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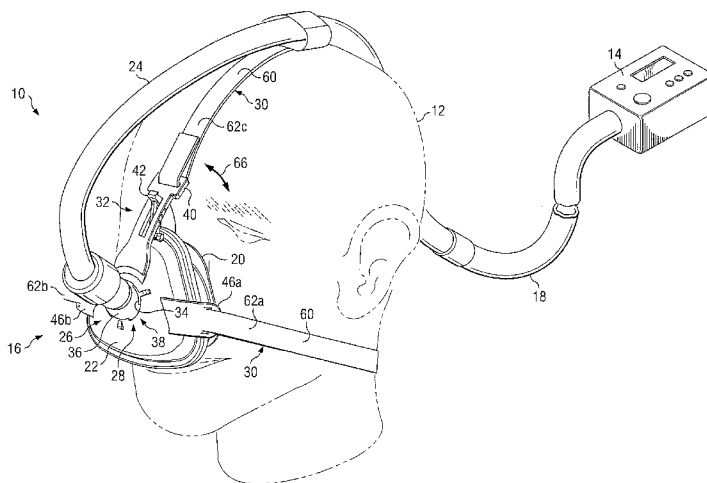
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(54) Title: ADJUSTMENT SYSTEM FOR A MASK APPARATUS FOR USE IN A BREATHING ASSISTANCE SYSTEM



(57) Abstract: An adjustable mask apparatus for use in a breathing assistance system may include a housing, an adjustment arm, and a locking member. The housing may support a cushion configured to provide a seal against a patient's face. The adjustment arm may include a first end configured for attachment to a head gear, and a second end rotatably coupled to the housing to allow rotation of the adjustment arm to adjust a distance between the first end of the adjustment arm and the patient's head. The locking member may be coupled to the housing and may be configured to secure the adjustment arm in one of a plurality of predetermined rotational positions, each predetermined rotational position comprising a rotational position of the adjustment arm with respect to the housing.

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## **ADJUSTMENT SYSTEM FOR A MASK APPARATUS FOR USE IN A BREATHING ASSISTANCE SYSTEM**

### TECHNICAL FIELD

The present disclosure relates generally to the field of breathing assistance systems, e.g., an adjustment system for a mask apparatus for use in a breathing assistance system.

### BACKGROUND

In recent years, continuous positive airway pressure (CPAP) therapy has become a common prescription for individuals suffering from sleep apnea and/or other breathing ailments. Such therapy may involve placement of a nose or face mask on the subject during sleeping, while positive pressure air is continuously delivered to the subject through the mask. The positive pressure air may be delivered to the patient's upper airway via a face mask or other patient interface in order to prevent the upper airway tissues from collapsing during sleep, thus reducing the occurrence and/or severity of sleep apnea.

### SUMMARY

In accordance with one embodiment of the disclosure, an adjustable mask apparatus for use in a breathing assistance system includes a housing, an adjustment arm, and a locking member. The housing may support a cushion configured to provide a seal against a patient's face. The adjustment arm may include a first end configured for attachment to a head gear, and a second end rotatably coupled to the housing to allow rotation of the adjustment arm to adjust a distance between the first end of the adjustment arm and the patient's head. The locking member may be coupled to the housing and may be configured to secure the adjustment arm in one of a plurality of predetermined rotational positions, each predetermined rotational position comprising a rotational position of the adjustment arm with respect to the housing.

In accordance with another embodiment of the disclosure, an adjustable mask apparatus for use in a breathing assistance system may include a housing and an adjustment arm. The housing may support a cushion configured to provide a seal against a patient's face. The adjustment arm may include a first end configured for attachment to

a head strap that extends from the first end of the adjustment arm upward toward the top of the patient's head, and a second end rotatably coupled to the housing to allow rotation of the adjustment arm between a plurality of predetermined rotational positions to adjust a distance between the first end of the adjustment arm and the patient's head.

5           In accordance with another embodiment of the disclosure, an adjustable mask apparatus for use in a breathing assistance system may include housing means, adjustment means, and locking means. The housing means may be configured to support a cushion configured to provide a seal against a patient's face. The adjustment means may be configured for adjust a head gear attachment position, and may include a first end  
10           configured for attachment to a head gear, and a second end rotatably coupled to the housing means to allow rotation of the adjustment means to adjust a distance between the first end of the adjustment means and the patient's head. The locking means may be configured for securing the adjustment means in one of a plurality of predetermined rotational positions, each predetermined rotational position comprising a rotational  
15           position of the adjustment means with respect to the housing means.

#### BRIEF DESCRIPTION OF THE DRAWINGS

FIGURE 1 illustrates an example breathing assistance system for providing breathing assistance to a patient, according to one embodiment of the disclosure;

20           FIGURE 2 illustrates an exploded view of a portion of mask apparatus, indicating the assembly of a housing, a ball member, and a mounting system to form a ball joint, according to one embodiment of the disclosure;

FIGURE 3 illustrates an example mask apparatus with a mounting plate aligned for attachment to a housing, according to one embodiment of the disclosure;

25           FIGURES 4A-4C illustrates a detailed view of an example securing member and corresponding attachment member for securing a mounting plate to a housing, according to one embodiment of the disclosure;

FIGURE 5 illustrates the inside of a mask apparatus with a mounting plate secured to a housing, forming a ball joint, according to one embodiment of the disclosure;

30           FIGURE 5 also illustrates an adjustment arm of an adjustment system releasably locked with a locking member of the adjustment system;

FIGURES 6A-6B illustrate a gas exhaust system for removing exhaled gas away from a patient, according to one embodiment of the disclosure; and

FIGURES 7A-7D illustrate the operation of an adjustment system for adjusting the fit of a mask apparatus against a patient's head (e.g., for adjusting the fit of a mask cushion against the patient's face), according to one embodiment of the disclosure.

#### DETAILED DESCRIPTION OF THE DRAWING

Selected embodiments of the disclosure may be understood by reference, in part, to FIGURES 1-7D, wherein like numbers refer to same and like parts. The present disclosure relates generally to mask apparatuses for breathing assistance systems (e.g., ventilators, CPAP devices, or BiPAP devices).

In some embodiments, a mask apparatus may include a cushion for providing a seal against a patient's face, a housing configured to support the cushion, and a ball joint disposed in the housing that allows multi-axial rotation of a gas delivery conduit relative to the housing. The gas delivery conduit may be configured to deliver gas through the housing for delivery to the patient. The ball joint may include a ball member positioned in an opening formed in the housing, and a mounting system configured to secure the ball member in the housing opening such that the housing, the ball member, and the mounting system define a ball joint allowing the ball member to rotate about multiple axes relative to the housing and the mounting system. The ball member may have a passageway extending therethrough for communicating gas from the gas delivery conduit into the housing and toward the patient.

In some embodiments including a ball joint, a gas exhaust system may be defined by or associated with the ball joint. For example, one or more exhaust passageways may be defined between an outer surface of the ball member and the housing opening, wherein the one or more exhaust passageways are configured for communicating exhaust gas away from the patient.

In some embodiments, a mask apparatus may include a cushion for providing a seal against a patient's face, a housing configured to support the cushion, and an adjustment system supported by the housing and configured to adjust the fit of the mask apparatus (e.g., the cushion) against the face. For example, the adjustment system may include an adjustment arm that interrelates with a locking member to adjust and/or lock

the angle of the adjustment arm relative to the housing. The adjustment arm may be rotatably coupled to the housing at a first end and may be coupled to a head gear (e.g., a head strap) at a second, free end. The adjustment arm may rotate relative to the housing to adjust a distance between the free end of the adjustment arm and the patient's head  
5 (e.g., proximate the forehead). The locking member may be coupled to the housing and may be configured to secure the adjustment arm in one of a plurality of predetermined rotational positions with respect to the housing.

A mask apparatus according to the present disclosure may include any one, some, or all of such features. For example, a mask apparatus may include a ball joint, an  
10 exhaust system associated with the ball joint, and an adjustment system. As another example, a mask apparatus may include a ball joint, an exhaust system associated with the ball joint, but no adjustment system. As another example, a mask apparatus may include a ball joint, an adjustment system, and an exhaust system unrelated to the ball joint. As another example, a mask apparatus may include an adjustment system, but not ball joint.

FIGURE 1 illustrates an example breathing assistance system 10, according to one  
15 embodiment of the disclosure. Breathing assistance system 10 may be generally configured to provide breathing assistance (e.g., providing ventilation and/or treating an apnea or other breathing condition) to a patient 12. Breathing assistance system 10 may include a gas delivery system 14, a mask apparatus 16, and a connection system 18  
20 between gas delivery system 14 and mask apparatus 16.

Gas delivery system 14 may include any device or devices configured to generate, supply, and/or deliver gas (e.g., pressurized air) toward patient 12 via mask apparatus 16. For example, gas delivery system 14 may comprise a device capable of generating pressurized air (e.g., a ventilator, CPAP system, or BiPAP system), a wall outlet through  
25 which pressurized air may be supplied (e.g., in a hospital or clinic), one or more tanks of compressed gas, a compressor, or any other suitable source of pressurized or non-pressurized gas. As used herein, the term "gas" may refer to any one or more gases and/or vaporized substances suitable to be delivered to and/or from a patient via one or more breathing orifices (e.g., the nose and/or mouth), such as air, nitrogen, oxygen, any  
30 other component of air, CO<sub>2</sub>, vaporized water, vaporized medicines, and/or any combination of two or more of the above, for example. The term "patient" may refer to any person or animal that may receive breathing assistance from system 10, regardless of

the medical status, official patient status, physical location, or any other characteristic of the person. Thus, for example, patients may include persons under official medical care (e.g., hospital patients), persons not under official medical care, persons receiving care at a medical care facility, persons receiving home care, etc.

5 Mask apparatus 16 may be generally configured to deliver gas supplied by gas delivery system 14 to patient 12 and/or to communicate exhaust gas away from patient 12. In various embodiments, mask apparatus 16 may include one, some or all of the following features:

(a) a cushion 20 configured to provide a seal against the patient's face (e.g.,  
10 around the patient's nose and/or mouth);

(b) a housing 22 configured to support cushion 20;

(c) a gas delivery conduit 24 configured to communicate gas from gas delivery system toward cushion 20;

(d) a ball joint 26 configured to provide a flexible, movable, and/or adjustable  
15 connection between housing 22 and gas delivery conduit 24;

(e) a gas exhaust system 28 configured to remove exhaled gas away from patient  
12;

(f) a headgear 30 configured to secure mask apparatus 16 on the patient's head  
and/or to secure cushion 20 against the patient's face; and/or

(g) an adjustment system 32 for adjusting the fit of mask apparatus 16 against the  
20 patient's head (e.g., for adjusting the fit of cushion 20 against the patient's face).

Mask apparatus 16 may also include any other suitable components, e.g., a forehead cushion or other forehead support system, one or more additional adjustment systems, connection members, and/or conduits for communicating gas toward and/or  
25 away from patient 12.

Mask apparatus 16 may be coupled to gas delivery system 14 by connection system 18. Connection system 18 may include any one or more conduits (e.g., one or more flexible hoses and/or rigid conduits) for communicating gas from gas delivery system 14 to mask apparatus 16. In some embodiments, connection system 18 may be  
30 coupled to delivery conduits 24 of mask apparatus 16. When assembled, breathing assistance system 10 may define one or more gas delivery passageways from gas delivery system 14 to patient 12, passing through connection system 18, mask apparatus 16, and/or

one or more other components of system 10. Such passageways may be used to deliver gas from gas delivery system 14 to patient 12. In addition, in some embodiments, mask apparatus 16 and/or connection system 18 may include or define one or more passageways for communicating exhaled gas away from patient 12.

5 Cushion 20 may comprise any structure suitable for contacting and/or providing a seal against a patient's face. In some embodiments, cushion 20 may be configured to surround, cover, or interface with the nose and/or the mouth. For example, cushion 20 may comprise a nasal cushion configured to fit around the nose, a mouth cushion configured to fit around the mouth, a face cushion configured to fit around both the nose  
10 and mouth, or nasal pillows configured to directly interface with the nostrils.

Cushion 20 may be formed from any suitable materials, e.g., materials suitable for forming a seal with the patient's face. In some embodiments, cushion 20 may be formed from relatively flexible or deformable materials, such as flexible or deformable plastic, rubber, polymer, silicon, or gel, for example. In some embodiments, cushion 20 may  
15 have one or more membranes which may be contoured to provide a seal against the patient's face. In other embodiments, cushion 20 may include one or more inflatable portions. Cushion 20 may have any suitable shape and/or cross-section. In some embodiments in which cushion 20 is configured to fit around the patient's nose (e.g., as shown in FIGURE 1), cushion 20 may have a generally triangular shape.

20 Housing 22 may comprise any one or more components of mask apparatus 16 configured to support (directly or indirectly) cushion 20. For example, housing 22 may comprise a shell structure, a support member, a frame member, a base member, a connection member, an arm member, or a conduit. In the example embodiment shown in FIGURE 1, housing 22 comprises a mask shell or frame to which cushion 20 is directly  
25 attached.

In addition, housing 22 may house or form a portion of ball joint 26. As discussed below with reference to FIGURE 2, housing may define an opening 34 in which a ball member 36 may be positioned such that ball member 36 may rotate about multiple axes relative to housing 22.

30 In addition, housing 22 may provide or help define gas exhaust system 28. For example, as discussed below with reference to FIGURES 2 and 6A-6B, one or more exhaust passageways 38 may be defined between opening 34 of housing 22 and an outer

surface of ball member 36. Such exhaust passageways 38 may be configured to communicate exhaust gas from patient 12 (e.g., CO<sub>2</sub>) away from patient 12.

In addition, housing 22 may support (directly or indirectly) adjustment system 32 for adjusting the fit of mask apparatus 16 against the patient's head (e.g., for adjusting the fit of cushion 20 against the patient's face). In the embodiment shown in FIGURE 1, adjustment system 32 may include an adjustment arm 40 and a locking member 42 supported by housing 22, which may interact in order to adjust the distance between a free end of adjustment arm 40 and the patient's head.

In addition to supporting adjustment system 32 that is coupled to headgear 30, housing 22 may be further configured to support headgear 30. For example, housing 22 may include one or more headgear attachment members 46 for securing headgear 30. In the illustrated embodiment, housing 22 includes a headgear attachment member 46 located on each lateral side of housing 22. A head strap may be adjustably attached to each headgear attachment member 46 to help secure mask apparatus 16 against the patient's head.

Housing 22 may be a single, integrated component, or may include multiple components coupled together.

Cushion 20 may be directly or indirectly coupled to housing 22. In some embodiments, cushion 20 is releasably coupled to housing 22 such that cushion 20 may be removed from, and reattached to, housing 22. Cushion 20 may be releasably coupled to housing 22, directly or indirectly, in any suitable manner. For example, cushion 20 may be releasably coupled to housing 22 in any manner disclosed in co-pending U.S. Patent Application 11/469,260, filed August 31, 2006, and entitled "Patient Interface Assembly for a Breathing Assistance System," which is hereby incorporated by reference. As another example, cushion 20 may be releasably coupled to housing 22 using any suitable clips or other connectors.

Gas delivery conduit 24 may comprise any one or more conduits configured to communicate gas from gas delivery system 14 toward cushion 20. Such conduits may include, e.g., one or more flexible hoses and/or rigid conduits. Gas delivery conduit 24 may be coupled at a first end to connection system 18 (e.g., a breathing circuit), and may be directly or indirectly coupled at a second end to housing 22 and/or cushion 20 in order to deliver gas to patient 12 via cushion 20. In the embodiment shown in FIGURE 1, gas



delivery conduit 24 is removably coupled to ball joint 26. As discussed below, ball member 36 includes an opening extending therethrough such that gas may be delivered from gas delivery conduit 24, through the opening in ball member 36, through housing 22 and cushion 20, and to patient 12.

5 In some embodiments, gas delivery conduit 24 may be secured to the patient's head. For example, as shown in FIGURE 1, gas delivery conduit 24 may be extend upwardly in front of the patient's head and may be releasably secured to headgear 30 near the top of the patient's head.

10 Ball joint 26 may be configured to provide a flexible, movable, and/or adjustable connection between gas delivery conduit 24 and housing 22. In some embodiments, ball joint 26 may provide for multi-axial rotation of gas delivery conduit 24 relative to housing 22. In the illustrated embodiment, ball joint 26 includes ball member 36 positioned in opening 34 formed in housing 22. Ball member 36 may be secured against housing 22 may a mounting system 50 (discussed below with reference to FIGURE 2).  
15 Together, ball member 36, housing 22, and mounting system 50 may form ball joint 26.

Gas exhaust system 28 may be configured to remove exhaled gas away from patient 12. In the illustrated embodiments, gas exhaust system 28 includes one or more exhaust passageways 38 defined between opening 34 of housing 22 and an outer surface of ball member 36. Such exhaust passageways 38 may be configured to communicate  
20 exhaust gas from patient 12 (e.g., CO<sub>2</sub>) away from patient 12. In some embodiments, opening 34 may define a perimeter including one or more contact portions alternative with one or more non-contact portions. The non-contact portions may be portions of the perimeter of opening 34 that do not contact ball member 36, thus defining an exhaust passageway 38 between ball member 36 and opening 34. Gas exhaust system 28 is  
25 discussed in greater detail below with reference to FIGURES 6A-6B.

Headgear 30 may be configured to secure mask apparatus 16 on the patient's head and/or to secure cushion 20 against the patient's face. Headgear 30 may include any one or more components. For example, headgear 30 may include a head strap 60 including multiple strap portions 62 coupled to mask apparatus 16 at various locations. In the  
30 illustrated embodiment, head strap 60 includes: (a) a left side strap portion 62a extending around the left side of the patient's face and secured to a left headgear attachment member 46a, (b) a right side strap portion 62b extending around the right side of the

patient's face and secured to a right headgear attachment member 46b, and (c) a top strap portion 62c extending over the top of the patient's head and secured to a free end of adjustment arm 40.

Strap portions 62 may be coupled to mask apparatus 16 in any suitable manner. For example, as shown in FIGURE 1, each strap portion 62 may be threaded through an opening formed in a component of mask apparatus 16, and folded back and attached to itself using hook and loop fasteners. Thus, each strap portion 62 may be adjustable as desired by patient 12. Each strap portion 62 may be integrated with or coupled to other strap portions 62 in any suitable manner, e.g., using hook and loop fasteners or other connection devices. In one embodiment, strap portions 62a, 62b, and 62c are integrated in a single piece head strap 60. Strap portions 62 may be formed from any one or more flexible and/or elastic materials. For example, strap portions 62 may be formed from elastomeric materials, neoprene, fabric, or other similar materials.

Adjustment system 32 may be configured for adjusting the fit of mask apparatus 16 against the patient's head (e.g., for adjusting the fit of cushion 20 against the patient's face). As discussed above, adjustment system 32 may include an adjustment arm 40 and a locking member 42 supported by housing 22. At least one of adjustment arm 40 and a locking member 42 may be configured for attachment to headgear 30, and may be adjusted relative to housing 22 in order to adjust the fit of mask apparatus 16 against the patient's head. For example, as discussed below with reference to FIGURES 7A-7B, adjustment arm 40 may be rotatably coupled to housing 22 such that adjustment arm 40 may rotate as indicated by arrow 66, in order to adjust the distance between a free end of adjustment arm 40 and the patient's head. Locking member 42 may interact with adjustment arm 40 in order to lock adjustment arm 40 in one of a plurality of rotational positions.

As discussed above, adjustment system 32 may be used for adjusting the fit of mask apparatus 16 against the patient's head. For example, mask apparatus 16 may be adjusted using adjustment system 32 in order to properly secure mask apparatus 16 onto the patient's head, and/or to provide a proper seal between cushion 20 and the patient's face. In this manner, adjustment system 32 may be used to adjust mask apparatus 16 to fit a variety of patient's having various head or face shapes and/or sizes. For example, mask apparatus 16 may be adjusted to fit both children and adults.

FIGURE 2 illustrates an exploded view of a portion of mask apparatus, indicating the assembly of housing 22, ball member 36, and mounting system 50 to form ball joint 26, according to one embodiment of the disclosure. Ball member 36 may be inserted through an opening 34 formed in housing 22. Mounting system 50 may be configured to  
5 secure ball member 36 in housing opening 34 such that housing 34, ball member 36, and mounting system 50 form ball joint 26 allowing ball member 36 to rotate relative to the housing 22 and mounting system 50.

Ball member 36 may include a cylindrical portion 52 configured to be coupled to gas delivery conduit 24 and a spherical portion 54 positioned in opening 34 in housing 22.  
10 Ball member 36 may include an opening 56 extending therethrough such that when mask apparatus is assembled and secured to patient 12, gas may be delivered from gas delivery conduit 24, through opening 56, through housing 22 and cushion 20, and to patient 12. Ball member 36 may be a single integrated component, or may include multiple components coupled together in any suitable manner. For example, in one embodiment,  
15 ball member 36 includes (a) a body portion 57 that defines cylindrical portion 52 and opening 56, and (b) a hemispherical cap portion 58 that slides over cylindrical portion 52 and cooperates with a hemispherical portion of body portion 57 to define spherical portion 54.

Mounting system 50 may comprise any one or more mounting members  
20 configured to secure ball member 36 in housing opening 34. One or more of such mounting members may be directly or indirectly coupled to housing 22. In addition, such one or more mounting members may define an opening into which a portion of ball member 36 may be positioned.

In the illustrated embodiment, mounting system 50 comprises a mounting plate 70  
25 including a mounting plate opening 72. Once mounting plate 70 is assembled with housing 22, a first, front portion of ball member 36 may extend through housing opening 34 and a second, rear portion of ball member 36 may extend through mounting plate opening 34.

Mounting system 50 may be releasably attached to housing 22 such that ball joint  
30 26 may be assembled and disassembled, and such that ball member 36 may be removed from housing opening 34. Mounting system 50 may be releasably attached to housing 22 in any suitable manner. In some embodiments, mounting system 50 may include a

securing system 74 for releasably securing mounting system 50 to housing 22. For example, in the illustrated embodiment, mounting plate 70 may include one or more securing members 76 configured for releasable attachment to housing 22. As discussed below with reference to FIGURES 4A-4C, securing members 76 may be manually moved  
5 from a first position for securing mounting plate 70 to housing 20 and a second position for releasing mounting plate 70 from housing 22.

As discussed above, gas exhaust system 28 may include one or more exhaust passageways 38 defined between housing opening 34 and an outer surface of ball member 36 for communicating exhaust gas away from patient 12. As shown in FIGURE 2,  
10 opening 34 may define a perimeter including one or more contact portions 80 alternating with one or more non-contact portions 82. Contact portions 82 generally contact ball member 36 when ball joint 26 is assembled. Non-contact portions 82 generally do not contact ball member 36, thus defining exhaust passageways 38 between ball member 36 and opening 34. In this embodiment, three contact portions 82 are alternated with three  
15 non-contact portions 82, thus defining three exhaust passageways 38. In other embodiments, mask apparatus 16 may include any other number and/or configuration of contact portions 82, non-contact portions 82, and/or exhaust passageways 38.

As shown in FIGURE 2, each non-contact portion 82 may be a cut-away or recessed portion from the perimeter of opening 34. Each contact portion 80 and/or non-  
20 contact portion 82 may have any suitable size, shape, and/or configuration. For example, contact portions 80 and/or non-contact portions 82 may be sized, shaped, and/or configured to form exhaust passageways 38 that allow a particular flow rate of exhaust gas through such passageways 38. As another example, contact portions 80 and/or non-  
25 contact portions 82 may be sized, shaped, and/or configured to form exhaust passageways 38 that direct exhaust gasses in one or more particular direction.

Mounting system 50 may define one or more pathways for exhaust gas to be communicated from patient 12 to exhaust passageways 28. In the illustrated embodiment, mounting plate 70 may include or define one or more openings allowing exhaust gas from patient 12 to pass through toward exhaust passageways 28. For example, mounting plate  
30 70 may be shaped and/or sized to define one or more passages between the outer perimeter of mounting plate 70 and an inner surface of housing 22. As another example, mounting plate 70 may define one or more passages allowing exhaust gas to pass through

toward exhaust passageways 28. In the illustrated embodiment, each securing member 76 defines an opening 84 allowing exhaust gas to pass through toward exhaust passageways 28. As another example, mounting plate 70 may include one or more openings 86 allowing exhaust gas to pass through toward exhaust passageways 28.

5 Mounting system 50 may also include one or more alignment devices for aligning mounting system 50 with housing 22. In this embodiment, mounting plate 70 includes one or more alignment holes 88 configured to receive one or more alignment members for aligning mounting plate 70 with housing 22, as discussed below with reference to FIGURE 3.

10 One or more stiffening members 92 may be disposed proximate the housing opening 34 for providing structural integrity around opening 34 (e.g., to resist deformation of housing opening 34). Stiffening members 92 may be integrated with or coupled to housing 22 in any suitable manner. In the illustrated embodiment, housing 22 includes an integrated stiffening member 92 proximate each contact portion 80 for providing  
15 structural integrity around opening 34.

Gas exhaust system 28 is further discussed below with reference to FIGURES 6A-6B.

FIGURE 2 also illustrates adjustment system 32 for adjusting the fit of mask apparatus 16 against the patient's head (e.g., for adjusting the fit of cushion 20 against the  
20 patient's face). Adjustment arm 40 and locking member 42 may be coupled to housing 22. In some embodiments, adjustment arm 40 and/or locking member 42 are formed integral with housing 22. For example, in the illustrated embodiment, adjustment arm 40 is integrally coupled to housing 22 by a living hinge, which allows adjustment arm 40 to rotate relative to housing 22 in the direction indicated by arrow 66. In addition, locking  
25 member 42 may be integrally coupled to housing 22 by a living hinge or a less flexible joint that allows some flexing of locking member 42 relative to housing 22, but less than that of adjustment arm 40.

Adjustment arm 40 and locking member 42 may interact with adjustment arm 40 in any suitable manner to allow adjustment arm 40 to be releasably locked in a plurality  
30 of different positions. In the illustrated embodiment, adjustment arm 40 includes a slot 100 configured to receive locking member 42. Locking member 42 may slide through slot 100 as adjustment arm 40 rotates along path 66.

Locking member 42 may include one or more first locking elements 104, and adjustment arm 40 may include one or more second locking elements 106 configured to interact with first locking elements 104 to releasably secure adjustment arm 40 in one of multiple different predetermined rotational positions. Locking elements 104 and 106 are better illustrated in FIGURES 5 and 7A-7D, which are discussed in greater detail below.

Locking elements 104 and 106 may include any elements configured to interact to releasably couple adjustment arm 40 and locking member 42. For example, locking elements 104 and/or 106 may comprise any suitable projections, bumps, teeth, indentations, holes, grooves, clips, hooks, latches, or any other suitable members or devices.

In the illustrated embodiment, locking member include three projections (e.g., bumps) 104 and adjustment arm 40 includes three indentations or openings 106. Each indentation 106 is configured to receive a corresponding projection 104 to lock adjustment arm 40 in a particular rotational position. Thus, adjustment arm 40 may be releasably locked in three predetermined rotational positions. In some embodiments, adjustment arm 40 may be manually moved between the three locking positions, which may include manual manipulation of adjustment arm 40 and/or locking member 42. For example, in one embodiment, if adjustment arm 40 is locked in a first position in which a first projection 104 is secured in a first indentation 106, adjustment arm 40 and locking member 42 may be flexed laterally in opposite directions to release the first projection 104 from the first indentation 106. Adjustment arm 40 may then be rotated along path 66 until a second projection 104 is received in a second indentation 106 to lock adjustment arm 40 in a second rotational position.

Adjustment system 32 may also include one or more stop elements 110 to limit the rotation of adjustment arm 40 in one or more directions. In the illustrated embodiment, locking member 42 includes a hook portion that acts as a first stop 112 to limit the rotation of adjustment arm 40 in a direction away from the patient's face. A second stop 114 may be located proximate the base of locking member 42 to limit the rotation of adjustment arm 40 in a direction toward the patient's face.

FIGURE 3 illustrates mask apparatus 16, with mounting plate 70 aligned for attachment to housing 22, according to one embodiment of the disclosure. In this illustration, ball member 36 has been inserted in housing opening 34, and mounting plate

70 may be coupled to housing 22 to secure ball member 36 between housing 22 and mounting plate 70 to form ball joint 26.

In this embodiment, mounting plate 70 has a substantially triangular shape and includes three securing members 76 positioned around the perimeter of plate 70. Each  
5 securing member 76 may be configured to be releasably coupled to a corresponding attachment member 120 for coupling plate 70 to housing 22. In this embodiment, three attachment members 120 are formed integral with, or coupled to, an inner surface of housing 22. As discussed with reference to FIGURES 4A-4C, each securing member 76 may comprise a flexible arm or clip that may be manually flexed between a first position  
10 for attaching that securing member 76 to the corresponding attachment member 120 and a second position for releasing the securing member 76 from the attachment member 120.

In addition, one or more alignment members 124 may be provided for aligning mounting plate 70 with housing 22. In this embodiment, an alignment member 124 is configured to fit within an alignment hole 88 formed in mounting plate 70 in order to  
15 align mounting plate 70 with housing 22.

FIGURES 4A-4C illustrates a detailed view of an example securing member 76 and corresponding attachment member 120 for securing mounting plate 70 to housing 22, according to one embodiment of the disclosure. Securing member 76 may comprise a flexible arm or clip that may be manually flexed to attach or detach securing member 76  
20 from attachment member 120. In this embodiment, securing member 76 includes a forked, or arced, end portion 130 that may be configured to interlock with (e.g., snap into) attachment member 120. Attachment member 120 may comprise a peg or other element having an undercut boss region 132 configured to receive forked end portion 130 of securing member 76. To attach mounting plate 70 to housing 22, securing members 76  
25 may be flexed to move end portions 130 inwardly toward the center of mounting plate 70, plate 70 may then be aligned (e.g., using alignment member 124 and alignment hole 88) and pressed against housing 22, and securing members 76 may then be released such that end portions 130 of securing members 76 interlock with undercut boss region 132 of attachment members 120. It should be understood that any other suitable members or  
30 devices may be used for releasably attaching mounting plate 70 to housing 22.

FIGURE 5 illustrates the inside of mask apparatus 16 with mounting plate 70 secured to housing 22, thus forming ball joint 26, according to one embodiment of the

disclosure. A rear portion of ball member 36 may extend into and/or through opening 72 formed in mounting plate 70. As discussed above, openings 86 in mounting plate 70 may provide passageways for exhaust gas to pass from patient 12 to exhaust passageways 28 (shown in FIGURES 2 and 6A-6B).

5           FIGURE 5 also illustrates adjustment arm 40 releasably locked with locking member 42. As discussed above, in this embodiment, locking member 42 includes three projection 104 configured to lock with three indentations 106 formed in adjustment arm 40. In this illustration, a first projection (not shown) is received in a first indentation 106a to releasably secure adjustment arm 40 in a first of three predetermined rotational  
10 positions. FIGURE 5 also illustrates second stop 114 (discussed above regarding FIGURE 2) located proximate the base of locking member 42 for limiting the rotation of adjustment arm 40 in a direction toward the patient's face.

          FIGURES 6A-6B illustrate gas exhaust system 28 for removing exhaled gas away from patient 12, according to one embodiment of the disclosure. As discussed above, gas  
15 exhaust system 28 may include one or more exhaust passageways 38 defined between housing opening 34 and an outer surface of ball member 36 for communicating exhaust gas away from patient 12. In some embodiments, opening 34 may define a perimeter including one or more contact portions 80 alternating with one or more non-contact portions 82. Contact portions 82 generally contact ball member 36 when ball joint 26 is  
20 assembled. Non-contact portions 82 generally do not contact ball member 36, thus defining exhaust passageways 38 between ball member 36 and opening 34. In this embodiment, three contact portions 82 are alternated with three non-contact portions 82, thus defining three exhaust passageways 38. In other embodiments, mask apparatus 16 may include any other number and/or configuration of contact portions 82, non-contact  
25 portions 82, and/or exhaust passageways 38.

          As shown in FIGURES 6A-6B, each non-contact portion 82 may be a cut-away or recessed portion from the perimeter of opening 34. Each contact portion 80 and/or non-contact portion 82 may have any suitable size, shape, and/or configuration, e.g., to form exhaust passageways 38 having desired shapes, sizes, and/or configurations. For  
30 example, a width 140 and depth 142 of each non-contact portion 82 may be selected for defining exhaust passageways 38 that (a) allow a particular flow rate of exhaust gas through passageways 38, (b) provide for particular sound characteristics for gasses



flowing through passageways 38, and/or (c) direct exhaust gasses in one or more particular direction.

For example, width 140 and depth 142 of each non-contact portion 82 may be sized to provide a total gas passageway area of about 0.13-0.25 cm<sup>2</sup>. As another example, width 140 and depth 142 of each non-contact portion 82 may be sized to provide a gas flow of about 10-40 liter/min at 10 cm H<sub>2</sub>O. In some embodiments, width 140 and depth 142 of each non-contact portion 82 may be sized to provide a gas flow of about 15-25 liter/min at 10 cm H<sub>2</sub>O. In one example embodiment, each non-contact portion 82 has a width 140 of about 0.5 inch and a depth 142 of about 0.015 inch.

FIGURES 7A-7D illustrate the operation of adjustment system 32 for adjusting the fit of mask apparatus 16 against the patient's head (e.g., for adjusting the fit of cushion 20 against the patient's face), according to one embodiment of the disclosure. As discussed above, adjustment arm 40 may be rotatably coupled to housing 22 such that adjustment arm 40 may rotate as indicated by arrow 66, in order to adjust the distance between a free end 150 of adjustment arm 40 and the patient's head. Adjustment arm 40 and locking member 42 may interact with adjustment arm 40 in any suitable manner to allow adjustment arm 40 to be releasably locked in a plurality of different positions. In the illustrated embodiment, locking member 42 slides through slot 100 formed in adjustment arm 40.

In this embodiment, locking member 42 includes three locking elements 104, and adjustment arm 40 includes three locking elements 106 configured to interact with locking elements 104 to releasably secure adjustment arm 40 in three predetermined rotational positions. In addition, adjustment system 32 may include one or more stop elements 110 to limit the rotation of adjustment arm 40 in one or more directions. In the illustrated embodiment, locking member 42 includes a first stop 112 (e.g., a hook portion) to limit the rotation of adjustment arm 40 in a first direction indicated by arrow 152, and a second stop 114 proximate the base of locking member 42 to limit the rotation of adjustment arm 40 in a second direction indicated by arrow 154.

FIGURE 7A illustrates adjustment arm 40 free from locking arm 40.

FIGURES 7B-7D interacting with locking arm 40. To move adjustment arm 40 from the position shown in FIGURE 7A to any of the positions shown in FIGURES 7B-7D, locking member 42 may be inserted through slot 100 formed in adjustment arm 40.

In one embodiment, in order to position locking member 42 within slot 100, a user may flex locking member 42 slightly toward adjustment arm 40 such that the free end of locking member 42 fits within slot 100. Adjustment arm 40 may then be rotated along path 66 between the multiple different locking positions. To release adjustment arm 40 from locking member 42 (i.e., to return adjustment arm 40 to the position shown in FIGURE 7A), the user may again flex locking member 42 slightly toward adjustment arm 40 such that the free end of locking member 42 may be removed from slot 100.

As shown in FIGURES 7B-7D, adjustment arm 40 may be secured in any of the three predetermined rotational positions using locking elements 104 and 106, positioned against first stop 112, or positioned against second stop 114. In particular, FIGURE 7B illustrates adjustment arm 40 locked in a middle locking position; FIGURE 7C illustrates adjustment arm 40 positioned against first stop 112; and FIGURE 7D illustrates adjustment arm 40 positioned against second stop 114. Adjustment arm 40 may be manually moved between the three locking positions and two stop positions. As discussed above, in one embodiment, in order to move adjustment arm 40 may be manually moved between the three locking positions, adjustment arm 40 and locking member 42 may be flexed laterally in opposite directions to release a particular projection 104 from a corresponding indentation 106. Adjustment arm 40 may then be rotated along path 66 until another projection 104 is received in another indentation 106 to lock adjustment arm 40 in a different rotational position.

It will be appreciated that while the disclosure is particularly described in the context of breathing assistance systems, the apparatuses, techniques, and methods disclosed herein may be similarly applied in other contexts. Additionally, it should be understood that various changes, substitutions and alterations can be made herein without departing from the spirit and scope of the disclosure as illustrated by the following claims.

WHAT IS CLAIMED

1. An adjustable mask apparatus for use in a breathing assistance system, the adjustable mask apparatus comprising:
  - 5 a housing for supporting a cushion configured to provide a seal against a patient's face;
  - an adjustment arm including:
    - a first end configured for attachment to a head gear; and
    - a second end rotatably coupled to the housing to allow rotation of the
    - 10 adjustment arm to adjust a distance between the first end of the adjustment arm and the patient's head; and
    - a locking member coupled to the housing and configured to secure the adjustment arm in one of a plurality of predetermined rotational positions, each predetermined rotational position comprising a rotational position of the adjustment arm with respect to
    - 15 the housing.
2. An adjustable mask apparatus according to Claim 1, wherein at least one of the adjustment arm and the locking member is formed integral with the housing.
- 20 3. An adjustable mask apparatus according to Claim 1, wherein both the adjustment arm and the locking member are formed integral with the housing.
4. An adjustable mask apparatus according to Claim 1, wherein the adjustment arm is coupled to the housing by a living hinge.
- 25 5. An adjustable mask apparatus according to Claim 1, wherein the first end is configured for attachment to a head strap.
6. An adjustable mask apparatus according to Claim 1, wherein the first end
- 30 is configured for attachment to a head strap that extends from the first end of the adjustment arm upward toward the top of the patient's head.

7. An adjustable mask apparatus according to Claim 1, wherein the locking member comprises an arm coupled to the housing at a first end.

8. An adjustable mask apparatus according to Claim 1, wherein the locking member is pivotally coupled to the housing.

9. An adjustable mask apparatus according to Claim 1, wherein:  
the locking member includes one or more first locking elements; and  
the adjustment arm includes one or more second locking elements configured to interact with the one or more first locking elements to secure the adjustment arm in one of the plurality of predetermined rotational positions.

10. An adjustable mask apparatus according to Claim 1, wherein:  
the locking member includes a plurality of first locking elements; and  
the adjustment arm includes a plurality of second locking elements, each second locking element configured to interact with a corresponding one of the first locking elements to secure the adjustment arm in one of the plurality of predetermined rotational positions.

11. An adjustable mask apparatus according to Claim 1, wherein the locking member includes one or more stop elements to limit the rotation of the adjustment arm.

12. An adjustable mask apparatus according to Claim 1, wherein the locking member includes:  
a first stop element configured to limit the rotation of the adjustment arm in a direction away from the patient's head; and  
a second stop element configured to limit the rotation of the adjustment arm in a direction towards the patient's head.

13. An adjustable mask apparatus according to Claim 1, wherein:  
the adjustment arm includes a slot; and  
the locking member extends at least partially through the slot.

5 14. An adjustable mask apparatus according to Claim 1, wherein:  
the locking member is pivotally coupled to the housing;  
the adjustment arm includes a slot; and  
the locking member is pivoted from an unloaded position in order to insert the  
locking member into the slot in the adjustment arm.

10

15 15. An adjustable mask apparatus according to Claim 1, wherein the  
adjustment arm includes a slot configured to receive a head strap.

16. An adjustable mask apparatus according to Claim 1, further comprising:  
15 a first head strap connection device associated with a first lateral side of the  
housing; and  
a second head strap connection device associated with a second lateral side of the  
housing;  
wherein the first and second head strap connection devices are configured for  
20 connection to a pair of head straps extending generally laterally around the patient's head;  
and  
wherein the first end of the adjustment arm is configured for connection to a head  
strap extending generally upward towards the top of the patient's head.

25 17. An adjustable mask apparatus according to Claim 1, further comprising a  
head gear coupled to the first end of the adjustment arm.

18. An adjustable mask apparatus for use in a breathing assistance system, the adjustable mask apparatus comprising:

a housing for supporting a cushion configured to provide a seal against a patient's face; and

5 an adjustment arm including:

a first end configured for attachment to a head strap that extends from the first end of the adjustment arm upward toward the top of the patient's head; and

a second end rotatably coupled to the housing to allow rotation of the adjustment arm between a plurality of predetermined rotational positions to adjust a  
10 distance between the first end of the adjustment arm and the patient's head.

19. An adjustable mask apparatus according to Claim 18, wherein the adjustment arm is formed integral with the housing.

15 20. An adjustable mask apparatus according to Claim 18, wherein the adjustment arm is coupled to the housing by a living hinge.

21. An adjustable mask apparatus according to Claim 18, further comprising a locking member coupled to the housing and configured to lock the adjustment arm in  
20 each of the plurality of predetermined rotational positions.

22. An adjustable mask apparatus according to Claim 21, wherein:  
the locking member includes one or more first locking elements; and  
the adjustment arm includes one or more second locking elements configured to  
25 interact with the one or more first locking elements to secure the adjustment arm in one of the plurality of predetermined rotational positions.

23. An adjustable mask apparatus according to Claim 21, wherein:  
the locking member includes a plurality of first locking elements; and  
the adjustment arm includes a plurality of second locking elements, each second  
locking element configured to interact with a corresponding one of the first locking  
5 elements to secure the adjustment arm in one of the plurality of predetermined rotational  
positions.

24. An adjustable mask apparatus according to Claim 21, wherein the locking  
member includes one or more stop elements to limit the rotation of the adjustment arm.  
10

25. An adjustable mask apparatus according to Claim 21, wherein:  
the adjustment arm includes a slot; and  
the locking member extends at least partially through the slot.

26. An adjustable mask apparatus according to Claim 18, wherein the first end  
of the adjustment arm includes a slot configured to receive the head strap.  
15

27. An adjustable mask apparatus according to Claim 18, further comprising:  
a first head strap connection device associated with a first lateral side of the  
20 housing; and  
a second head strap connection device associated with a second lateral side of the  
housing;

wherein the first and second head strap connection devices are configured for  
connection to a pair of head straps extending generally laterally around the patient's head.  
25

28. An adjustable mask apparatus according to Claim 18, further comprising a  
head gear coupled to the first end of the adjustment arm.

29. An adjustable mask apparatus for use in a breathing assistance system, the adjustable mask apparatus comprising:

housing means for supporting a cushion configured to provide a seal against a patient's face;

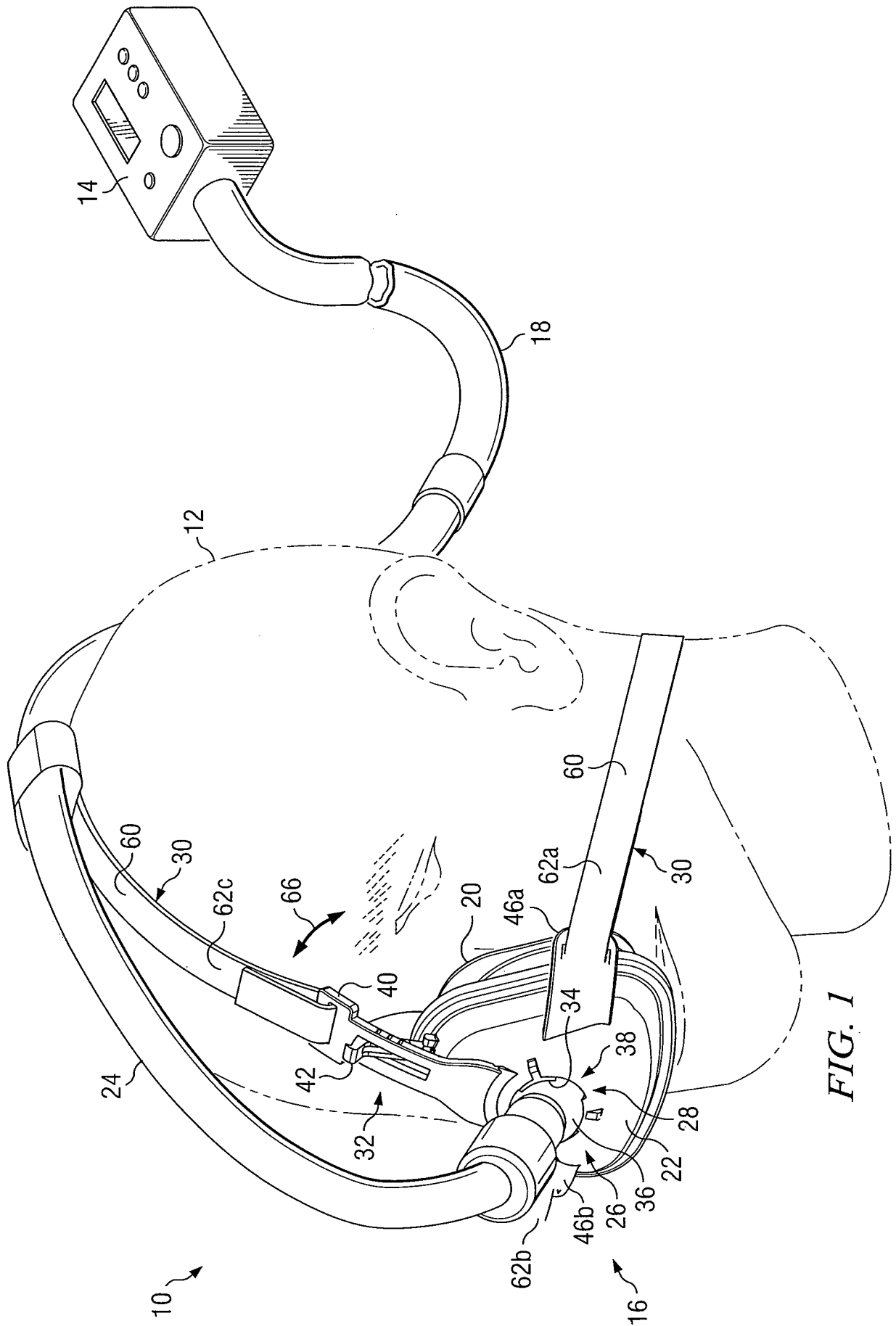
5 adjustment means for adjusting a head gear attachment position, the adjustment means including:

a first end configured for attachment to a head gear; and

10 a second end rotatably coupled to the housing means to allow rotation of the adjustment means to adjust a distance between the first end of the adjustment means and the patient's head; and

locking means for securing the adjustment means in one of a plurality of predetermined rotational positions, each predetermined rotational position comprising a rotational position of the adjustment means with respect to the housing means.





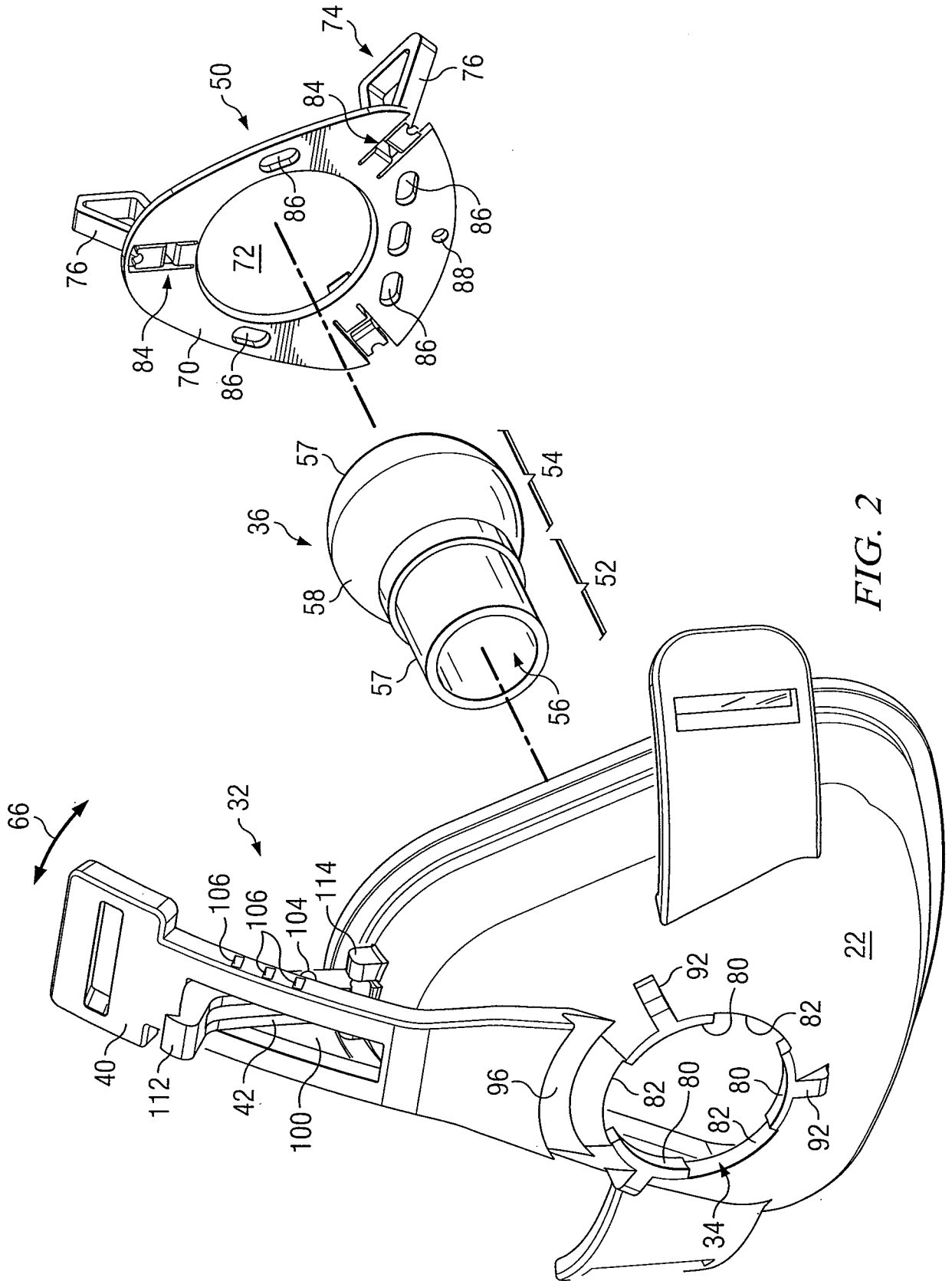
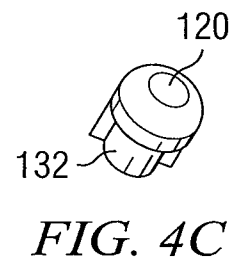
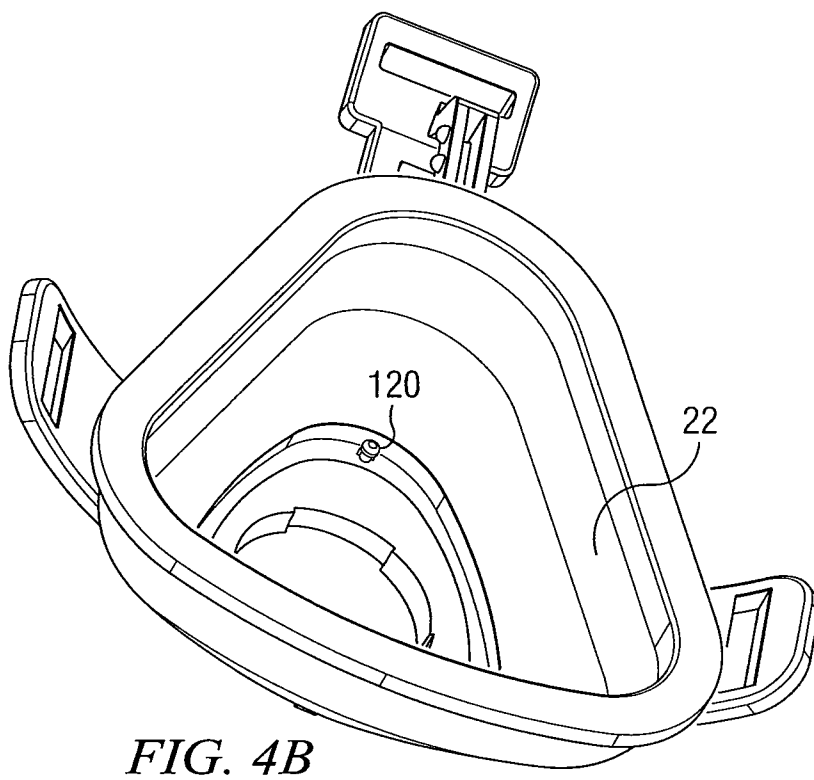
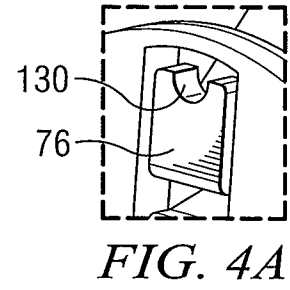
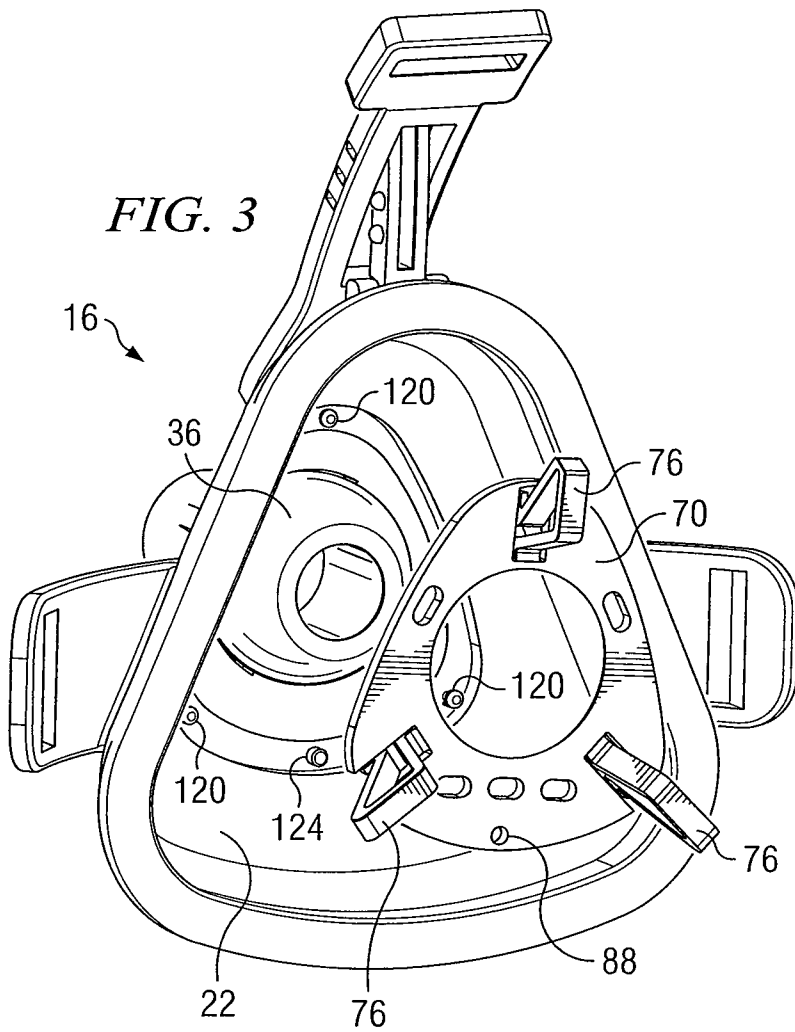


FIG. 2



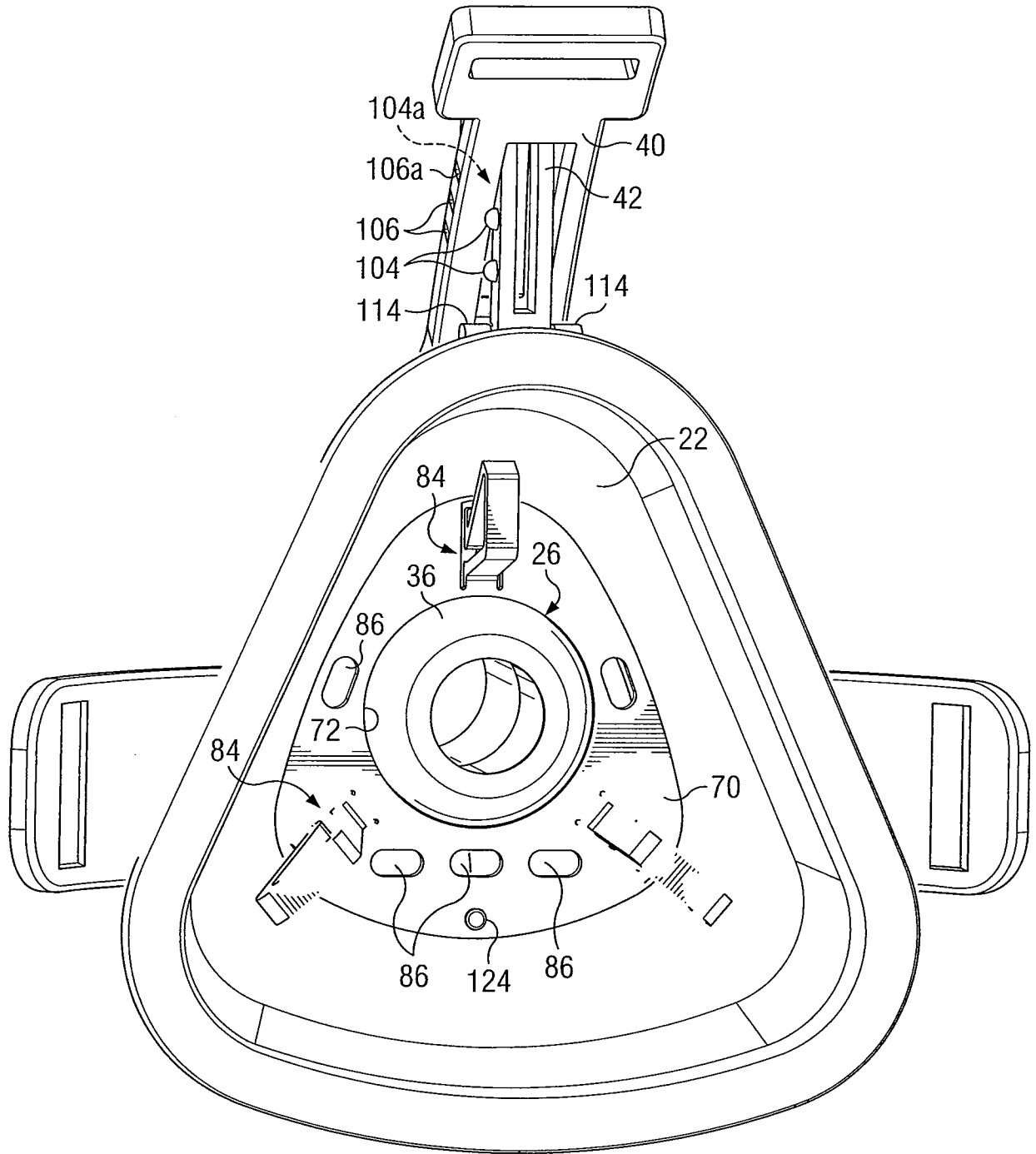
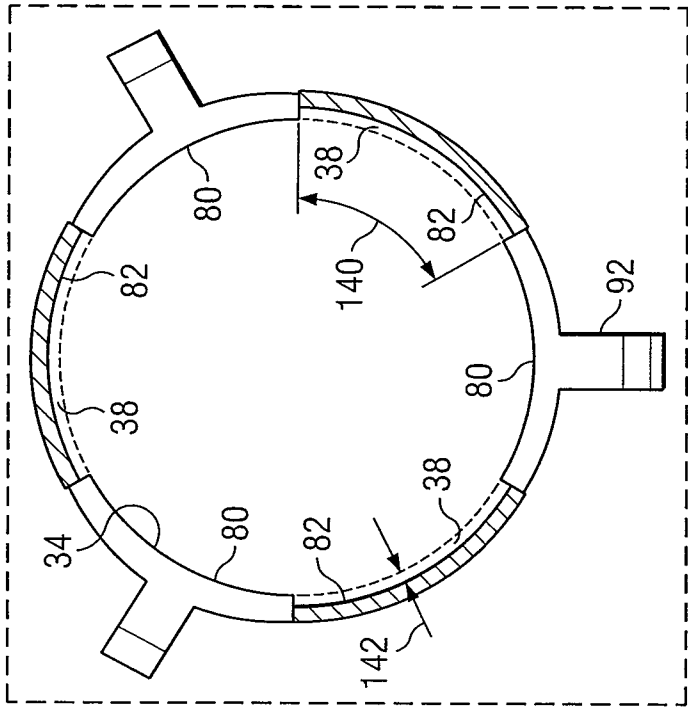
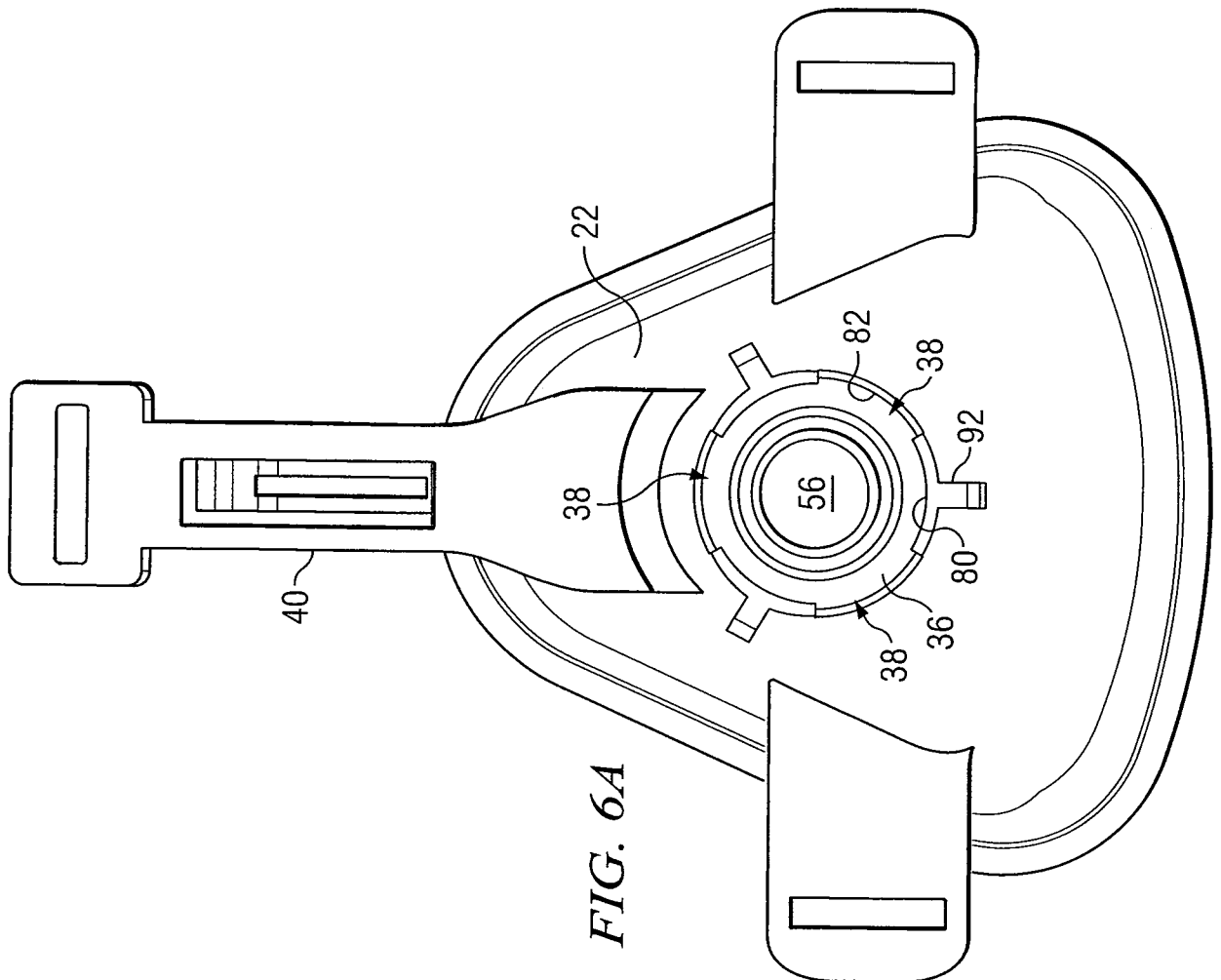
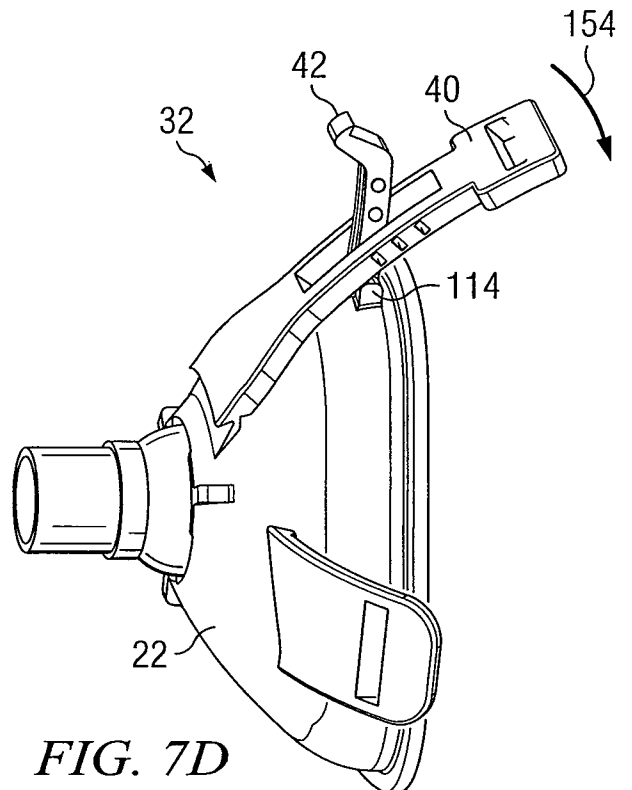
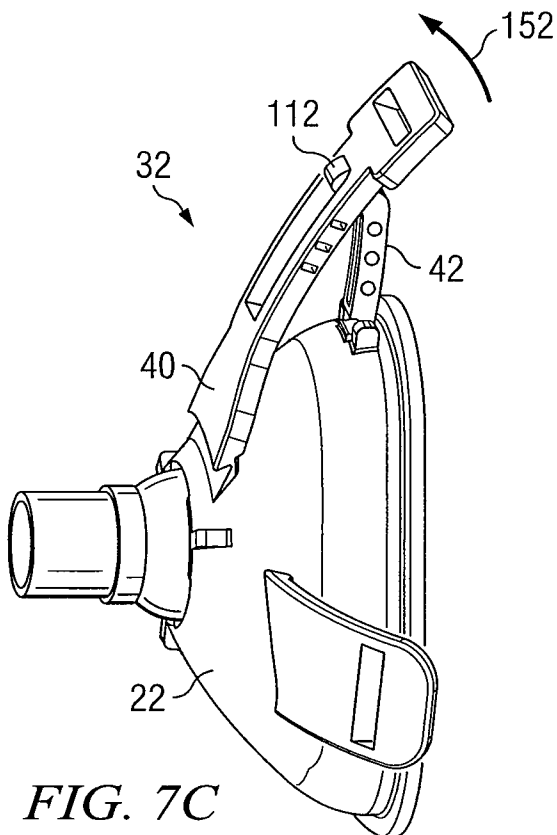
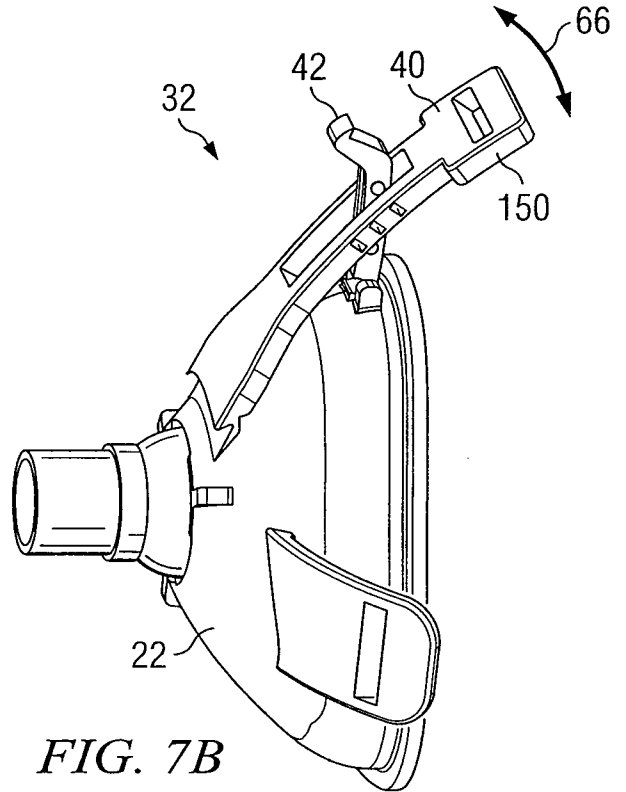
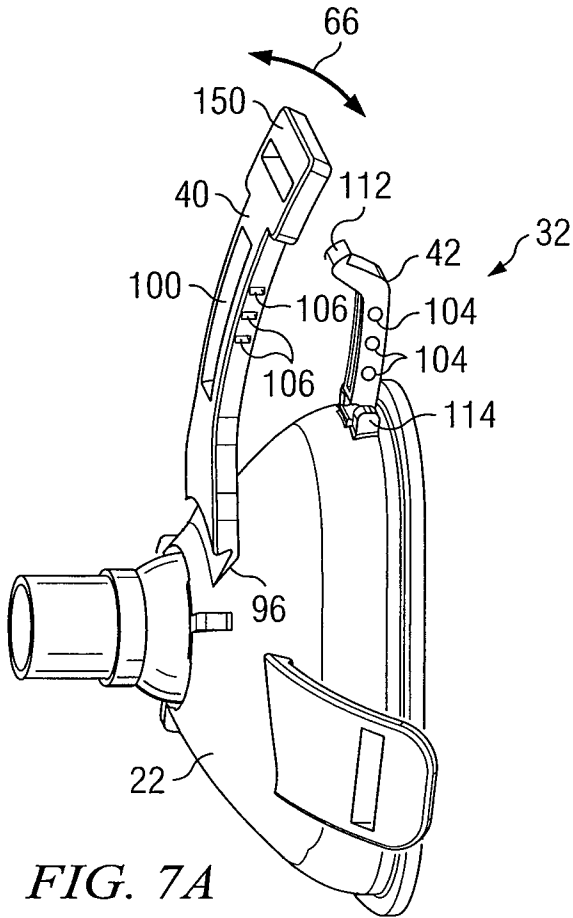


FIG. 5





**INTERNATIONAL SEARCH REPORT**

International application No  
PCT/US2007/078726

**A. CLASSIFICATION OF SUBJECT MATTER**  
INV. 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)  
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

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2005/005940 A1 (GUNARATNAM MICHAEL KASSIPILLAI [AU]) 13 January 2005 (2005-01-13)	1-11, 13-29
A	paragraph [0048] - paragraph [0077]; figures 23,24a-b	12
X	EP 1 555 039 A (WEINMANN G GERAETE MED [DE]) 20 July 2005 (2005-07-20)  paragraph [0021] - paragraph [0035]; figures 1,6,7 & US 2005/155603 A1 (FRERICHS ARNOLD [DE] ET AL) 21 July 2005 (2005-07-21)	1,2,5,6, 9,11,13, 15-18, 21,22, 24-29
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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	*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
*E* earlier document but published on or after the international filing date	*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
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*O* document referring to an oral disclosure, use, exhibition or other means	*Z* document member of the same patent family
*P* document published prior to the international filing date but later than the priority date claimed	

Date of the actual completion of the international search  14 February 2008	Date of mailing of the international search report  22/02/2008
Name and mailing address of the ISA/ 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	Authorized officer  Kroeders, Marleen

## INTERNATIONAL SEARCH REPORT

International application No  
PCT/US2007/078726

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
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