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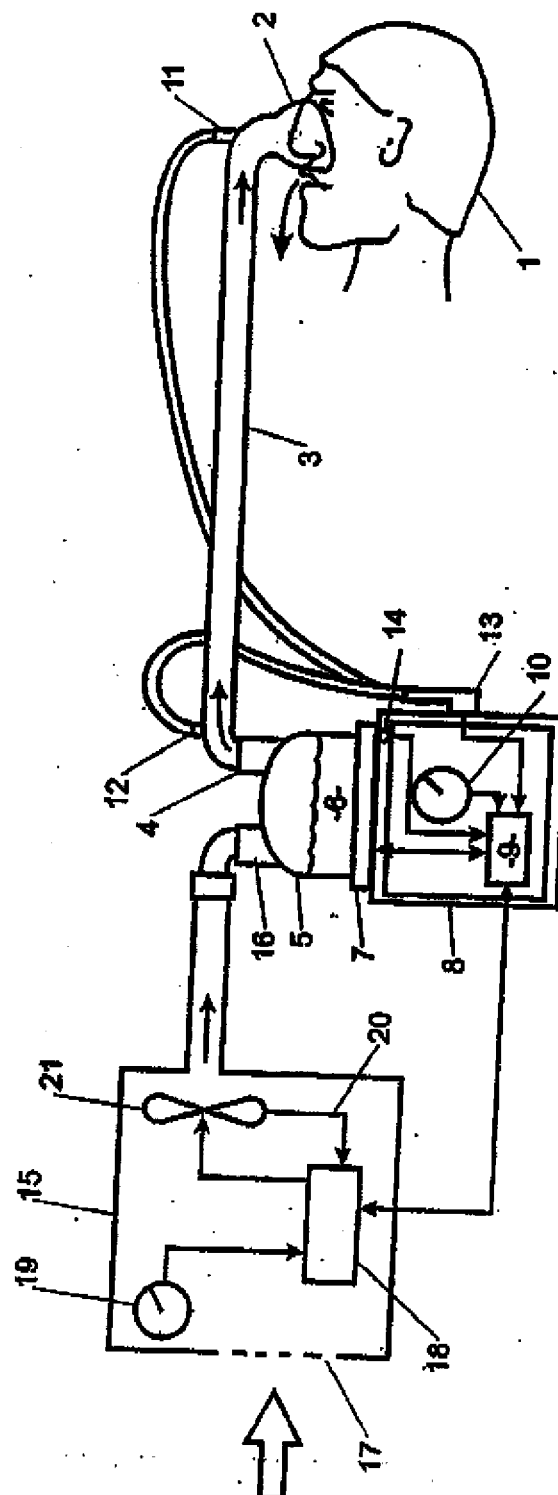
(56) Related Art  
**US 6341606**  
**GB 2176404**  
**US 6357440**  
**US 2001/0054422**  
**US 1990199**  
**EP 1163923**  
**US 2002/0005201**

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**ABSTRACT**

A patient interface is disclosed which is comfortable for the user to wear and includes at least in part a moisture permeable or breathable area in the body of the patient interface. In another embodiment the patient interface is a strapless mask that is moulded to fit the contours of a user's face and maximise the mask-to-skin seal. An adhesive material is bonded to the mask cushion and is stamped in place to form substantially the same shape as the cushion such that it fits the facial contours of the user.

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**FIGURE 1**

- 1 -

Regulation 3.2

**AUSTRALIA  
PATENTS ACT, 1990**

**COMPLETE SPECIFICATION**

**FOR A STANDARD PATENT**

**ORIGINAL**

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Invention Title:	Breathing Assistance Apparatus

The following statement is a full description of this invention, including the best method of performing it known to us.

## **"BREATHING ASSISTANCE APPARATUS"**

### **FIELD OF INVENTION**

5 This invention relates to patient interfaces particularly though not solely for use in delivering artificial respiration therapy to patients requiring respiratory humidification treatment. In particular the present invention relates to a mask with a moisture permeable or breathable body and an improved sealing mechanism.

### **BACKGROUND OF THE INVENTION**

10 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 user's 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.

15 One application of such a mask is in respiratory humidification treatment. This system normally consists of a ventilator, humidifier, breathing circuit and user interface, being a mask. In this form of treatment humid air is supplied to the patient and as a result of the temperature difference between the humid air and the surrounding environment, the humid air can condense and form water droplets. In cases where treatment is prolonged  
20 (up to several days) these droplets may form water pools in the mask that can hamper the treatment, increase the risk of the patient inadvertently inhaling water and may cause discomfort to the patient.

One requisite of such 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  
25 mask configurations, a good mask-to-face seal has been attained in many instances only with considerable discomfort for 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  
30 be achieved, or will be achieved with great difficulty and considerable user discomfort.

US Patent No. 6,196,223 and US Patent No. 6,341,606 are examples of prior art that attempts to improve the mask system. US Patent No. 5,715,814 is an example of an attempt to improve the mask sealing mechanism.

### **SUMMARY OF THE INVENTION**

35 It is an object of the present invention to attempt to provide a patient interface which

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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 consists in a patient interface for delivering a supply of gases to a user comprising or including:

5 a rigid body and a sealing member configured to in use rest against the face of a user, said rigid body having at least one cut-out area

at least one cut out area covered with a breathable film that allows water vapour to pass through but not condensed water, whereby said film alleviates build up of water condensation within rigid body. .

10 Preferably said patient interface has headgear adapted to attach to or around the head of said user.

Preferably said body has a plurality of sliding members connecting said headgear to said patient interface when said patient interface is engaged with said user.

15 Preferably said patient interface body has a plurality of cut-out areas producing a framework.

Preferably said breathable film is attached to the inner surface of said framework.

Preferably said patient interface has a plurality of slots cut-out of said patient interface body.

20 Preferably said slots and said patient interface body is covered by said moisture permeable film.

Preferably a rigid mesh is attached to the inner surface of said framework to form said body.

Preferably said moisture permeable film is attached to the inner surface of said rigid mesh and said framework.

25 Preferably said patient interface further includes an adhesive member stamped to said sealing member configured to in use rest against the face of the user.

Preferably said sealing member in use remains attached to the user's face for the duration of the treatment.

#### **BRIEF DESCRIPTION OF THE DRAWINGS**

30 Preferred forms of the present invention will now be described with reference to the

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accompanying 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 of the present invention.

5 Figure 2 is an illustration of the patient interface according to a first embodiment of the present invention.

Figure 3 is a front view of the patient interface body of Figure 2 showing the upper and lower engaging clips, sliding straps and headgear attachment.

10 Figure 4 is a rear view of the patient interface of Figure 2 illustrating the bead sealing arrangement.

Figure 5 is a front view of a second embodiment of a patient interface of the present invention where the interface body has chevron cut-out areas.

Figure 6 is a rear view of the patient interface of Figure 5 illustrating the bead sealing arrangement.

15 Figure 7 is a front view of a third embodiment of a patient interface of the present invention where the interface body has a mesh surface.

Figure 8 is a side view of the sliding strap.

20 Figure 9 is a rear view of a fourth embodiment of a patient interface illustrating an adhesive attachment that allows the patient interface to be held on the patient's face without headgear straps or other attachment means.

Figure 10 is an exploded view of the patient interface of Figure 10 showing the body to cushion locking arrangement.

Figure 11 is a perspective view of a fifth embodiment of the patient interface of the present invention, where the patient interface covers the full face of the user.

25 Figure 12 is a rear perspective view of the patient interface of Figure 12, showing the mask cushion configuration.

Figure 13 is an exploded view of the patient interface of Figure 12, showing the patient interface body and mask cushion separated.

30 Figure 14 is a rear view of the patient interface of Figure 12, showing an adhesive attachment that allows the patient interface to be held on the patient's face without headgear straps.

Figure 15 is a front view of a sixth embodiment of the patient interface of the present invention where the interface body has a plurality of cut out areas in a chevron configuration.

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Figure 16 is a front view of the patient interface of Figure 12, showing the upper and lower engaging clips and headgear strap attachment points.

Figure 17 is a front perspective view of the patient interface of Figure 12, showing mask attachment to the user's face using headgear straps.

5 Figure 18 is a front perspective view of the patient interface of Figure 12, showing mask attachment to the user's face using sliding straps attached to headgear straps.

#### DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

The present invention provides improvements in the delivery of respiratory therapy. In particular a patient interface is described which is comfortable for the user to wear and includes at least in part a moisture permeable and preferably breathable area in the body of the patient interface. It will be appreciated that the patient interface as described in the preferred embodiment of the present invention can be used in respiratory care generally or with a ventilator but will now be described below with reference to use in a humidified Positive Airway Pressure (PAP) system. It will also be appreciated that the present invention can be applied to, nasal masks, oral masks, and combination nasal-oral masks or full-face masks.

With reference to Figure 1 a humidified PAP system is shown in which 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. It should be understood that delivery systems could also be continuous, variable or bi-level positive airway pressure or numerous other forms of respiratory therapy. The inspiratory conduit 3 is connected to the outlet 4 of a humidification chamber 5 which contains a volume of water 6. The 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. The humidification chamber 6 is preferably formed from a plastics material and may have a highly heat conductive base (for example an aluminium base) which is in direct contact with a heater plate 7 of humidifier 8. The 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.

30 The controller 9 receives input from sources such as user input means or 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 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 user 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. Exhaled gases from the patient's mouth are passed directly to ambient surroundings in Figure 1 or returned to the ventilator via a return tube (not shown).

10 The 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 be carried out by controller 9) in response to inputs from controller 9 and a user set predetermined required value (preset value) of pressure or fan speed via dial 15 19.

#### Respiratory Mask

According to a first embodiment of the present invention the patient interface is shown in Figures 2, 3 and 4 as a nasal-oral mask. It will be appreciated the patient interface could equally be a nasal mask, oral mask or full-face mask. The mask 2 includes a hollow body 30 with an inlet 31 connected to the inspiratory conduit 3. The mask 2 is positioned on the face of the user 1 with the headgear 32 secured around the back of the head of the patient 1. The restraining force from the headgear 32 on the hollow body 30 ensures enough compressive force on the mask cushion 33, to provide an effective seal against the user's face.

25 The hollow body 30 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. The hollow body 30 has areas cut out 34 of the front surface such that the hollow body 30 substantially consists of a framework 35 having an outer circumference surface 36, a vertical member 37 extending from the apex of the outer circumference surface 36 to the apex of the inlet 31, plus an upper horizontal cross-member 38 and a lower horizontal cross-member 39. A number of engaging clips 40 are connected to the upper and lower horizontal members 38 and 39 respectively for the

attachment of sliding members 41 to connect the patient interface 2 to the headgear 32. A moisture permeable or breathable film 42 is bonded to the inner surfaces of the hollow body frame 35 to cover the cut-out areas 34 in order to prevent or reduce the formation of water droplets inside the mask 2 during prolonged humidification treatment thereby allowing moisture to escape to the surrounding environment. A number of techniques exist as a means of attaching the moisture permeable film 42 to the hollow body frame 35 which may include gluing, sonic welding techniques, over-moulding or a snap-tight connection between the moisture permeable film surface 42 and the hollow body frame 35.

A second embodiment of the patient interface of the present invention is shown in Figures 5 and 6. The hollow body 30 is constructed of a relatively inflexible material and comprises a rigid outer circumference surface 36 and a front surface 43 to which the inspiratory conduit 3 is attached. The hollow body front surface 43 contains a plurality of slots 44 of equal dimension equidistant in the vertical direction about the mid-line of the front surface 43 and placed between the upper and lower sets of engaging clips 40a and 40b. The slots 44 are formed in a herring bone configuration with the distance between the mid-line of the front surface 43 to each row of slots increasing from the bottom surface of the upper engaging clips 40a towards the apex of the inlet 31. A moisture permeable film 42 is bonded to the hollow body 30 on the inside surface of the front surface 43 covering the slots 44 in order to alleviate the build-up of condensation within the patient interface during prolonged humidification treatment.

A third embodiment of the patient interface of the present invention is shown in Figure 7. The hollow body 30 is formed in the manner as described in the preferred embodiment of the present invention. A rigid mesh structure 45 is bonded to the vertical and horizontal members 37, 38 and 39 respectively and the outer circumference surface 36. A moisture permeable film 42 is further bonded to the inside surface of the hollow body framework 35 and rigid mesh 45 to alleviate the build-up of condensation within the patient interface during prolonged humidification treatment. The rigid mesh 45 provides additional strength and support to the hollow body framework 35 and a larger surface area on which to bond the moisture permeable film 42.

A fourth embodiment of the patient interface may be a full face mask 46, such as shown in Figures 11 to 18. The patient interface 2 is capable of covering the whole face of the user 1, not merely the nose and/or mouth. The full face mask is constructed of a relatively inflexible material such as polycarbonate plastic. Such a material would provide the requisite rigidity as well as being transparent, a relatively good insulator and allows the

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patient to be monitored and the user to see. The patient interface 2 has a body 47 and a cushion 48, where the body includes at least one cut-out area 49 or window of moisture permeable film 42. Figure 11 illustrates two areas of moisture permeable film 42, but any number of areas or alternatively one large window could be provided. A rigid mesh structure 45 of the type previously described may be bonded to the mask body 47 to provide additional support whilst also providing a body to which the moisture permeable film 42 can be adhered to. Alternatively, as shown in Figure 15, the mask body 47 may have a plurality of slots 60 of the type previously described, providing a rigid surface to which the moisture permeable film 42 can be adhered to.

The mask body 47 has a tubular aperture 51 located at the front surface 50 from which a tubular extension member 52 protrudes. When in use a tube or conduit (not shown) can be attached to the tubular extension 51 to allow gases to be supplied to the interior of the patient interface 2 during treatment. The mask cushion 48 is of similar configuration to that described in relation to the nasal masks, oral masks and combination nasal-oral masks but extends around and fits the contours of the periphery of the user's face 1.

In other forms of the patient interface 2 of the present invention different configurations of the cut-out areas 34 and the placement of the moisture permeable film 42 on the mask body 30 can be varied depending on the size and application of the patient interface 2.

#### **Moisture Permeable Film**

The moisture permeable or breathable film 42 bonded to the interior of the patient interface 2 of the present invention is preferably a flexible and breathable membrane that allows water vapour to pass through it but not condensed water. In particular, the moisture permeable film 42 may be a hydrophilic polyester block copolymer, such as SYMPATEX™, or a perfluorosulfonate ionomer membrane, such as NAFION™.

#### **Mask Seal**

Referring now to Figures 9 and 10, a mask cushion 33 is attached to the periphery of the hollow body 30 to provide an effective seal onto the face of the user 1 to prevent leakage. The mask cushion 33 is shaped, and is dependent on the mask type, to approximately follow the contours of a patient's face. The mask cushion 33 will deform when pressure is applied by the headgear 32 to adapt to the individual contours of any particular user.

In Figure 10 we see that the mask cushion 33 is composed of an inner foam cushion

52 covered by an outer sealing sheath 53. The inner cushion 52 is constructed of a resilient material for example polyurethane foam, to distribute the pressure evenly along the seal around the user's face. The inner cushion 52 is located around the outer periphery 54 of the open face 55 of the hollow body 30. Similarly the outer sheath 53 may be commonly  
5 attached at its base 56 to the periphery 54 and loosely covers over the top of the inner cushion 52.

The outer sheath 53 fits in place over the cushion 52, holding it in place. The sheath 53 is secured by a snap-fit 57 to the periphery 54 of the hollow body 30. In Figure 10 the periphery 54 is shown including an outer bead 58. The sheath 53 includes a matching bead  
10 59, whereby once stretched around the periphery 54; the two beads 58 and 59 engage to hold the sheath 53 in place.

In the alternative embodiment shown in Figure 9, the patient interface 1 is a strapless face mask 60 which is moulded to fit the contours of a user's face and maximise the mask-to-skin seal. An adhesive material 61 is bonded to the mask cushion 33 and is stamped in  
15 place to form substantially the same shape as the inner cushion 52 such that it fits the facial contours of the user 1. The inner cushion surface 52 is protected by a layer of cover tape (not shown) prior to use in order to maintain the adhesive properties of the adhesive material 61. When required for use the cover tape 62 is removed to reveal the adhesive  
20 material 61 on the inner cushion surface 52. The mask cushion 33 is thereby adhered to the user's face reducing the amount of leakage from the mask 60 and increasing the user's comfort by negating the requirement of the user wearing headgear. It is the intention for the mask cushion 33 of the alternative embodiment of the present invention to remain attached to the user's face for the duration of the humidification respiratory treatment. This system would allow for quick removal of the hollow body 30, enable other treatments  
25 to be administered with minimal disruption to the user 1 and increase user comfort by substantially reducing the compressive force of the patient interface 2 on the user's face.

The strapless face mask configuration as disclosed may also be applied to the full-face mask 46 as shown in Figure 14. The adhesive material 61 is adhered to the mask cushion 48 which is shaped to fit the contours of the user's face thereby increasing user  
30 comfort and reducing the amount of gas leakage from the mask 46.

In other forms the mask cushion may be a solid cushion stamped, for example, from silicon or other similar material. Such a silicon cushion would be shaped to fit a user's facial contours and in some forms have an adhesive layer applied to allow the cushion to be adhered to the user's face for the duration of the treatment.

### Headgear

To further ensure user comfort and effective pressure on the mask cushion 33, the headgear 32 may be constructed either using two straps 32a and 32b running around the back of the user's head as shown in Figure 2 or with a partial skull cap or any other configurations as are known in the art. In this case the straps 32a and 32b or partial skull cap would be constructed using neoprene but may also be constructed using any material as is known in the art which will be comfortable for the user.

### Hollow Body to Headgear Attachment

Referring now to Figure 3 the present invention is illustrated using an upper and lower sliding strap 41 to attach the headgear 32 to the hollow body 30. The strap 41, shown in Figure 8 in isolation, is constructed of polyacetal (Delrin 500P NC010) using injection moulding techniques to give a polished finish. This material is similar to other nylon based derivatives, with its polished finish having a particularly low friction co-efficient, and therefore slides with respect to the hollow body 30 with very little resistance.

As shown in Figure 3, the hollow body 30 includes a number of engaging clips 40 connected to the upper and lower horizontal members 38 and 39 respectively ensuring adequate direct force on the mask cushion 33 to the user's face thereby minimizing mask-to-skin leaks. In use the sliding strap 41 snaps into place into engaging clips 40 and can only be removed therefrom using a substantial force. This means that with any normal use the sliding strap 41 will stay retained within the engaging clips 40.

Figure 8 illustrates the sliding strap which is described in our co-pending New Zealand application number 514184 and is herein described by way of reference. The sliding strap includes a mid-section 204 intended to reciprocate with the engaging clips 40, terminated at each end by loops 206, 208 which attach to the headgear 32. The first loop 206 is a full loop through which the headgear 32 may be permanently attached with for example, a Velcro<sup>TM</sup> strap. The loop 208 at the other end, is a partial loop 210 designed so that a strap or loop from the headgear 32 can be easily slipped in or out of the open section 212 to allow easy removal and attachment of the mask.

The present invention as shown in Figure 3 uses two sliding straps 41 which are terminated at each end by loops 208 being partial loops 210. This sliding strap configuration is used to allow easy connection to the headgear straps 32 plus removal and attachment of the mask.

Referring now to the fourth embodiment of the present invention, Figure 16 shows a

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full-face mask 46 having an upper and lower set of engaging clips 40 attached to the mask front surface 47. In use the sliding straps 41 as previously described in the present invention, snap into place into the engaging clips 40. The mask front surface 47 also shows an upper and lower set of headgear attachment points 65 permanently fixed to the upper portion and lower portion of the periphery of the front surface 47 which in use Velcro™ straps, connected to the end portion of the headgear straps 66, may be attached.

#### Full Face Mask Headgear

In a further form of the present invention the headgear assembly comprises an upper and a lower adjustable strap member 66 which runs around the back of the user's head 1 as shown in Figure 17. In this case the straps 66 would be constructed using neoprene but may also be constructed using any material as is known in the art which will be comfortable for the user 1. As illustrated in Figure 17, two sets of headgear attachment points 65 are permanently fixed to the periphery of the upper portion and lower portion of the full-face mask 46 to which the upper and lower adjustable straps 66 are attached. Headgear adjustment means is achieved using Velcro™ near the end portions of the upper and lower straps 66 to ensure user comfort and effective pressure on the mask cushion 48 to minimize gas leakage from the mask 46.

Referring now to Figure 18 an alternative form of the present invention is shown using an upper and lower sliding strap 41 to attach the headgear 67 to the full-face mask front surface 47. In use, the sliding straps 41 snap into the upper and lower engaging clips 40. The sliding straps are terminated at each end by partial loops 210 so that a strap or loop from the upper and lower headgear members 67 can be easily slipped in or out of the open section 212 to allow easy removal and attachment of the full-face mask 46. Headgear adjustment means is achieved using Velcro™ near the end portions of the upper and lower straps 67 to ensure user comfort and effective pressure on the mask cushion 48 to minimize gas leakage from the mask 46.

**THE CLAIMS DEFINING THE INVENTION ARE AS FOLLOWS:**

1. A patient interface for delivering a supply of gases to a user comprising or including:  
a rigid body and a sealing member configured to in use rest against the face of a  
5 user,

said rigid body having at least one cut out area,

at least one cut out area covered with a breathable film that allows water vapour to  
pass through but not condensed water, whereby the film alleviates build up of condensation  
within the rigid body.

2. A patient interface for delivering a supply of gases to a user according to claim 1 or 2  
wherein said patient interface has headgear adapted to attach to or around the head of said  
10 user.

3. A patient interface for delivering a supply of gases to a user according to any one of  
claims 1 to 2 wherein said body has at least one sliding member connecting said headgear  
15 to said patient interface when said patient interface is engaged with said user.

4. A patient interface for delivering a supply of gases to a user according to any one of  
claims 1 to 3 wherein said body has a plurality of cut-out areas forming a framework of  
said body.

5. A patient interface for delivering a supply of gases to a user according claim 4  
20 wherein said breathable film is attached to the inner surface of said framework.

6. A patient interface for delivering a supply of gases to a user according to any one of  
claims 1 to 3 wherein said patient interface has a plurality of slots cut-out of said patient  
interface body.

7. A patient interface for delivering a supply of gases to a user according to claim 6  
25 wherein said plurality of slots and said patient interface body is covered by said breathable  
film.

8. A patient interface for delivering a supply of gases to a user according to any one of  
claims 4 to 7 wherein a rigid mesh is attached to the inner surface of said framework to  
form said body.

9. A patient interface for delivering a supply of gases to a user according to claim 8  
30 wherein said moisture permeable film is attached to the inner surface of said rigid mesh  
and said framework.

10. A patient interface for delivering a supply of gases to a user according to any one of  
claims 1 to 9 wherein said patient interface further includes an adhesive member stamped  
35 to said sealing member configured to in use rest against the face of the user.

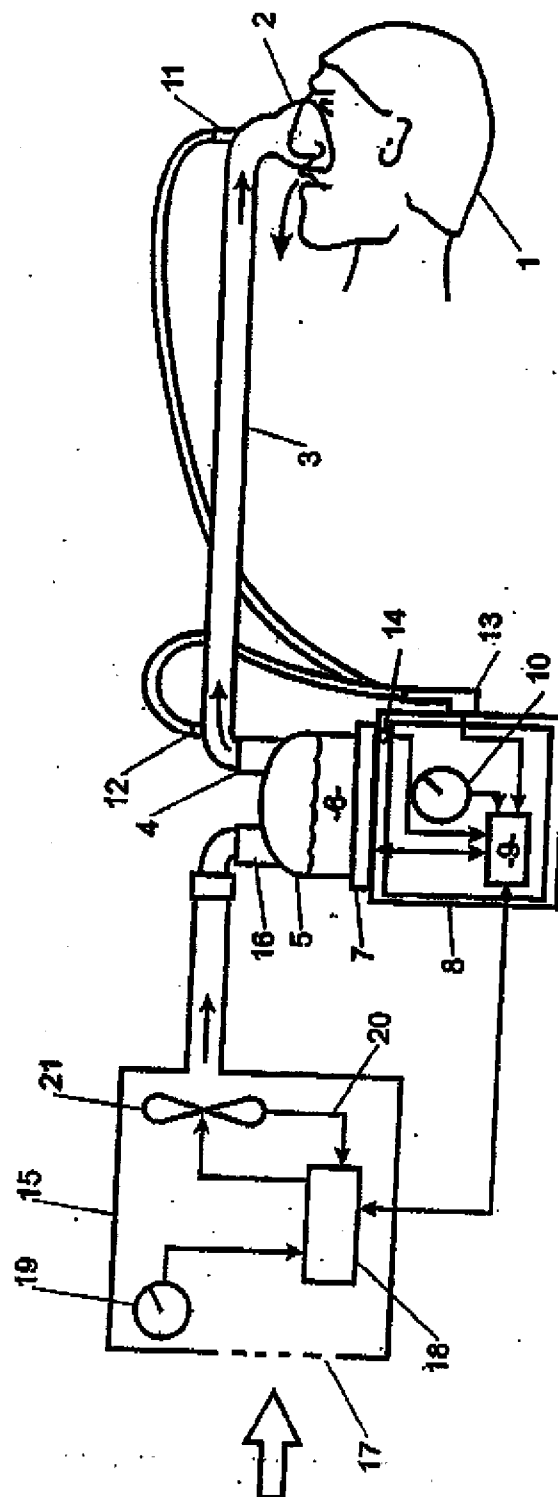
11. A patient interface for delivering a supply of gases to a user according to claim 10 wherein said sealing member in use remains attached to the user's face for the duration of the treatment.

12. A patient interface for delivering a supply of gases to a user as herein described with  
5 reference to the accompanying drawings.

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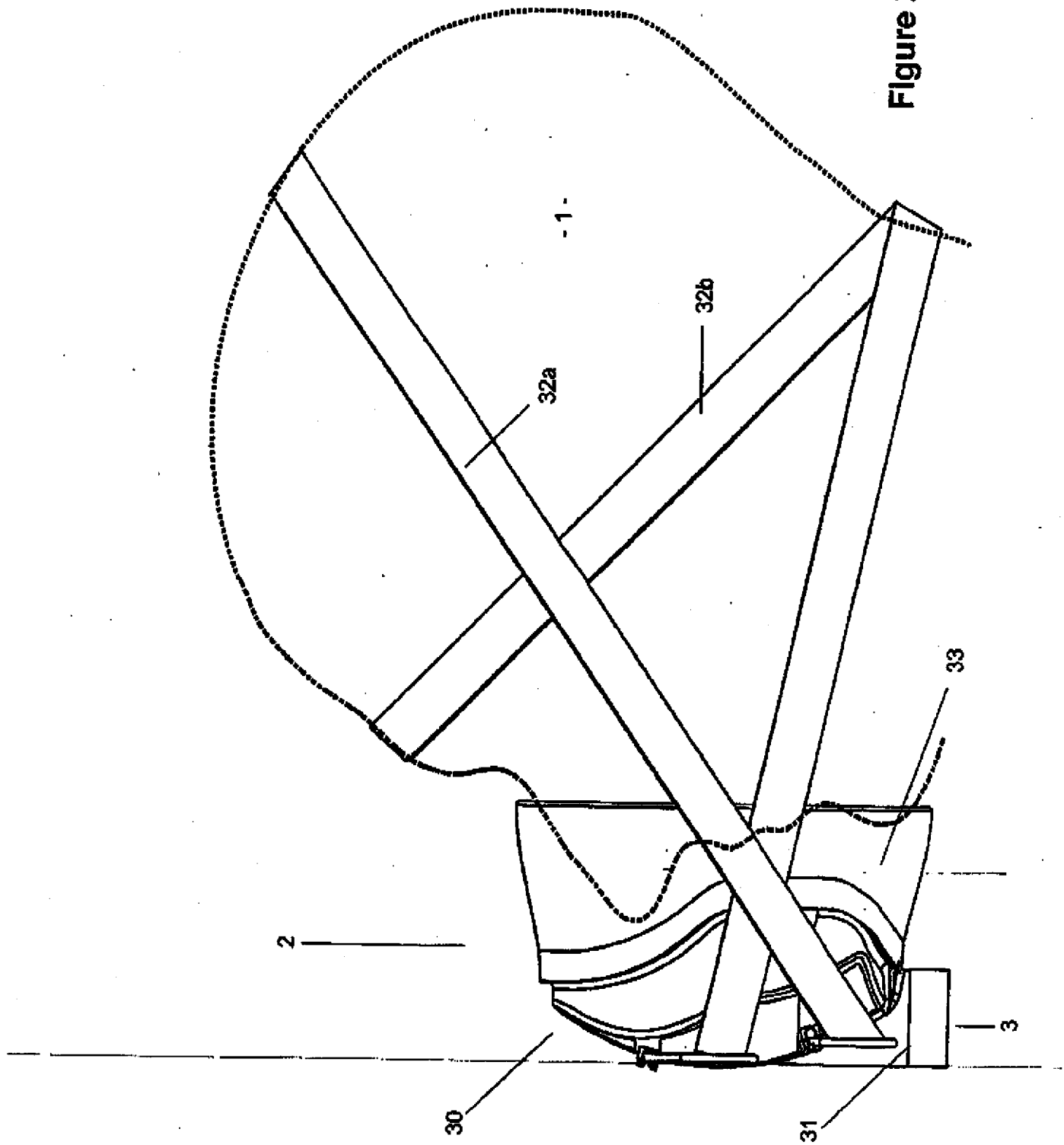


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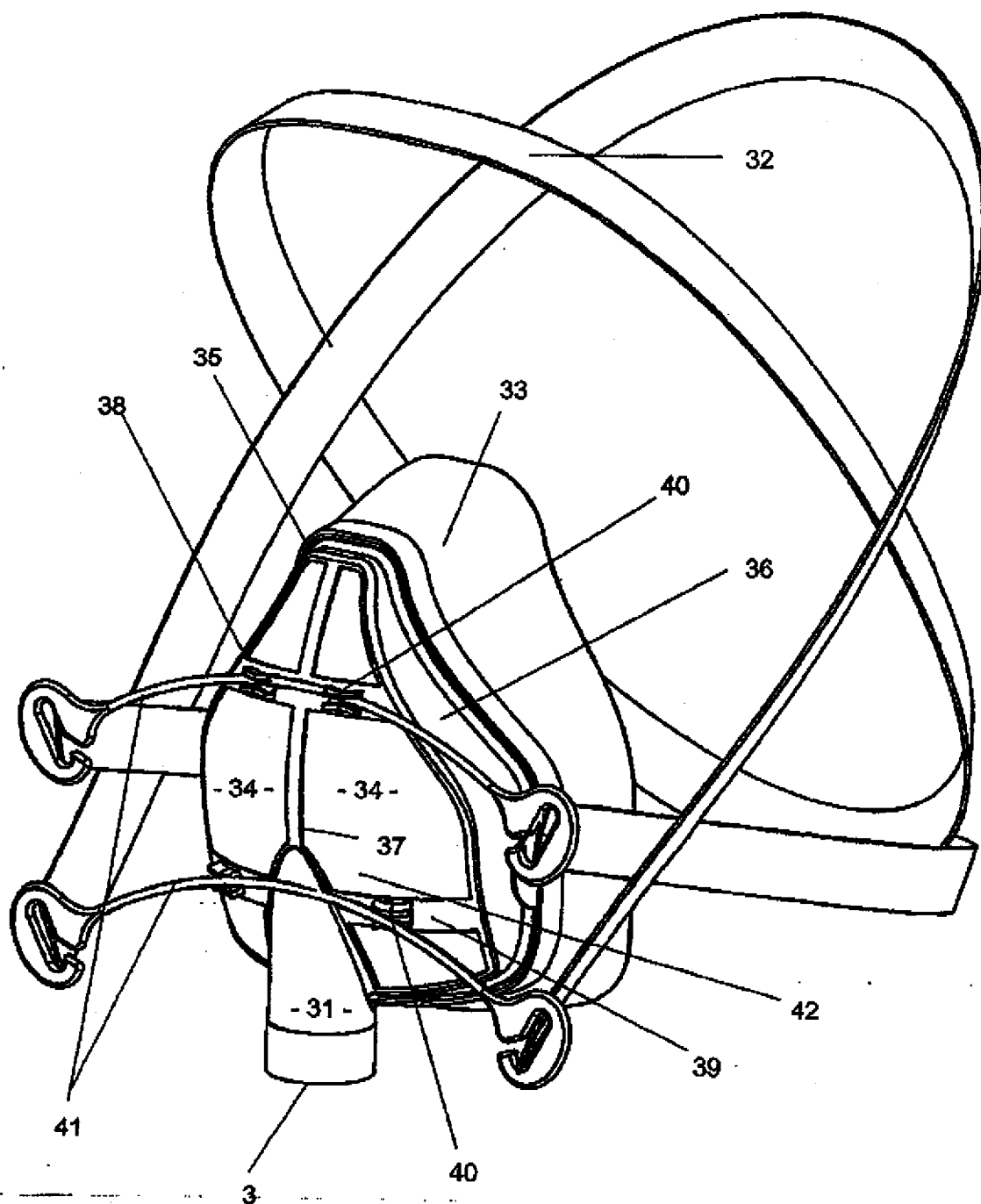
**FIGURE 1**

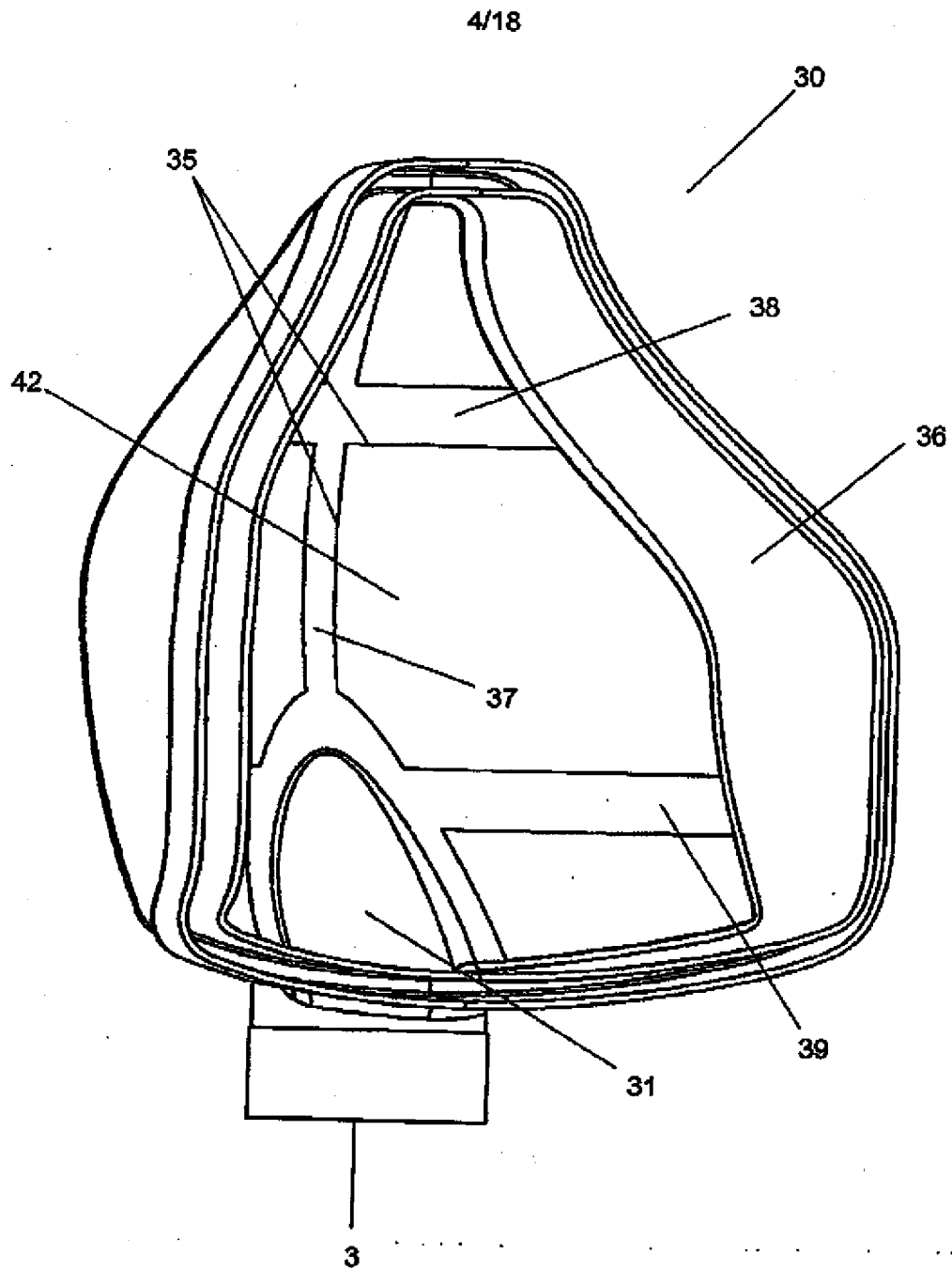
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Figure 2

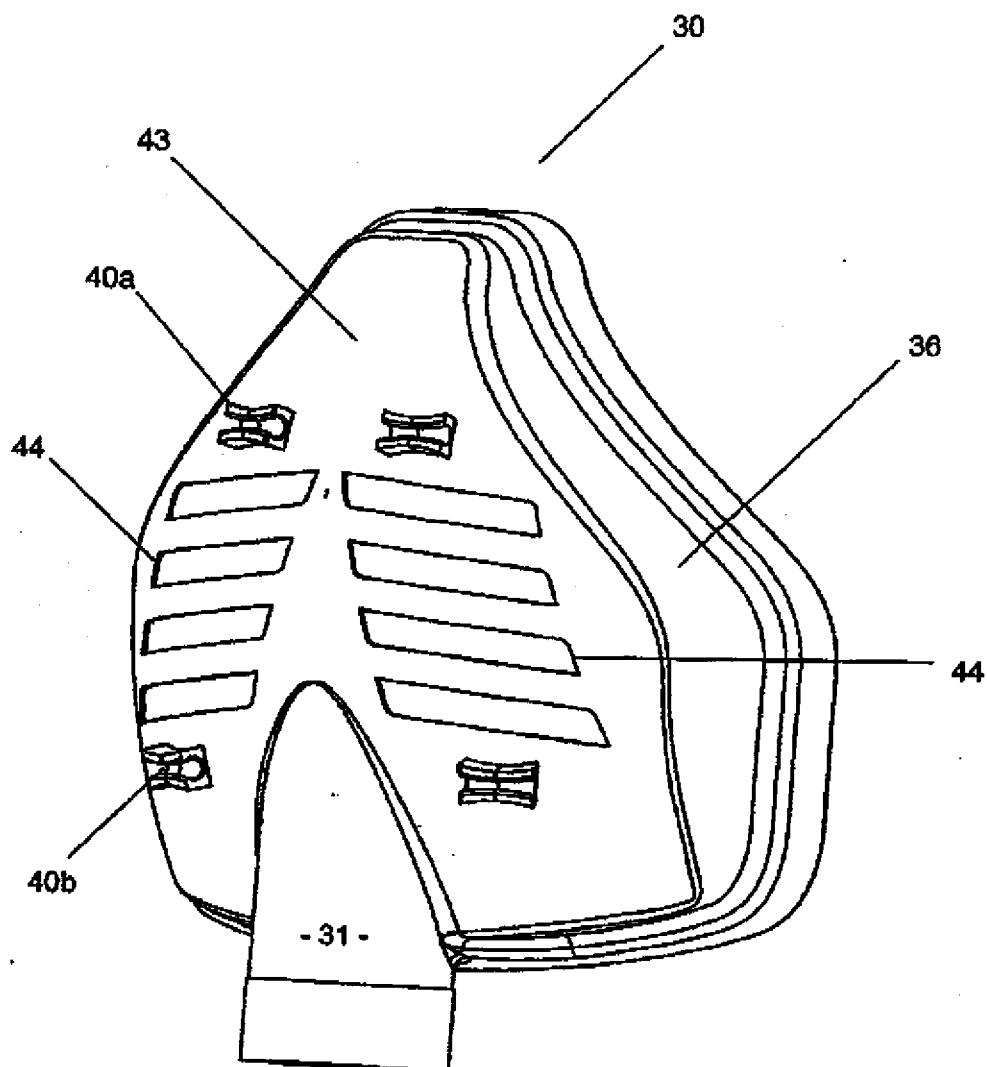


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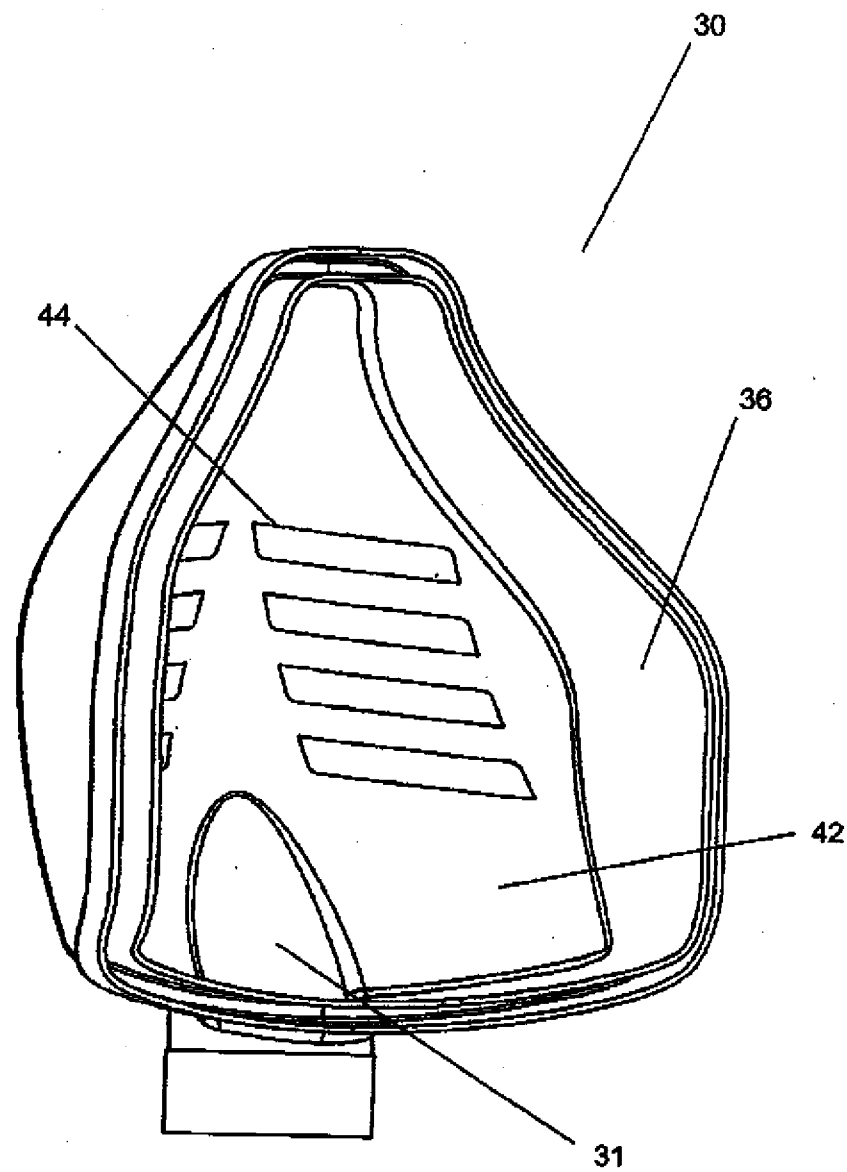
**Figure 3**

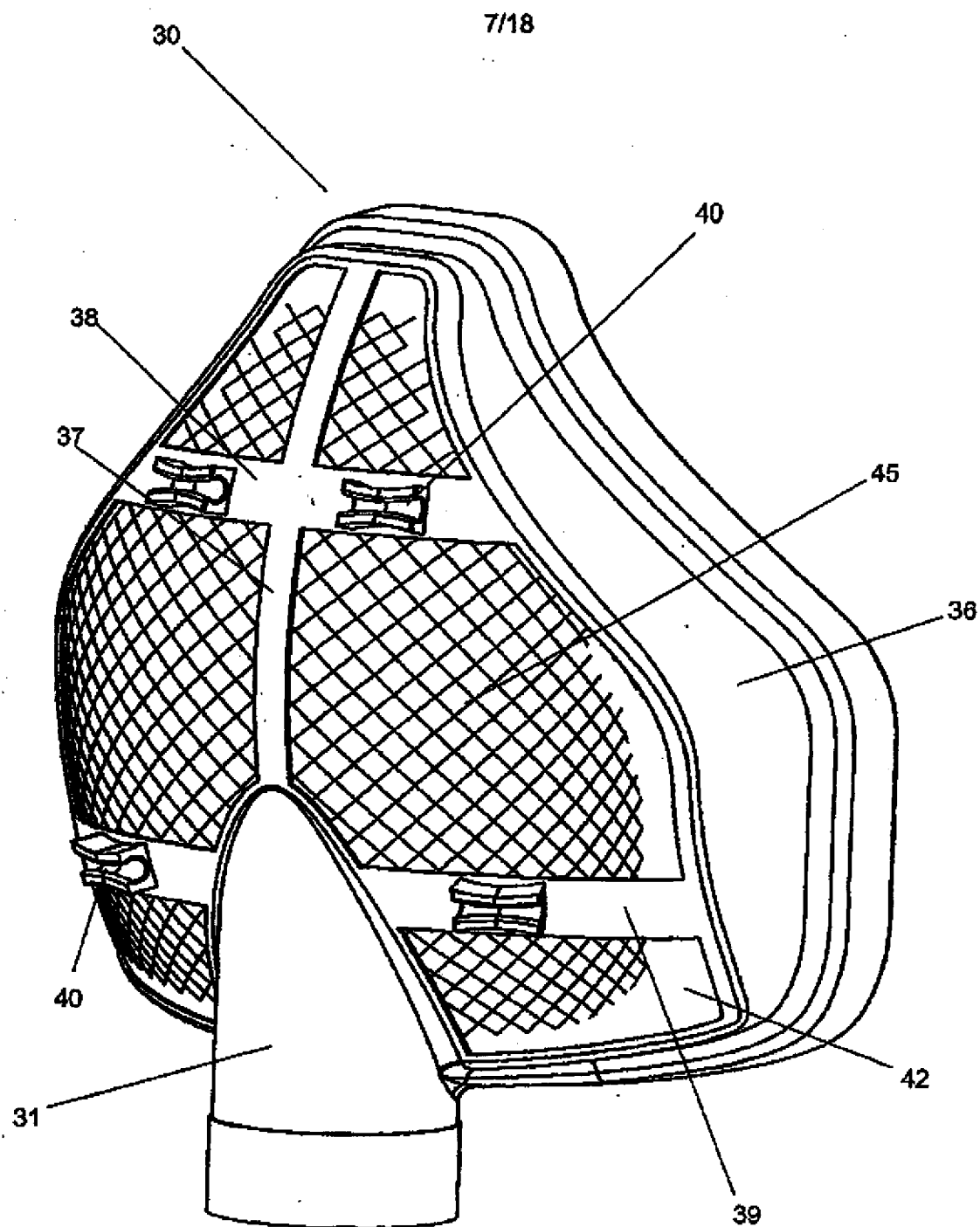
**Figure 4**

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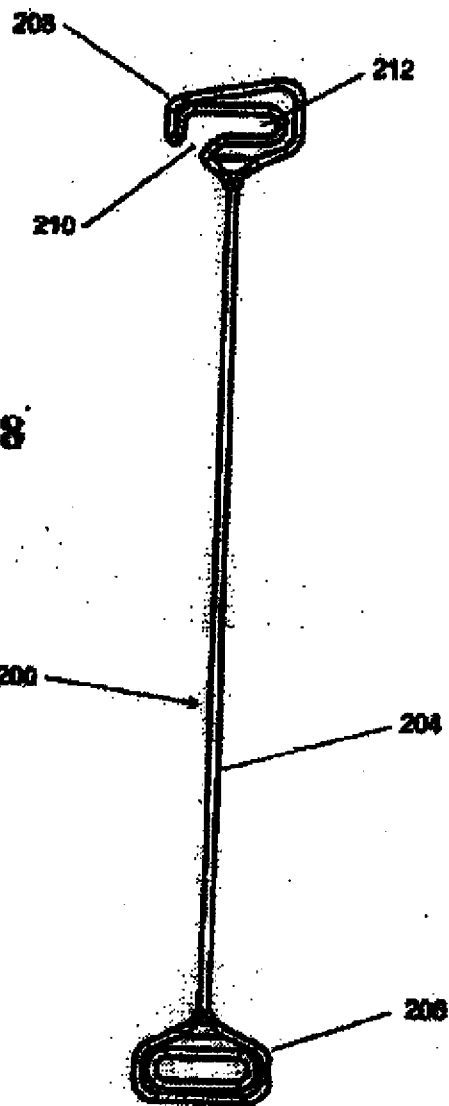
**Figure 5**

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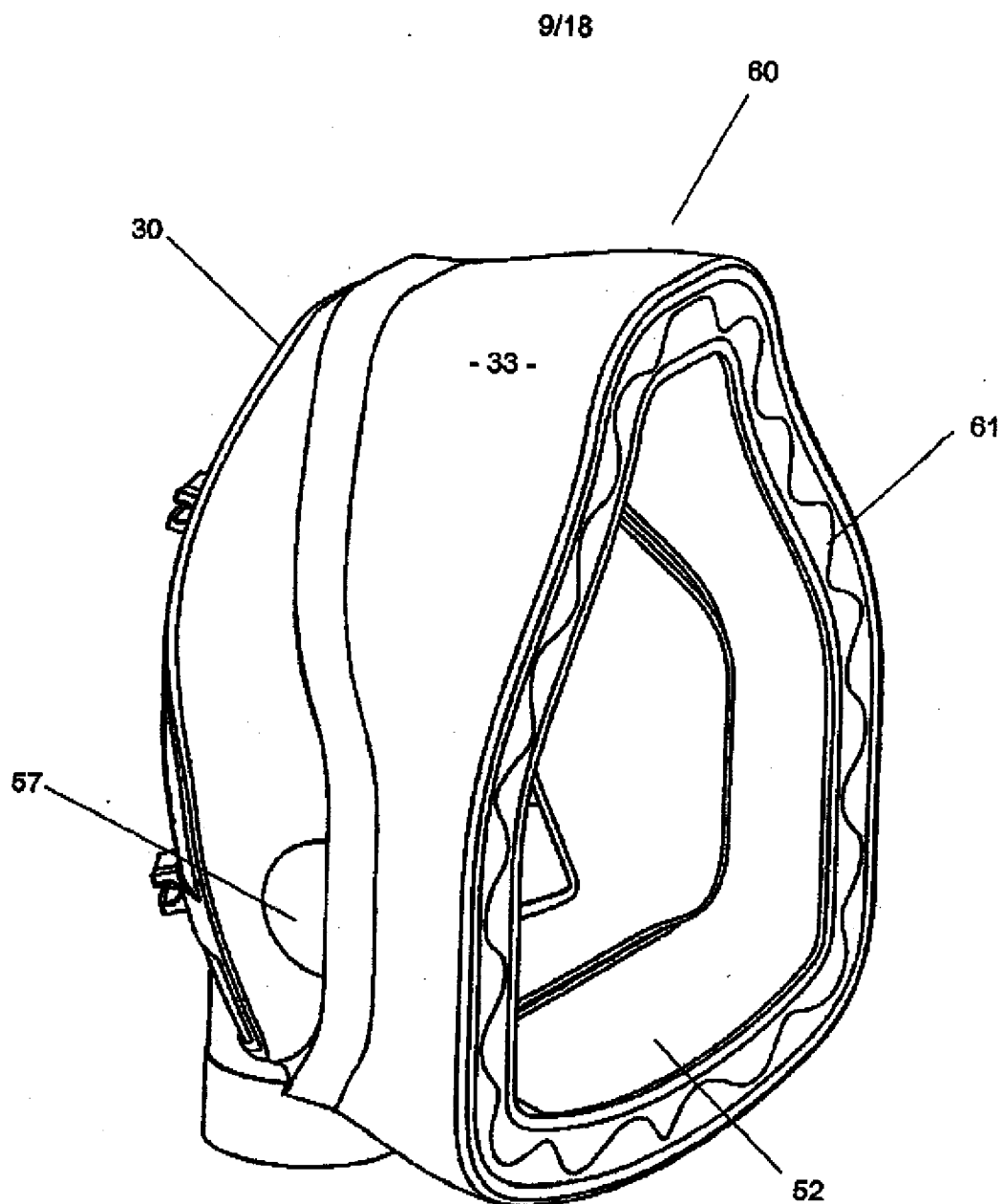
**Figure 6**

**Figure 7**

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**FIGURE 8**





**Figure 9**

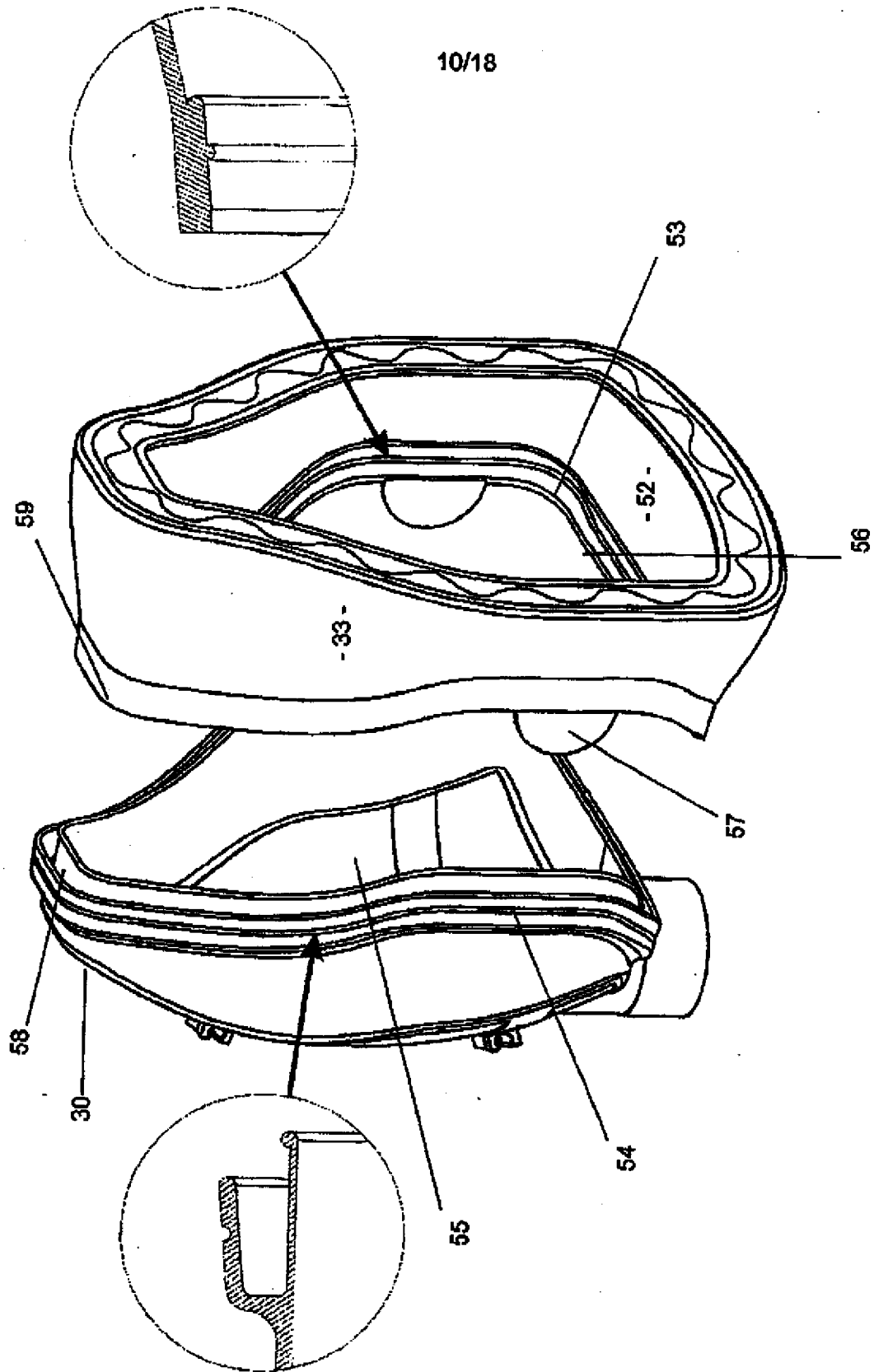
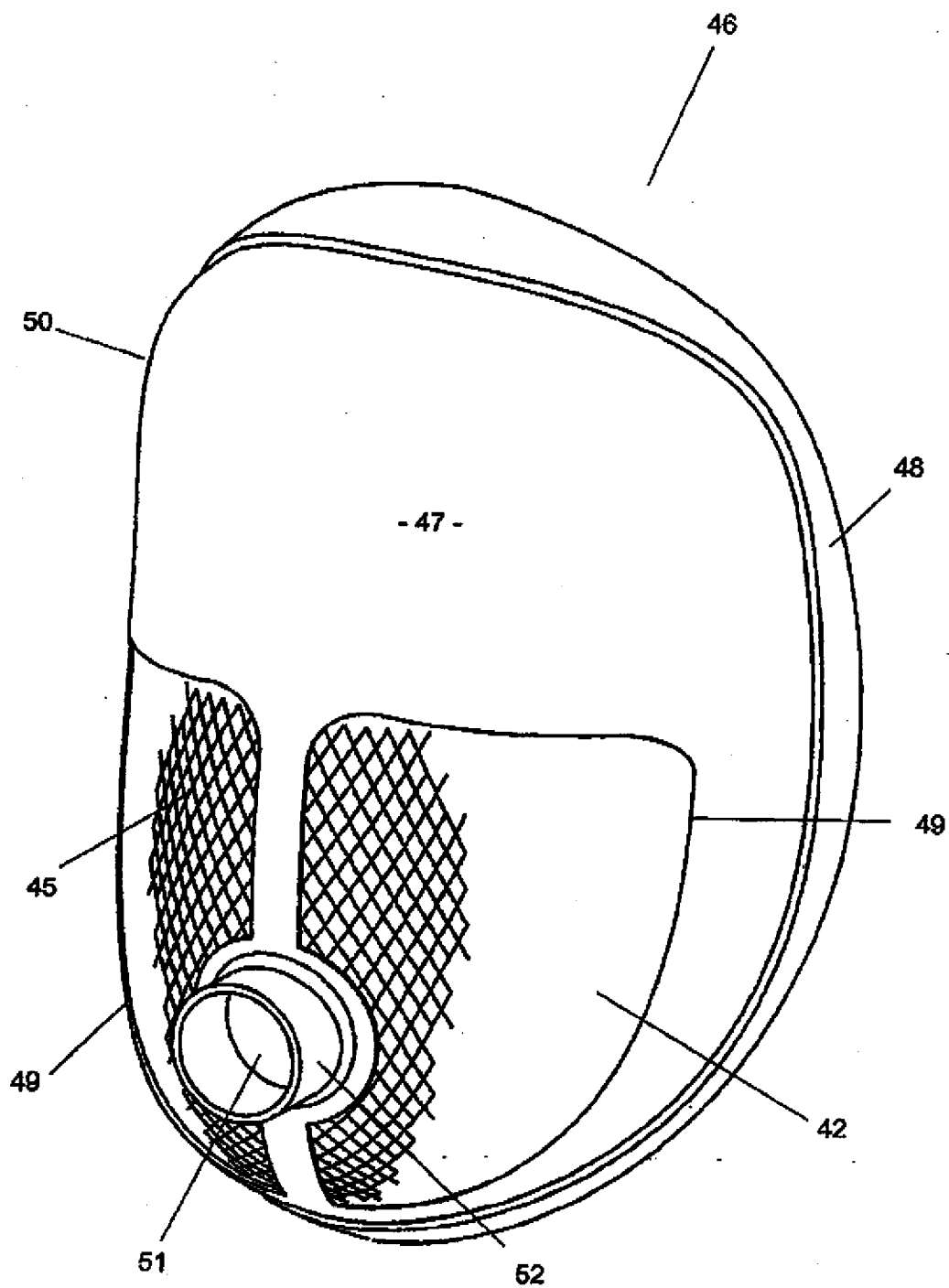
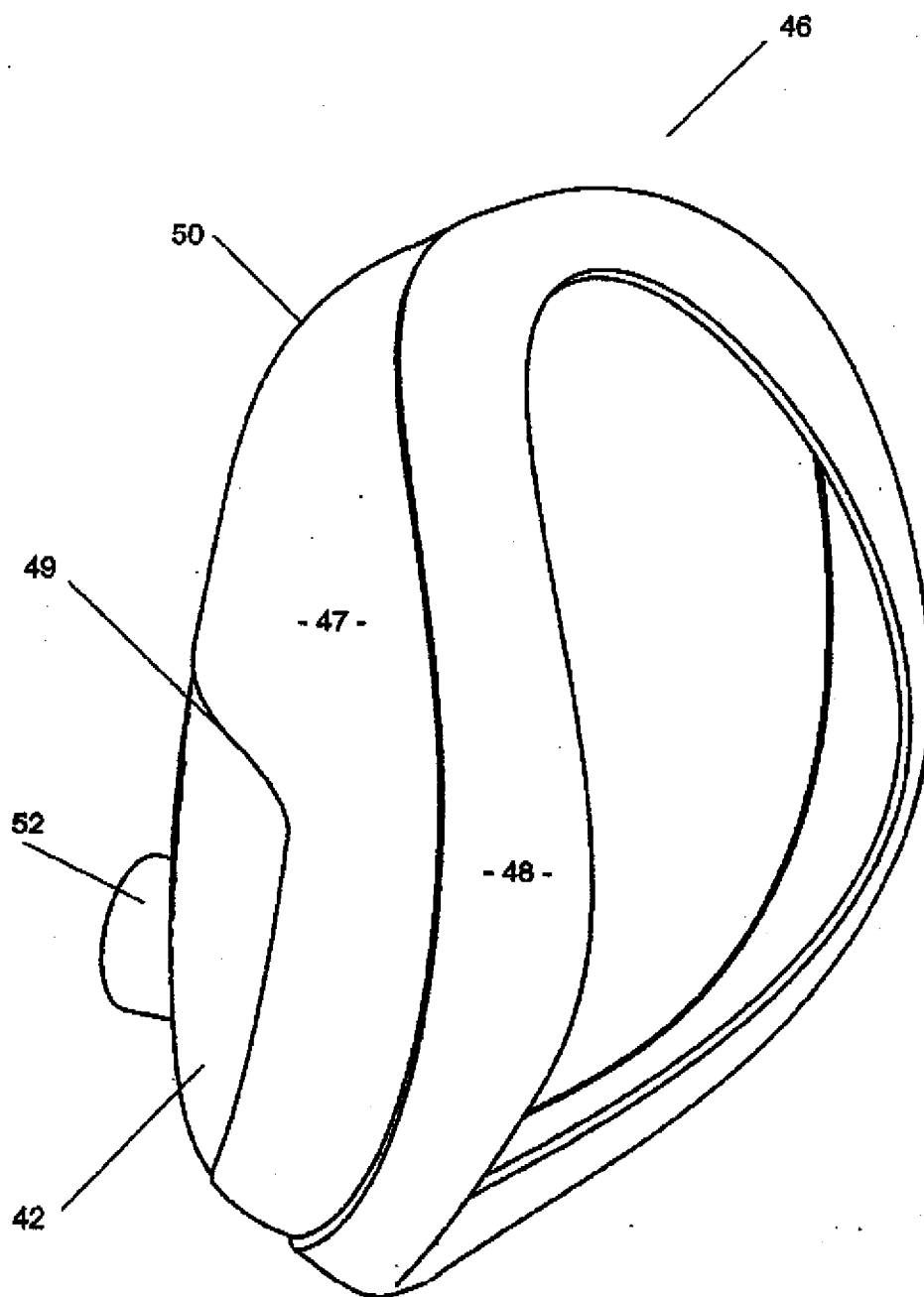


Figure 10

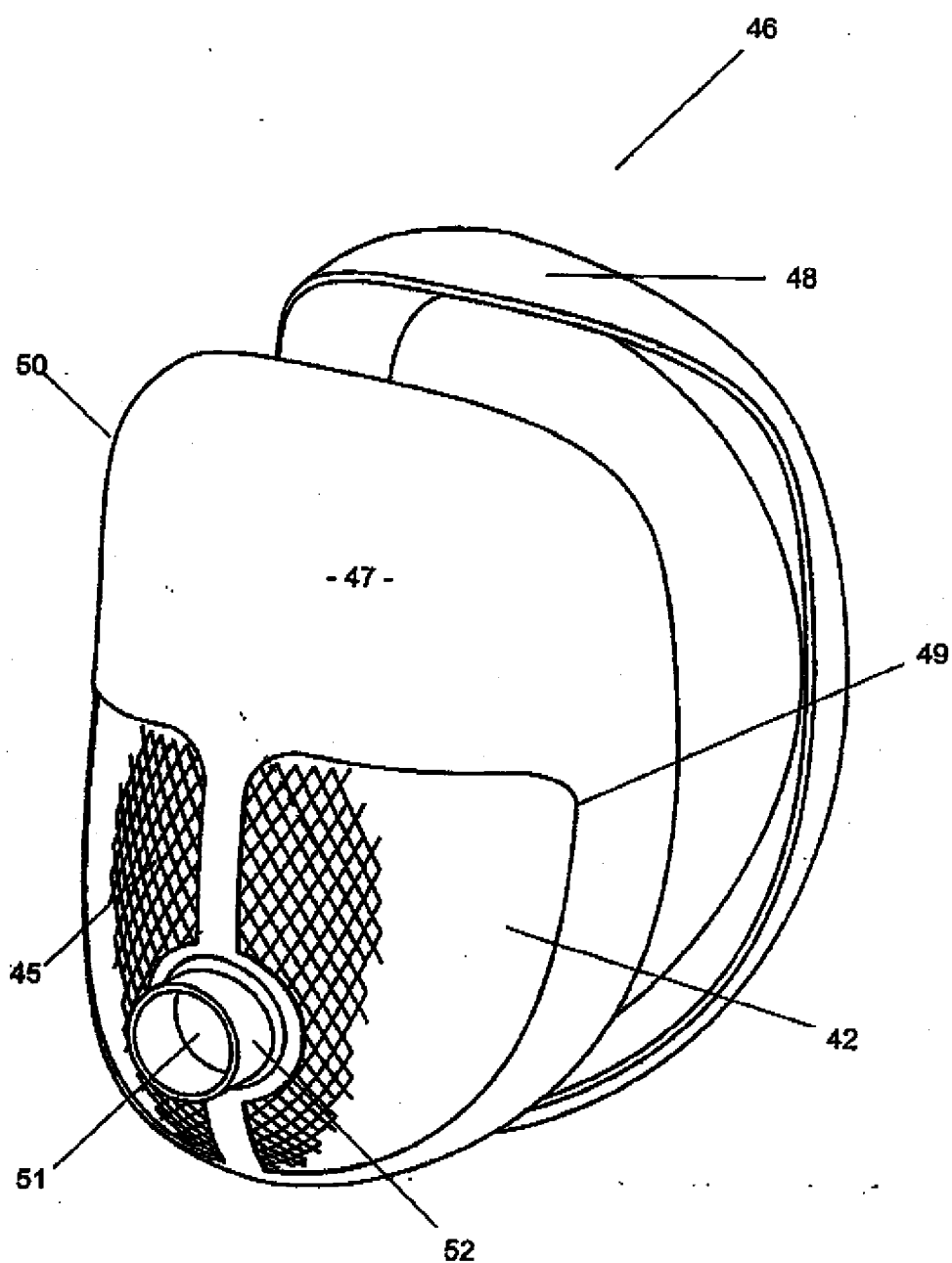
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**Figure 11**

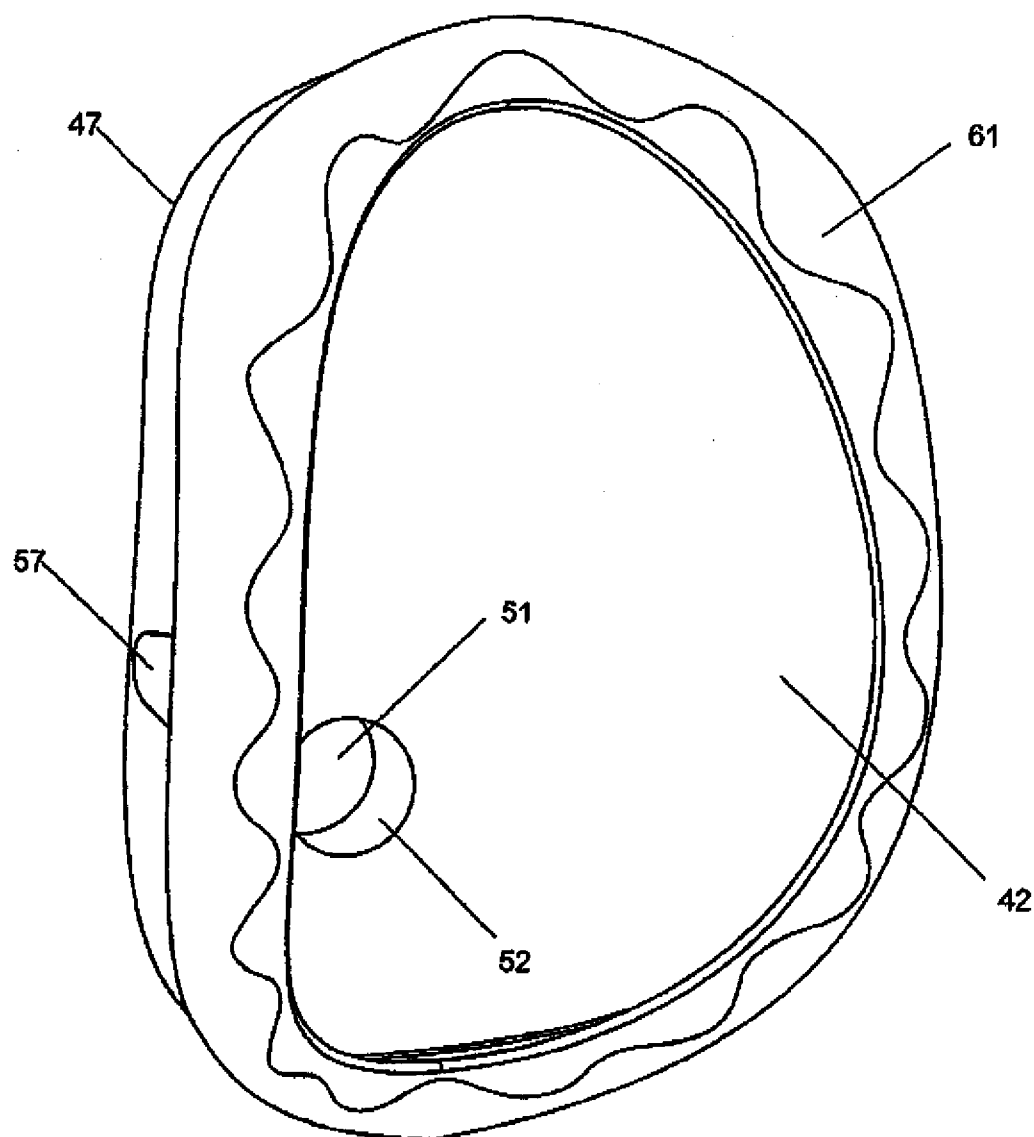
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**Figure 12**

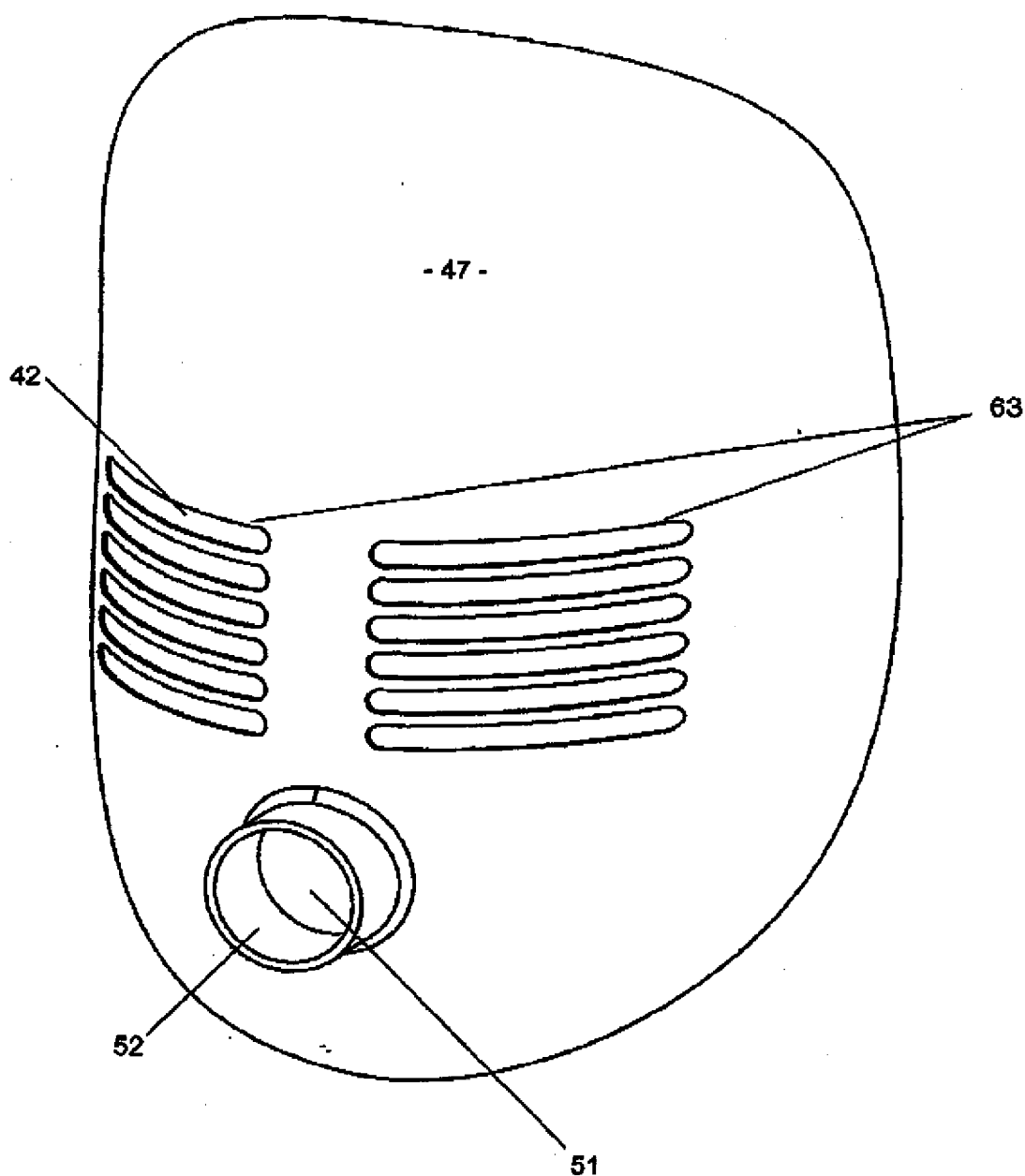
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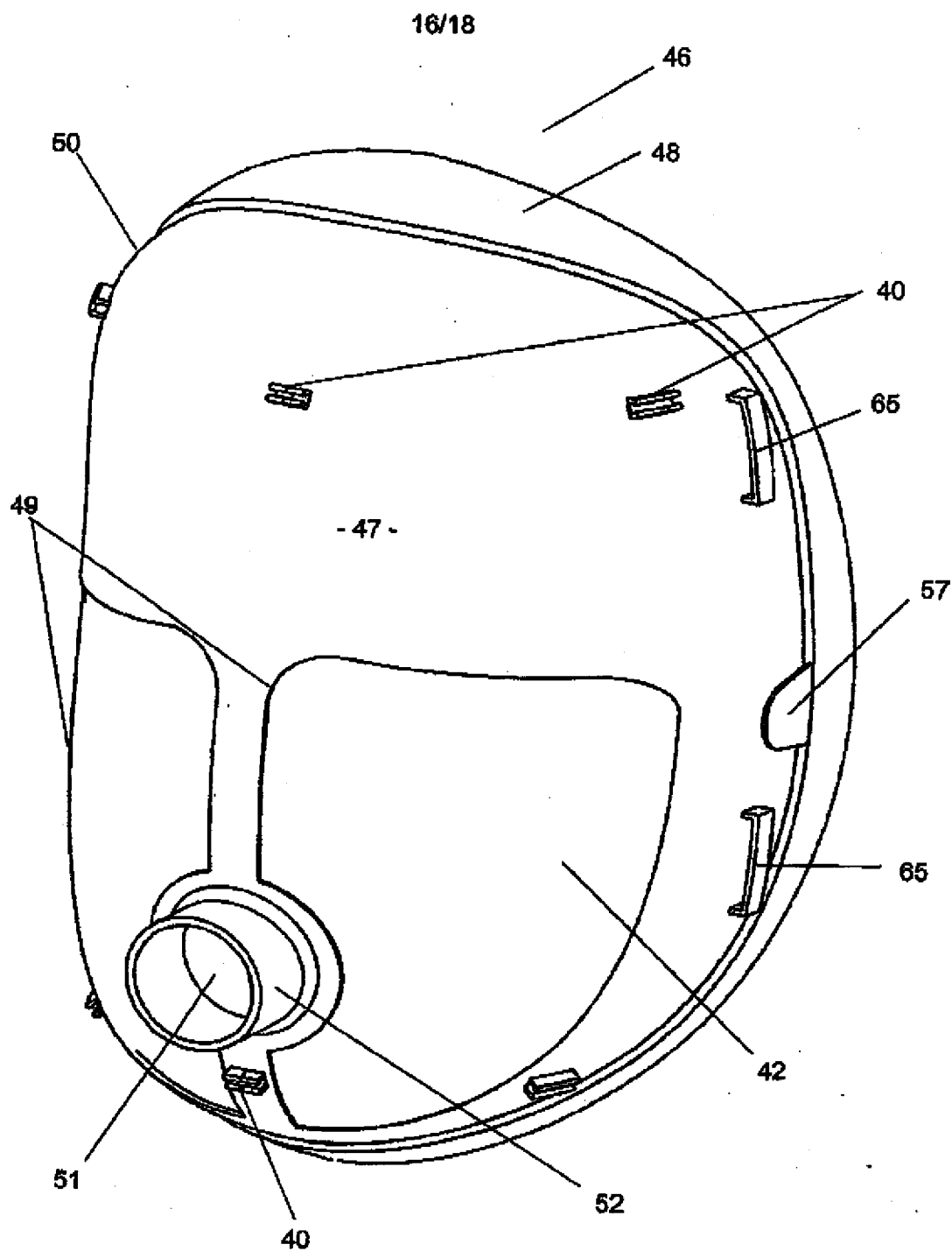
**Figure 13**

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**Figure 14**

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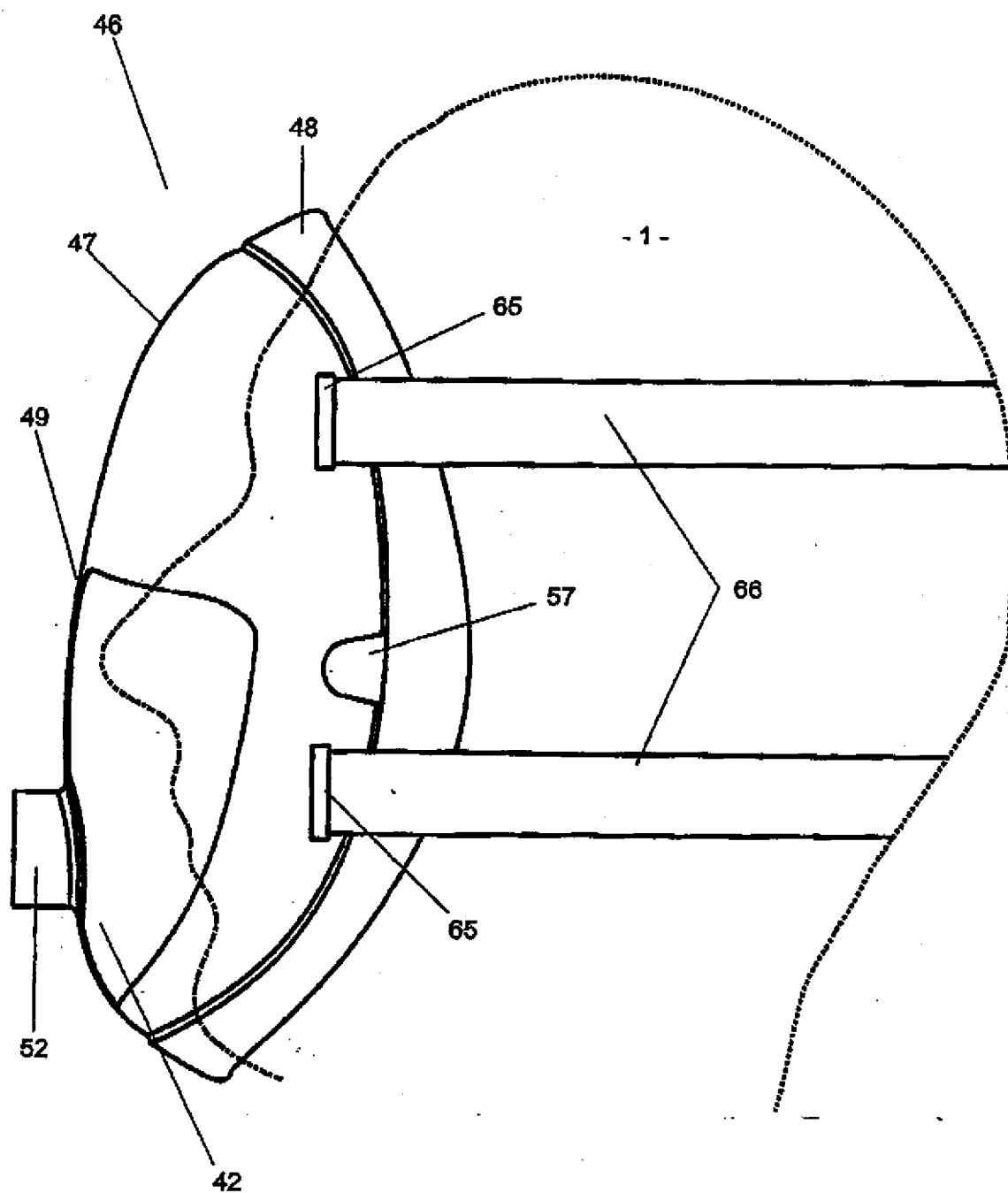
**Figure 15**



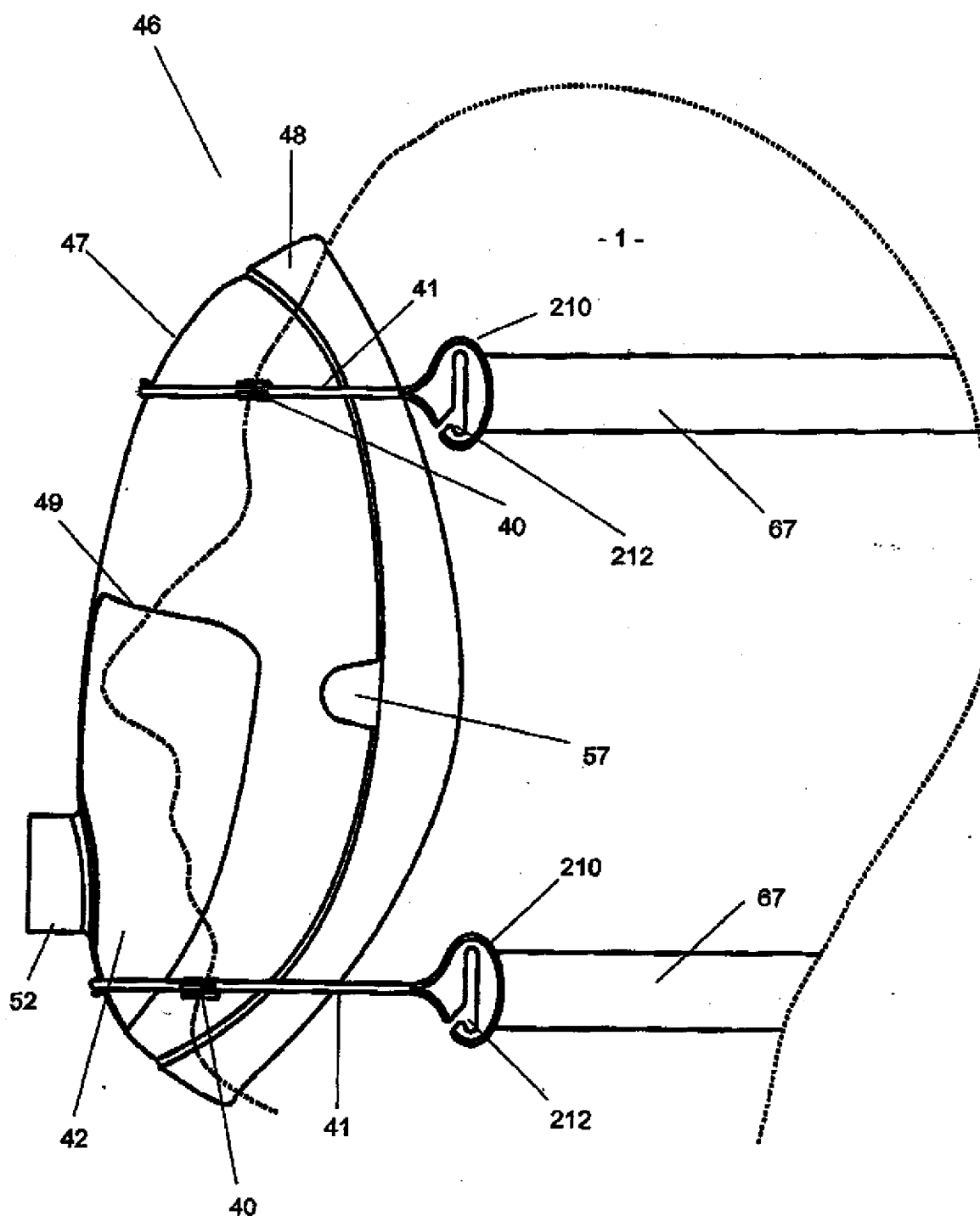
### Figure 16



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**Figure 17**

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**Figure 18**