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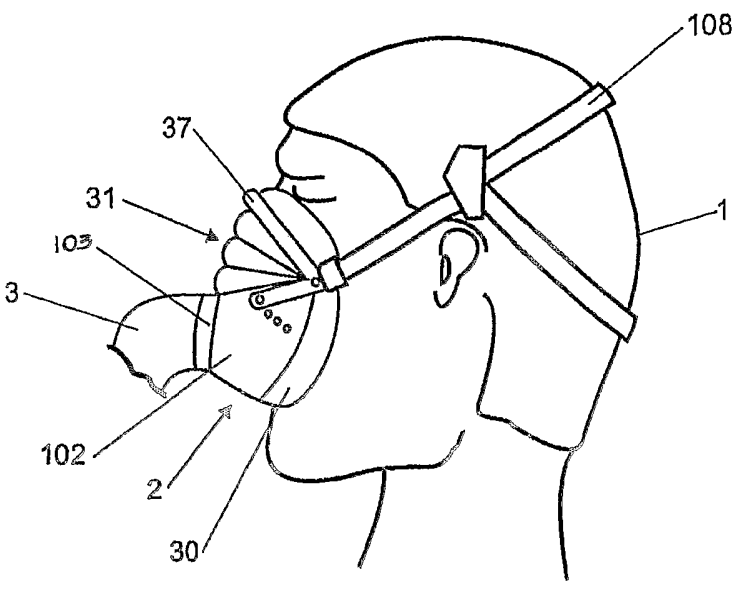
(54) Title: PATIENT INTERFACE



(57) Abstract: The present invention relates to patient interfaces (2) for use in respiratory therapy. In particular the invention relates to an interface (2) that can be adjusted to fit the contours of patient's face (1). The interface (2) includes a means for adjusting the spacing between the patient interface seal (30) and the face of the patient (1). This means for adjusting is generally an adjustable portion (31) that is an integral part of the seal (30) and interface body (102). The adjustable portion (31) can be manually moved to a position that will accommodate different sized and shaped patients (1). The adjustable portion (31) may be located on the forehead, upper lip or chin sections of the interface (2). Once adjusted the adjustable portion (31) can be locked into the desired position. The adjustable portion (31) may be a series of moveable baffles or a thin membrane that can be flexed, allowing the sealing portion (30) to be altered.

WO 2004/071565 A1

"PATIENT INTERFACE"

TECHNICAL FIELD

This invention relates to the delivery of respiratory gases, and in particular to patient interfaces for providing gases to patients requiring respiratory therapy.

BACKGROUND ART

In the art of respiration devices, there are well known a variety of patient interfaces which cover the nose and/or mouth of a human patient 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 for consumption by the patient. The uses for such interfaces range from high altitude breathing (i.e. aviation applications) to mining and fire fighting applications, to various medical diagnostic and therapeutic applications.

One requisite of such respiratory interfaces has been that they provide an effective seal against the patient's face to prevent leakage of the gas being supplied. Commonly, in prior configurations, a good interface face seal has been attained in many instances only with considerable discomfort for the patient. This problem is most crucial in those applications, especially medical applications, which require the patient to wear such an interface continuously for hours or perhaps even days. In such situations, the patient will not tolerate the interface for long durations and optimum therapeutic or diagnostic objectives thus will not be achieved, or will be achieved with great difficulty and considerable patient discomfort.

Commonly with prior art designs there is an inability to seal effectively around the nasal region for different sized patients. Prior art attempts to overcome this includes Japanese patent publication number 1000397 and United States patent publication number 5074297.

DISCLOSURE OF INVENTION

It is an object of the present invention to provide an interface which 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 the present invention consists in a patient interface for delivery of gases to a patient comprising:

an interface body receiving gases and supplying gases to said patient,

sealing means for sealing said body to the face of a patient, and

an adjustable portion associated with said sealing means to adjust the spacing of said seal with respect to the face of said patient.

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.

BRIEF DESCRIPTION OF THE DRAWINGS

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

Figure 1 is a block diagram of a humidified continuous positive airway pressure (CPAP system) as might be used in conjunction with the patient interface present invention.

Figure 2 is an illustration of the patient interface in use according to the preferred embodiment of the present invention.

Figure 3 is a side view of the patient interface showing multiple locator positions according to the preferred embodiment of the present invention.

Figure 4 is a side view of the patient interface showing the multiple locator positions according to another embodiment of the present invention.

Figure 5 is plan view of the means for adjusting or baffles of the present invention when removed from the patient interface of the present invention.

Figure 6 is a side view of an alternative embodiment of the patient interface of the present invention, where the means for adjusting is a thin flexible membrane.

MODES FOR CARRYING OUT THE INVENTION

The present invention provides improvements in the field of patient interfaces for use in respiratory therapy. In particular an interface that can manually be adjusted to fit the contours of the patient's face which as a result is more comfortable for the patient to wear and reduces leakage as compared with interfaces of the prior art. It will be appreciated that while a patient interface is described in the preferred embodiment in use in a humidified CPAP system, the interface can be used in respiratory care generally or with a ventilator. It will be appreciated the present invention could equally be used with any form of positive pressure respiratory therapy.

With reference to Figure 1 a humidified Continuous Positive Airway Pressure (CPAP) system is shown in which a patient 1 is receiving humidified and pressurised gases through a 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. Inspiratory conduit 3 is connected to the outlet 4 of a humidification

chamber 5 which contains a volume of water 6. Inspiratory conduit 3 may contain heating means or heater wires (not shown) which heat the walls of the conduit to reduce condensation of humidified gases within the conduit. Humidification chamber 6 is preferably formed from a plastics material and may have a highly heat conductive base (for example an aluminum base) which is in direct contact with a heater plate 7 of humidifier 8. Humidifier 8 is provided with control means or electronic controller 9 which may comprise a microprocessor based controller executing computer software commands stored in associated memory.

Controller 9 receives input from sources such as a patient input means or dial 10 through which a patient 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 may also receive input from other sources; for example temperature and/or flow velocity sensors 11 and 12 through connector 13 and heater plate temperature sensor 14. In response to the patient set humidity or temperature value input via dial 10 and the other inputs, controller 9 determines when (or to what level) to energise heater plate 7 to heat the water 6 within humidification chamber 5. As the volume of water 6 within 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 which enters the chamber through inlet 16.

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

It will be appreciated that the mask referred to may be a nasal mask, full face mask or any other type of mask. Referring to Figure 2, the mask 2 when in operation is positioned around the nose and/or mouth of the patient 1 with the headgear 108 secured around the back of the head of the patient 1. The restraining force from the headgear 108 on the hollow body 102 ensures enough compressive force on the mask cushion or seat 30, to provide an effective seal against the patient's face. The mask 2 includes a hollow body 102 with an inlet 103 connected to the inspiratory conduit 3.

The headgear 108 can be attached to the mask 2 by any method as is provided by the mask. The headgear 108 is securely fixed to the mask, as shown in Figure 2; alternately the headgear 108 is slidably, pivotably or flexibly connected to the mask 2. An example sliding connection is disclosed in US Application Number 09/881633. An example of pivoting

connection is given in US Patent Number 5662010. The contents of each of these are incorporated herein by reference.

The hollow body 102 is constructed of a relatively inflexible material for example, polycarbonate plastic. Such a material would provide the requisite rigidity as well as being transparent and a relatively good insulator. The expiratory gases can be expelled through a valve (not shown) in the mask, a further expiratory conduit (not shown), or any other such method as is known in the art. On the periphery of the hollow body 102 is a seal 30.

The seal 30 is preferably manufactured as one piece and may be made from any suitable gas tight, tough, flexible material which does not irritate the human skin on contact. The seal material must be very thin (typically 0.1 - 0.6 mm thick) so that it moulds easily to the contours of the face. Silicone rubber has been found to be a suitable material, but other appropriate materials may be used, such as foam or other rubber materials. The seal 30 is larger overall than the internal dimensions of the hollow body 102, so that in use the edges of the seal extend beyond the mask to form an airtight seal with the patient's 1 face.

The patient interface 2 of the present invention is a mask that includes a means for adjusting the spacing between the mask seal and the face of a patient. This means for adjusting is generally an adjustable portion 31 that is an integral part of the seal 30 and mask body 102. The adjustable portion 31 is designed to move and fix into a various number of positions so to accommodate facial features of a patient 1. For example, if a patient has a high bridge nose, a normal mask will not fit properly around their nose, therefore leaks may occur and it will be uncomfortable for the patient to wear. In this invention, the adjustable portion 31 can be manually moved to a position that will accommodate the patient's high-bridged nose. This eliminates the possibility of leaks and increases the comfort for the patient 1. The adjustable portion 31 may be located on the forehead, upper lip or chin sections of the mask 2. In Figure 2, the adjustable portion 31 is a set of baffles located in the nasal bridge region of the mask 2. In use, when the mask 2 is placed on the patient's face. If the mask 2 does not fit the patient, for example the bridge of the patient's nose pushes the mask 2 off the patient's face; the fitting mechanism 31 may be manually adjusted by the patient or other person to suit the patient. In this example, the bellows may be retracted to move the top of the seal 30 off the patient's face by a predetermined level. The adjustable portion 31 will then be locked into the desired position. The structure of the adjustable portion 31 will now be described.

Figure 3 shows a nasal mask 3 of the preferred embodiment. In this embodiment, the adjustable portion 31 is located on the nasal bridge region of the mask 2. The adjustable

portion 31 is comprised of a series of baffles 33, 34, 35, a locking member 32 and locators 36a to 36d, (of which only one of two sets is shown). The baffles 33, 34, 35 are preferably manufactured from the same flexible material as the seal 30 and can be manufactured to be an integral part of the seal 30. Alternately the baffles 33, 34, 35 are attached to the seal 30 in a flexible manner.

The seal 30 is very flexible; the seal 30 conforms readily to the contours of the patient's face and forms an effective seal whilst applying a relatively light and uniform pressure to the face. The rigid or semi rigid material of the shell 102 provides support for a major proportion of the seal 30.

The baffles 33, 34, 35 are of a substantially similar shape; for this description only one baffle 33 will be described in detail, but the same description will apply to the baffles 33, 34, 35. In Figure 3, the baffle 33 has a profile similar to that of a semicircle. As shown in Figure 5, the baffle 33 extends between either sides of the rigid shell 102. The result of this is a wider midsection compared to the outer edges of the baffles 33. The outer edges and one side of the midsection of the baffle 33 are connected to the rigid shell 102 while the mid section of the baffle 33 is connected to the next baffle 34. Similarly baffle 34 is connected to baffle 35 and baffle 35 is connected to the seal 30. This allows the baffles 33, 34, 35 to be compressed and extended in a concertina-like fashion.

A locking member 32 is disposed on the exterior of the rigid shell 102 and connected to the end baffle 35. The locking member 32 is preferably made from a lightweight resilient plastic. The locking 32 member is comprised a locking arm 37 that extends between either side of the rigid shell 102, two locating arms 38 (of which only one of two is shown) located on either side of the rigid shell 102, pivot points 40a, 40b (of which only one 40a is shown in Figure 3) and locking points 41 (of which only one of two is shown). The locking arm 37 sits in the junction between the seal 30, and the baffle 35 connected to the seal 30. The locking arm 37 is connected to the mask 2 by way of pivot points 40a, 40b. The pivot points 40a, 40b are located on either side of the rigid shell 102 near the ends of the baffles 33, 34, 35 and the seal 30. Reference will be made to one half of the mask 2 as shown in Figure 3, but also applies to the other side of the mask 2 which is not shown. Extending from both pivot points 40 are two locating arms 38. The locating arm 38 extends at approximately a 60 degree angle from the locking arm 37 and is connected to and made from the same material as the locking arm 37. At the furthest end of the locating arms 38 away from the pivot point 40a, is a locking point 41. The locking points 41 are holes in the locating arm 38 and is adapted to connect to locators 36a to 36d on the rigid shell 102.

The locators 36a to 36d are plastic protrusions that extend from the rigid shell 102 and are able to be connected to the locking point 41. In the preferred embodiment there are four locators 36a to 36d on each side of the rigid shell 102, but in alternate embodiments there may be more or less locators. The locators 36a to 36d are matched in position on the shell 102 to the locators on the other side of the mask (not shown). The locators 36a to 36d are uniformly spread across the each side of the shell 102. They are spread in a fashion so that when in use, each locator 36a to 36d provides a different shape to the seal 30 of mask 2.

In order to lock the baffles in a particular position the locking point 41 is clipped onto one of the protrusions of the locator's 36a to 36d. In addition to locking the mask 2 into a predetermined shape, as dictated by the number and position of the plastic protrusions 36a to36d, the mask 2 may also be locked into an infinite number of positions.

Figure 4 shows the mask 2' of an alternate embodiment of the present invention. In this embodiment, the mask 2' is a full face mask with the adjustable portion 31' located at the nasal bridge region of the mask 2'. The adjustable portion 31' is comprised of a series of baffles 33', 34', 35' and a locking member 32'. The baffles 33', 34', 35' are the same as described previously. In this embodiment, the locking member 32' is attached to the mask 2' at three positions, at the pivot points 40', locking points 41', and at the top of the seal 30'.

The following description is made with reference to one half of the mask 2', as shown in Figure 4 but also applies to the other side of the mask 2' that is not shown in the figures.

The locking member 32' is comprised of a locating arm 38', a locking point 41', a pivot point 40' and a support arm 42'. Support arm 42' runs perpendicular to both the baffles 33', 34', 35', and extends perpendicularly away from the junction between the locating arms 38'. The end of the support arm 42' is connected the top of the seal 30'. The locating arm 38' extends over the top of the baffles 33', 34', 35' between the pivot points 40'. Pivot point 40' is located on the shell 102' near the junction between the outer edges of the baffles 33', 34', 35' and the seal 30'. The operation of locking the adjustable portion 31' is the same as described above.

The baffles 33', 34', 35' as described above may vary in number. The preferred embodiment of the mask of the present invention has been described with reference to three baffles, but it is envisioned that there can be a greater or fewer number of baffles present on the mask 2'.

In alternate forms the baffles may be made from rigid material, for example the same material as the shell 102' and flexibly connected together to create flexible baffles.

A further alternative embodiment of the mask is shown in Figure 6, where the means

for adjusting or adjustable portion on the mask 50 is a flexible portion 51 that is not baffles as described above, but a single thin membrane 51. This thin membrane 51 may be manufactured in same material that the seal 30 (see Figure 3) is manufactured from. Alternately the membrane 51 may be manufactured from other appropriate flexible and thin materials. The mask will generally function in the same way as previously described. For example, in order to adjust the seal so as to reduce the spacing between the mask seal 54 and the face of a patient the locking arm 53 may be moved and the membrane 51 will flex inwardly and shift into a position as shown by the dashed line 52.

Further embodiments of the mask of the present invention could include apparatus and a method for creating a continuous locking mechanism. For example, locators are connected to form a long continuous protrusion. Locking points are modified to slide along this continuous protrusion and lock into position wherever the patient desires.

The above described patient interfaces are preferably supported by conventional strapping (not shown) secured to the edges of the interface body in known manners.

WE CLAIM:

1. A patient interface for delivery of gases to a patient comprising:
an interface body receiving gases and supplying gases to said patient,
sealing means for sealing said body to the face of a patient, and
an adjustable portion associated with said sealing means to adjust the spacing of said seal with respect to the face of said patient.

2. A patient interface for delivery of gases to a patient according to claim 1 wherein said sealing means is a flexible cushion.

3. A patient interface for delivery of gases to a patient according to claims 1 or 2 wherein said adjusting portion is connected to said interface body and said sealing means.

4. A patient interface for delivery of gases to a patient according to any one of claims 1 to 3 wherein said adjustable portion includes a locking mechanism configured to selectively lock said adjustable portion in any of a predetermined range of positions.

5. A patient interface for delivery of gases to a patient according to claims 1 or 4 wherein said adjustable portion is adjacent the nasal region of said patient in use.

6. A patient interface for delivery of gases to a patient according to any one of claims 1 to 5 wherein said adjustable portion is at least two baffles.

7. A patient interface for delivery of gases to a patient according to any one of claims 1 to 5 wherein said adjustable portion is a thin membrane.

8. A patient interface for delivery of gases to a patient as herein described with reference to the accompanying figures.

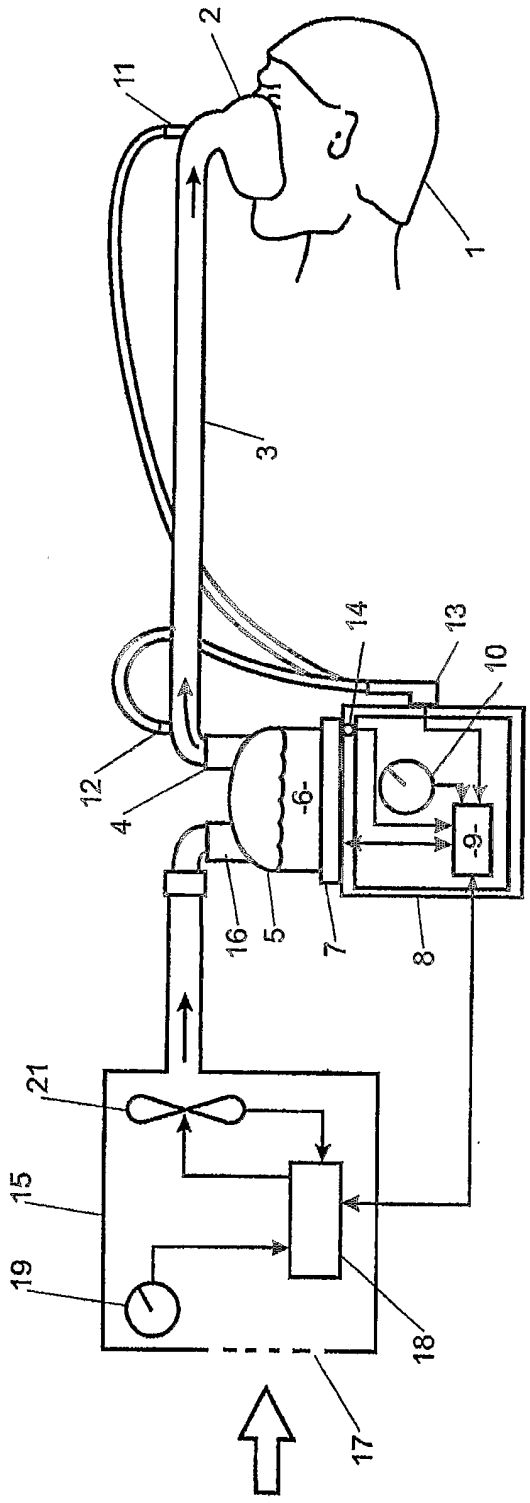


FIGURE 1

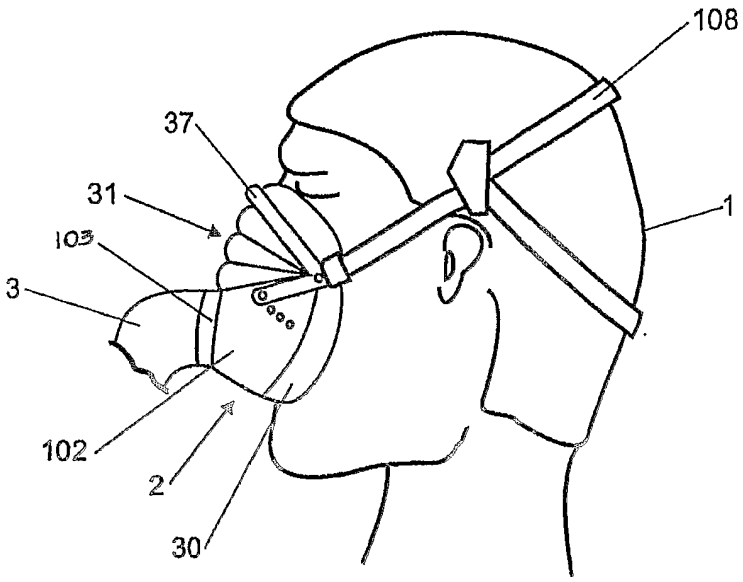


FIGURE 2

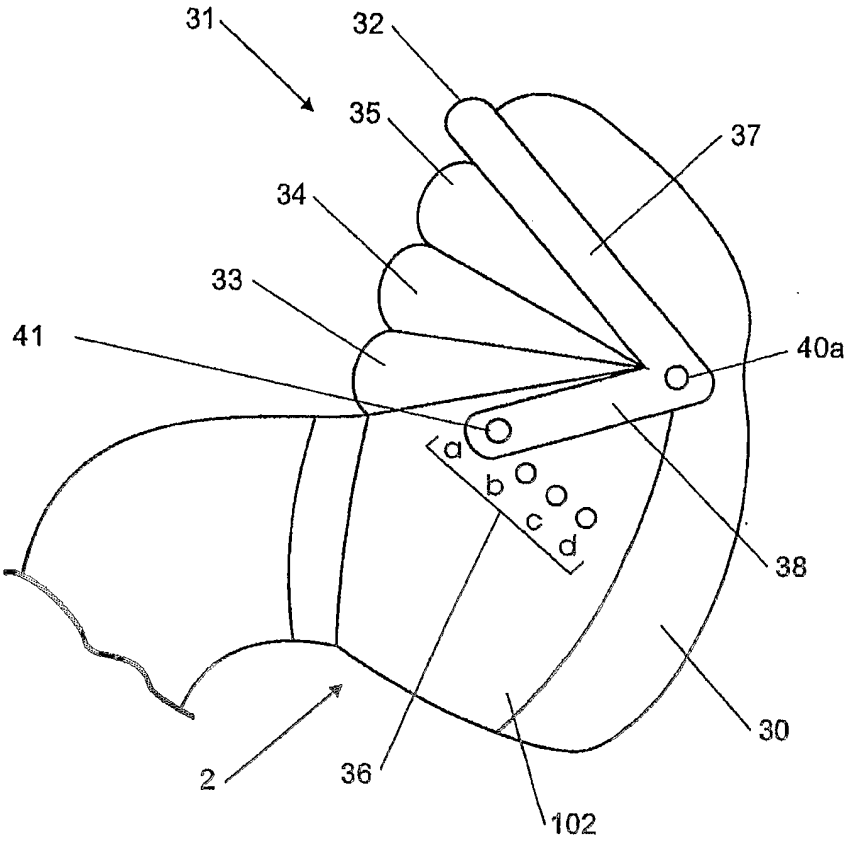


FIGURE 3

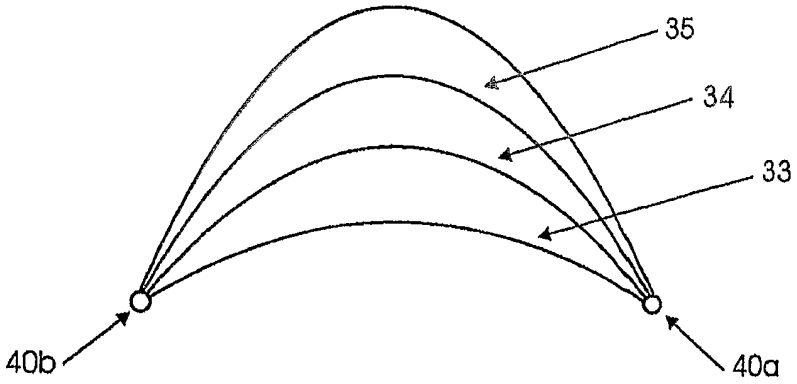


FIGURE 5

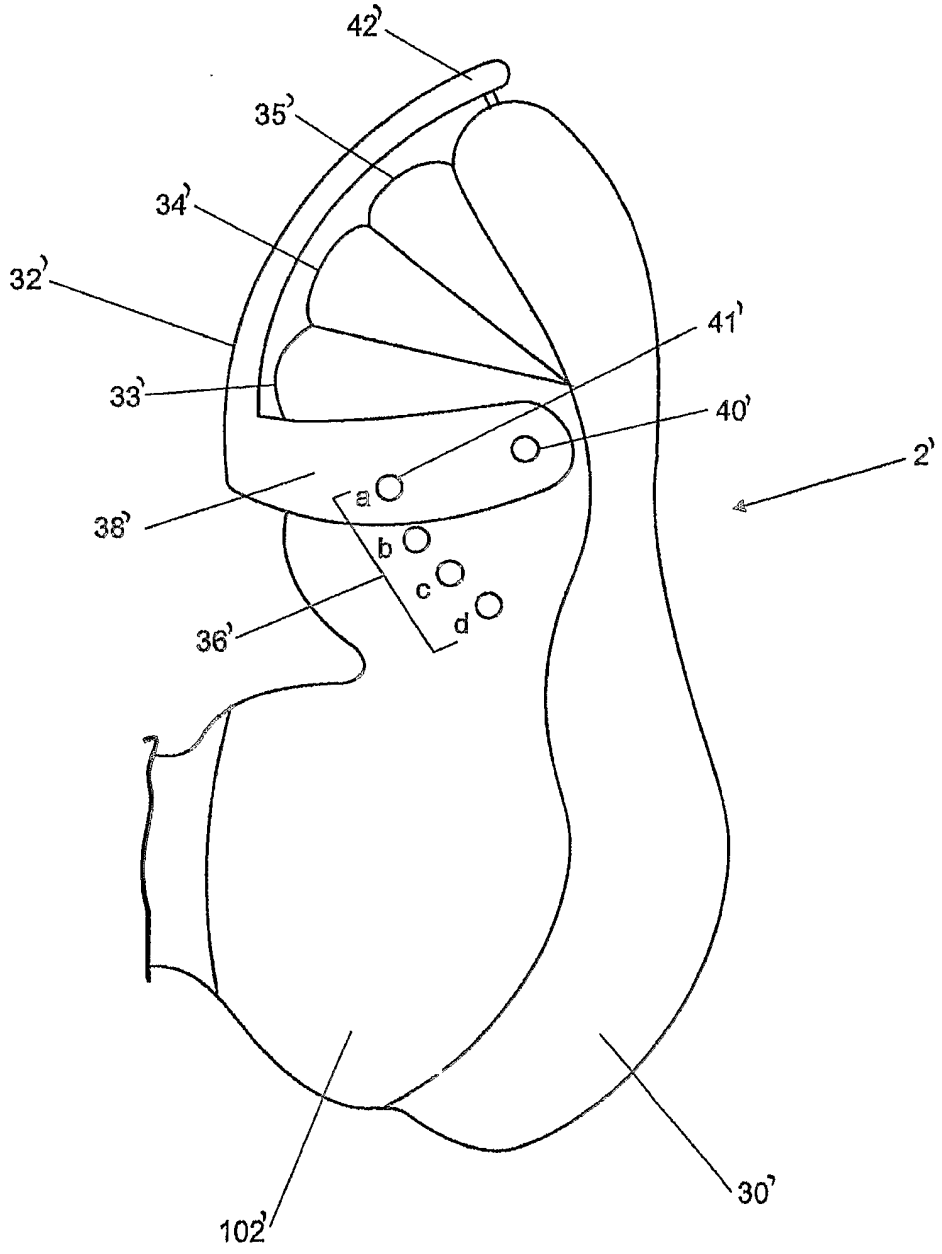


FIGURE 4

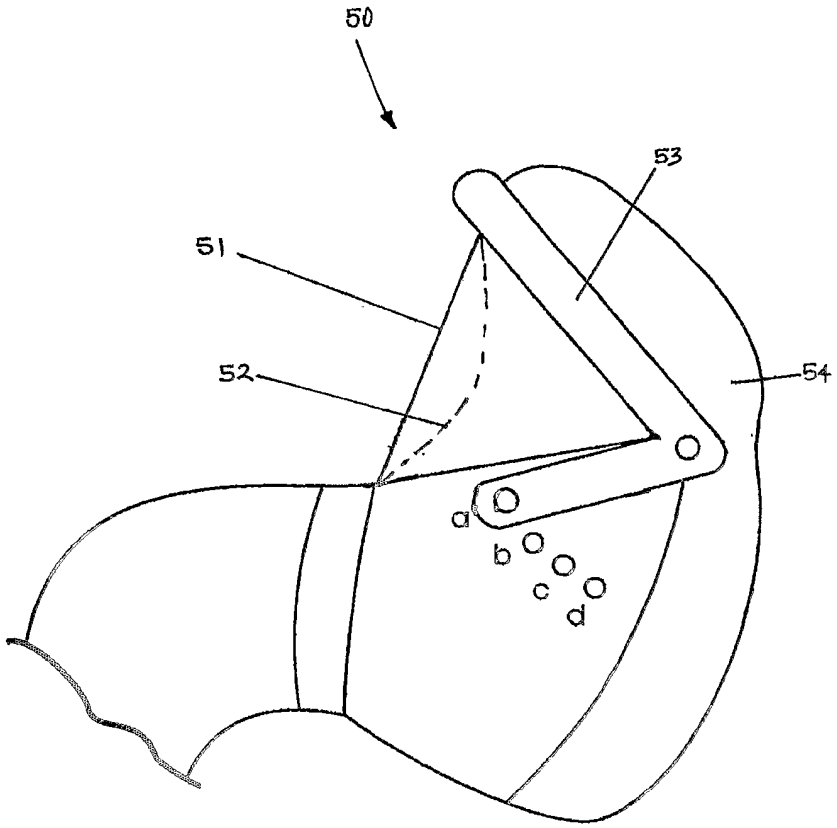


FIGURE 6

INTERNATIONAL SEARCH REPORT

International application No.
PCT/NZ2004/000026

A. CLASSIFICATION OF SUBJECT MATTER

Int. Cl. [7]: A61M 16/06; A62B 18/02

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 18/- & keywords: (mask, patient interface, adjustable, fit, size, seal, bellows, baffle) 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.
P,X	US 2003/0127101 A (DENNIS) 10 July 2003 Whole patent	1-8
X	GB 823887 A (ELECTRIC STORAGE BATTERY COMPANY) 18 November 1959 Whole document	1-8
X	US 5050594 A (BABB) 24 September 1991 Whole document	1-8

[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

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"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
25 March 2004	- 1 APR 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 **KAREN VIOLANTE** Telephone No : (02) 6283 7933

INTERNATIONAL SEARCH REPORT

International application No.
PCT/NZ2004/000026

C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	EP 1147782 A2 (MAP MEDIZINTECHNIK FUR ARTZ UND PATIENT GMBH & CO KG) 24 October 2001 Whole document	1-8
A	US 5074297 A (VENAGAS) 24 December 1991 Whole document	1-8
A	US 4971051 A (TOFFOLON) 20 November 1990 Whole document	1-8
A	GB 2275614 A (BEARD) 7 September 1994 Whole document	1-8

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No.
PCT/NZ2004/000026

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	200300127101		NONE
GB	823887		NONE
US	5050594		NONE
EP	1147782	DE	10019358
US	5074297		NONE
US	4971051		NONE
GB	2275614	EP	0613699

END OF ANNEX