100 through window 102 and thence through either of vent holes a or b. Fig. 4c shows a detail of the vent with small holes.

[0060] In a second embodiment of the invention the vent assembly is formed as part of a swivel elbow 120, for example, the swivel elbow used on the MIRAGE® VISTA™ mask, manufactured by ResMed Limited, as shown in Fig. 6-9. The elbow 120 includes a shaft 130 with an orifice 132 therein. The shaft 130 includes an alignment tab 134. A sleeve 140 includes a pair of alternative vents 142, 144 and a pair of slots 146, 148, each one associated with one vent, each adapted to receive the alignment tab of the shaft. In use, the orifice 132 of the shaft 130 aligns with either vent 142 or vent 144. In order to change from one vent to another, the vent assembly is pulled apart, rotated 180°, and re-assembled. In this way, at least one of and only one of vents 142 or 144 is used at one time.

[0061] In a third embodiment of the invention the vent assembly includes a moving part. The moving part can be located in each of two positions by having a protrusion on one part match a depression on the matching part. Alternatively, the two positions can simply be defined by use of appropriate positioning structure, e.g., detents, ratchets, etc. When the vent assembly is partway between the two vent positions, the protrusion can act to

separate the matching parts so that the vented airflow is greater than in either of the two correct positions. This provides a fail-safe mechanism where an incorrect position results in high airflow (a safe condition) and also higher noise (warning the user of the mistake). Generally speaking, the assembly can be configured such that a warning, e.g., a noise, can be created when the vent parts are misaligned.

[0062] A typical vent comprises a number of vent holes. For example, three vent holes with a diameter of 2.7mm. The effective area of a vent hole is generally smaller than the actual cross-sectional area of the vent hole. Small holes have a relatively smaller effective area than large holes, e.g. about 10% smaller. The effective area of a vent is the sum of effective areas of its constituent vent holes. In one form the alternative vents have the same effective areas.

[0063] In another embodiment of the invention, alternative vent constructions are used instead of using holes. For example, vent a and vent b are laminar flow elements, such as used in the ULTRA MIRAGE® mask. In another form sintered materials are used to construct the vent. In another form, vents are constructed from foam polymers. Combinations of different vents may be used, for example, a vent with holes and a vent constructed from a sintered material. The assembly may comprise more than two vents, for example a vent with holes, a sintered vent and a laminar flow element-type vent.

[0064] In some cases, such as clinical studies, it is desirable to test the effectiveness of a particular treatment regime, or mask and compare it with a suitable control. For example, it might be desired to test the effectiveness of an algorithm for providing nasal CPAP therapy. In such a situation, it would be desirable to be able to discount the effect of wearing the mask per se. This could be achieved by using a "sham" mask, for example, a mask with a very large vent hole. An example of a sham mask is taught in published PCT patent application WO 02/066,105. A difficulty of using a dedicated "sham" mask is that the patient may be aware that they are using the sham mask, or that it may be necessary to disturb their sleep in order to don such a sham mask.

[0065] The vent assembly may include a sham vent as an alternative. Such a sham vent would have a very high permeability, e.g. a large hole. By use of the invention, it would be possible for a clinician to switch from a "treatment" vent to a "sham" vent, with minimal disturbance to a sleeping patient and thus obtain clearer results for a clinical study.

[0066] Whilst in a preferred form the different vents are alternatives, in one form more than one vent may be used at once, for example, 1/2 vent a and 1/2 vent b.

[0067] In a vent comprising vent holes, increasing or decreasing the number of holes in the vent allows the vent flow to be set to any desired level. In this way a vent assembly in accordance with the invention can be designed to have pressure flow characteristics that mimic prior art masks which use vents with holes.

[0068] A variety of materials may be used to construct the vent assembly, for example, polycarbonate (e.g. MAKROLON), or other polymers, stainless steel, sintered ceramic or PTFE, and foam polymers. It may be particularly advantageous to use hydrophobic materials such as PTFE for small pored vents to reduce clogging of pores.

[0069] In an alternative form, instead of being mounted on a swivel elbow, a vent assembly 200 in accordance with an embodiment of the invention is mounted on or formed as part of a patient interface frame 210. Figs. 11a-14 show a frame for a patient interface which comprises two generally cylindrical end portions 220 interconnected by a generally rectangular backbone 230. A clip 240 is slidably positioned on the backbone 230. The clip 240 includes at least two alternative vents 250, 260. One or more orifices or windows in the backbone 230, similar to orifice or window 102, provides for fluid communication to an interior of the patient interface. By sliding the clip 240 to alternatively align vent 250 or 260 with the orifice, exhaled air can be vented via vent 250 or 260. Fig. 11a shows the clip 240 in a first position in which the vent 260 is aligned with an orifice in the backbone, and one or both vents 250 are sealed. Fig. 11b shows the

clip 240 in a second position in which one or both vents 250 are aligned with respective orifices in the backbone, and the vent 260 is sealed.

[0070] Fig. 22 and 23 show an alternative embodiment of the invention in a nasal mask 300. This form of the invention includes a slidable vent cover 310 which in a first position 305 exposes a set of large vent holes 320 and in a second position 315 exposes a set of small vent holes 330. In one form the large and small vent holes are molded into a silicone grommet 325 which is removably insertable into a mask frame, in a similar manner to US Patents 6,561,190 and 6,561,191 (Kwok). When holes are exposed the passage of air between the interior of the mask and the exterior of the mask can occur therethrough.

[0071] Fig. 23a illustrates another embodiment of the present invention having a mask assembly 700 with a shell 702 and a cushion attached or otherwise provided to the shell 702. The shell 702 includes an aperture 706 by which pressurized breathable gas is provided to an interior chamber defined by the shell 702 and cushion. Alternatively, a swivel elbow may be provided to a frontal aperture of the shell 702, in which case the elbow would include a conduit that delivers breathable gas from a source to the frontal aperture.

[0072] The shell 702 includes at least one aperture 708, in this case formed in a rectangular shape to make it easily visible. The aperture 708 is structured to continuously vent CO_2 during administration of CPAP or NIPPV therapy, for example. A slidable vent plate 710 includes first, second and third aperture portions 712, 714, 716 that may be selectively aligned (via sliding along the direction of arrows A) with the aperture 708. As shown in Fig. 23a, the second aperture portion 714 is aligned with shell aperture 708, while Fig. 23b shows the plate 710 in a shifted position in which third aperture portion 716 is aligned with shell aperture 708. Therefore, the clinician or patient may change the venting characteristics of the mask.

[0073] As shown in Fig. 23c, a partial schematic cross-section of Fig. 23a, the vent plate 710 may be releasably held by the shell 702. For example, the shell 702 may include a pair of legs 702a each forming a groove 702b with which a leg portion 710a of the plate 710 may slidingly engage.

[0074] Fig. 24 shows an alternative form of the invention in a nasal mask 400. This form of the invention includes a hinged vent cover 410. In the form shown in Fig. 24, the vent cover is generally rectangular and one side is hinged. Similarly to the vent assembly shown in Fig. 22 and 23, the holes of Fig. 24 may be moulded into a removably insertable grommet 425. The vent cover 410 can alternatively block the set of small vent holes 430 and the set of large vent holes 420.

[0075] Fig. 25a and 25b show an embodiment of the invention 500 incorporating a rotating vent cover 510 in a first and second position respectively on a vent elbow. The vent cover 510 is generally disc shaped having a window 525 therethrough. By rotating the vent cover 510 through, for example 120° different sets of holes are exposed. In the view shown in Fig. 25a, a set of large holes 520 are exposed. In the view shown in Fig. 25b a set of small holes 530 are exposed. Each respective set of holes 520, 530 provides a conduit communicating with an interior of the mask. In an alternative form (not shown) the rotatable vent cover includes different sets of holes and there is a fixed position window to which the vent cover is attached. Rotating the vent cover presents a different set of vent holes to the window resulting in a different vent characteristic.

[0076] Figs. 25c-25e illustrate yet another embodiment of the present invention. As shown in the assembled view of Fig. 25c, a frame 800 includes a swivel elbow 802 that may rotate with respect to the frame 800. A rear end 803 of the swivel elbow is connected or provided to the frame 800, while the a lower end 805 is connected to a source of pressurized air or other breathable gas. A vent assembly 806 may be provided to a front portion of the elbow 802.

[0077] Fig. 25d shows the frame 800 and elbow 802 without the vent assembly 806. Front portion 807 of elbow 802 is similar to that shown in Fig. 7, in that it includes a vent opening 809 that continuously exhausts CO_2 to atmosphere. In the case of Fig. 7, exhausted air is initially directed to vent cover 70 (see Fig. 2) provided to cover the front portion of the elbow, and then the exhausted air is directed to atmosphere via one or more apertures 50.

[0078] As shown in Fig. 25d, at least a portion 810 is closed or blocked, so that air may not pass therethrough. Thus, exhausted air is directed solely through that portion of the elbow including vent opening 809. Once air is exhausted through opening 809, it is directed to vent assembly 806. In particular, the exhaust can be selectively directed to either first vent portion 812 or second vent portion 814, as shown in Fig. 25c.

[0079] First vent portion 812 may be similar to the vent cover in Fig. 2, in that it can be made of an elastomeric material that is stretched to fit over a lip 813 provided to the front portion 807 of elbow 802. The first vent portion 812 may include one or more apertures 816 to exhaust exhaled gas. The first vent portion 812, unlike the vent cover in Fig. 2, may rotate with respect to the elbow 802. Rotation allows the user or clinician to select whether exhausted gas is directed to the first or second vent portion 812, 814.

[0080] Fig. 25e shows vent assembly 806 in isolation. Vent assembly 806 an opening 818 adapted to be engaged with the rim 813 positioned on front portion of elbow 802. Vent assembly includes an interior wall member 820 which partially divides the second vent portion 814 from a chamber 822 in communication with first vent portion 812. The chamber 822 and the second vent portion 814 can be in communication with one another via interior aperture 824, depending on the relative position of the vent assembly 806 with respect to the elbow 802.

[0081] For example, if the vent assembly is rotated so that the interior wall member 820 is aligned with blocked portion 810 of elbow 802 (Fig. 25d) and the aperture 824 is aligned with aperture 809, then exhausted gas can be directed through second vent portion

814. In this position, a portion of the exhaust could also be vented through first vent portion 812. If the aperture 824 is aligned with blocked portion 810, then exhausted air would be directed solely to first vent portion 810. Preferably, the blocked portion 810 may include an elastic material that can easily form an air tight seal with respect to aperture 824.

[0082] The second vent portion 808 may be in the form of a cylinder that could be filled with foam 815, to reduce noise and/or the possibility of cross-infection. As an alternative to foam, a ceramic material or GORE-TEX™ could be used.

[0083] Figs. 25f and 25g show yet another vent assembly 830, which, e.g., is adapted for use with the frame and elbow shown in Fig. 25d. Vent assembly includes a first vent portion 832 (Fig. 25g) like first vent portion shown in Fig. 25c. Vent assembly 830 includes a second vent portion 834 which includes a plurality of apertures 836. Exhausted air is selectively directed to the first or second vent portion, depending on the relative rotational position of the vent assembly compared to the elbow, with interior wall member 838 being selectively aligned with either the aperture 809 or the blocked portion 810 of elbow 802 (Fig. 25d). In Fig. 25f, the second vent portion 834 can be seen through aperture 840. Fig. 25f also shows opening 842 adapted to be engaged with rim 813 (Fig. 25d). The vent assembly 830 is more compact than the vent assembly shown in Fig. 25e.

[0084] Fig. 26, 27a and 27b show an alternative form of the invention including a replaceable vent cartridge. In this form of the invention the vent assembly comprises a shaft 600, a rotatable sleeve 620 including a window 625 and a replaceable cartridge 630 with holes therethrough. The vent assembly is shown in exploded view in Fig. 26. When assembled, the cartridge 630 is slid into position over the shaft 600 and under the sleeve 620. In the form shown in Fig. 27a-27b, in use the cartridge 630 is designed to be not rotatable about a longitudinal axis of the shaft 600. In contrast, the sleeve 620 is designed to be so rotatable exposing a different set of holes in the cartridge 630 as shown in Fig. 27a and 27b. In use the holes of the cartridge 630 provide for fluid communication from

the interior of the shaft 600 to atmosphere. Because small vent holes can become clogged with use, the sleeve 620 can be rotated after a suitable period (e.g. overnight). One cartridge might thus provide each night a clean set of vent holes for a week without requiring cleaning. At the end of the week, the cartridge may be disposed of a replaced with a clean one.

[0085] Advantages of the invention include:

When in the quiet position (fine holes) the mask will be extremely quiet, and with no discernable air jets. This makes the mask far less disturbing to both the wearer and any bed partner.

[0086] When in the normal (large holes) position, the mask will be suitable for use with a humidifier which might clog smaller holes. When the humidifier is not needed, the vent assembly can be switched easily to the quiet, small hole vent.

[0087] The use of a moveable part means that the patient does not need to keep spare parts and is precluded from losing components or not being able to fit them.

[0088] Use of the invention enables masks to be compatible with a range of different flow generators or blowers. For example, a first flow generator or blower may be pre-programmed to operate assuming a first vent characteristic and a second blower, a second vent characteristic. Since the same mask can mimic different vent characteristics, the same mask can be used on both blowers once set to the appropriate vent.

[0089] Another advantage of the invention is to provide different vents for different pressure ranges. For example, at low pressures, it may be appropriate to have a vent with large holes in order to provide sufficient vent flow. The same vent at higher pressures would have unnecessarily high vent flow which leads to increased noise. Hence in accordance with an embodiment of the invention, when a patient is using a generally low pressure treatment, they can utilize a first vent, but when treatment pressures are higher they can use a second vent.

[0090] Another advantage of the invention is that it provides a quick and simple system of replacing disposable vents. For example, certain styles of vents may clog easily and be designed for a single night's use. In accordance with an embodiment of the invention a vent assembly can comprise a set of "single use" vents. After a first night's use, the patient can switch to the second vent. After a second night's use, the patient can switch to a third vent, and so on.

[0091] In another form of the invention, sensors and/or indicators are included in the vent assembly as shown in Fig. 20 & 21. The vent assembly 300 includes a shaft 302 and a sleeve 304. The shaft 302 includes an orifice 306 which allows air to pass through. By rotating the sleeve 304 alternative vents 308 and 310 are aligned over the orifice 306. The sensor detects which of the vents is being used and conveys the information to a flow generator controller. In one form the sensor has a different electrical resistance, depending on the vent being used, as shown in Fig. 21 and discussed further below. Sensor information may be conducted to the flow generator controller via wires along the air delivery conduit, or wirelessly, for example via a BLUETOOTH™ compatible system. The flow generator controller receives the sensor information and adjusts the parameters for the algorithms controlling therapy. Alternatively or additionally the vent assembly includes an indicator of vent position which may be visual, aural, tactile or some combination. As shown in Fig. 20, the vent assembly 300 includes an alignment arrow 312 moulded on the shaft 302. Each vent 308, 310 has an adjacent indicator (e.g. an arrow, dot or some other shape) 309, 311 molded onto the sleeve 304. The indicators may present a characteristic feel depending on the vent position so that they can be recognized in the dark. Additionally or alternatively, the vent assembly may exhibit a characteristic "click" as its vent is changed as shown in Fig. 20. The vent assembly may display a tag of different color depending on the vent position.

[0092] Fig. 21 shows schematic of a slidable cover 350 forming part of the vent assembly similar to Fig. 11-14. When the appropriate vent 352or 354 is aligned over an orifice (not

shown), a corresponding resistor 353 or 355 electrically connects to a connector 356 which is in electrical communication with a flow generator controller 358. Thus the flow generator controller 358 can detect which vent is being used and adjust pressure, flow or some other parameter of the blower as necessary.

[0093] This ability to communicate the selected vent to the flow generator allows for the flow generator to provide an appropriate response. A response may be to make an adjustment to its control algorithm taking into account the characteristic of the recognized selected vent. In addition or alternatively the flow generator may not operate in treatment mode or only operate within a predetermined pressure range when the user attempts to commence treatment having selected the less than optimum vent or the characteristics of the selected vent is not recognized by the flow generator.

[0094] In addition or alternatively the flow generator may prompt the selection of the optimum vent for a given control algorithm or air circuit configuration. Having detected the selection of a vent the flow generator may present a messages to the user. The message may be by way of an auditory or visual alarm. Through use of the flow generator status display (typically an alpha-numeric LCD panel) the flow generator may present a statement as to the detected vent condition and either confirm its appropriateness or suggest corrective action.

[0095] As the invention allows for a selection to be made between vents the flow generator may communicate to the user that a selected vent is satisfactory or unsatisfactory depending on the treatment pressure range it is set to deliver. For a higher pressure range the flow generator may prompt the use of a small hole vent while suggesting a larger hole vent where it is to operate in the lower pressure range.

[0096] If the flow generator can detect a deterioration of vent performance over time (for example due to the vent becoming blocked during one treatment session or over a number of sessions) then a prompt may be given for the selection of an alternative vent.

[0097] Such a system is of use where available air circuit configurations may include a humidifier. If the flow generator detects that a small hole (e.g. mesh vent) is selected while the air circuit is set up to operate with a humidifier the flow generator may send a message to the user in order to prompt the selection of a more suitable vent.

[0098] Flow and noise levels may thus be adjusted in accordance with the above embodiments. For example, by switching from a vent with large holes to a vent with small holes and/or foam, the flow and/or noise level can be reduced about 5-50%, preferably about 15-35%, and most preferably about 20-30%. In the embodiment of Figures 11a-14, the flow for large holes may be in the range of about 45-55 l/min, while the flow for the small holes may be about 55-65 l/min. In other embodiments, the difference of flow between the smaller and larger holes may be more or less pronounced, depending on patient requirements and mask configuration.

[0099] Although the invention has been described with reference to particular embodiments, it is to be understood that these embodiments are merely illustrative of the application of the principles of the invention. Numerous modifications may be made therein and other arrangements may be devised without departing from the spirit and scope of the invention.

[00100] For example, in the embodiment shown in Figs. 28a and 28b, the mask, e.g., mask 30 in Fig. 1, may be provided with two or more elastic vent inserts each having different flow characteristics. In Fig. 28a, the vent 31 has a plurality of relatively larger holes 33, while the vent 35 in Fig. 28b may have a larger number of relatively smaller holes 37. The clinician/patient may change the vent to best suit the desired noise and/or flow characteristics.

WHAT IS CLAIMED IS:

1. A mask assembly for a patient comprising:

a frame;

a cushion provided to the frame; and

a vent assembly including a first vent, a second vent, and a selector to switch the flow of exhaled gas from the patient between the first and second vents.

2. The mask assembly of claim 1, wherein the first and second vents include at least one characteristic relating to noise and/or flow which are different from one another.

3. The mask assembly according to any one of claims 1-2, wherein the frame comprises a shell and the vent assembly is provided on the shell.

4. The mask assembly according to any one of claims 1-3, wherein the cushion includes nozzle elements and the selector includes a clip that is slidable with respect to the frame to select between the first and second vents.

5. The mask assembly according to any one of claims 1-4, wherein the selector is rotatable.

6. The mask assembly according to any one of claims 1-5, wherein the selector is pivotable.

7. The mask assembly according to any one of claims 1-6, wherein the selector is slidable.

8. The mask assembly according to any one of claims 1, 2 or 4-7, wherein the frame includes an elbow and the selector is provided on the elbow.

9. The mask assembly of claim 8, wherein the selector is provided on a depending arm of the elbow.

10. The mask assembly according to any one of claims 1-9, wherein one of the first and second vents is provided with a material configured to reduce at least one of noise level and risk of cross-infection.

11. The mask assembly of claim 10, wherein the material is selected from the group consisting of foam, GORE-TEX™ and ceramic.

12. The mask assembly according to any one of claims 1-11, wherein the selector is adjustable between first and second positions corresponding to the first and second vents, respectively, and the selector includes positioning structure to define the first and second positions.

13. The mask assembly of claim 12, wherein the positioning structure comprises detents.

14. The mask assembly according to any one of claims 12-13, wherein the vent assembly is configured to vent exhaled gas even if the vent assembly is not in the first or second positions.

15. The mask assembly according to any one of claims 12-14, wherein an alarm is sounded if the vent assembly is not in the first or second positions.

16. The mask assembly of claim 15, wherein the alarm is defined by a higher noise level produced by the vent assembly.

17. A vent assembly including a first vent, a second vent, and a selector to switch the flow of exhaled gas from a patient between the first and second vents.

18. The vent assembly of claim 17, wherein the first and second vents include at least one characteristic relating to noise and/or flow which are different from one another.

19. The vent assembly according to any one of claims 1-2, wherein the selector is rotatable, pivotable and/or slidable.

20 The vent assembly according to any one of claims 17-19, wherein one of the first and second vents is provided with a material configured to reduce at least one of noise level and risk of cross-infection.

21. The vent assembly of claim 20, wherein the material is selected from the group consisting of foam, GORE-TEX™ and ceramic.

22. The vent assembly according to any one of claims 17-21, wherein the selector is adjustable between first and second positions corresponding to the first and second vents, respectively, and the selector includes positioning structure to define the first and second positions.

23. The vent assembly of claim 22, wherein the positioning structure comprises detents.

24. The vent assembly according to any one of claims 22-23, wherein the vent assembly is configured to vent exhaled gas even if the vent assembly is not in the first or second positions.

25. The vent assembly according to any one of claims 22-24, wherein an alarm is sounded if the vent assembly is not in the first or second positions.

26. The mask assembly of claim 25, wherein the alarm is defined by a higher noise level produced by the vent assembly.

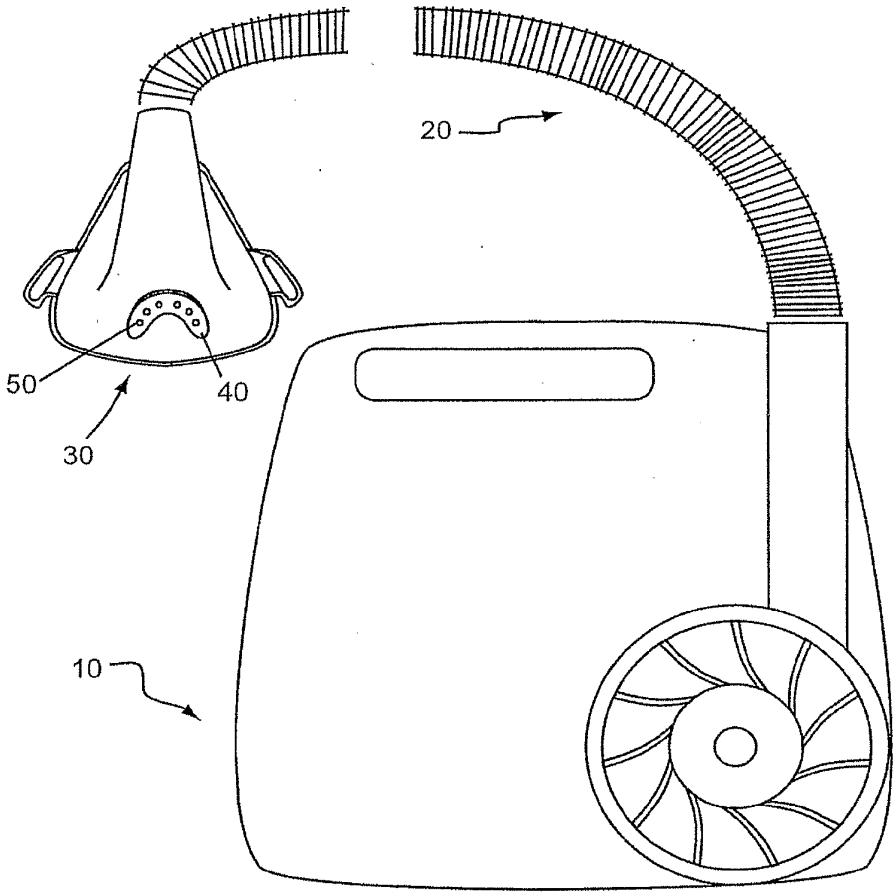


Fig. 1

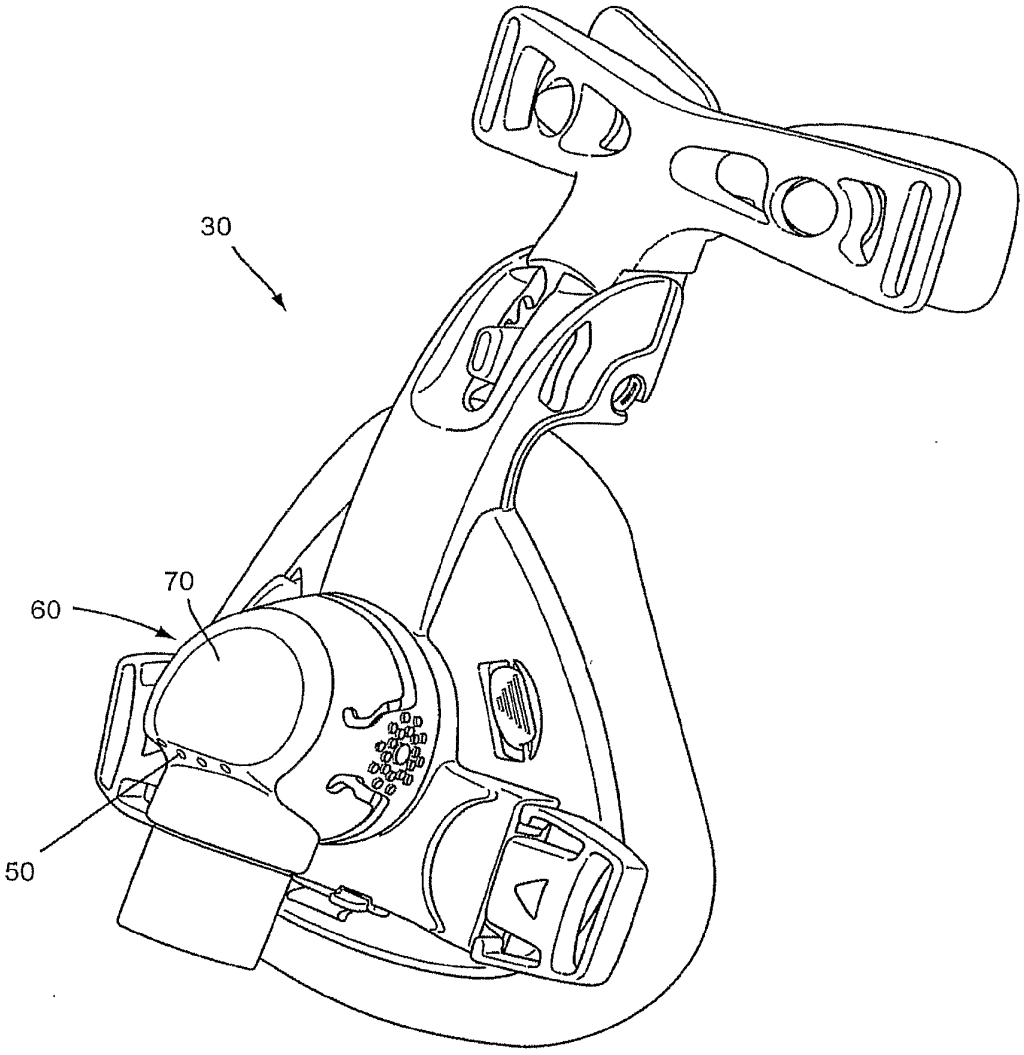


Fig. 2

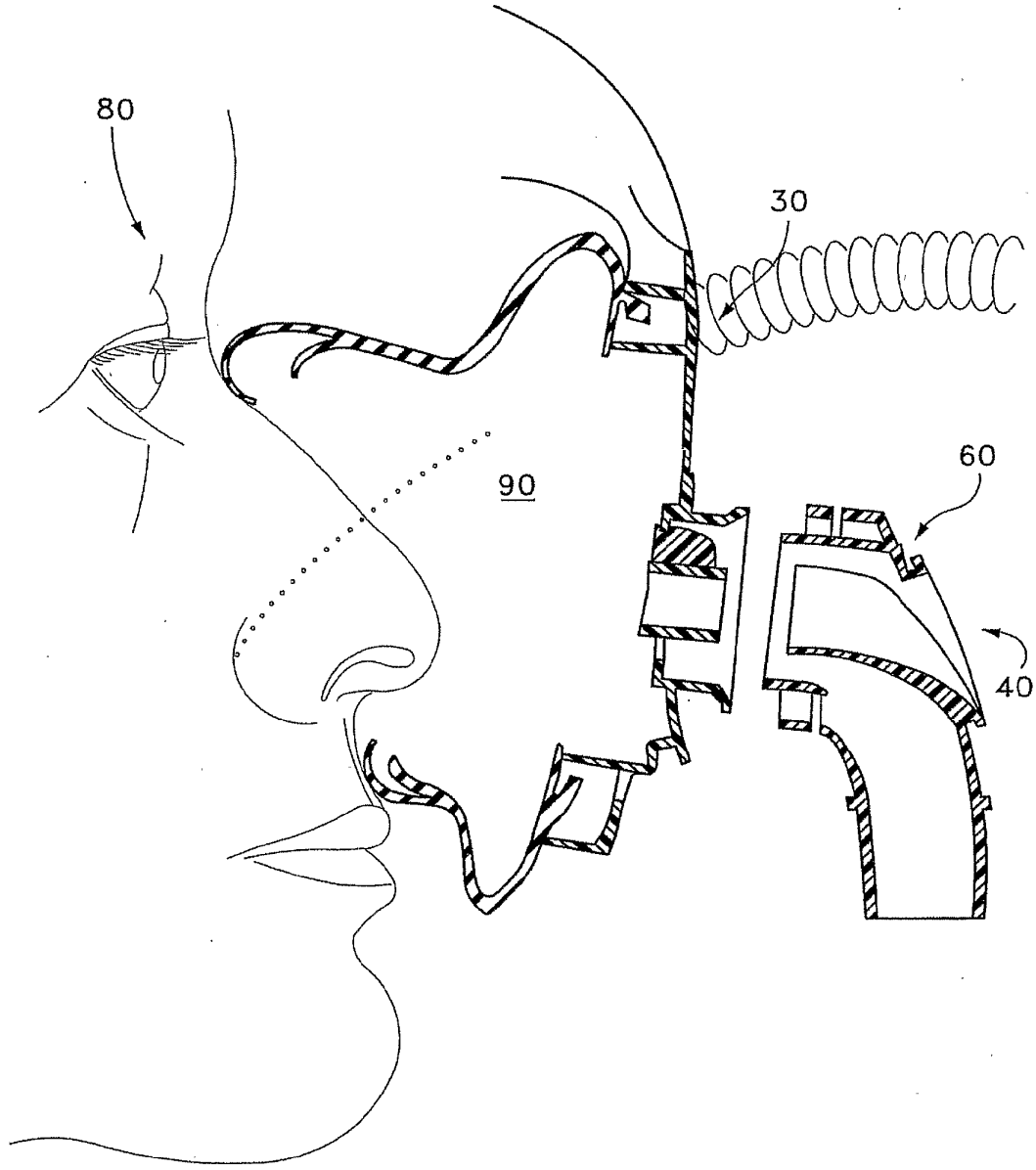


Fig. 3

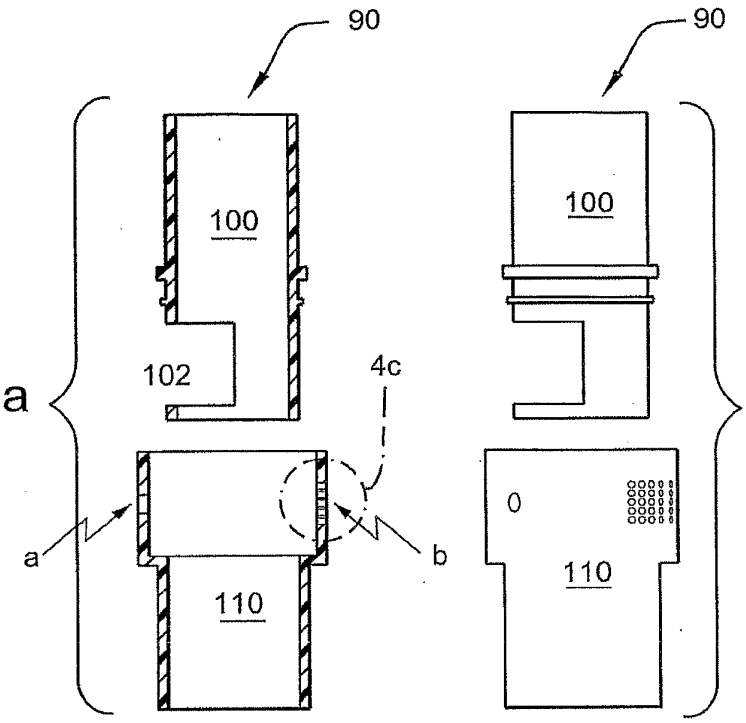


Fig. 4a

Fig. 4b

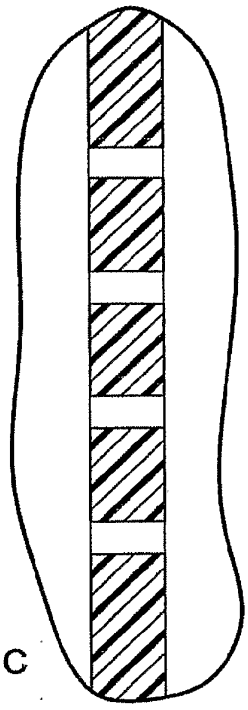


Fig. 4c

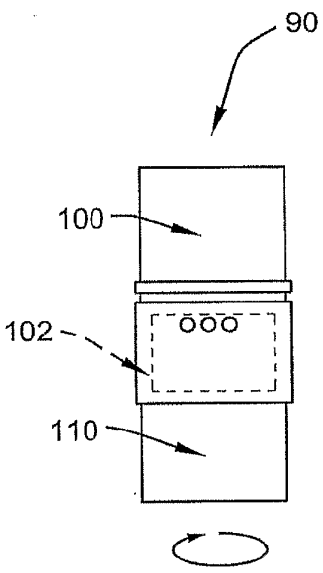


Fig. 5a

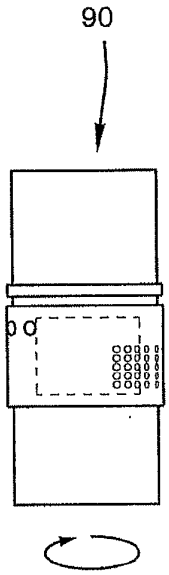


Fig. 5b

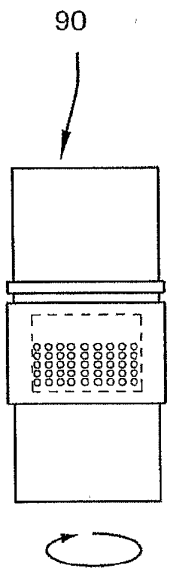


Fig. 5c

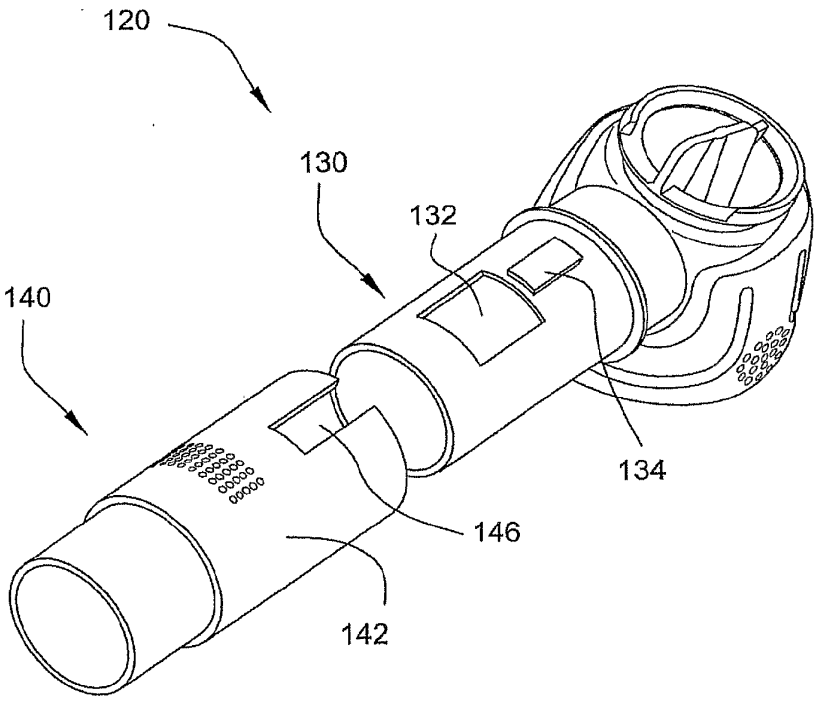


Fig. 6

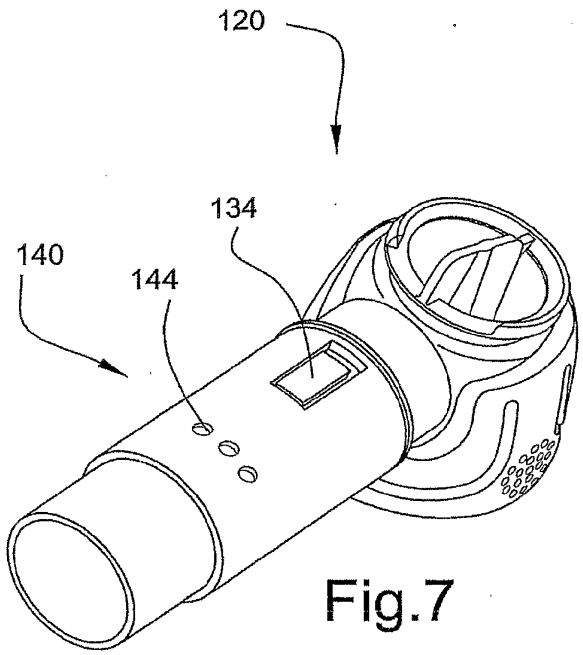


Fig.7

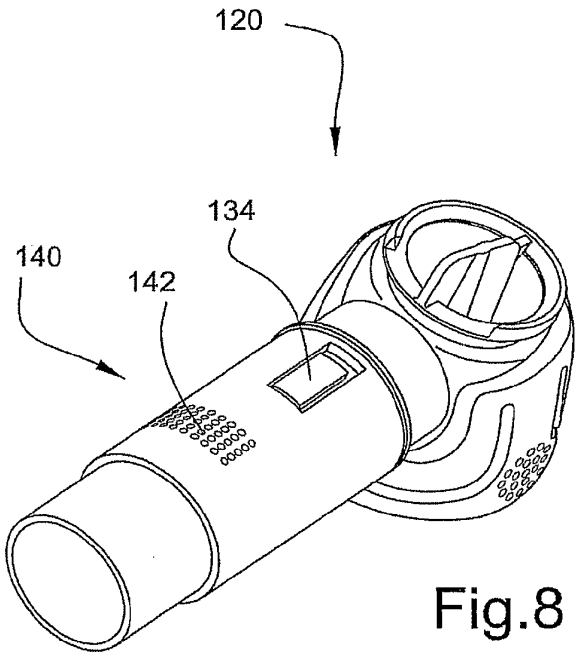


Fig.8

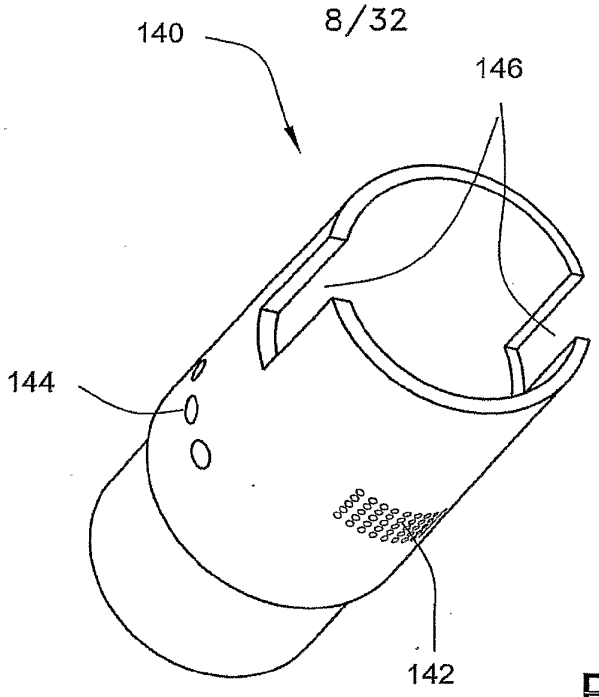


Fig.9

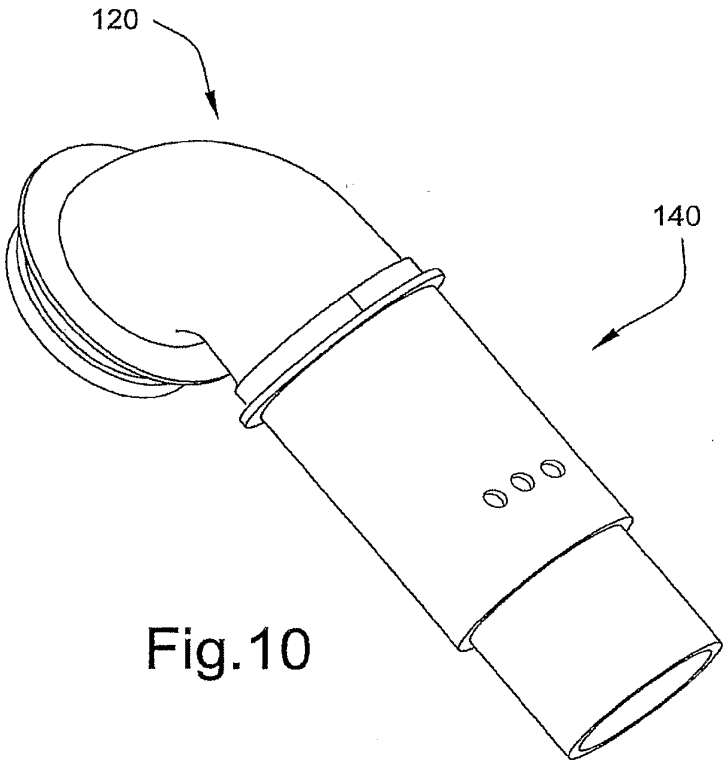


Fig.10

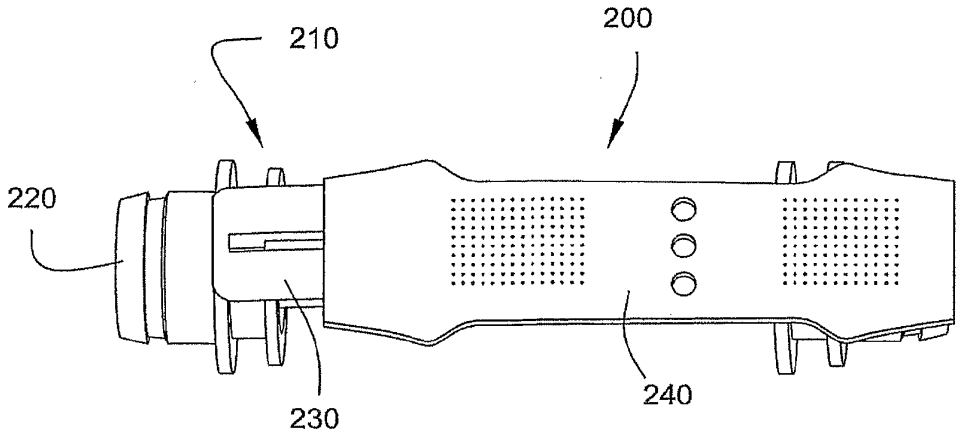


Fig.11a

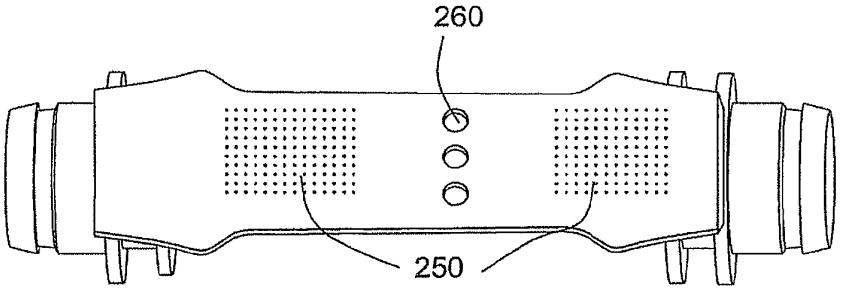


Fig.11b

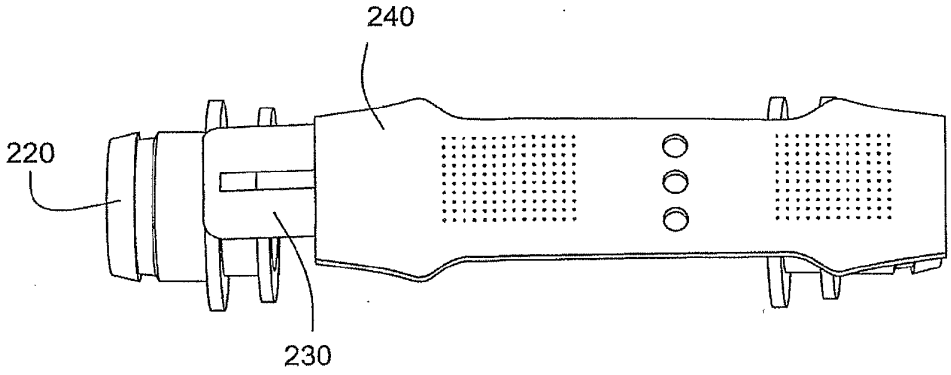


Fig.12

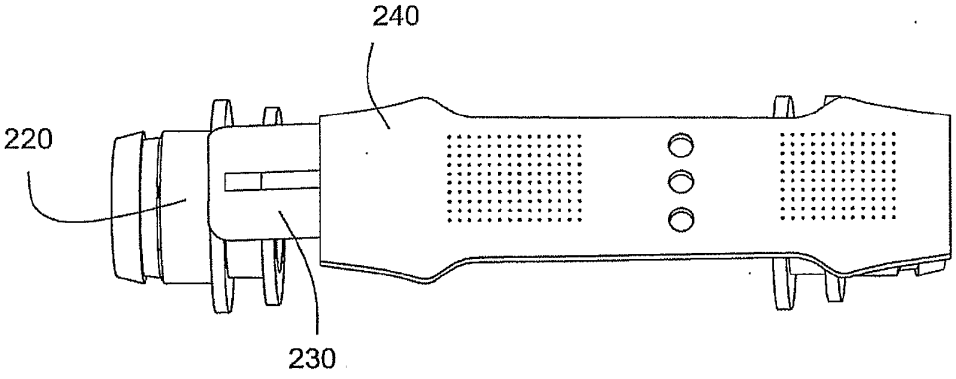


Fig.13

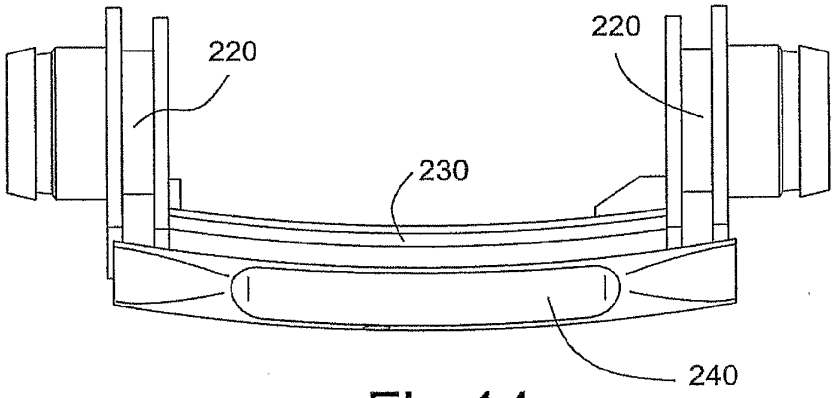


Fig.14

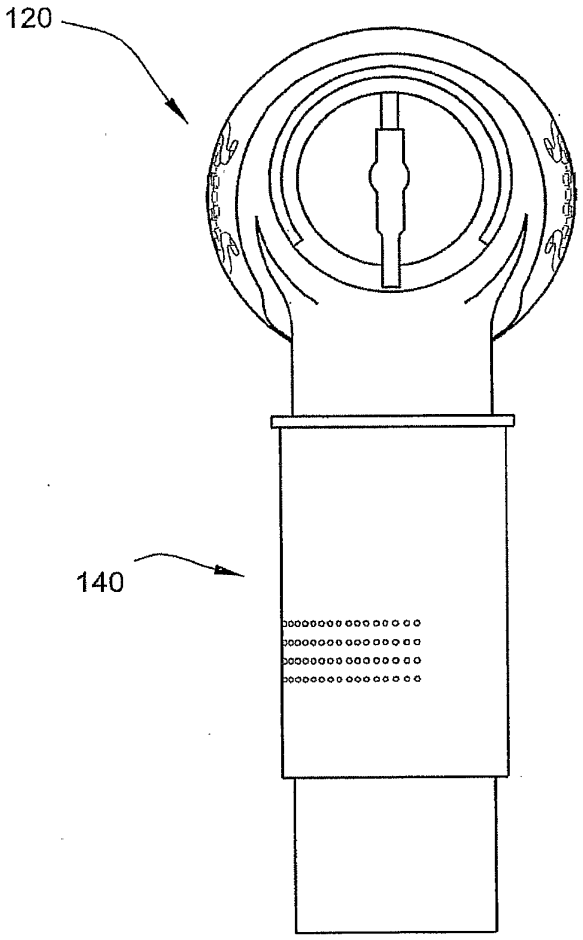


Fig. 15

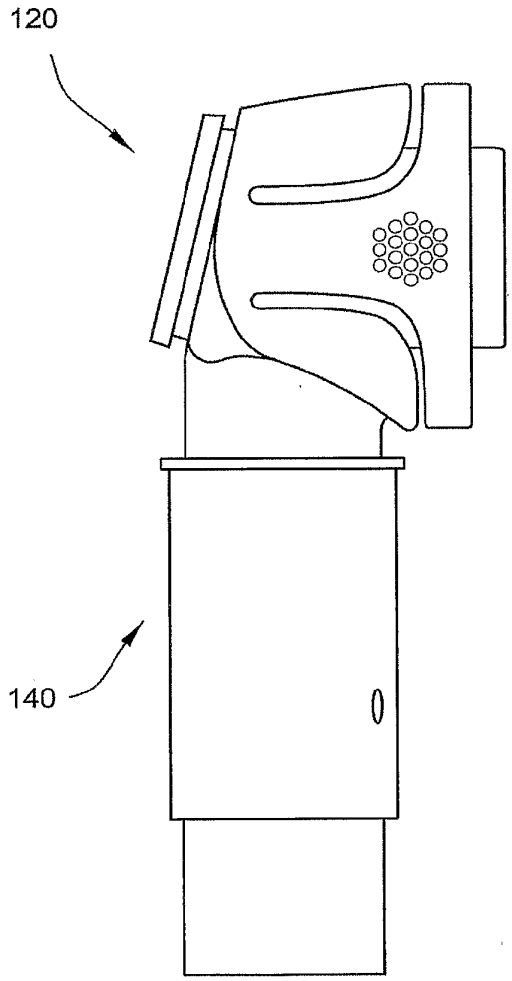


Fig. 16

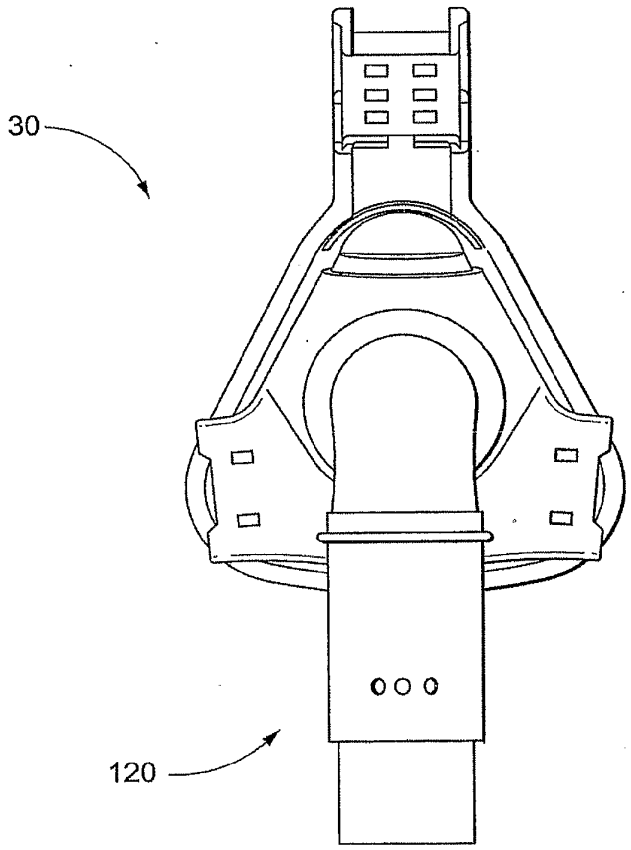


Fig. 17

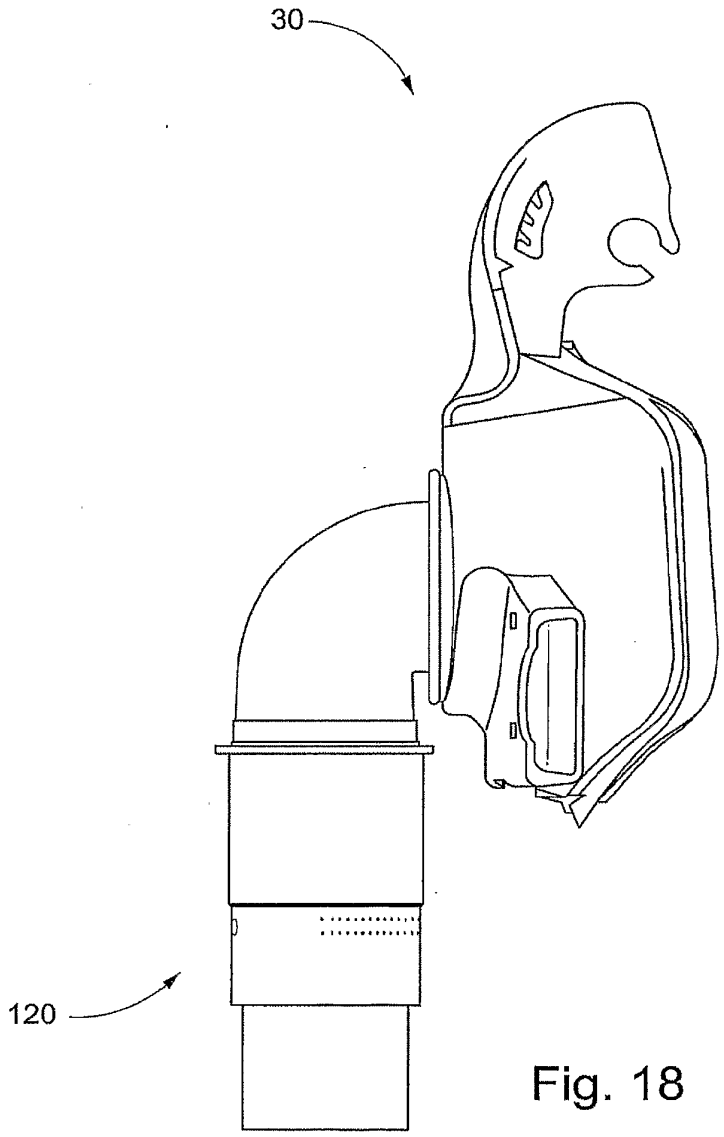


Fig. 18

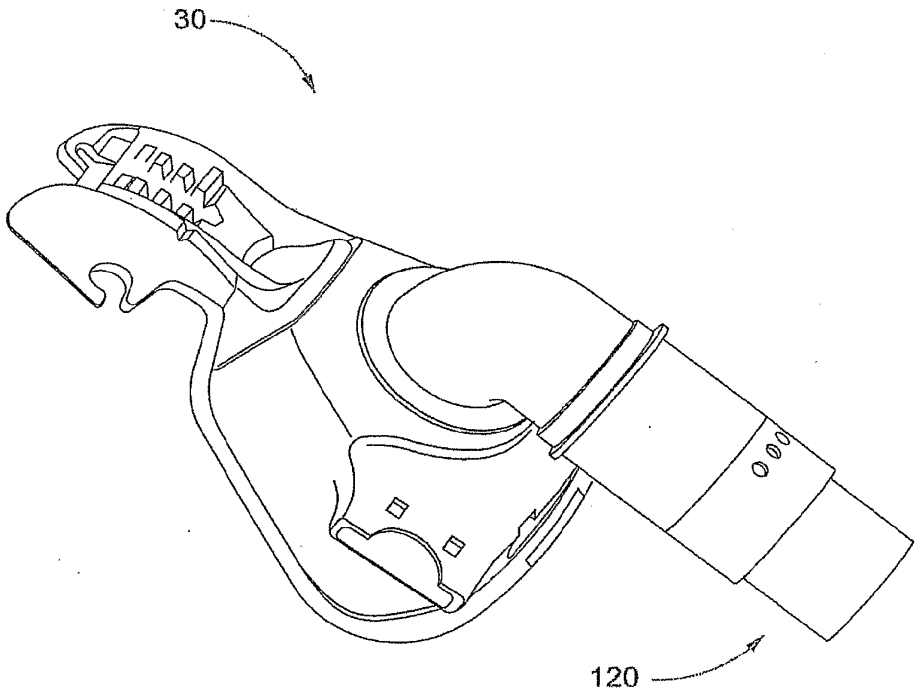


Fig. 19

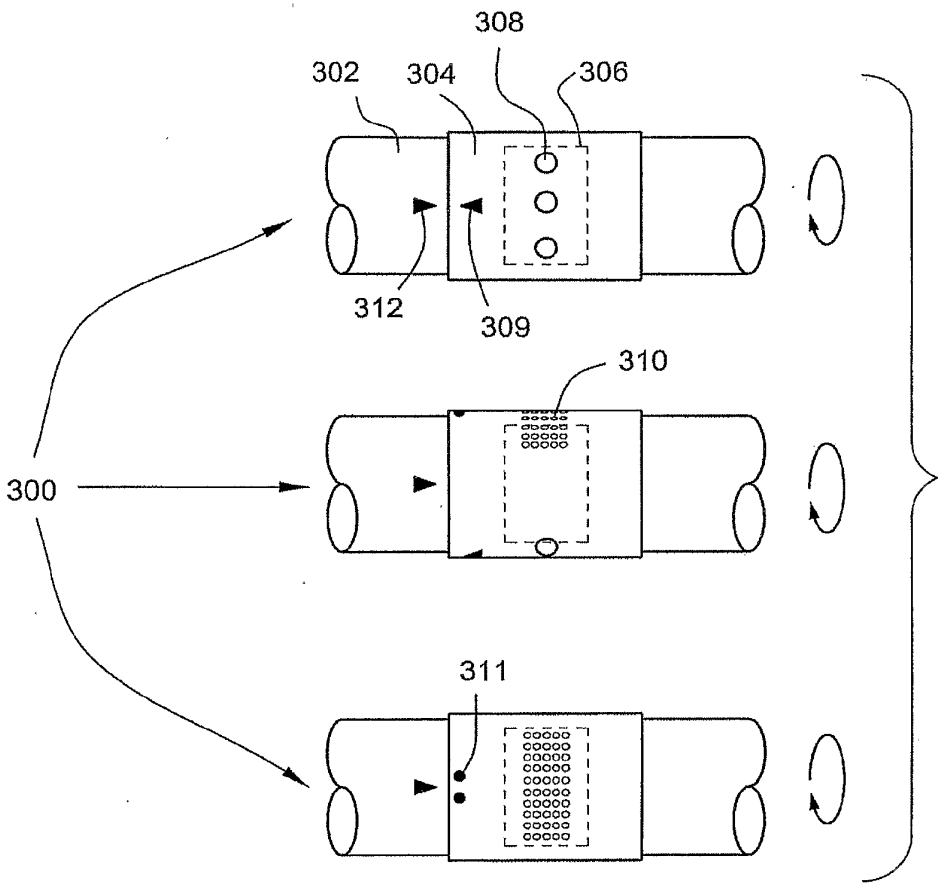


Fig. 20

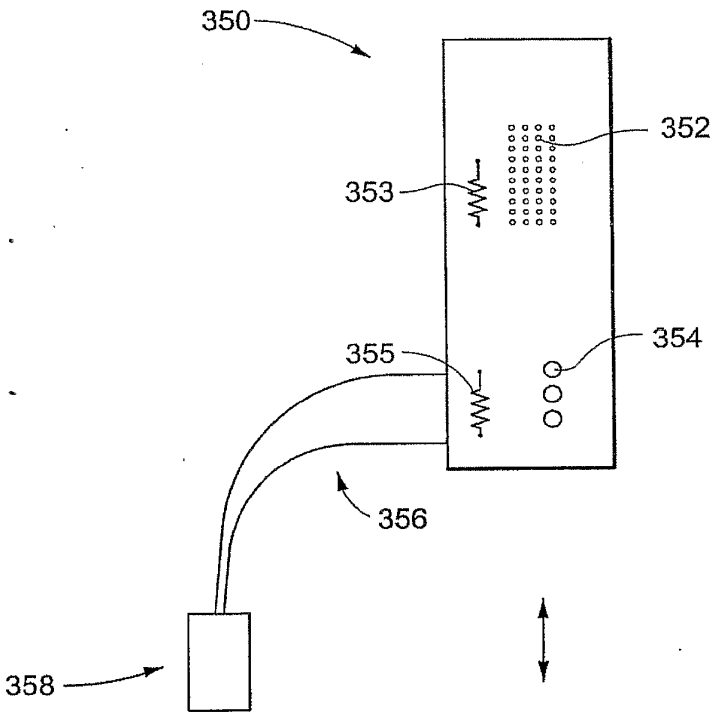


Fig.21

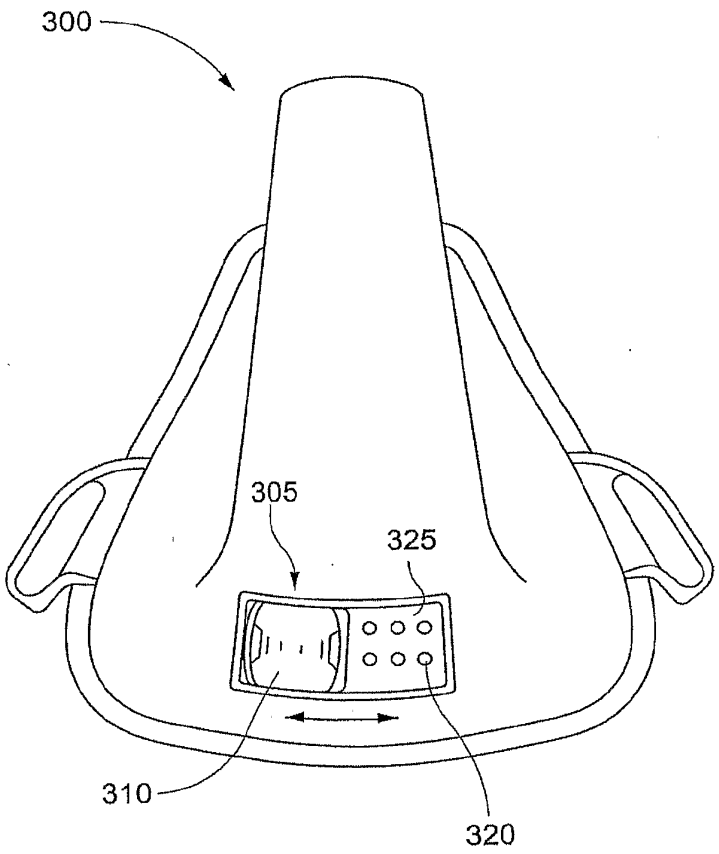


Fig. 22

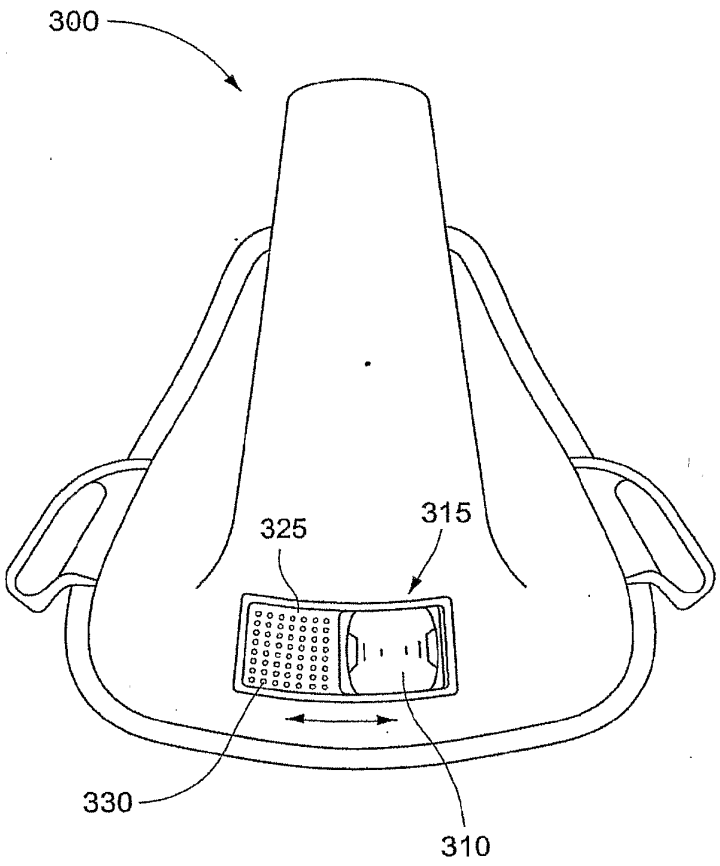


Fig. 23

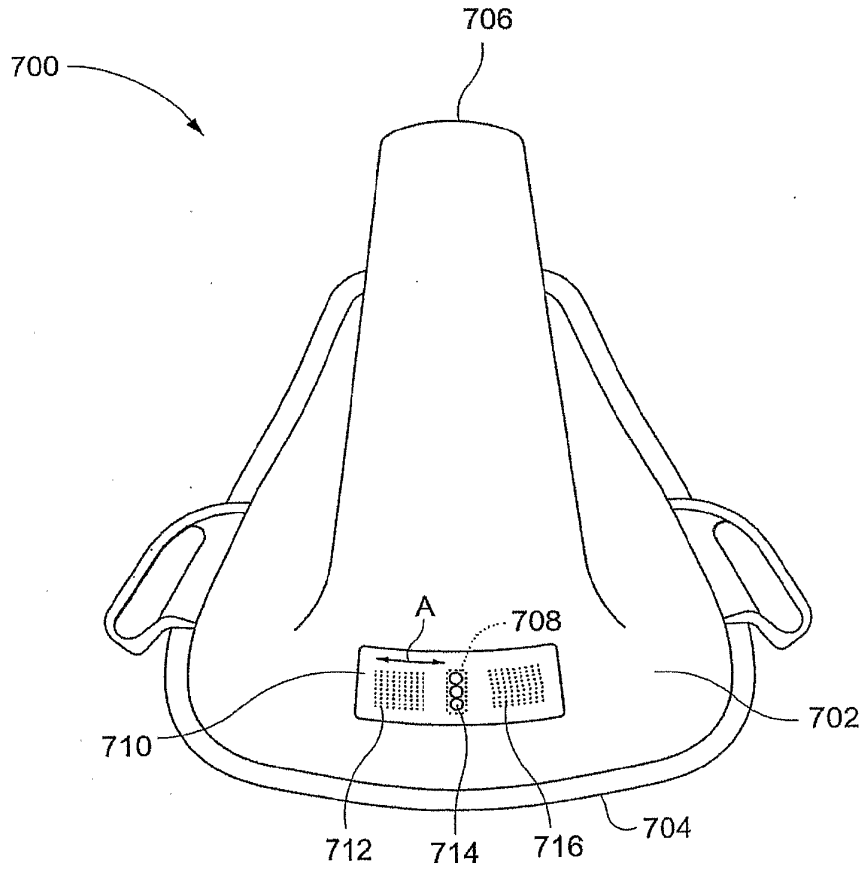


Fig. 23a

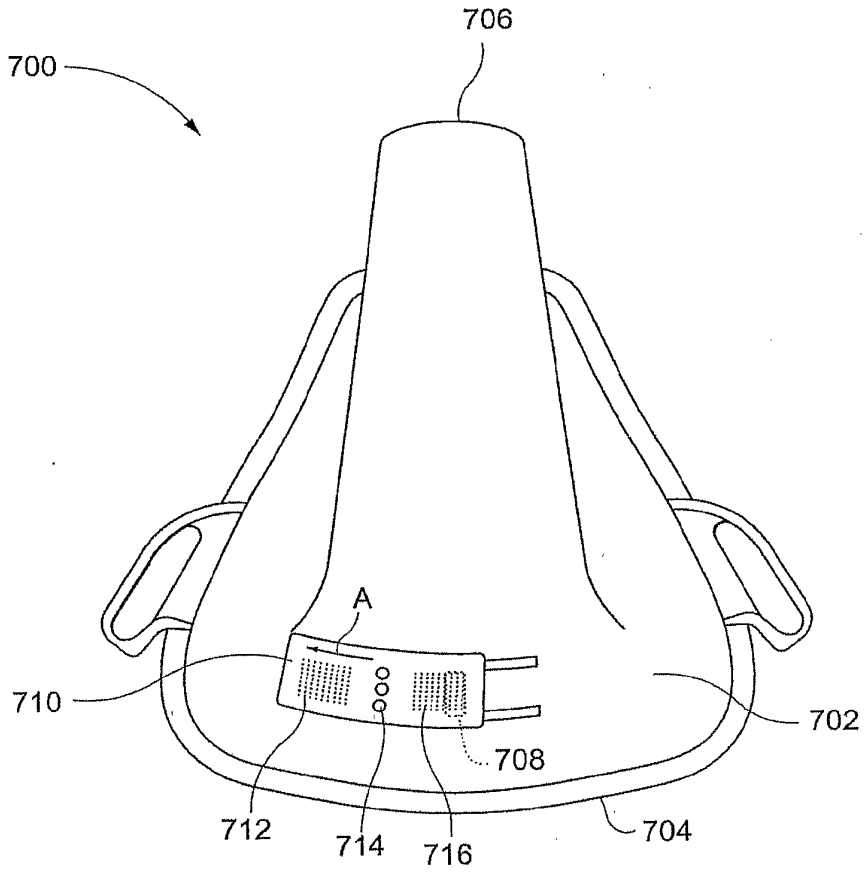


Fig. 23b

PCT/AU2004/001650

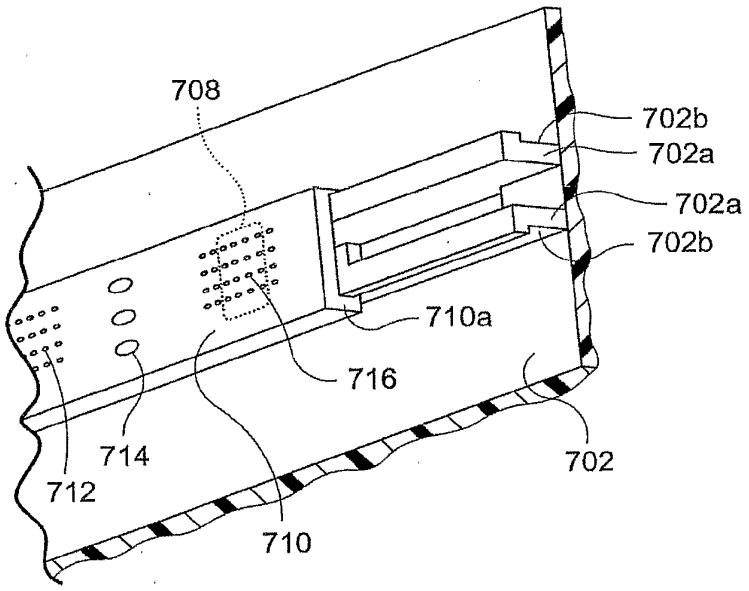


Fig. 23c

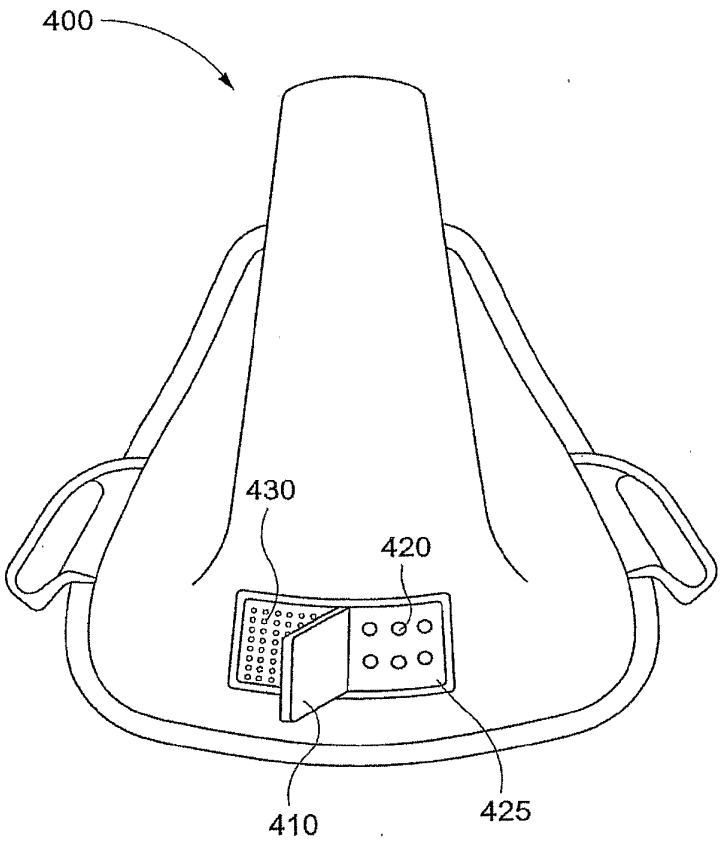


Fig. 24

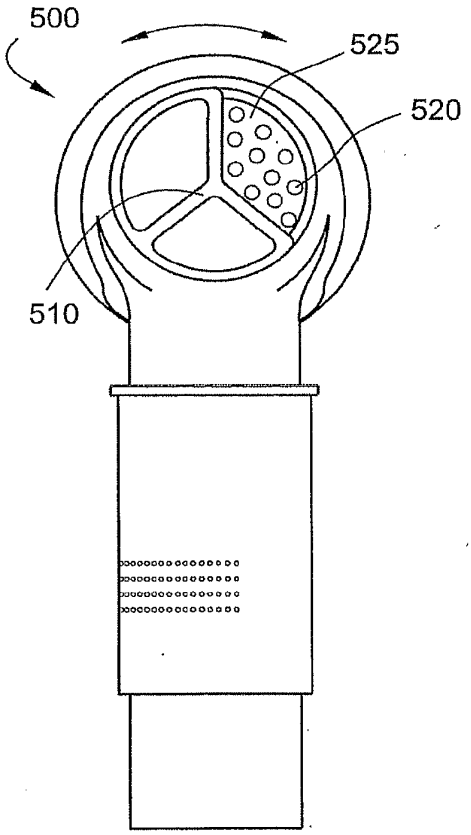


Fig. 25a

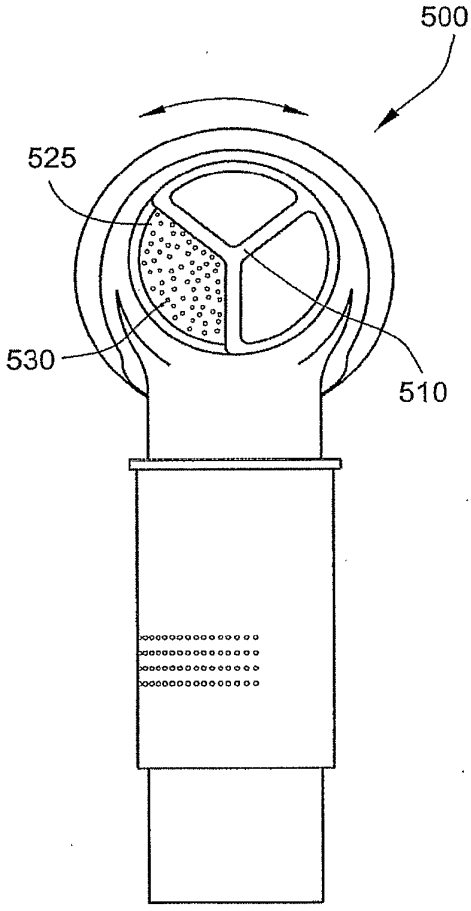


Fig. 25b

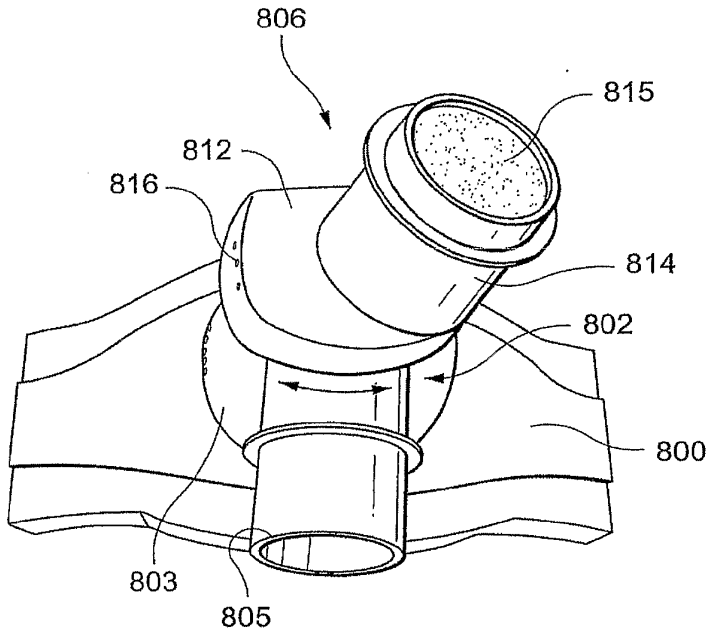


Fig. 25c

PCT/AU2004/001650

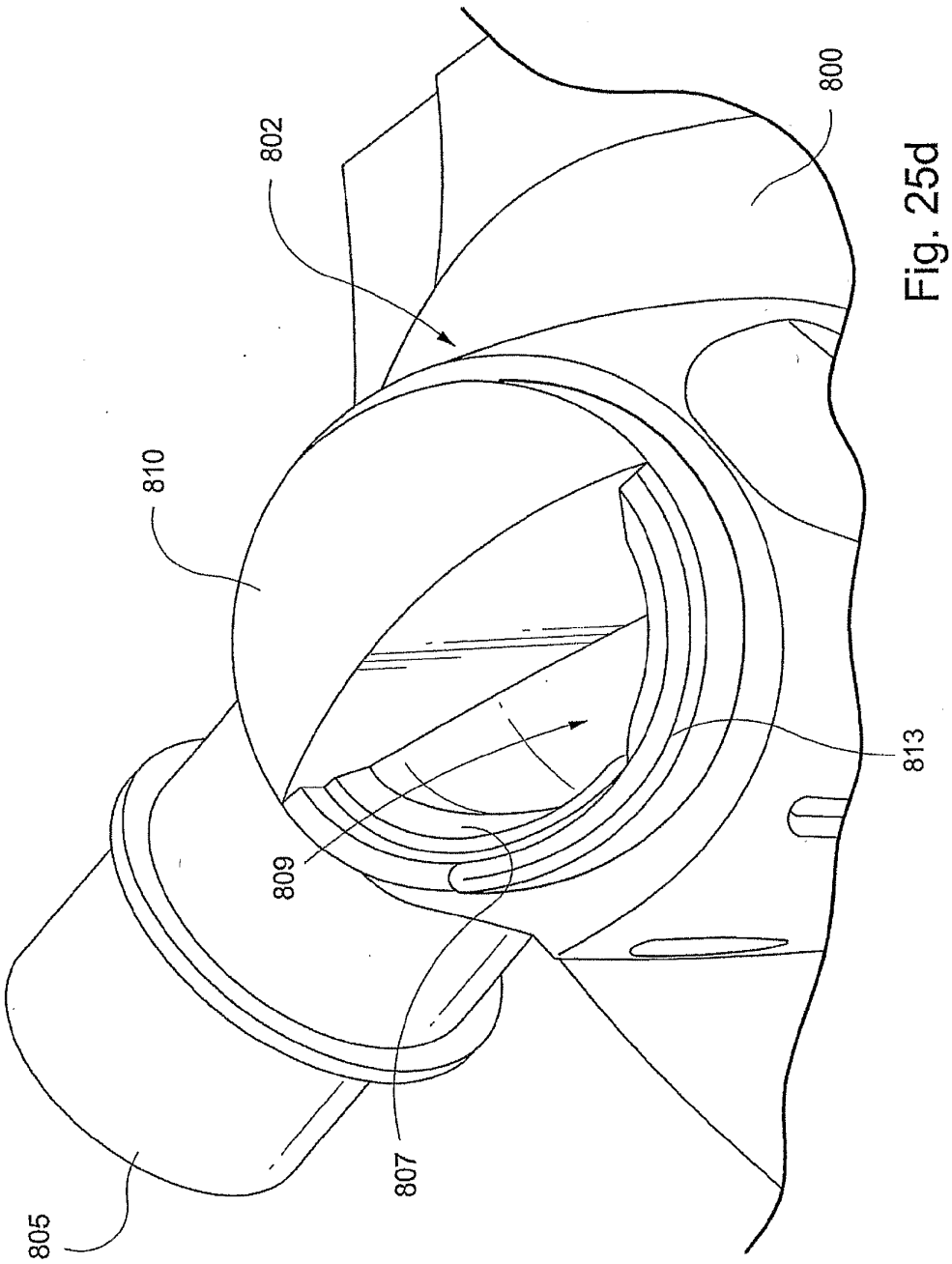


Fig. 25d

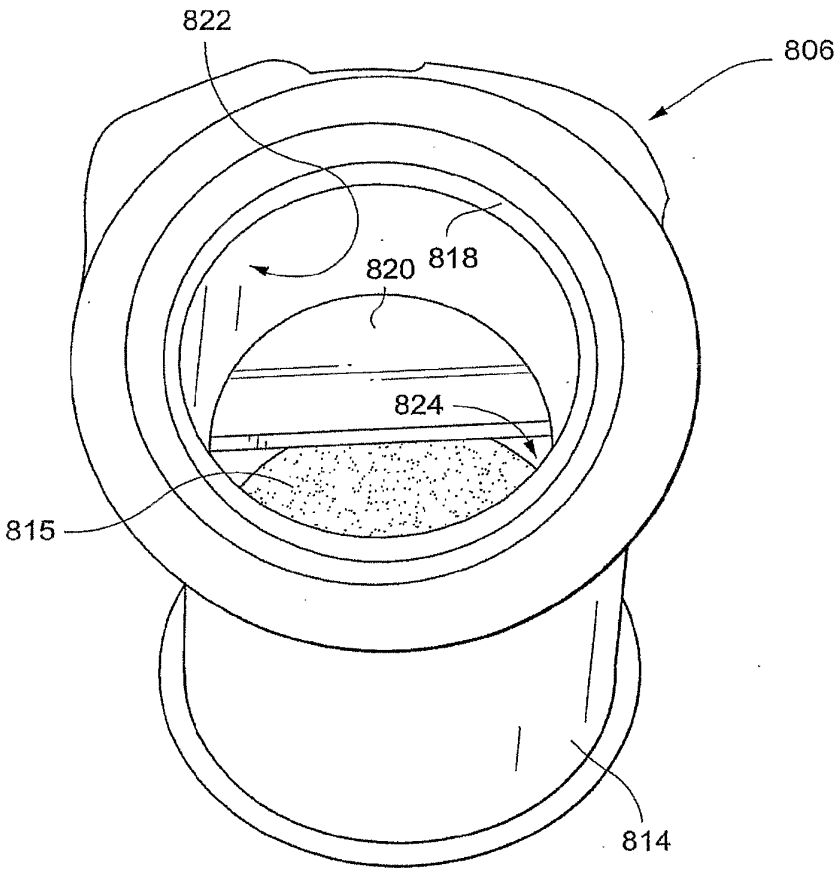


Fig. 25e

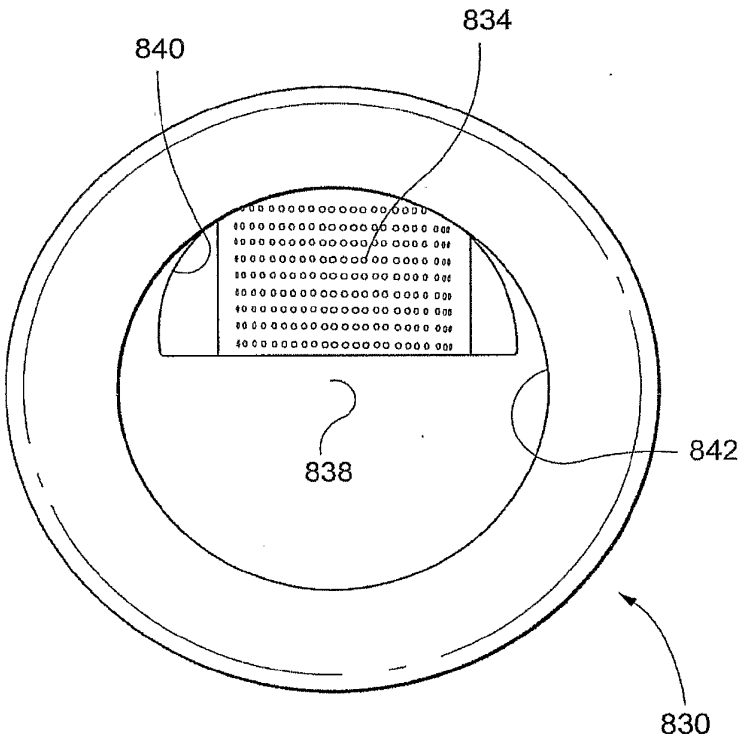


Fig. 25f

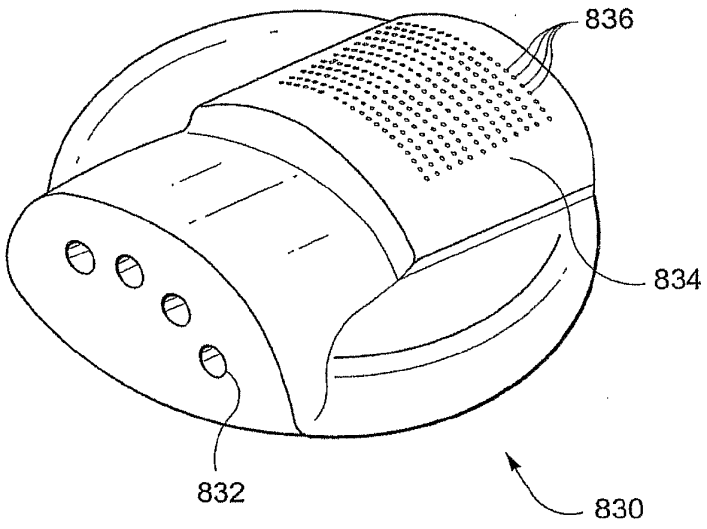


Fig. 25g

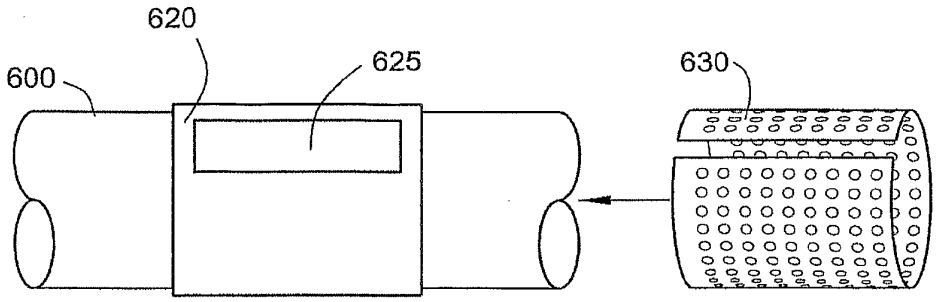


Fig. 26

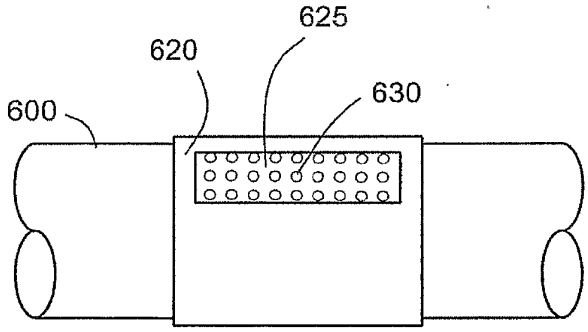


Fig. 27a

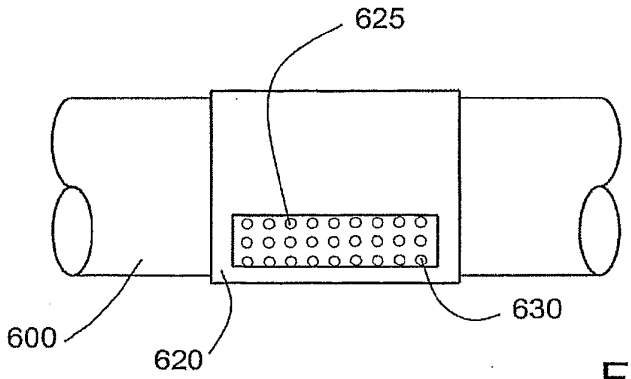


Fig. 27b

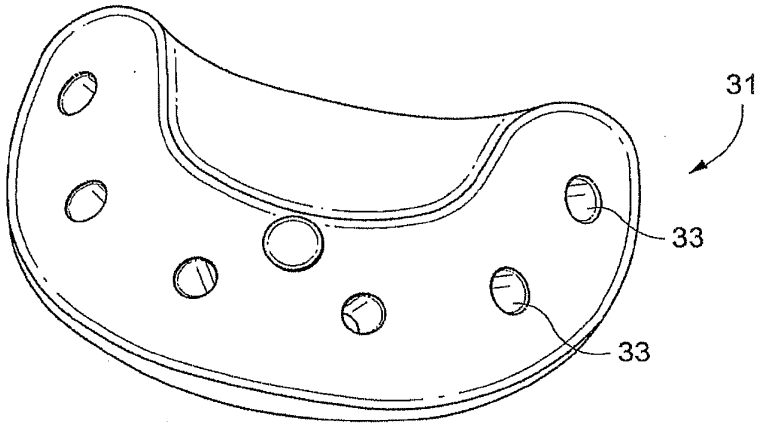


Fig. 28a

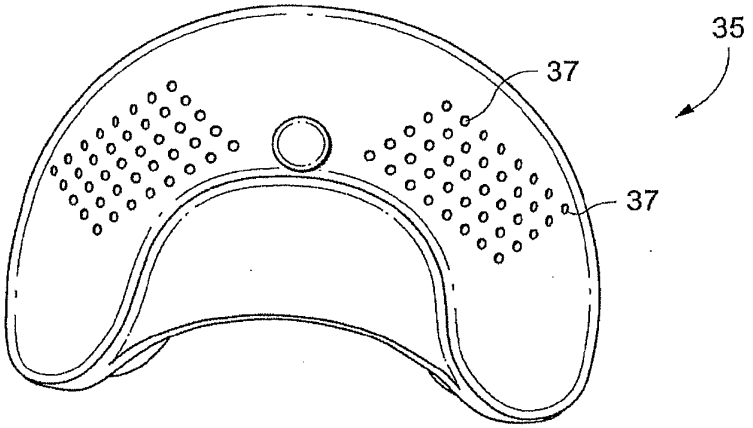


Fig. 28b

INTERNATIONAL SEARCH REPORT

International application No.
PCT/AU2004/001650

A. CLASSIFICATION OF SUBJECT MATTER

Int. Cl. [7]: A61M 16/00

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

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)
DWPI + keywords:(A61M 16/-, A62B /- breath, respirat, expirat, CPAP, vent, exhaust, switch, select) and similar terms.
Claims 17-26 were only searched for use with a mask assembly as in the abstract and description.

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 6561191 B1 (KWOK) 13 May 2003 Whole document	
A	US 6557555 B1 (HOLLIS) 6 May 2003 Whole document	
A	GB 1548374 A (PENLON LTD) 11July 1979 Whole document	
A	US 4437461 A (GREENBERG) 20 March 1984 Whole document	

☐ Further documents are listed in the continuation of Box C ☒ See patent family annex

* Special categories of cited documents:

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier application or patent but published on or after the international filing date

"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)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"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

"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

"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

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
24 January 2005	1 FEB 2005
Name and mailing address of the ISA/AU AUSTRALIAN PATENT OFFICE PO BOX 200, WODEN ACT 2606, AUSTRALIA E-mail address: pct@ipaustralia.gov.au Facsimile No. (02) 6285 3929	Authorized officer **Sue Thomas** Telephone No : (02) 6283 2454

Form PCT/ISA/210 (second sheet) (January 2004)

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No.
PCT/AU2004/001650

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 Search Report		Patent Family Member					
US	4437461	NIL					
GB	1548374	NIL					
US	6557555	AU	41018/97	US	6006748	US	2003127100
US	6561191	AU	53019/98	AU	58476/98	EP	968022
		JP	2004344671	US	2003079751	US	2003116160
		WO	9834665				

Due to data integration issues this family listing may not include 10 digit Australian applications filed since May 2001.END OF ANNEX

Electronic Acknowledgement Receipt

EFS ID:	13001493
Application Number:	12307993
International Application Number:	
Confirmation Number:	7084
Title of Invention:	BREATHING ASSISTANCE APPARATUS
First Named Inventor/Applicant Name:	Alastair Edwin McAuley
Customer Number:	20995
Filer:	Robert J. Roby/Adriana Perez
Filer Authorized By:	Robert J. Roby
Attorney Docket Number:	FPHCR.131NP
Receipt Date:	13-JUN-2012
Filing Date:	17-JUN-2009
Time Stamp:	14:00:59
Application Type:	U.S. National Stage under 35 USC 371

Payment information:

Submitted with Payment	no

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1		FPHCR-131NP_IDS.pdf	82108 a471ae9df0f25276f2646a8bf0893756d519059d	yes	2

	Multipart Description/PDF files in .zip description				
	Document Description		**Start**	**End**	
	Transmittal Letter		1	1	
	Information Disclosure Statement (IDS) Form (SB08)		2	2	
Warnings:					
Information:					
2	Foreign Reference	WO2005-051468.PDF	1615607 6204988c7f85d8f4ff80c07ba4ea3b58ced2c575	no	58
Warnings:					
Information:					
3	Non Patent Literature	AU_Examination_Report_May_22_2012.PDF	60049 eb2910dbe533c92487027d15a6a4d2faa9ddbf79	no	3
Warnings:					
Information:					
		Total Files Size (in bytes):	1757764		

This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.

New Applications Under 35 U.S.C. 111
If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

National Stage of an International Application under 35 U.S.C. 371
If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office
If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

INFORMATION DISCLOSURE STATEMENT

Applicant	:	Alastair Edwin McAuley, et al.
App. No.	:	12/307993
Filed	:	June 17, 2009
For	:	BREATHING ASSISTANCE APPARATUS
Examiner	:	Steven O. Douglas
Art Unit	:	3771
Conf. No.	:	7084

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

References and Listing

Submitted herewith in the above-identified application is an Information Disclosure Statement listing references for consideration. Copies of any listed foreign and non-patent literature references are being submitted.

Timing of Disclosure

This Information Disclosure Statement is being filed before the receipt of a first Office Action on the merits, and presumably no fee is required. If a first Office Action on the merits was mailed before the mailing date of this Statement, the Commissioner is authorized to charge the fee set forth in 37 CFR 1.17(p) to Deposit Account No. 11-1410.

Respectfully submitted,
KNOBBE, MARTENS, OLSON & BEAR, LLP

Dated: June 13, 2012

By: _____
Robert J. Roby
Registration No. 44,304
Attorney of Record
Customer No. 20995
(949) 760-0404

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060412

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
12/307,993	06/17/2009	Alastair Edwin McAuley	FPHCR.131NP	7084

20995 7590 07/05/2012

KNOBBE MARTENS OLSON & BEAR LLP
2040 MAIN STREET
FOURTEENTH FLOOR
IRVINE, CA 92614

EXAMINER	
DOUGLAS, STEVEN O	
ART UNIT	**PAPER NUMBER**
3771	

NOTIFICATION DATE	DELIVERY MODE
07/05/2012	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

eOAPilot@kmob.com
jayna.cartee@knobbe.com
efiling@knobbe.com

Office Action Summary	Application No.	Applicant(s)	
	12/307,993	MCAULEY ET AL.	
	Examiner	Art Unit	
	STEVEN DOUGLAS	3771	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 November 2011*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on _____; the restriction requirement and election have been incorporated into this action.

4)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

5)☒ Claim(s) *38-55* is/are pending in the application.

5a) Of the above claim(s) _____ is/are withdrawn from consideration.

6)☐ Claim(s) _____ is/are allowed.

7)☒ Claim(s) *38-55* is/are rejected.

8)☐ Claim(s) _____ is/are objected to.

9)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

10)☐ The specification is objected to by the Examiner.

11)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

12)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *06132012, 10052011, 04262010, 03042009, 01082009*
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language; or
>
> the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 38, 39, 41-44, 46, 48-50 and 53 are rejected under 35 U.S.C. 102(e) as being anticipated by Lovell et al. (US 7,219,669).

The Lovell et al. reference discloses a nasal mask comprising a mask body 2 including two nasal pillows (38,40), a ring 12, an elbow 14 including vents 20, a tube or conduit (not shown) connected to the free end of the elbow, and side straps (44,46).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 40 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lovell et al.

The Lovell et al. reference discloses a nasal mask (supra), but fails to disclose the mask body as being made of an elastomeric material. It would have been obvious to one of ordinary skill in the art at the time the invention was made to make the mask body of an elastomeric material, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of design choice. *In re Leshin, 125 USPQ 416.*

Claim 45, 47, 51, 52, 54 and 55 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lovell et al. in view of Gunaratnam et al. (US 2004/0226566).

In regard to claims 45, 51 and 52, the Lovell et al. reference discloses a nasal mask (supra), but fails to disclose a pair of molded side arms. The Gunaratnam et al. reference discloses another nasal mask that incorporates a pair of arms in numerous embodiments (see elements 608 and the unnumbered arms in Figure 135) so as to enhance the fit between the mask and face of a user by adding rigidity between the straps and mask. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the nasal mask of Lovell et al. to have a pair of molded side arms in view of the teachings of Gunaratnam

et al. to enhance the fit between the mask and face of a user by adding rigidity between the straps and mask.

In regard to claim 47, the modified Lovell et al. device (see treatment of claim 40 above) defines a nasal mask device substantially as claimed, but fails to disclose the nasal pillows as comprising conical portion and cylindrical portion. Gunaratnam et al. reference discloses another nasal mask having a mask body with a pair of nasal pillows (see Figures 5-8) having conical portions 58 and cylindrical portions 56. It would have been obvious to one of ordinary skill in the art at the time the invention was made to substitute a mask body as, for example, shown by Gunaratnam for the mask body of Lovell et al wherein so doing would amount to the mere substitution of one type of nasal mask interface for another that would work equally as well in the device of Lovell et al.

In regard to claims 54 and 55, the Lovell et al. discloses a nasal mask device substantially as claimed, but fails to disclose the nasal pillows as comprising conical portion and cylindrical portion. Gunaratnam et al. reference discloses another nasal mask having a mask body with a pair of nasal pillows (see Figures 5-8) having conical portions 58 and cylindrical portions 56, see also see the defined offset profiles shown in Figures 7 and 8. It would have been obvious to one of ordinary skill in the art at the time the invention was made to substitute a mask body as, for example, shown by Gunaratnam for the mask body of Lovell et al wherein so doing would amount to the mere substitution of one type of nasal mask interface for another that would work equally as well in the device of Lovell et al.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. The Matula et al. and Wood et al. references pertain to various nasal masks with similar nasal interface features.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to STEVEN DOUGLAS whose telephone number is (571)272-4885. The examiner can normally be reached on Mon-Thurs 6:30-5:00.

The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Steven O. Douglas/
Primary Examiner
Art Unit 3771

/sd/
6/28/12

Notice of References Cited	Application/Control No. 12/307,993	Applicant(s)/Patent Under Reexamination MCAULEY ET AL.	
	Examiner STEVEN DOUGLAS	Art Unit 3771	Page 1 of 1

U.S. PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Name	Classification
*	A	US-2005/0235999 A1	10-2005	Wood et al.	128/207.18
*	B	US-7,896,003 B2	03-2011	Matula et al.	128/200.24
	C	US-			
	D	US-			
	E	US-			
	F	US-			
	G	US-			
	H	US-			
	I	US-			
	J	US-			
	K	US-			
	L	US-			
	M	US-			

FOREIGN PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Country	Name	Classification
	N					
	O					
	P					
	Q					
	R					
	S					
	T					

NON-PATENT DOCUMENTS

*		Include as applicable: Author, Title Date, Publisher, Edition or Volume, Pertinent Pages)
	U	
	V	
	W	
	X	

*A copy of this reference is not being furnished with this Office action. (See MPEP § 707.05(a).)
Dates in MM-YYYY format are publication dates. Classifications may be US or foreign.

PTO/SB/08 Equivalent

INFORMATION DISCLOSURE STATEMENT BY APPLICANT	Application No.	12/307993
	Filing Date	June 17, 2009
	First Named Inventor	Alastair Edwin McAuley
	Art Unit	3771
(Multiple sheets used when necessary)	Examiner	Yu, Justine Romang
SHEET 1 OF 1	Attorney Docket No.	FPHCR.131NP

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials	Cite No.	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T^1
	1	English Translation of Chinese Examination Report; 5 pages (no date).	

12036919:ah
100411

Examiner Signature	/Steven Douglas/	Date Considered	06/27/2012

*Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

T^1 - Place a check mark in this area when an English Language Translation is attached.

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /SD/

Index of Claims	Application/Control No.	Applicant(s)/Patent Under Reexamination
	12307993	MCAULEY ET AL.
	Examiner	Art Unit
	STEVEN DOUGLAS	3771

✓	Rejected	-	Cancelled	N	Non-Elected	A	Appeal
=	Allowed	÷	Restricted	I	Interference	O	Objected

☐ Claims renumbered in the same order as presented by applicant ☐ CPA ☐ T.D. ☐ R.1.47

CLAIM		DATE								
Final	Original	06/28/2012								
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	12307993	MCAULEY ET AL.
	Examiner	Art Unit
	STEVEN DOUGLAS	3771

✓	Rejected	-	Cancelled	N	Non-Elected	A	Appeal
=	Allowed	÷	Restricted	I	Interference	O	Objected

☐ Claims renumbered in the same order as presented by applicant ☐ CPA ☐ T.D. ☐ R.1.47

CLAIM		DATE								
Final	Original	06/28/2012								
	37	-								
	38	✓								
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	55	✓								

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BIB DATA SHEET

CONFIRMATION NO. 7084

SERIAL NUMBER	FILING or 371(c) DATE	CLASS	GROUP ART UNIT	ATTORNEY DOCKET NO.
12/307,993	06/17/2009 RULE	128	3771	FPHCR.131NP

APPLICANTS

Alastair Edwin McAuley, Auckland, NEW ZEALAND;
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Evan Stuart Erstich, Auckland, NEW ZEALAND;
Simon Eric Freeman, Auckland, NEW ZEALAND;
Neil Glen Davies, Auckland, NEW ZEALAND;
Stephen John Schoenberg, Auckland, NEW ZEALAND;
Kamman Law, Auckland, NEW ZEALAND;
Craig Robert Prentice, Auckland, NEW ZEALAND;

**** CONTINUING DATA ***************************

This application is a 371 of PCT/NZ2007/000185 07/13/2007

**** FOREIGN APPLICATIONS ***************************

NEW ZEALAND 548575 07/14/2006
NEW ZEALAND 551103 11/06/2006

**** IF REQUIRED, FOREIGN FILING LICENSE GRANTED ****

09/22/2009

Foreign Priority claimed ☑ Yes ☐ No 35 USC 119(a-d) conditions met ☑ Yes ☐ No Verified and Acknowledged /STEVEN O DOUGLAS/ Examiner's Signature	☐ Met after Allowance Initials	STATE OR COUNTRY	SHEETS DRAWINGS	TOTAL CLAIMS	INDEPENDENT CLAIMS
		NEW ZEALAND	21	31	2

ADDRESS

KNOBBE MARTENS OLSON & BEAR LLP
2040 MAIN STREET
FOURTEENTH FLOOR
IRVINE, CA 92614
UNITED STATES

TITLE

BREATHING ASSISTANCE APPARATUS

FILING FEE RECEIVED		
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BIB (Rev. 05/07).

Doc code: IDS
Doc description: Information Disclosure Statement (IDS) Filed

PTO/SB/08a (11-08)
Approved for use through 12/31/2008. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

INFORMATION DISCLOSURE STATEMENT BY APPLICANT
(Not for submission under 37 CFR 1.99)

Application Number	12307993
Filing Date	2009-01-08
First Named Inventor	ALASTAIR EDWIN McAULEY
Art Unit	
Examiner Name	
Attorney Docket Number	1171/48067/202

U.S.PATENTS

Examiner Initial*	Cite No	Patent Number	Kind Code[1]	Issue Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1	6951218		2005-10-04	Gradon et al.	

If you wish to add additional U.S. Patent citation information please click the Add button.

U.S.PATENT APPLICATION PUBLICATIONS

Examiner Initial*	Cite No	Publication Number	Kind Code[1]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1	20040226566		2004-11-18	Gunaratnam et al.	

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FOREIGN PATENT DOCUMENTS

Examiner Initial*	Cite No	Foreign Document Number[3]	Country Code[2]	Kind Code[4]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear	T[5]
	1	2004/073778	WO		2004-09-02	Resmed Ltd.		☐

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Examiner Initials*	Cite No	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc), date, pages(s), volume-issue number(s), publisher, city and/or country where published.	T[5]

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
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	Examiner Name	
	Attorney Docket Number	1171/48067/202

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	First Named Inventor	ALASTAIR EDWIN McAULEY
	Art Unit	
	Examiner Name	
	Attorney Docket Number	1171/48067/202-PCT-US

U.S.PATENTS						Remove
Examiner Initial*	Cite No	Patent Number	Kind Code[1]	Issue Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1	7318437		2008-01-15	GUNARATNAM ET AL.	
	2	6679257		2004-01-20	ROBERTSON ET AL.	
	3	5148802		1992-09-22	SANDERS ET AL.	
	4	5245995		1993-09-21	SULLIVAN ET AL.	
	5	5477852		1995-12-26	LANDIS ET AL.	
	6	6119694		2000-09-19	CORREA ET AL.	
	7	6907882		2005-06-21	GING ET AL.	
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Receipt date: 01/08/2009	Application Number	12307993 - GAU: 3771
INFORMATION DISCLOSURE STATEMENT BY APPLICANT	Filing Date	
(Not for submission under 37 CFR 1.99)	First Named Inventor	ALASTAIR EDWIN McAULEY
	Art Unit	
	Examiner Name	
	Attorney Docket Number	1171/48067/202-PCT-US

Examiner Initial*	Cite No	Publication Number	Kind Code[1]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1	20030172936		2003-09-18	WILKIE ET AL.	
	2	20060060200		2006-03-23	HO ET AL.	
	3	20060196511		2006-09-07	LAU ET AL.	
	4	20060237018		2006-10-26	McAULEY ET AL.	
	5	20070089749		2007-04-26	HO ET AL.	

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	1	2007/041786	WO		2007-04-19	RESMED LTD		☐
	2	2004/041341	WO		2004-05-21	RESMED LTD		☐

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	First Named Inventor	ALASTAIR EDWIN McAULEY
	Art Unit	
	Examiner Name	
	Attorney Docket Number	1171/48067/202-PCT-US

Examiner Initials*	Cite No	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc), date, pages(s), volume-issue number(s), publisher, city and/or country where published.	T[5]
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	Examiner Name	
	Attorney Docket Number	1171/48067/202

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Examiner Initial*	Cite No	Patent Number	Kind Code[1]	Issue Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1	7210481		2007-05-01	LOVELL ET AL.	
	2	7219669		2007-05-22	LOVELL ET AL.	
	3	6631718		2003-10-14	LOVELL	
	4	5042478		1991-08-27	KOPALA ET AL.	
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Examiner Initial*	Cite No	Publication Number	Kind Code[1]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
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Examiner Initial*	Cite No	Foreign Document Number[3]	Country Code[2] i	Kind Code[4]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear	T[5]

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Receipt date: 03/04/2009	Application Number	12307993 12307993 - GAU: 3771
INFORMATION DISCLOSURE STATEMENT BY APPLICANT	Filing Date	2009-01-08
	First Named Inventor	ALASTAIR EDWIN McAULEY
(Not for submission under 37 CFR 1.99)	Art Unit	
	Examiner Name	
	Attorney Docket Number	1171/48067/202

	1	00/74758	WO		2000-12-14	SLEEP-NET CORPORATION		☐

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	1		☐

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EXAMINER SIGNATURE

Examiner Signature	/Steven Douglas/	Date Considered	06/27/2012

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through a citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

[1] See Kind Codes of USPTO Patent Documents at www.USPTO.GOV or MPEP 901.04. [2] Enter office that issued the document, by the two-letter code (WIPO Standard ST.3). [3] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [4] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. [5] Applicant is to place a check mark here if English language translation is attached.

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /SD/

PTO/SB/08 Equivalent

INFORMATION DISCLOSURE STATEMENT BY APPLICANT	Application No.	12/307993
	Filing Date	June 17, 2009
	First Named Inventor	Alastair Edwin McAuley
	Art Unit	3771
(Multiple sheets used when necessary)	Examiner	Steven O. Douglas
SHEET 1 OF 1	Attorney Docket No.	FPHCR.131NP

U.S. PATENT DOCUMENTS					
Examiner Initials	Cite No.	Document Number *Number - Kind Code (if known)* Example: 1,234,567 B1	Publication Date MM-DD-YYYY	Name of Patentee or Applicant	Pages, Columns, Lines Where Relevant Passages or Relevant Figures Appear
	1	6,581,594	06-24-2003	Drew et al.	
	2	2005/0076913	04-14-2005	Ho et al.	
	3	2007/0125385	06-07-2007	Ho et al.	

FOREIGN PATENT DOCUMENTS						
Examiner Initials	Cite No.	Foreign Patent Document *Country Code-Number-Kind Code* Example: JP 1234567 A1	Publication Date MM-DD-YYYY	Name of Patentee or Applicant	Pages, Columns, Lines Where Relevant Passages or Relevant Figures Appear	T[1]
	4	WO 2005/051468	06-09-2005	Resmed Limited		

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials	Cite No.	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T[1]
	5	Examination Report; Australian Application No. 2007273324; dated May 22, 2012; 3 pages	

13392047:ah
060412

Examiner Signature	/Steven Douglas/	Date Considered	06/27/2012

***Examiner:** Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

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ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /SD/

Search Notes	Application/Control No.	Applicant(s)/Patent under Reexamination
	12/307,993	MCAULEY ET AL.
	Examiner	Art Unit
	STEVEN DOUGLAS	3771

SEARCHED			
Class	Subclass	Date	Examiner
128	207.18 206.21 206.24 206.27		
	207.11		
	207.13	6/28/2012	SD

INTERFERENCE SEARCHED			
Class	Subclass	Date	Examiner

SEARCH NOTES (INCLUDING SEARCH STRATEGY)		
	DATE	EXMR

PTO/SB/08 Equivalent

INFORMATION DISCLOSURE STATEMENT BY APPLICANT	Application No.	12/307993
	Filing Date	June 17, 2009
	First Named Inventor	Alastair Edwin McAuley
	Art Unit	3771
(Multiple sheets used when necessary)	Examiner	Steven O. Douglas
SHEET 1 OF 1	Attorney Docket No.	FPHCR.131NP

U.S. PATENT DOCUMENTS					
Examiner Initials	Cite No.	Document Number *Number - Kind Code (if known)* Example: 1,234,567 B1	Publication Date MM-DD-YYYY	Name of Patentee or Applicant	Pages, Columns, Lines Where Relevant Passages or Relevant Figures Appear
	1	7,210,481	05-01-2007	Lovell et al.	

FOREIGN PATENT DOCUMENTS						
Examiner Initials	Cite No.	Foreign Patent Document *Country Code-Number-Kind Code* Example: JP 1234567 A1	Publication Date MM-DD-YYYY	Name of Patentee or Applicant	Pages, Columns, Lines Where Relevant Passages or Relevant Figures Appear	T[1]

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials	Cite No.	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T[1]
	2	Examination Report; Australian Application No. 2007273324; dated May 22, 2012; 3 pages	
	3	English Translation of Chinese Examination Report; 5 pages	

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100212

Examiner Signature	Date Considered
***Examiner:** Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.	

T[1] - Place a check mark in this area when an English language Translation is attached.

Electronic Patent Application Fee Transmittal

Application Number:	12307993
Filing Date:	17-Jun-2009
Title of Invention:	BREATHING ASSISTANCE APPARATUS
First Named Inventor/Applicant Name:	Alastair Edwin McAuley
Filer:	Robert J. Roby/Mary Gatus
Attorney Docket Number:	FPHCR.131NP

Filed as Large Entity

U.S. National Stage under 35 USC 371 Filing Fees

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Basic Filing:				
Pages:				
Claims:				
Miscellaneous-Filing:				
Petition:				
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				
Extension-of-Time:				

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Miscellaneous:				
Submission- Information Disclosure Stmt	1806	1	180	180
		Total in USD ($)		**180**

Electronic Acknowledgement Receipt	
EFS ID:	13903311
Application Number:	12307993
International Application Number:	
Confirmation Number:	7084
Title of Invention:	BREATHING ASSISTANCE APPARATUS
First Named Inventor/Applicant Name:	Alastair Edwin McAuley
Customer Number:	20995
Filer:	Robert J. Roby/Garett Gomez
Filer Authorized By:	Robert J. Roby
Attorney Docket Number:	FPHCR.131NP
Receipt Date:	04-OCT-2012
Filing Date:	17-JUN-2009
Time Stamp:	14:07:44
Application Type:	U.S. National Stage under 35 USC 371

Payment information:

Submitted with Payment	yes
Payment Type	Credit Card
Payment was successfully received in RAM	$180
RAM confirmation Number	837
Deposit Account	111410
Authorized User	KNOBBE MARTENS OLSON AND BEAR
The Director of the USPTO is hereby authorized to charge indicated fees and credit any overpayment as follows: Charge any Additional Fees required under 37 C.F.R. 1.492 (National application filing, search, and examination fees) Charge any Additional Fees required under 37 C.F.R. Section 1.17 (Patent application and reexamination processing fees)	

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Transmittal Letter	IDS_FPHCR_131NP.pdf	32368 c05312e0f5929d94db8cc6787299ff3839eb0a37	no	1
Warnings:					
Information:					
2	Information Disclosure Statement (IDS) Form (SB08)	IDS_LIST_FPHCR_131NP.pdf	35909 40aa5b606895ce5b2da3275238b96fd7ea030770	no	1
Warnings:					
Information:					
This is not an USPTO supplied IDS fillable form					
3	Non Patent Literature	NPL_1_FPHCR_131NP.pdf	64673 eff7b015c03ab20d3fc9e5a6433ee940aa349b23	no	3
Warnings:					
Information:					
4	Non Patent Literature	NPL_2_FPHCR_131NP.pdf	410199 13f17b12803159c757df2f30af8444e398bbc5d8	no	5
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Information:					
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Warnings:					
Information:					
		Total Files Size (in bytes):	573467		

This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.

New Applications Under 35 U.S.C. 111
If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

National Stage of an International Application under 35 U.S.C. 371
If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office
If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

INFORMATION DISCLOSURE STATEMENT

Applicant	:	Alastair Edwin McAuley, et al.
App. No.	:	12/307,993
Filed	:	January 17, 2009
For	:	BREATHING ASSISTANCE APPARATUS
Examiner	:	Douglas, Steven O
Art Unit	:	3771
Conf. No.	:	7084

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

References and Listing

Submitted herewith in the above-identified application is an Information Disclosure Statement listing references for consideration. Copies of any listed foreign and non-patent literature references are being submitted.

Timing of Disclosure

This Information Disclosure Statement is being filed after receipt of a first office action, but before the mailing date of a final action and before the mailing date of a Notice of Allowance. This Statement is accompanied by the fees set forth in 37 C.F.R. § 1.17(p). The Commissioner is hereby authorized to charge any additional fees which may be required or to credit any overpayment to Account No. 11-1410.

Respectfully submitted,

KNOBBE, MARTENS, OLSON & BEAR, LLP

Dated: October 4, 2012

By:/Robert J. Roby/
Robert J. Roby
Registration No. 44,304
Attorney of Record
Customer No. 20995
(949) 760-0404

14082164/100212

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants	:	Alastair Edwin McAuley, et al.
App. No.	:	12/307993
Filed	:	June 17, 2009
For	:	BREATHING ASSISTANCE APPARATUS
Examiner	:	Steven O. Douglas
Art Unit	:	3771
Conf No.	:	7084

RESPONSE TO OFFICE ACTION DATED JULY 5, 2012

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

In response to the Office Action of July 5, 2012, Applicants submit the following:

Amendments to the Claims are reflected in the listing of claims which begins on page 2 of this paper.

Remarks/Arguments begin on page 8 of this paper.

AMENDMENTS TO THE CLAIMS

Claims 1-37 (Canceled).

38. (**Currently Amended**) A patient interface comprising:

a mask assembly having:

a mask body including two nasal pillows extending from it, which in use rest in a substantially sealed manner against the nares of a user, the mask body sized and shaped to leave the mouth of the user uncovered by the mask body when in use;

a ring engaged with the mask body;

a plane substantially bisecting the ring, each of the two nasal pillows positioned on opposite sides of the plane;

an elbow rotatably engaged with the ring, the ring forming a socket into which a portion of the elbow fits to facilitate the rotatable engagement between the elbow and the ring, the elbow comprising a plurality of vent holes[[,]]; and

a tube or conduit extending from the elbow; and

a headgear assembly having:

two side straps that pass down the cheeks of the user to secure the mask body to a face of the user;

a top strap including a buckle configured to facilitate length adjustment of the top strap; and

a back strap adjustably connected to at least one of the top strap and the two side straps;

wherein the two side straps are configured to connect and disconnect with the mask assembly while the elbow remains rotatably engaged with the ring and the ring remains engaged with the mask body, wherein the mask assembly is configured to connect to only the two side straps; and

wherein the top strap connects only with one or more of the side straps and the back strap.

39. (**Original**) A patient interface as claimed in claim 38, wherein the mask body includes a lip and the ring includes a channel receiving the lip of the mask body.

40. (**Original**) A patient interface as claimed in claim 39, wherein the mask body comprises a molded elastomeric material.

41. (**Original**) A patient interface as claimed in claim 38, wherein the elbow is able to swivel in the ring such that the tubing is available to be adjacent to either side strap.

42. (**Original**) A patient interface as claimed in claim 38, wherein the ring comprises a hard plastic material.

43. (**Canceled**)

44. (**Canceled**)

45. (**Original**) A patient interface as claimed in claim 38 further comprising molded side arms extending away from the ring to connect with the side strap, the molded side arms connecting to the side straps that pass down the cheeks of the user.

46. (**Original**) A patient interface as claimed in claim 38, wherein, in use, gases flow from the tube or conduit, through the elbow, through the ring, through the mask body and through the pillows.

47. (**Currently Amended**) A patient interface comprising:

a mask assembly having a mask body, the mask body comprising a substantially flexible elastomeric material, the mask body comprising a first nasal pillow and a second nasal pillow, the first nasal pillow and the second nasal pillow being angled toward one another, the first nasal pillow comprising a first generally conical portion and a first generally cylindrical portion, the second nasal pillow comprising a second generally conical portion and a second generally cylindrical portion, the first nasal pillow comprising a first outlet opening and the second nasal pillow comprising a second outlet opening, the mask body also comprising a mask body inlet opening, the mask body inlet opening being spaced apart ~~form~~ from the first outlet opening and the second outlet opening, the mask body sized and shaped to leave the mouth of a user uncovered by the mask body when in use, the mask body inlet opening comprising a generally circular opening into the mask body, the mask assembly having a ring-like connector releasably connected to the mask body inlet, wherein a plane bisects the ring-like connector and the first nasal pillow is located on a side of the plane opposite the second nasal pillow;

a tube assembly configured to deliver airflow to the mask body, the tube assembly comprising a flexible conduit, the flexible conduit comprising a first end and a second end, the first end of the flexible conduit comprising a connector, the second end of the flexible conduit comprising an elbow, the elbow comprising a wall, the wall comprising a vent, the vent comprising a plurality of holes extending through the wall of the elbow, [[~~a~~]] the ring-like connector end being secured [[~~to a~~]]around an outer portion of the elbow, ~~the connector end being ring-like,~~ the elbow and the mask body being connected at least in part by the ring-like connector end such that airflow from the tube assembly can be directed from the elbow through the generally circular opening of the mask body and into the mask body, the elbow and the mask body being capable of rotating relative to each other; and

a headgear assembly configured to secure the mask body to a face of the user, the headgear assembly comprising a first side strap and a second side strap, [[~~and~~]] a top strap being connected to the first side strap and the second side strap, the top strap including a buckle configured to adjust a length of the top strap, and a back strap adjustably connected to at least one of the top strap, the first side strap, and the second side strap;

wherein the first side strap and the second side strap are configured to connect and disconnect with the mask assembly while the elbow is connected with the mask body, wherein the mask assembly is configured to connect to only two side straps, and wherein top strap connects only with one or more of the first side strap, the second side strap, and the back strap.

48. (**Currently Amended**) A patient interface comprising:

a mask assembly having:

a mask body comprising a molded elastomeric material, the mask body comprising two nasal pillows and a lip, the two nasal pillows, in use, resting in a substantially sealed manner against corresponding nares of a user, the mask body sized and shaped to leave the mouth of a user uncovered by the mask body when in use;

a ring of a hard plastic material engaged with the lip of the mask body;

a plane substantially bisecting the ring, each of the two nasal pillows positioned on opposite sides of the plane;

an elbow rotatably engaged with the ring such that a portion of the elbow is received within the ring, the elbow comprising a wall, a vent comprising a plurality of holes in the wall of the elbow; and

a tube or conduit extending from the elbow; and

a headgear assembly having:

a top strap removably connected to side straps, the side straps adapted to pass down the cheeks of the user, the elbow being able to swivel in the ring such that the ~~tubing~~ tube or conduit can be positioned adjacent to either side strap or can fall freely; and

a back strap adjustably connected with one or more of the top strap and the side straps;

wherein the side straps are configured to connect and disconnect with the mask body while elbow is rotatably engaged with the ring and the ring is engaged with the mask body, wherein the mask assembly is configured to connect to only two side straps, and wherein the top strap connects only with one or more of the side straps and the back strap.

49. (**Original**) A patient interface as claimed in claim 48, wherein the ring comprises a channel receiving the lip of the mask body.

50. (**Original**) A patient interface as claimed in claim 48, wherein the two nasal pillows are angled toward one another.

51. (**Original**) A patient interface as claimed in claim 48 further comprising two molded side arms that extend away from the mask body to connect with the two side straps.

52. (**Original**) A patient interface as claimed in claim 51, wherein the two side arms overlap a portion of the two side straps.

53. (**Original**) A patient interface as claimed in claim 48, wherein, in use, gases flow from the tube or conduit, through the elbow, through the ring, through the mask body and through the pillows.

54. (**Original**) A patient interface as claimed in claim 48, wherein each of the two nasal pillows comprises an inner profile and an outer profile, the inner profile defining an outlet of the nasal pillow, and the inner profile being offset inward relative to the outer profile.

55. (**Original**) A patient interface as claimed in claim 48, wherein each of the two nasal pillows comprises an inner profile and an outer profile, the inner profile defining an outlet of the nasal pillow, and the inner profile being offset downward relative to the outer profile such that, in use, the inner profile is offset toward the user's lip relative to the outer profile.

56. (**New**) A patient interface as claimed in claim 38, wherein the ring comprises a first wall and a second wall defining a space therebetween, and wherein a portion of the mask body is configured to removably attach to the ring via friction within the space and with the first wall and the second wall.

57. (**New**) A patient interface as claimed in claim 38, wherein the top strap is integrally formed with one or more of the side straps and the back strap.

58. (**New**) A patient interface as claimed in claim 57, wherein the top strap is integrally formed with one or more of the side straps.

59. (**New**) A patient interface as claimed in claim 47, wherein the top strap is integrally formed with one or more of the side straps and the back strap.

60. (**New**) A patient interface as claimed in claim 59, wherein the top strap is integrally formed with one or more of the side straps.

61. (**New**) A patient interface as claimed in claim 48, wherein the top strap is integrally formed with one or more of the side straps and the back strap.

62. (**New**) A patient interface as claimed in claim 61, wherein the top strap is integrally formed with one or more of the side straps.

63. (**New**) A patient interface as claimed in claim 38, wherein the top strap is releasably connected to one or more of the side straps and the back strap.

64. (**New**) A patient interface as claimed in claim 63, wherein the top strap is releasably connected to the back strap.

65. (**New**) A patient interface as claimed in claim 47, wherein the top strap is releasably connected to one or more of the side straps and the back strap.

66. (**New**) A patient interface as claimed in claim 65, wherein the top strap is releasably connected to the back strap.

67. (**New**) A patient interface as claimed in claim 48, wherein the top strap is releasably connected to one or more of the side straps and the back strap.

68. (**New**) A patient interface as claimed in claim 67, wherein the top strap is releasably connected to the back strap.

REMARKS

Claims 38-42 and 45-68 are currently pending. Claims 38, 47, and 48 are amended. Claims 43 and 44 have been cancelled without prejudice and Applicants reserve the right to pursue the subject matter in the cancelled claims at a later date. New Claims 56-68 have been added. No new matter is believed to have been introduced.

Claim Rejections – 35 U.S.C. § 102(e)

The Office Action rejected claims 38, 39, 41-44, 46, and 48-50 under 35 U.S.C. § 102(e) as being anticipated by U.S. Patent No. 7,219,669 ("Lovell"). The Applicants respectfully traverse this rejection because Lovell fails to disclose every element of at least the presently-amended Claims 38 and 48. See M.P.E.P. § 2131 (stating that in order to anticipate a claim, a prior art reference must identically teach every element of the claim).

Amended Claim 38 recites, among other limitations, "an elbow rotatably engaged with the ring such that a portion of the elbow is received **within the ring**" and "the mask assembly is configured to connect to **only two** side straps." Similarly, amended Claim 48 recites, among other limitations, "an elbow rotatably engaged with the ring such that a portion of the elbow is received **within the ring** … wherein the top strap connects only with one or more of the side straps and the back strap." Lovell does not disclose the limitations presently claimed.

In contrast, Lovell discloses a nasal mask 1 connected to a headgear apparatus 48 having two upper retention straps 44 and two lower retention straps 46 (total of 4 straps). Lovell, col. 6, ll. 18-48, Figure 5. Furthermore, Lovell discloses a "conduit elbow 14 that fits **onto** swivel connector 12." Lovell, col. 5, ll. 26-28, Figure 4B. Thus, Lovell fails to teach or suggest a nasal mask having "an elbow rotatably engaged with the ring such that a portion of the elbow is received **within the ring**" or a "mask assembly [that] is configured to connect to **only two** side straps."

FIG. 5

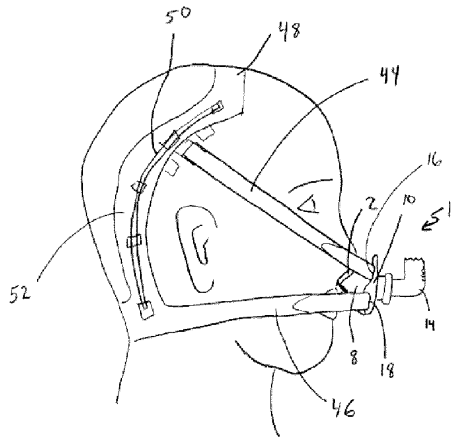
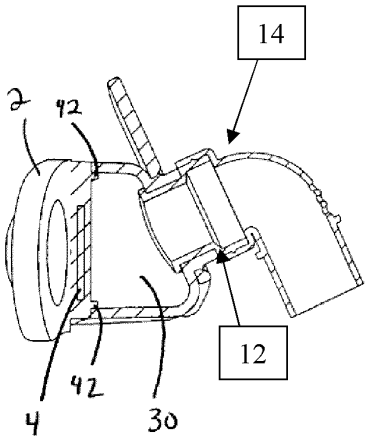


FIG. 4B



For the foregoing reasons, Applicants respectfully submit that independent Claims 38 and 48 are patentable over Lovell. Moreover, Applicants respectfully submit that all dependent claims that depend either directly or indirectly from Claims 38 or 48 are patentable over the cited art not only because they depend from an allowable independent claim, but also because each claim recites a unique combination of features not taught or suggested by the cited art.

Claim Rejections – 35 U.S.C. § 103(a)

The Office Action rejected Claim 40 under 35 U.S.C. § 103(a) as being unpatentable over Lovell and Claims 45, 47, 51, 52, 54, and 55 under 35 U.S.C. § 103(a) as being unpatentable over Lovell in view of U.S. Patent Pub. No. 2004/0226566 ("Gunaratnam"). Applicants respectfully traverse this rejections because Lovell fails to teach or suggest the elements of the claims and modifying Lovell in light of Gunaratnam would change the principle of operation of the mask disclosed in Lovell. See M.P.E.P. § 2143.01 (stating that "[i]f the proposed modification or combination of the prior art would change the principle of operation of the prior art invention being modified, then the teachings of the references are not sufficient to render the claims prima facie obvious").

Amended Claim 47 recites a "mask assembly is configured to connect to **only two** side straps." As explained above, Lovell discloses a mask having **four** side straps connected to the

mask body. Furthermore, Lovell teaches that the "four point restraining system allows for the nasal mask 1 to be securely positioned against the nares of a user." Lovell, col. 6, ll. 58-59, Figure 5. As such, removing two of the straps from the nasal mask of Lovell would change the principle of operation of Lovell by preventing the nasal mask from being securely positioned against the nares of a user. Such an elimination of straps "would require a substantial reconstruction and redesign of the elements shown in [Lovell] as well as a change in the basic principle under which the [Lovell] construction was designed to operate," thus rendering the combination of Lovell with Gunaratnam non-obvious. See M.P.E.P. § 2143.01 (citing *In re Ratti*, 270 F.2d 810, 813 (CCPA 1959)).

For these reasons, Applicants respectfully submit that it would not have been obvious for one of skill in the art to combine the teachings of Lovell with the teachings of Gunaratnam. As such, Applicants respectfully request withdrawal of the present rejection. Furthermore, Applicants respectfully submit that all dependent claims that depend either directly or indirectly from Claims 38, 47, or 48, including claims 40, 45, 51, 52, 54, and 55, are patentable over the cited art not only because they depend from an allowable independent claim, but also because each claim recites a unique combination of features not taught or suggested by the cited art.

Conclusion

For the foregoing reasons, Applicants respectfully submit that independent Claims 38, 47, and 48 are patentable over the cited art of record. Moreover, Applicants respectfully submit that dependent claims 39-42, 45, 46, and 49-68, which depend either directly or indirectly from Claims 38, 47, or 48, are patentable over the cited art not only because they depend from an allowable independent claim, but also because each claim recites a unique combination of features not taught or suggested by the cited art.

No Disclaimers or Disavowals

Although the present communication may include alterations to the application or claims, or characterizations of claim scope or referenced art, Applicants are not conceding in this application that previously pending claims are not patentable over the cited references. Rather, any alterations or characterizations are being made to facilitate expeditious prosecution of this

application. Applicants reserve the right to pursue at a later date any previously pending or other broader or narrower claims that capture any subject matter supported by the present disclosure, including subject matter found to be specifically disclaimed herein or by any prior prosecution. Accordingly, reviewers of this or any parent, child or related prosecution history shall not reasonably infer that Applicants have made any disclaimers or disavowals of any subject matter supported by the present application.

Co-Pending Applications of Assignee

Applicants wish to draw the Examiner's attention to the following co-pending applications of the present application's assignee.

Docket No.	Serial No.	Title	Filed
FPHCR.131C1	12/353640	Breathing Assistance Apparatus	01/14/09
FPHCR.131C2	12/633135	Breathing Assistance Apparatus	12/08/09

Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

KNOBBE, MARTENS, OLSON & BEAR, LLP

Dated: December 20, 2012

By: /Robert J. Roby/
Robert J. Roby
Registration No. 44,304
Attorney of Record
Customer No. 20995
(949) 760-0404

13923591

Electronic Patent Application Fee Transmittal

Application Number:	12307993
Filing Date:	17-Jun-2009
Title of Invention:	BREATHING ASSISTANCE APPARATUS
First Named Inventor/Applicant Name:	Alastair Edwin McAuley
Filer:	Robert J. Roby/Amy Hill
Attorney Docket Number:	FPHCR.131NP

Filed as Large Entity

U.S. National Stage under 35 USC 371 Filing Fees

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Basic Filing:				
Pages:				
Claims:				
Miscellaneous-Filing:				
Petition:				
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				
Extension-of-Time:				
Extension - 3 months with $0 paid	1253	1	1290	1290

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Miscellaneous:				
		Total in USD ($)		**1290**

Electronic Acknowledgement Receipt	
EFS ID:	14532454
Application Number:	12307993
International Application Number:	
Confirmation Number:	7084
Title of Invention:	BREATHING ASSISTANCE APPARATUS
First Named Inventor/Applicant Name:	Alastair Edwin McAuley
Customer Number:	20995
Filer:	Robert J. Roby/ADRIANA PEREZ
Filer Authorized By:	Robert J. Roby
Attorney Docket Number:	FPHCR.131NP
Receipt Date:	20-DEC-2012
Filing Date:	17-JUN-2009
Time Stamp:	17:18:24
Application Type:	U.S. National Stage under 35 USC 371

Payment information:

Submitted with Payment	yes
Payment Type	Credit Card
Payment was successfully received in RAM	$1290
RAM confirmation Number	5979
Deposit Account	111410
Authorized User	KNOBBE MARTENS OLSON AND BEAR
The Director of the USPTO is hereby authorized to charge indicated fees and credit any overpayment as follows: Charge any Additional Fees required under 37 C.F.R. 1.492 (National application filing, search, and examination fees) Charge any Additional Fees required under 37 C.F.R. Section 1.17 (Patent application and reexamination processing fees)	

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1		FPHCR-131NP_Response.pdf	429537 9dc652bfc8b7a7cef471dbba8d4e7f114989d6e1	yes	11
	Multipart Description/PDF files in .zip description				
	Document Description		**Start**	**End**	
	Amendment/Req. Reconsideration-After Non-Final Reject		1	1	
	Claims		2	7	
	Applicant Arguments/Remarks Made in an Amendment		8	11	
Warnings:					
Information:					
2	Fee Worksheet (SB06)	fee-info.pdf	30421 f642a83c1bbb3a7aca70d57430f1bd2f10bd1c50	no	2
Warnings:					
Information:					
		Total Files Size (in bytes):	459958		

This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.

New Applications Under 35 U.S.C. 111
If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

National Stage of an International Application under 35 U.S.C. 371
If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office
If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

PTO/SB/06 (07-06)
Approved for use through 1/31/2007. OMB 0651-0032
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

PATENT APPLICATION FEE DETERMINATION RECORD

Substitute for Form PTO-875

Application or Docket Number	Filing Date	☐ To be Mailed
12/307,993	06/17/2009	

APPLICATION AS FILED – PART I

	(Column 1)	(Column 2)	SMALL ENTITY ☐		OR	OTHER THAN SMALL ENTITY	
FOR	NUMBER FILED	NUMBER EXTRA	RATE ($)	FEE ($)		RATE ($)	FEE ($)
☐ BASIC FEE (37 CFR 1.16(a), (b), or (c))	N/A	N/A	N/A			N/A	
☐ SEARCH FEE (37 CFR 1.16(k), (i), or (m))	N/A	N/A	N/A			N/A	
☐ EXAMINATION FEE (37 CFR 1.16(o), (p), or (q))	N/A	N/A	N/A			N/A	
TOTAL CLAIMS (37 CFR 1.16(i))	minus 20 =	*	X $ =		OR	X $ =	
INDEPENDENT CLAIMS (37 CFR 1.16(h))	minus 3 =	*	X $ =			X $ =	
☐ APPLICATION SIZE FEE (37 CFR 1.16(s))	If the specification and drawings exceed 100 sheets of paper, the application size fee due is $250 ($125 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).						
☐ MULTIPLE DEPENDENT CLAIM PRESENT (37 CFR 1.16(j))							
* If the difference in column 1 is less than zero, enter "0" in column 2.			TOTAL			TOTAL	

APPLICATION AS AMENDED – PART II

AMENDMENT	12/20/2012	(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA	SMALL ENTITY RATE ($)	ADDITIONAL FEE ($)	OR	OTHER THAN SMALL ENTITY RATE ($)	ADDITIONAL FEE ($)
	Total (37 CFR 1.16(i))	* 29	Minus	** 32	= 0	X $ =		OR	X $62=	0
	Independent (37 CFR 1.16(h))	* 3	Minus	***3	= 0	X $ =		OR	X $250=	0
	☐ Application Size Fee (37 CFR 1.16(s))									
	☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))							OR		
						TOTAL ADD'L FEE		OR	TOTAL ADD'L FEE	0

AMENDMENT		(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA	RATE ($)	ADDITIONAL FEE ($)	OR	RATE ($)	ADDITIONAL FEE ($)
	Total (37 CFR 1.16(i))	*	Minus	**	=	X $ =		OR	X $ =	
	Independent (37 CFR 1.16(h))	*	Minus	***	=	X $ =		OR	X $ =	
	☐ Application Size Fee (37 CFR 1.16(s))									
	☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))							OR		
						TOTAL ADD'L FEE		OR	TOTAL ADD'L FEE	

* If the entry in column 1 is less than the entry in column 2, write "0" in column 3.

** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, enter "20".

*** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 3, enter "3".

The "Highest Number Previously Paid For" (Total or Independent) is the highest number found in the appropriate box in column 1.

Legal Instrument Examiner:
/KIM WATSON/

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

NOTICE OF ALLOWANCE AND FEE(S) DUE

20995 7590 01/28/2013

KNOBBE MARTENS OLSON & BEAR LLP
2040 MAIN STREET
FOURTEENTH FLOOR
IRVINE, CA 92614

EXAMINER
DOUGLAS, STEVEN O

ART UNIT	PAPER NUMBER
3771	

DATE MAILED: 01/28/2013

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
12/307,993	06/17/2009	Alastair Edwin McAuley	FPHCR.131NP	7084

TITLE OF INVENTION: BREATHING ASSISTANCE APPARATUS

APPLN. TYPE	SMALL ENTITY	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	NO	$1770	$300	$0	$2070	04/29/2013

THE APPLICATION IDENTIFIED ABOVE HAS BEEN EXAMINED AND IS ALLOWED FOR ISSUANCE AS A PATENT. PROSECUTION ON THE MERITS IS CLOSED. THIS NOTICE OF ALLOWANCE IS NOT A GRANT OF PATENT RIGHTS. THIS APPLICATION IS SUBJECT TO WITHDRAWAL FROM ISSUE AT THE INITIATIVE OF THE OFFICE OR UPON PETITION BY THE APPLICANT. SEE 37 CFR 1.313 AND MPEP 1308.

THE ISSUE FEE AND PUBLICATION FEE (IF REQUIRED) MUST BE PAID WITHIN THREE MONTHS FROM THE MAILING DATE OF THIS NOTICE OR THIS APPLICATION SHALL BE REGARDED AS ABANDONED. THIS STATUTORY PERIOD CANNOT BE EXTENDED. SEE 35 U.S.C. 151. THE ISSUE FEE DUE INDICATED ABOVE DOES NOT REFLECT A CREDIT FOR ANY PREVIOUSLY PAID ISSUE FEE IN THIS APPLICATION. IF AN ISSUE FEE HAS PREVIOUSLY BEEN PAID IN THIS APPLICATION (AS SHOWN ABOVE), THE RETURN OF PART B OF THIS FORM WILL BE CONSIDERED A REQUEST TO REAPPLY THE PREVIOUSLY PAID ISSUE FEE TOWARD THE ISSUE FEE NOW DUE.

HOW TO REPLY TO THIS NOTICE:

I. Review the SMALL ENTITY status shown above.

If the SMALL ENTITY is shown as YES, verify your current SMALL ENTITY status:

A. If the status is the same, pay the TOTAL FEE(S) DUE shown above.

B. If the status above is to be removed, check box 5b on Part B - Fee(s) Transmittal and pay the PUBLICATION FEE (if required) and twice the amount of the ISSUE FEE shown above, or

If the SMALL ENTITY is shown as NO:

A. Pay TOTAL FEE(S) DUE shown above, or

B. If applicant claimed SMALL ENTITY status before, or is now claiming SMALL ENTITY status, check box 5a on Part B - Fee(s) Transmittal and pay the PUBLICATION FEE (if required) and 1/2 the ISSUE FEE shown above.

II. PART B - FEE(S) TRANSMITTAL, or its equivalent, must be completed and returned to the United States Patent and Trademark Office (USPTO) with your ISSUE FEE and PUBLICATION FEE (if required). If you are charging the fee(s) to your deposit account, section "4b" of Part B - Fee(s) Transmittal should be completed and an extra copy of the form should be submitted. If an equivalent of Part B is filed, a request to reapply a previously paid issue fee must be clearly made, and delays in processing may occur due to the difficulty in recognizing the paper as an equivalent of Part B.

III. All communications regarding this application must give the application number. Please direct all communications prior to issuance to Mail Stop ISSUE FEE unless advised to the contrary.

IMPORTANT REMINDER: Utility patents issuing on applications filed on or after Dec. 12, 1980 may require payment of maintenance fees. It is patentee's responsibility to ensure timely payment of maintenance fees when due.

PART B - FEE(S) TRANSMITTAL

Complete and send this form, together with applicable fee(s), to: Mail **Mail Stop ISSUE FEE**
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450
or Fax (571)-273-2885

INSTRUCTIONS: This form should be used for transmitting the ISSUE FEE and PUBLICATION FEE (if required). Blocks 1 through 5 should be completed where appropriate. All further correspondence including the Patent, advance orders and notification of maintenance fees will be mailed to the current correspondence address as indicated unless corrected below or directed otherwise in Block 1, by (a) specifying a new correspondence address; and/or (b) indicating a separate "FEE ADDRESS" for maintenance fee notifications.

CURRENT CORRESPONDENCE ADDRESS (Note: Use Block 1 for any change of address)

20995 7590 01/28/2013
KNOBBE MARTENS OLSON & BEAR LLP
2040 MAIN STREET
FOURTEENTH FLOOR
IRVINE, CA 92614

Note: A certificate of mailing can only be used for domestic mailings of the Fee(s) Transmittal. This certificate cannot be used for any other accompanying papers. Each additional paper, such as an assignment or formal drawing, must have its own certificate of mailing or transmission.

Certificate of Mailing or Transmission

I hereby certify that this Fee(s) Transmittal is being deposited with the United States Postal Service with sufficient postage for first class mail in an envelope addressed to the Mail Stop ISSUE FEE address above, or being facsimile transmitted to the USPTO (571) 273-2885, on the date indicated below.

(Depositor's name)
(Signature)
(Date)

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
12/307,993	06/17/2009	Alastair Edwin McAuley	FPHCR.131NP	7084

TITLE OF INVENTION: BREATHING ASSISTANCE APPARATUS

APPLN. TYPE	SMALL ENTITY	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	NO	$1770	$300	$0	$2070	04/29/2013

EXAMINER	ART UNIT	CLASS-SUBCLASS
DOUGLAS, STEVEN O	3771	128-207180

1. Change of correspondence address or indication of "Fee Address" (37 CFR 1.363).

❑ Change of correspondence address (or Change of Correspondence Address form PTO/SB/122) attached.

❑ "Fee Address" indication (or "Fee Address" Indication form PTO/SB/47; Rev 03-02 or more recent) attached. **Use of a Customer Number is required.**

2. For printing on the patent front page, list

(1) the names of up to 3 registered patent attorneys or agents OR, alternatively,

(2) the name of a single firm (having as a member a registered attorney or agent) and the names of up to 2 registered patent attorneys or agents. If no name is listed, no name will be printed.

1 _____
2 _____
3 _____

3. ASSIGNEE NAME AND RESIDENCE DATA TO BE PRINTED ON THE PATENT (print or type)

PLEASE NOTE: Unless an assignee is identified below, no assignee data will appear on the patent. If an assignee is identified below, the document has been filed for recordation as set forth in 37 CFR 3.11. Completion of this form is NOT a substitute for filing an assignment.

(A) NAME OF ASSIGNEE (B) RESIDENCE: (CITY and STATE OR COUNTRY)

Please check the appropriate assignee category or categories (will not be printed on the patent) : ❑ Individual ❑ Corporation or other private group entity ❑ Government

4a. The following fee(s) are submitted:

❑ Issue Fee
❑ Publication Fee (No small entity discount permitted)
❑ Advance Order - # of Copies _____

4b. Payment of Fee(s): (**Please first reapply any previously paid issue fee shown above**)

❑ A check is enclosed.
❑ Payment by credit card. Form PTO-2038 is attached.
❑ The Director is hereby authorized to charge the required fee(s), any deficiency, or credit any overpayment, to Deposit Account Number _____ (enclose an extra copy of this form).

5. **Change in Entity Status** (from status indicated above)

❑ a. Applicant claims SMALL ENTITY status. See 37 CFR 1.27.

❑ b. Applicant is no longer claiming SMALL ENTITY status. See 37 CFR 1.27(g)(2).

NOTE: The Issue Fee and Publication Fee (if required) will not be accepted from anyone other than the applicant; a registered attorney or agent; or the assignee or other party in interest as shown by the records of the United States Patent and Trademark Office.

Authorized Signature _____ Date _____

Typed or printed name _____ Registration No. _____

This collection of information is required by 37 CFR 1.311. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, Virginia 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450.

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
12/307,993	06/17/2009	Alastair Edwin McAuley	FPHCR.131NP	7084

20995 7590 01/28/2013

KNOBBE MARTENS OLSON & BEAR LLP
2040 MAIN STREET
FOURTEENTH FLOOR
IRVINE, CA 92614

EXAMINER	
DOUGLAS, STEVEN O	

ART UNIT	PAPER NUMBER
3771	

DATE MAILED: 01/28/2013

Determination of Patent Term Adjustment under 35 U.S.C. 154 (b)
(application filed on or after May 29, 2000)

The Patent Term Adjustment to date is 612 day(s). If the issue fee is paid on the date that is three months after the mailing date of this notice and the patent issues on the Tuesday before the date that is 28 weeks (six and a half months) after the mailing date of this notice, the Patent Term Adjustment will be 612 day(s).

If a Continued Prosecution Application (CPA) was filed in the above-identified application, the filing date that determines Patent Term Adjustment is the filing date of the most recent CPA.

Applicant will be able to obtain more detailed information by accessing the Patent Application Information Retrieval (PAIR) WEB site (http://pair.uspto.gov).

Any questions regarding the Patent Term Extension or Adjustment determination should be directed to the Office of Patent Legal Administration at (571)-272-7702. Questions relating to issue and publication fee payments should be directed to the Customer Service Center of the Office of Patent Publication at 1-(888)-786-0101 or (571)-272-4200.

Privacy Act Statement

The Privacy Act of 1974 (P.L. 93-579) requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

The information provided by you in this form will be subject to the following routine uses:

1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether disclosure of these records is required by the Freedom of Information Act.
2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.
3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.
4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).
5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.
6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).
7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.
8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspection or an issued patent.
9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

Notice of Allowability	Application No.	Applicant(s)	
	12/307,993	MCAULEY ET AL.	
	Examiner	Art Unit	
	STEVEN DOUGLAS	3771	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to *papers filed 12/20/12*.

2. ☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on _____; the restriction requirement and election have been incorporated into this action.

3. ☒ The allowed claim(s) is/are *38-42 and 45-68*.

4. ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
   a) ☒ All b) ☐ Some* c) ☐ None of the:
      1. ☒ Certified copies of the priority documents have been received.
      2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
      3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

   * Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

5. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.

6. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
   (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
      1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
   (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.

   Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).

7. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
3. ☒ Information Disclosure Statements (PTO/SB/08), Paper No./Mail Date 10042012
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5. ☐ Notice of Informal Patent Application
6. ☐ Interview Summary (PTO-413), Paper No./Mail Date _____ .
7. ☐ Examiner's Amendment/Comment
8. ☐ Examiner's Statement of Reasons for Allowance
9. ☐ Other _____.

/Steven O. Douglas/
Primary Examiner
Art Unit: 3771

PTO/SB/08 Equivalent

INFORMATION DISCLOSURE STATEMENT BY APPLICANT	Application No.	12/307993
	Filing Date	June 17, 2009
	First Named Inventor	Alastair Edwin McAuley
	Art Unit	3771
(Multiple sheets used when necessary)	Examiner	Steven O. Douglas
SHEET 1 OF 1	Attorney Docket No.	FPHCR.131NP

U.S. PATENT DOCUMENTS					
Examiner Initials	Cite No.	Document Number *Number - Kind Code (if known)* Example: 1,234,567 B1	Publication Date MM-DD-YYYY	Name of Patentee or Applicant	Pages, Columns, Lines Where Relevant Passages or Relevant Figures Appear
	1	7,210,481	05-01-2007	Lovell et al.	

FOREIGN PATENT DOCUMENTS						
Examiner Initials	Cite No.	Foreign Patent Document *Country Code-Number-Kind Code* Example: JP 1234567 A1	Publication Date MM-DD-YYYY	Name of Patentee or Applicant	Pages, Columns, Lines Where Relevant Passages or Relevant Figures Appear	T[1]

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials	Cite No.	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T[1]
	2	Examination Report; Australian Application No. 2007273324; dated May 22, 2012; 3 pages	
	3	English Translation of Chinese Examination Report; 5 pages (no date)	

14081233
100212

Examiner Signature	/Steven Douglas/	Date Considered	01/14/2013

***Examiner:** Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

T[1] - Place a check mark in this area when an English language Translation is attached.

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /SD/

Search Notes	Application/Control No.	Applicant(s)/Patent under Reexamination
	12/307,993	MCAULEY ET AL.
	Examiner	Art Unit
	STEVEN DOUGLAS	3771

SEARCHED			
Class	Subclass	Date	Examiner
all	previous	1/14/2013	SD

INTERFERENCE SEARCHED			
Class	Subclass	Date	Examiner
all	**previous**	1/14/2013	**SD**

SEARCH NOTES (INCLUDING SEARCH STRATEGY)		
	DATE	EXMR
PG PUB	1/14/2013	SD

Index of Claims	Application/Control No.	Applicant(s)/Patent Under Reexamination
	12307993	MCAULEY ET AL.
	Examiner	Art Unit
	STEVEN DOUGLAS	3771

✓	Rejected	-	Cancelled	N	Non-Elected	A	Appeal
=	Allowed	÷	Restricted	I	Interference	O	Objected

☒ Claims renumbered in the same order as presented by applicant ☐ CPA ☐ T.D. ☐ R.1.47

CLAIM		DATE								
Final	Original	06/28/2012	01/14/2013							
	1	-	-							
	2	-	-							
	3	-	-							
	4	-	-							
	5	-	-							
	6	-	-							
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Index of Claims	Application/Control No.	Applicant(s)/Patent Under Reexamination
	12307993	MCAULEY ET AL.
	Examiner	Art Unit
	STEVEN DOUGLAS	3771

✓	Rejected	-	Cancelled	N	Non-Elected	A	Appeal
=	Allowed	÷	Restricted	I	Interference	O	Objected

☒ Claims renumbered in the same order as presented by applicant ☐ CPA ☐ T.D. ☐ R.1.47

CLAIM		DATE								
Final	Original	06/28/2012	01/14/2013							
	37	-	-							
	38	✓	=							
	39	✓	=							
	40	✓	=							
	41	✓	=							
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Issue Classification	Application/Control No.	Applicant(s)/Patent Under Reexamination
	12307993	MCAULEY ET AL.
	Examiner	Art Unit
	STEVEN DOUGLAS	3771

ORIGINAL		INTERNATIONAL CLASSIFICATION										
CLASS	SUBCLASS	CLAIMED					NON-CLAIMED					
128	207.18	A	6	1	M	11 / 00 (2006.01.01)						

CROSS REFERENCE(S)					
CLASS	SUBCLASS (ONE SUBCLASS PER BLOCK)				
128	206.24	207.11	207.13		

☒ Claims renumbered in the same order as presented by applicant ☐ CPA ☐ T.D. ☐ R.1.47

Final	Original	Final	Original	Final	Original	Final	Original	Final	Original	Final	Original	Final	Original	Final	Original

NONE		Total Claims Allowed:	
(Assistant Examiner)	(Date)	29	
/STEVEN DOUGLAS/ Primary Examiner.Art Unit 3771	1/14/13	O.G. Print Claim(s)	O.G. Print Figure
(Primary Examiner)	(Date)	1	3

PART B - FEE(S) TRANSMITTAL

Complete and send this form, together with applicable fee(s), to: Mail **Mail Stop ISSUE FEE**
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450
or Fax (571)-273-2885

INSTRUCTIONS: This form should be used for transmitting the ISSUE FEE and PUBLICATION FEE (if required). Blocks 1 through 5 should be completed where appropriate. All further correspondence including the Patent, advance orders and notification of maintenance fees will be mailed to the current correspondence address as indicated unless corrected below or directed otherwise in Block 1, by (a) specifying a new correspondence address; and/or (b) indicating a separate "FEE ADDRESS" for maintenance fee notifications.

CURRENT CORRESPONDENCE ADDRESS (Note: Use Block 1 for any change of address)

20995 7590 01/28/2013
KNOBBE MARTENS OLSON & BEAR LLP
2040 MAIN STREET
FOURTEENTH FLOOR
IRVINE, CA 92614

Note: A certificate of mailing can only be used for domestic mailings of the Fee(s) Transmittal. This certificate cannot be used for any other accompanying papers. Each additional paper, such as an assignment or formal drawing, must have its own certificate of mailing or transmission.

Certificate of Mailing or Transmission
I hereby certify that this Fee(s) Transmittal is being deposited with the United States Postal Service with sufficient postage for first class mail in an envelope addressed to the Mail Stop ISSUE FEE address above, or being facsimile transmitted to the USPTO (571) 273-2885, on the date indicated below.

(Depositor's name)
(Signature)
(Date)

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
12/307,993	06/17/2009	Alastair Edwin McAuley	FPHCR.131NP	7084

TITLE OF INVENTION: BREATHING ASSISTANCE APPARATUS

APPLN. TYPE	SMALL ENTITY	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	NO	~~$1770~~ $1780	$300	$0	~~$2070~~ $2080	04/29/2013

EXAMINER	ART UNIT	CLASS-SUBCLASS
DOUGLAS, STEVEN O	3771	128-207180

1. Change of correspondence address or indication of "Fee Address" (37 CFR 1.363).
☐ Change of correspondence address (or Change of Correspondence Address form PTO/SB/122) attached.
☐ "Fee Address" indication (or "Fee Address" Indication form PTO/SB/47; Rev 03-02 or more recent) attached. **Use of a Customer Number is required.**

2. For printing on the patent front page, list
(1) the names of up to 3 registered patent attorneys or agents OR, alternatively,
(2) the name of a single firm (having as a member a registered attorney or agent) and the names of up to 2 registered patent attorneys or agents. If no name is listed, no name will be printed.

1 Knobbe, Martens
2 Olson & Bear LLP
3

3. ASSIGNEE NAME AND RESIDENCE DATA TO BE PRINTED ON THE PATENT (print or type)

PLEASE NOTE: Unless an assignee is identified below, no assignee data will appear on the patent. If an assignee is identified below, the document has been filed for recordation as set forth in 37 CFR 3.11. Completion of this form is NOT a substitute for filing an assignment.

(A) NAME OF ASSIGNEE: Fisher & Paykel Healthcare Limited
(B) RESIDENCE: (CITY and STATE OR COUNTRY): Auckland, New Zealand

Please check the appropriate assignee category or categories (will not be printed on the patent) : ☐ Individual ☒ Corporation or other private group entity ☐ Government

4a. The following fee(s) are submitted:
☒ Issue Fee
☒ Publication Fee (No small entity discount permitted)
☐ Advance Order - # of Copies _____

4b. Payment of Fee(s): (**Please first reapply any previously paid issue fee shown above**)
☐ A check is enclosed.
☐ Payment by credit card. Form PTO-2038 is attached.
☒ The Director is hereby authorized to charge ~~the required fee(s)~~, any deficiency, or credit any overpayment, to Deposit Account Number 11-1410 (enclose an extra copy of this form).

5. **Change in Entity Status** (from status indicated above)
☐ a. Applicant claims SMALL ENTITY status. See 37 CFR 1.27.
☐ b. Applicant is no longer claiming SMALL ENTITY status. See 37 CFR 1.27(g)(2).

NOTE: The Issue Fee and Publication Fee (if required) will not be accepted from anyone other than the applicant; a registered attorney or agent; or the assignee or other party in interest as shown by the records of the United States Patent and Trademark Office.

Authorized Signature /Benjamin P. Johnson/ Date April 22, 2013

Typed or printed name Benjamin P. Johnson Registration No. 70,348

This collection of information is required by 37 CFR 1.311. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, Virginia 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450.

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

Electronic Patent Application Fee Transmittal

Application Number:	12307993
Filing Date:	17-Jun-2009
Title of Invention:	BREATHING ASSISTANCE APPARATUS
First Named Inventor/Applicant Name:	Alastair Edwin McAuley
Filer:	Benjamin Paul Johnson/Amy Rodriguez
Attorney Docket Number:	FPHCR.131NP

Filed as Large Entity

U.S. National Stage under 35 USC 371 Filing Fees

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Basic Filing:				
Pages:				
Claims:				
Miscellaneous-Filing:				
Petition:				
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				
Utility Appl Issue Fee	1501	1	1780	1780
Publ. Fee- Early, Voluntary, or Normal	1504	1	300	300

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Extension-of-Time:				
Miscellaneous:				
			Total in USD ($)	**2080**

Electronic Acknowledgement Receipt	
EFS ID:	15576357
Application Number:	12307993
International Application Number:	
Confirmation Number:	7084
Title of Invention:	BREATHING ASSISTANCE APPARATUS
First Named Inventor/Applicant Name:	Alastair Edwin McAuley
Customer Number:	20995
Filer:	Benjamin Paul Johnson/Gustavo Lopez
Filer Authorized By:	Benjamin Paul Johnson
Attorney Docket Number:	FPHCR.131NP
Receipt Date:	22-APR-2013
Filing Date:	17-JUN-2009
Time Stamp:	15:35:26
Application Type:	U.S. National Stage under 35 USC 371

Payment information:

Submitted with Payment	yes
Payment Type	Credit Card
Payment was successfully received in RAM	$2080
RAM confirmation Number	2122
Deposit Account	111410
Authorized User	KNOBBE MARTENS OLSON AND BEAR
The Director of the USPTO is hereby authorized to charge indicated fees and credit any overpayment as follows: Charge any Additional Fees required under 37 C.F.R. 1.492 (National application filing, search, and examination fees) Charge any Additional Fees required under 37 C.F.R. Section 1.17 (Patent application and reexamination processing fees)	

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Issue Fee Payment (PTO-85B)	2013-04-22-Issue_Fee-FPHCR131NP.pdf	92114 c922bb0b5fbe70a5d1c2ed6a9c2afd219f48f884	no	1
Warnings:					
Information:					
2	Fee Worksheet (SB06)	fee-info.pdf	32134 d4a2c39ea6f58d434e1287a45d38118d1f6eedbb	no	2
Warnings:					
Information:					
		Total Files Size (in bytes):	124248		

This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.

New Applications Under 35 U.S.C. 111
If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

National Stage of an International Application under 35 U.S.C. 371
If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office
If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

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APPLICATION NO.	ISSUE DATE	PATENT NO.	ATTORNEY DOCKET NO.	CONFIRMATION NO.
12/307,993	05/21/2013	8443807	FPHCR.131NP	7084

20995 7590 05/01/2013

KNOBBE MARTENS OLSON & BEAR LLP
2040 MAIN STREET
FOURTEENTH FLOOR
IRVINE, CA 92614

ISSUE NOTIFICATION

The projected patent number and issue date are specified above.

Determination of Patent Term Adjustment under 35 U.S.C. 154 (b)
(application filed on or after May 29, 2000)

The Patent Term Adjustment is 932 day(s). Any patent to issue from the above-identified application will include an indication of the adjustment on the front page.

If a Continued Prosecution Application (CPA) was filed in the above-identified application, the filing date that determines Patent Term Adjustment is the filing date of the most recent CPA.

Applicant will be able to obtain more detailed information by accessing the Patent Application Information Retrieval (PAIR) WEB site (http://pair.uspto.gov).

Any questions regarding the Patent Term Extension or Adjustment determination should be directed to the Office of Patent Legal Administration at (571)-272-7702. Questions relating to issue and publication fee payments should be directed to the Application Assistance Unit (AAU) of the Office of Data Management (ODM) at (571)-272-4200.

APPLICANT(s) (Please see PAIR WEB site http://pair.uspto.gov for additional applicants):

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