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(54) Title: RESPIRATORY MASK

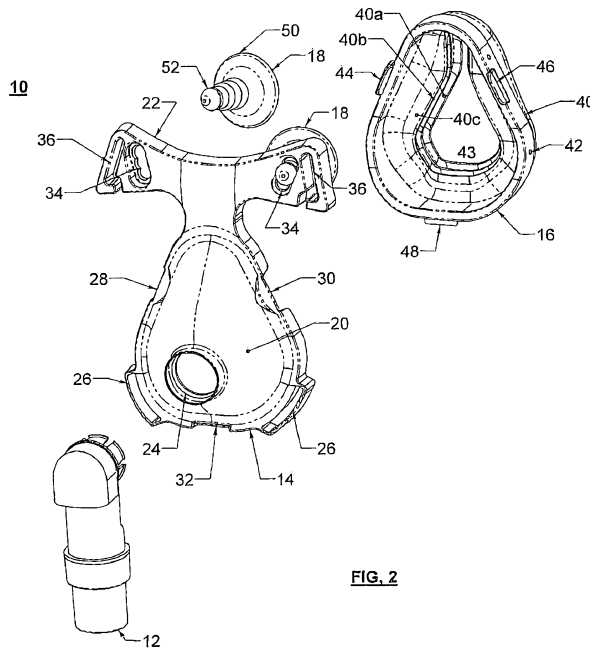


FIG. 2

(57) Abstract: A respiratory mask (10) includes a mask frame (14), a cushion (40) and a retaining element (42). The retaining element (42) is embedded within the cushion (40) and is configured to secure the cushion (40) to the mask frame (14). Forehead pads (18) can be positioned in the mask frame (14) and be adjustable independent of one another and with respect to the mask frame (14).

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## RESPIRATORY MASK

### Background

- [01] The present disclosure relates to respiratory masks. Respiratory masks are used in several different situations for treatment of respiratory disorders, for example obstructive sleep apnea. During treatment, a flow of breathable gas is provided to a patient through the mask. Current mask designs generally include a mask frame or body coupleable to a conduit that delivers the breathable gas flow. A cushion is coupled to the mask frame and presses against the patient to provide comfort and cover the nose and/or mouth of the patient. Additionally, a forehead pad can be provided for cushioning the mask against the forehead of the patient. Straps are provided to secure the mask to the patient's head.
- [02] One concern in mask design is assembly of mask components. In some instances, masks utilize a retaining ring to secure the cushion of the mask to the mask frame. One method of securing the cushion to the mask frame includes ultrasonically welding the retaining ring to the mask frame so as to permanently secure the cushion to the mask frame. The ultrasonic welding process requires tools to assemble the mask, which can add to the cost of the mask. Furthermore, while this method is effective in securing the cushion to the mask frame, there are additional disadvantages in having the cushion permanently secured to the mask frame. For example, some insurance companies only reimburse a patient for cushion replacement on a regular basis. Permanent assembly of the cushion to the mask frame prevents the patient from only replacing the cushion. Due to the lack of reimbursement, the patient, in some instances, will defer replacement of the mask or have to pay for a new mask out-of-pocket. Furthermore, the mask can be difficult to clean when the cushion and mask frame are assembled, leading to potentially unsanitary conditions.
- [03] In another method of securing the cushion to the mask, a separate retaining ring secures the cushion around its edges by utilizing a tongue and groove connection on either the outside or inside of the cushion. In yet another method, the cushion can be secured to the mask frame by sandwiching the cushion edge between the mask frame and the retaining ring. In any event, by utilizing a retaining ring that is separate from the cushion, securing the

cushion to the mask frame can be cumbersome and time consuming. For example, it may be difficult to properly align the cushion and the retaining ring so as to properly secure the cushion to the mask frame.

Another concern in mask design is comfort to the patient. Current masks can be uncomfortable and unable to accommodate different shapes and/or sizes of heads. For example, forehead pads can be stiff and thus not conform to various foreheads. In other masks, forehead pads can be adjustable, but many masks are difficult to conform to different shapes and/or sizes of heads and thus not desirable. Additionally, forehead pads may be formed of a material that retains water. As a result, water may be retained in the forehead pad after cleaning. Further still, perspiration from the patient can be retained in the forehead pad. Both of these situations can lead to unsanitary conditions.

### Summary of the Invention

One aspect of the present disclosure relates to a respiratory mask. The mask includes a mask frame defining a groove, a cushion formed of a first material and a retaining element formed of a second material that is more rigid than the first material embedded inside the cushion and adapted to secure the cushion to the mask frame, wherein the cushion and retaining element are disposed within the groove such that the cushion is exteriorly exposed to the groove. The retaining element may include a plurality of tabs positioned within corresponding tab receiving portions of the mask frame. Preferably the plurality of tabs each extend through the cushion.

Optionally the mask frame may further include a bridge that includes first and second slots that engage first and second forehead pads, and each of the first and second forehead pads are adapted to be positioned with respect to the mask frame independent of the other forehead pad. The first and second forehead pads may each include a bellows section defining grooves for selective positioning in the first and second slots and each bellows region may define an air channel at a tip end of the bellows region.

Preferably the cushion may include a plurality of overlapping layers.

Another aspect of the invention relates to a method of assembling a respiratory mask, including the steps of providing a mask frame; forming a cushion assembly including a cushion formed of a first material and a retaining element formed of a second material embedded inside the first material, the second material being more rigid than the first material, providing an annular, u-shaped groove in the mask frame; positioning the cushion assembly in the groove such that the cushion contacts the groove and the retaining element is disposed within the groove; and securing the cushion assembly to the mask frame using the retaining element.

Preferably the method may include the step of: providing a tab receiving portion on the mask frame having a first side and a second side; providing a tab extending from the retaining element through the cushion; positioning the tab in the tab receiving portion such that the tab contacts the first side of the tab receiving portion and the cushion contacts the second side of the tab receiving portion.

The method may also include the step of: providing first and second grooved slots in the mask frame; and providing first and second forehead pads in the first and second slots, respectively, wherein the first and second pads are adjustable with respect to each other and the mask frame. Preferably the method may include that the first and second forehead pads each include a bellows region defining grooves for selective positioning in the first and second slots.

Optionally the method includes the step of forming an air channel in a tip end of each bellows region. Optionally the method includes the step of forming a plurality of overlapping layers in the cushion.

Yet another aspect of the invention relates to a respiratory mask for use in delivering gas flow to a patient received from a respiratory therapy system, including a mask frame defining a mask shell forming an opening to receive the gas flow and a bridge portion extending from the mask shell and defining first and second slots; a cushion assembly including a cushion and a retaining element embedded inside the cushion, the retaining element including tabs to secure the cushion to the mask shell, said mask frame coupled to the entire perimeter of said cushion; and first and second forehead pads positioned in the first and second slots of the bridge portion, the first and second forehead pads being independently adjustable with respect to one another and with respect to the mask frame in both horizontal and vertical directions.

Preferably the respiratory mask may also include that the first and second forehead pads each include a pad region and a tapered bellows region, the tapered bellows region defining an air channel at a tip end of the bellows region.

5 Preferably the mask frame may define an annular groove and a plurality of tab receiving portions and wherein the cushion assembly is inserted into the groove such that the tabs engage the tab receiving portions.

10 Another aspect of the invention is a respiratory mask substantially as hereinbefore described with reference to the accompanying drawings. And yet another aspect of the invention is a method of assembling a respiratory mask substantially as hereinbefore described with reference to the accompanying drawings.

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

15 FIG. 1 is an isometric view of a mask assembly.

FIG. 2 is an exploded view of the mask assembly of FIG. 1.

- [09] FIG. 3 is a rear isometric view of a mask frame.
- [10] FIG. 4A is a front view of the mask assembly of FIG. 1.
- [11] FIG. 4B is a sectional view along line 4B-4B of FIG. 4A.
- [12] FIG. 4C is a sectional view along line 4C-4C of FIG. 4A.
- [13] FIG. 5A is a rear view of the mask assembly of FIG. 1
- [14] FIG. 5B is a sectional view along line 5B-5B of FIG. 5A.

#### Detailed Description

- [15] FIG. 1 is an isometric view of a mask or mask assembly 10 for use in a respiratory therapy system such as a Continuous Positive Airway Pressure (CPAP) system. In a respiratory therapy system, gas flow is provided to a patient through mask assembly 10, which can be secured to a head of the patient. Mask assembly 10 includes a gas supply conduit connector 12, a mask frame or body 14, a cushion assembly 16 and first and second forehead pads 18. Connector 12 is coupleable to a gas supply for delivery of gas to the mask frame 14. Straps (not shown) are coupled to the mask frame 14 in order to secure mask assembly 10 to the head of the patient.
- [16] Cushion assembly 16 is secured to mask frame 14 and configured to press against a face of the patient and cover a nose of the patient. In other embodiments, the mask frame can further cover the mouth of the patient. In any event, the cushion assembly 16 is designed to create a relatively air tight seal with the face of the patient such that gas flow is delivered to a patient airway (e.g. mouth, sinus). Forehead pads 18 press against a forehead of the patient and can be adjustably positioned with respect to the mask frame 14. In one embodiment, adjustments to the forehead pads 18 are made automatically based on movement of the patient. In another embodiment, manual adjustments to the forehead pads are made in order to adjust to a specific size and/or shape of the patient's head.
- [17] With further reference to FIG. 2, mask frame 14 includes a mask shell 20 and a bridge portion 22. Mask shell 20 defines an opening 24 for receiving the gas conduit connector 12.



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During operation, gas flows from conduit connector 12 and through opening 24 to the patient. Mask shell 20 also defines first and second strap receiving portions 26 and tab receiving portions 28, 30 and 32. A strap (not shown) is provided in the strap receiving portions 26 to secure a lower portion of the mask frame 14 to the patient's head. Tab receiving portions 28, 30 and 32 receive corresponding tabs of the cushion assembly 16 such that the cushion assembly 16 can be releasably secured to the mask frame 14. Furthermore, assembly of the cushion assembly 16 to the mask frame 14 can be performed quickly and without the need for specialized assembly tools.

[18] Bridge portion 22 is generally T-shaped and defines first and second slots 34 for receiving the first and second forehead pads 18. Together, the first and second forehead pads 18 cooperate with the first and second slots 34 to selectively adjust mask frame 14 with respect to the patient's head. In particular, forehead pads 18 can be selectively adjusted vertically (i.e., up and down with respect to the slots 34) as well as horizontally (i.e., in and out with respect to the slots 34). To this end, both of the forehead pads 18 and both slots 34 are grooved to facilitate selective position adjustment. Additionally, the forehead pads 18 can move with respect to mask frame 14 independent of one another, which can lead to a more comfortable fit. Additionally, bridge portion 22 includes first and second strap receiving portions 36 adapted to receive a strap (not shown) for securing mask assembly 10, in particular an upper portion thereof, to the forehead of the patient.

[19] Cushion assembly 16 is formed of a cushion 40 and a retaining element or ring 42. In the embodiment illustrated, cushion 40 includes three overlapping layers 40a, 40b and 40c of material to provide support and sealing around the patient's nose. In particular, layer 40a overlaps layers 40b and 40c, and wherein layer 40b overlaps layer 40c. Cushion 40 also forms an opening 43 in fluid communication with opening 24 on mask shell 20 so as to direct gas flow from the gas conduit connector 12 to the patient. Retaining element 42 is embedded within cushion 40 and is adapted to secure cushion 40 to mask shell 20. By embedding retaining element 42 within cushion 40, cushion assembly 16 can easily be assembled to the mask frame 14 without the need to align cushion 40 with retaining element 42 to create a proper seal between cushion assembly 16 and mask frame 14. In order to secure cushion 42 to mask shell 20, retaining element 42 includes tabs 44, 46 and 48 that are configured to be placed in tab receiving portions 28, 30 and 32 of mask shell 20, respectively.

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[20] In one embodiment, retaining element 42 is embedded within cushion 40 by an over molding process wherein tabs 44, 46 and 48 extend through cushion 40 and remain exteriorly exposed while the remaining portion of retaining element is embedded within cushion 40. Stated another way, the cushion 40 completely surrounds a circumference of the retaining element 42. With the exception of the tabs 44, 46 and 48, only the cushion material of the cushion assembly 16 is exteriorly exposed. Cushion 40 can be made of an elastomeric material such as silicone, a thermoplastic elastomer, etc. Retaining element 42 provides structural integrity to cushion 40 and engages mask frame 14 to secure cushion 40 to mask frame 14. To this end, retaining element 42 can be formed of a material that is more rigid than cushion 40, for example a rigid plastic material such as polycarbonate, polypropylene, etc.

[21] With further reference to FIG. 3, a rear view of mask frame 14 is illustrated. Mask shell 20 includes an annular groove 50 shaped to receive cushion assembly 16. In particular, annular groove 50 is generally U-shaped along a cross section and has a thickness to accommodate cushion 40 and retaining element 42. During assembly of mask assembly 10, tab 48 is inserted into tab receiving portion 32 and cushion assembly 16 is inserted into annular groove 50. In the embodiment illustrated, tab 48 is a projection adapted for insertion into tab receiving portion 32, which is an aperture in mask shell 20. Next, tabs 44 and 46 of retaining element 42 are pressed against tab receiving portions 28 and 30, respectively, locking into place against mask shell 20. Both of tabs 44 and 46 are hook shaped to engage respective tab receiving portions 28 and 30, which form recess portions in groove 50. In particular, the hook portions engage a front side of mask frame 14 (i.e., closer to opening 24 and on a side opposite annular groove 50).

[22] FIG. 4A is a front view of mask assembly 10, illustrating section line 4B-4B for FIG. 4B and section line 4C-4C for FIG. 4C. Together, FIGS. 4A-4C illustrate connection between mask frame 14 and cushion assembly 16. FIG. 4C is a close-up, sectional view of engagement between tab 44 of retaining element 42 and tab receiving portion 28 of mask shell 20. As illustrated, retaining element 42 is embedded within cushion 40, such that cushion 40 completely surrounds the circumference of retaining element 42 on all sides. Together, cushion 40 and retaining element 42 are disposed within annular groove 50. Illustratively, the U-shaped annular groove 50 includes three sides 50a, 50b and 50c.

Cushion 40 surrounds retaining element 42 such that cushion 40 is exteriorly exposed to all three sides (50a, 50b and 50c) of annular groove 50. In one embodiment, the resilient nature of cushion 40 can allow cushion assembly 16 to fit tightly within annular groove 50, as cushion 40 slightly compresses to fit into groove 50 and contacts at least sides 50a and 50b of groove 50 and, in one embodiment, also contacts side 50c. Tab 44 of retaining element 42 extends through cushion 40 and around tab receiving portion 28. Tab 44 can be resilient and shaped so as to deflect around tab receiving portion 28. A hook portion 52 of tab 44 snaps against tab receiving portion 28 to secure cushion assembly 16 to mask shell 20 once hook 52 is against a front side 54 of tab receiving portion 28.

[23] FIG. 5A is a rear view of mask assembly 10, illustrating section line 5B-5B for FIG. 5B. FIG. 5B is a sectional view of one of the forehead pads 18 that includes a pad region 60 and a tapered bellows region 62. In one embodiment, forehead pad 18 can be made of a rubber material such as silicone, a thermoplastic elastomer, etc. As illustrated, pad region 60 is concave shaped and presses against the forehead of the patient. Bellows region 62 extends from the pad region 60, defining an interior cavity 64 and an air channel 66, which terminates at a tip end 70. Interior cavity 64 allows bellows region 62 to be flexible such that pad region 60 can maintain constant contact with the patient's forehead. Air channel 66 prevents forehead pad 18 from sticking to the patient's forehead as well as promoting drainage of fluids from cleaning and/or perspiration.

[24] Tip end 70 is adapted for insertion into one of the slots 34 on mask frame 14. After insertion of tip end 70 into slot 34, bellows region 62 can be selectively adjustable to discrete positions within slot 34 as a function of grooves 72, 74, 76 and 78. For example, if it is desired to have mask frame 14 further away from the patient's face, forehead pad 18 can be adjusted such that groove 72 engages slot 34 (as illustrated in FIG. 5B). If it is desired to have mask frame 14 closer to the patient's face, forehead pad 18 can be adjusted such that groove 78 engages slot 34. Additionally, the forehead pad 18 can move to different vertical positions within slot 34 and thus with respect to mask frame 14. Slot 34 includes a plurality of grooves, in particular three grooves, which are illustrated in FIG. 3 as well as in section in FIG. 5B, namely a top groove 34a, a middle groove 34b and a bottom groove 34c. As illustrated in FIG. 5B, forehead pad 18 is positioned in middle groove 34b. If it is desired for mask frame 14 to sit lower with respect to the patient's head, forehead pad 18 can be adjusted

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to be positioned in the top groove 34a of slot 34. If it is desired for mask frame 14 to sit higher with respect to the patient's head, the forehead pad 18 can be adjusted to be positioned in the lower groove 34c of slot 34. Due to the resilient nature of forehead pad 18, a position of forehead pad 18 in slot 34 can adjust automatically, for example based on patient movement.

[25] Although the present disclosure has been described with reference to preferred embodiments, workers skilled in the art will recognize that changes can be made in form and detail without departing from the spirit and scope of the present disclosure.

## THE CLAIMS DEFINING THE INVENTION ARE AS FOLLOWS:

1. A respiratory mask, including:
  - a mask frame defining a groove;
  - a cushion formed of a first material; and
  - 5 a retaining element formed of a second material that is more rigid than the first material, embedded inside the cushion and adapted to be releasably secured to the mask frame, wherein the cushion and retaining element are disposed within the groove such that the cushion is exteriorly exposed to the groove.
- 10 2. The respiratory mask of claim 1 wherein the retaining element includes a plurality of tabs positioned within corresponding tab receiving portions of the mask frame.
3. The respiratory mask of claim 2 wherein the plurality of tabs each extend through the cushion.
- 15 4. The respiratory mask of any one of claims 1-3 wherein the mask frame further includes a bridge that includes first and second slots that engage first and second forehead pads, each of the first and second forehead pads adapted to be positioned with respect to the mask frame independent of the other forehead pad.
- 20 5. The respiratory mask of claim 4 wherein the first and second forehead pads each include a bellows region defining grooves for selective positioning in the first and second slot.
6. The respiratory mask of claim 5 wherein each bellows region defines an air channel at a tip end of the bellows region.
- 25 7. The respiratory mask of any one of claims 1-6 wherein the cushion includes a plurality of overlapping layers.

8. The method of assembling a respiratory mask, including:  
providing a mask frame;  
forming a cushion assembly including a cushion formed of a first material  
and a retaining element formed of a second material embedded inside the  
5 cushion, the second material being more rigid than the first material;  
providing an annular, u-shaped groove in the mask frame;  
positioning the cushion assembly in the groove such that the cushion  
contacts the groove, and the retaining element is disposed within the groove; and  
securing the cushion assembly to the mask frame using the retaining element.

10 9. The method of claim 8 and further including:  
providing a tab receiving portion on the mask frame having a first side and  
a second side;  
providing a tab extending from the retaining element through the cushion;  
positioning the tab in the tab receiving portion such that the tab contacts  
15 the first side of the tab receiving portion and the cushion contacts the second side  
of the tab receiving portion.

10. The method of any one of claims 8-9 and further including:  
providing first and second grooved slots in the mask frame; and  
providing first and second forehead pads in the first and second slots,  
20 respectively,  
wherein the first and second pads are adjustable with respect to each  
other and the mask frame.

11. The method of claim 10 wherein the first and second forehead pads each  
include a bellows region defining grooves for selective positioning in the first and  
25 second slots.

12. The method of claim 11 and further including:  
forming an air channel in a tip end of each bellows region.

13. The method of any one of claims 8-12 and further including:  
forming a plurality of overlapping layers in the cushion.

14. A respiratory mask for use in delivering gas flow to a patient received from  
a respiratory therapy system, including:

5 a mask frame defining a mask shell forming an opening to receive the gas  
flow and a bridge portion extending from the mask shell and defining first and  
second slots;

10 a cushion assembly including a cushion and a retaining element  
embedded inside the cushion, the retaining element including tabs to secure the  
cushion to the mask shell, said mask frame coupled to the entire perimeter of said  
cushion; and

15 first and second forehead pads positioned in the first and second slots of  
the bridge portion, the first and second forehead pads being independently  
adjustable with respect to one another and with respect to the mask frame in both  
horizontal and vertical directions.

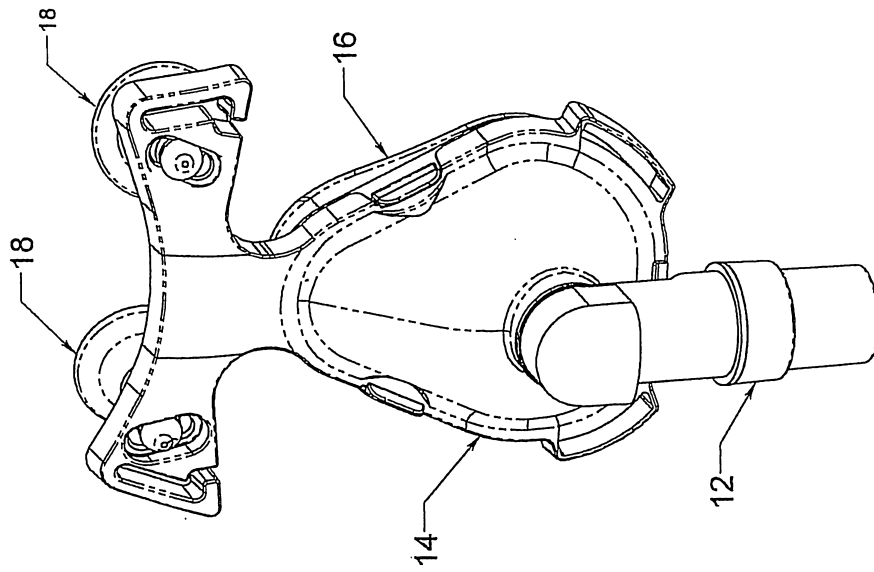
15. The respiratory mask of claim 14 wherein the first and second forehead  
pads each include a pad region and a tapered bellows region, the bellows region  
defining an air channel at a tip end of the bellows region.

20 16. The respiratory mask of any one of claims 14-15 wherein the mask frame  
defines an annular groove and a plurality of tab receiving portions and wherein  
the cushion assembly is inserted into the groove such that the tabs engage the  
tab receiving portions.

**CAREFUSION 2200, INC**

WATERMARK PATENT AND TRADE MARKS ATTORNEYS

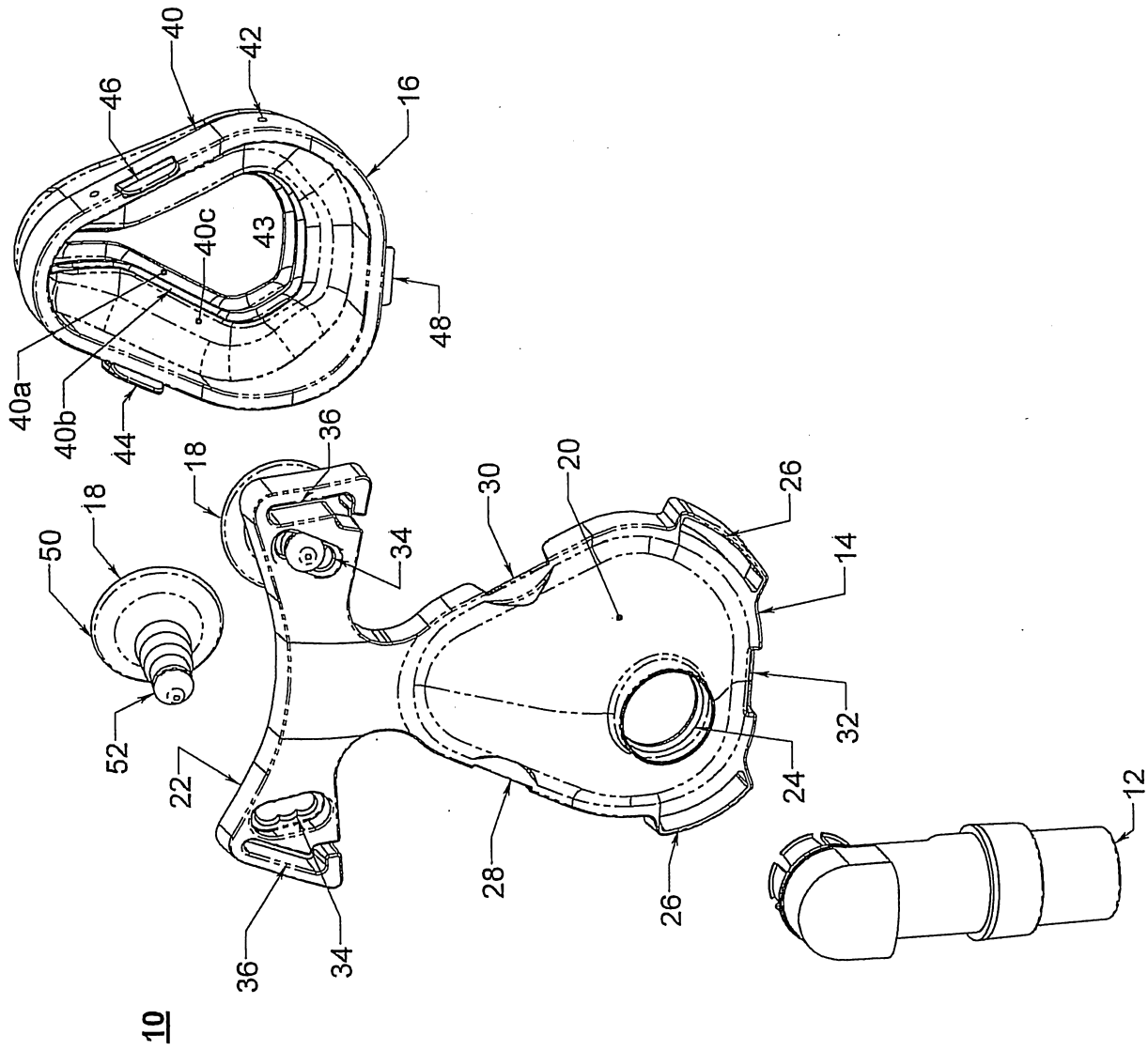
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FIG. 1





**FIG. 2**

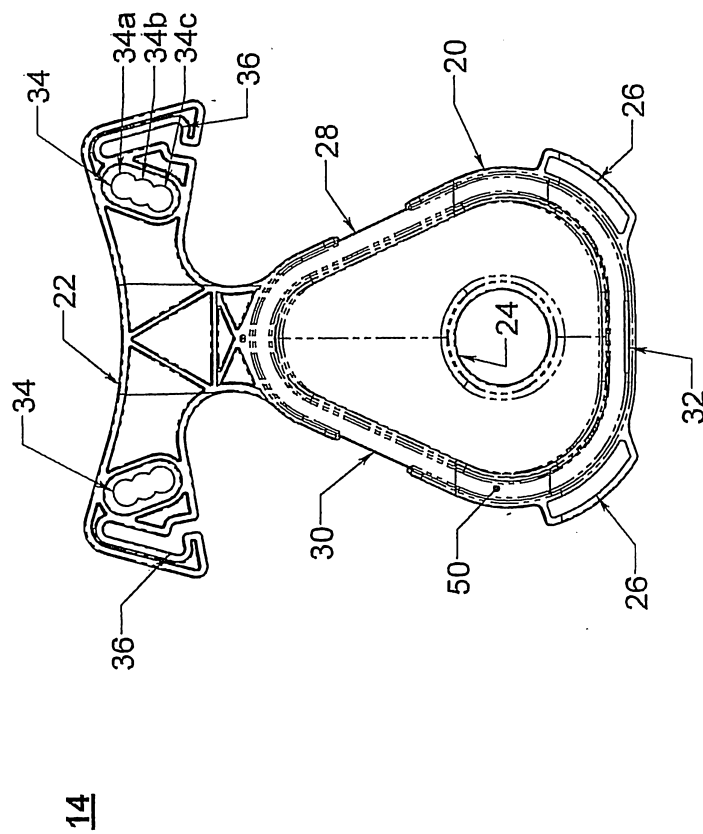


FIG. 3

