

1 ~~The present invention in one aspect relates to~~ It is provided a positioning device
2 that can either be retro-fit to existing operating room tables or built into future operating
3 room tables to facilitate the maintenance of a patent airway by correctly positioning a
4 patient's neck, head, and torso either while a patient is unconscious, lacks the ability to
5 maintain an open airway, or is under anesthesia during an operation or procedure while the
6 patient is lying on either of their sides. Although several pillows are designed to place the
7 user's head in the sniff position while the user is on his or her back, many procedures
8 require the patient to lay on their side, i.e., the so-called "lateral decubitus position".
9 Although one pillow currently exists (U.S. patent 2012/0180220) which claims to place a
10 patient in the sniffing position (aligning the three axes, oropharyngeal, tracheal,
11 laryngeal,) when lying on his or her side in the lateral decubitus position, a need exists for
12 a provider to have the option to perform a jaw thrust in a hands free fashion in case
13 emergency situations arise where medications have to be pushed or further management is
14 required. See also U.S. Patent 7,467,431 in which there is described a patient incline
15 device which includes an incline ramp and a centerline spinal support located on a base
16 member. The incline ramp supports the upper torso and head of a patient such that the
17 upper torso and head are elevated with respect to the base member. The centerline support
18 is located adjacent the inline ramp for contact with a central portion of the patient's back
19 located adjacent the spine to elevate the central back portion. According to one
20 embodiment, the incline ramp and the spinal support are adjustable to custom fit to the
21 patient's torso. The width of the spinal support is less than that of the incline ramp to
22 define lateral spaces along opposite sides of the centerline support to receive the arms and
23 the side portions of the patient for lateral extension of the chest wall. See also U.S. Patent
24 8,336,142.

25 For a patient in the lateral decubitus position, embodiments of the present
26 invention also provides an improvement over prior art positioning devices enabling the
27 sniff position, nasal and full-mask non-invasive positive pressure ventilation CPAP,
28 BiPAP, ventilation during intubation, oxygenation during patient transport, jaw thrust,
29 and comprising a base having a first surface for supporting an adjustable ramp and
30 carriage for supporting a patient's back, and a second surface for supporting a patient's
31 head on a second surface which is adjustable on two axis X & Y, to place the patient in a
32 desired sniffing position.

33 More particularly, embodiments of the present invention, ~~in one aspect~~ provides a
34 device including a base for supporting a carriage subassembly, the carriage subassembly

- 1 comprising three surfaces, a first surface, a second surface, and a third surface all
- 2 adjustable along the Z-axis along the base subassembly. The bases' surfaces each have

1 one side, wherein the base is configured to substantially support the carriage
2 subassembly arm. The carriage subassembly comprises a first surface connected to the
3 second surface and movable along the Z-axis. The first surface of the carriage
4 subassembly comprises two surfaces, a first surface or ramp which assists in maintaining
5 the patient's torso in an inclined position, and a second surface which provides a head-
6 supporting surface for supporting the patient in a desired, i.e., sniffing position.

7 In another embodiment of the invention, a back restraining device is provided
8 which includes a back board consisting of a rigid surface that comes in contact with the
9 patient's back and is adjustable in the y-axis; a flexible and soft back restraining device
10 having a first proximal end that attaches to one side of the back board, which can then
11 extend horizontally and come in contact with the patient's abdomen and attach to the
12 opposite side of the back board. The device is adjustable and able to secure the patient's
13 back to the back board.

14 In yet another embodiment of the invention, when the patient is in the lateral
15 decubitus position there is provided a head/neck support that may be independently
16 controlled to support the desired, i.e., sniff position by raising the head and neck
17 independently of the ramp, or if the patient is in either the right or left lateral decubitus
18 position the head and neck supports can be adjusted to ensure proper alignment of the
19 cervical, thoracic, and lumbar vertebra. More particularly, there is provided a pneumatic
20 or mechanical head/neck support that consists of either a mechanical jack or a compliant
21 bellows that is fixed or located on a top surface of head/neck rest.

22 Embodiments of theThe present invention also provides methods for positioning
23 a patient. The methods include the steps of: providing a device having a back board and
24 a support arm; placing the patient's head on a first surface of the support arm of the
25 device; adjusting a second surface of the support arm to come in contact with the
26 patient's neck, moving the placing the patient's head and neck in the desired position,
27 along with aligning the cervical, thoracic, and lumbar vertebra to the desired position;
28 restraining the patient's head to prevent the patient from being dislodged from the
29 desired position; moving a first mandible arm to contact the patient's jaw; and moving
30 the second mandible arm to contact the patient's jaw; wherein the contact of the first
31 mandible arm and the second mandible arm provides sufficient force to substantially
32 maintain the patient's head, neck, and/or jaw in a desired position. The back board may
33 then be adjusted to come in contact with the patient's back, and restrain the patient's
34 back to prevent the patient from being dislodged from the desired position.

1 In yet other embodiment, the present invention includes a mandible arm
2 including: a curved portion that consists of an adjustable and lockable mechanism that
3 attaches to a mandible pad, wherein the mandible pad is flexible, and wherein the
4 mandible pad has a distal side configured to attach to the curved portion and a proximal
5 side configured to contact a patient's jaw at a plurality of points, which can pivot in all
6 angles at the distal end. A connector portion is provided which is configured to attach to
7 a support. Preferably, the connector portion is configured to attach to a support that is
8 attached to a base comprising a left side and a right side, wherein the base is configured
9 to substantially accommodate a patients neck and head, and wherein the support is
10 moveable in three axis such that the mandible pad is positionable to be in contact with
11 the patients jaw at one or more points and to maintain a desired position.

12 Embodiments of theThe present invention also provides a method for positioning
13 a patient including the steps of: providing a device having an adjustment mechanism in
14 the z-axis (ie: a which may be a pneumatic jack such as a bellows or a mechanical jack,
15 etc), placing the patient's head substantially on top of the adjustment mechanism,
16 elevating the ramp and then adjusting the adjustment mechanism in the z-axis, as well as
17 a device having an adjustment mechanism in the vertical direction, (ie: a pneumatic jack
18 such as a bellows or a mechanical jack, etc), placing the patient's neck substantially on
19 top of the adjustment mechanism, and then adjusting the adjustment mechanism in the z-
20 axis so that the patient is initially in either a sniff position or an "ear-to-sternal notch
21 position".

22 ~~In another aspect the invention provides~~It is provided a method for positioning a
23 patient comprising providing a device as above described placing the patient's head and
24 neck substantially on the first surface of the carriage, and using either one or more
25 adjustable devices to place the patient's head and neck in a desired position. The first
26 mandible arm and second mandible arm are then moved to contact the patient's jaw,
27 wherein the contact of the first mandible arm and the second mandible arm provides
28 sufficient force to substantially maintain the patient's head and/or jaw in a desired
29 sniffing position.

30 For a patient lying on their back (supine position), ~~in yet another aspect of the~~
31 ~~invention,~~ there is provided a positioning device to facilitate the maintenance of a patent
32 airway by correctly positioning a patient's back, shoulders, neck and head, while the
33 patient is unconscious, unable to maintain a patent airway, sedated, or under anesthesia
34 during an operation or procedure. The present device includes a device including: a base

- 1 support comprising a first side, a second side, and an inner adjustable support structure.
- 2 The first side base is configured to substantially accommodate a patient's neck and head.

1 The distal end of the first base supports the patient's neck and consists of a support
2 adjustable in the z-axis, which assists in maintaining the desired sniffing position. The
3 proximal end of the base consists of a slightly inclined or flat surface adjustable in the z-
4 direction, with or without a cut-out center, which provides head support to further
5 optimize the sniffing position. An adjustable ramp can be placed under the patient's
6 back and shoulders to achieve the desired angles. A first support is positioned on the first
7 side of the base, and a second support positioned on the second side of the base. An
8 adjustable support structure within the interior of the base is provided to mechanically
9 adjust the height and length of the ramp to custom fit to the patient. A first mandible arm
10 is configured to contact the one side of the patient's jaw, and a second mandible arm
11 positioned on the second support, and is configured to contact the other side of the
12 patient's jaw. The first and second support of the mandible arms are moveable on the X,
13 y and z axis. The first and second proximal parts of the moveable arms are moveable
14 along the x, y and z axis, while the distal parts are rotatable, such that each is
15 positionable to be in contact with the patient's jaw, and maintain a desired position.

16 Embodiments of the The present invention also provides an improvement over
17 prior art positioning devices enabling both the sniff position and jaw thrust, and
18 comprising a base having a surface for supporting a carriage for supporting a patient's
19 head adjustable in a Z-axis, supporting a patient's neck on either the first surface or the
20 second surface, which is adjustable in the z-axis, to place the patient in a desired sniffing
21 position. An upper arm constrains the patient's head in translation along all three axes.
22 First and second mandible arms are provided extending from the first surface for contact
23 with the patient's jaw, so as to maintain the patient in a desired position the patient lies
24 on his or her back.

25 According to a first aspect of the invention, a nasal mask is described, the nasal
26 mask can be used separately, or with an oral mask releasably attached to the nasal mask
27 through a closable opening on the nasal mask.

28 According to a second aspect of the invention, a nasal mask or a combined nasal
29 mask/oral mask full face mask is described, the nasal mask or combined nasal mask/oral
30 mask full face mask comprising a nasal mask body adapted for connection with a supply
31 of breathable gas, preferably oxygen, air, or air anesthetic gas; a cushion secured to said
32 nasal mask body, the body and cushion forming a nose-receiving cavity, said cushion
33 including: a nasal bridge region, a cheek region and an upper lip region; a substantially
34 triangularly-shaped first nasal membrane formed of resilient material having a first

1 molded inwardly curved rim to surround patient's nose; a second nasal membrane
2 formed of resilient material, said second membrane being relatively more flexible than
3 said first nasal membrane, said second nasal membrane having a second molded
4 inwardly curved rim, said second molded rim being of the same general shape as said
5 first molded rim and fixed to and extending away from said first nasal membrane so as to
6 provide a second nasal membrane inner surface spaced a first distance from an outer
7 surface of said first molded rim in said cheek region and said second membrane inner
8 surface spaced a second distance from said first nasal membrane outer surface of said
9 first molded rim in said nasal bridge region, said second distance greater than said first
10 distance, said first and second distances measured when the mask is not in use, a portion
11 of said second molded rim forming a face contacting seal; and wherein said seal portion
12 is substantially coterminous with respect to said second molded rim and is resiliently
13 deformable towards said first nasal membrane when said mask is in use.

14 According to a third aspect of the invention, a nasal mask for connection to a
15 patient's face is described, the nasal mask comprising a mask body for connection with a
16 supply of breathable gas; and a mouth cushion secured to said mask body, the mask body
17 and mouth cushion forming a mouth-receiving cavity, said mouth cushion including: a
18 mouth region, a cheek region and an upper and lower lip region; a substantially oval-
19 shaped first mouth membrane of resilient material having a first molded inwardly curved
20 rim to surround a patient's nose; a second mouth membrane also of resilient material,
21 said second mouth membrane being relatively more flexible than said first mouth
22 membrane, said second mouth membrane having a second molded inwardly curved rim,
23 said second molded rim being of the same general shape as said first molded rim and
24 fixed to and extending away from said first mouth membrane so as to have a second
25 mouth membrane inner surface spaced a first distance from an outer surface of said first
26 molded rim in said cheek region and said second mouth membrane inner surface spaced
27 a second distance from said first mouth membrane outer surface of said first molded rim
28 in said mouth region, said second distance greater than said first distance, said first and
29 second distances measured when the mask is not in use, a portion of said second molded
30 rim forming a face contacting seal; wherein said seal portion is substantially coterminous
31 with respect to said second molded rim and is resiliently deformable towards said first
32 mouth membrane when said mask is in use.

1 | ~~In another aspect the invention provides~~It is provided a method for positioning a
2 patient providing a device as above described placing the patient's head substantially on
3 the first surface of the carriage, and using an adjustable device to place the patient's head
4 and/or neck in a desired position. The first mandible arm and second mandible arm are
5 then moved to contact the patient's jaw, wherein the contact of the first mandible arm and
6 the second mandible arm provides sufficient force either by the provider or mechanically
7 to substantially maintain the patient's head, neck, and/or jaw in a desired sniffing
8 position.

9 In still yet other embodiments, there is provided a flexible and soft head
10 restraining device either attachable or built in to an anesthesia full face mask, nasal
11 mask, and nasal-oral mask, comprising two ends; a first proximal end that attaches to one
12 side of the first surface of a base; which can then extend horizontally and come in

1 nasal-oral mask to the patient's nose or face, restraining the patient's head to prevent the
2 patient from being dislodged from the desired position; moving a first and second
3 mandible arm to contact the patient's jaw; wherein the contact of the first mandible arm
4 and the second mandible arm provides sufficient force to substantially maintain the
5 patient's head, neck, and/or jaw in a desired position.

6 ~~In still yet another aspect of the invention there~~ There is provided a simple and
7 elegant adjustable head rest neck rest, or combined head-neck rest, which may be a
8 pneumatic jack such as a bellows, or a mechanical jack, that is independently controllable
9 to support a patient's head and/or neck to obtain an optimal sniff position by raising a
10 patient's neck and head independently of the carriage. The head rest and/or head-neck
11 rest can either be fixed to the device or detachable and moved anywhere on either the
12 device, an operating room table, or any other surface used for patient's requiring airway
13 management. The head rest and/or head-neck rest will also have a cover to protect it from
14 blood, saline, and infectious agents that can also either be fixed to the device and reusable
15 or it can be disposable and detachable. The head rest and/or head-neck rest cover will
16 also have attachments for the mask anchor to attach to and be able to secure the patient's
17 head and/or neck in position, anywhere on the device, operating room table, or on other
18 surface used for patient's requiring airway management. The head rest and/or neck rest
19 cover will also have a second nasal mask, full face mask, or nasal-oral face mask strap
20 that is either reusable and attached to the cover or detachable and disposable and comes
21 from behind the patient's head and attaches to the anesthesia mask in front. This head rest
22 and/or neck rest cover with a mask strap either attached or detachable is novel allows a
23 patient's head and/or neck to remain in the desired position, while the anesthesia mask is
24 sealed to the patient's face anywhere on either the device, operating room table, or on
25 other surface used for patients requiring airway management.

26 In yet another embodiment the mask strap that is either attached or detached
27 from the head rest and/or neck cover will comprise of a base with one or more sides. The
28 first side can be used to come across the anesthesia mask from the front and attach to the
29 base on the opposite side in order to create a tight seal between either the nasal mask, full
30 face mask, or nasal-oral mask and the patient's face. In yet another embodiment the mask
31 strap will have one side that attaches to the left side of the anesthesia mask, while the
32 second side attaches to the right side or vice versa in order to create a tight seal between
33 either the nasal mask, full face mask, or nasal-oral mask and the patient's face. In yet
34 another embodiment the mask strap will have three sides where one side that attaches to

1 the left side of the anesthesia mask, while the second side attaches to the right side or vice
2 versa and the third side comes over the patient's head attaches to the top part of the
3 anesthesia mask in order to create a tight seal between either the nasal mask, full face
4 mask, or nasal-oral mask and the patient's face. ~~In yet another aspect~~ It is provided of
5 ~~the invention~~ an apparatus for providing anesthesia to a patient is provided including a
6 base comprising a first side, a second side, a third side, and an inner adjustable support
7 structure. The first side of the base is configured to substantially accommodate a patient's
8 neck and head. The distal end of the first base, which supports the patient's neck consists
9 of either a generally semi-cylindrical support, which assists in maintaining the desired
10 sniffing position or a generally flat surface both of which is adjustable in the z-axis. The
11 proximal end of the first base consists of either a slightly inclined or a generally flat
12 surface with or without a cut-out center also adjustable in the z-axis in order to provide
13 head support to further optimize the sniffing position. An adjustable support structure is
14 provided within the interior of the base to mechanically adjust the height of the patient.
15 and custom fit the patient's head, neck and torso to the surface to optimize positioning.
16 The second and third sides of the base each contain a plurality of protrusions, preferably
17 four protrusions. The anesthesia mask attaches to the patient from an anterior
18 perspective, with straps that attach to the mask connecting to the support behind the
19 patient's head. Current straps utilize a posteriorly, with the strap-s starting from behind the
20 head and attaching to the mask in front. The mask strap has four sides, sides one and two
21 which contain an aperture that is placed over the aperture of the mask of side one, and
22 sides three and four which contain one narrow extension each of which include a plurality
23 of holes adapted to attach to one of the protrusions on sides two and three of the base. An
24 alternate and preferred design consists of two cords that are attached to the mask, and the
25 cords can then attach to the support behind the head. These cords can be clipped through
26 friction, hook and loop, etc. on each side of the head. The mask strap is adapted to hold
27 the anesthesia mask against either the patient's nose only, nose, mouth, cheeks, and/or or
28 head to maintain the desired sniffing position where the patient's jaw is moved up and
29 forward, thereby preventing a patient's airway from becoming obstructed. The mask
30 strap is adapted to stabilize the patient's head and/or neck to the base preventing
31 movement of the patient's head and/or neck. The tight seal that the mask strap creates
32 also allows for non-invasive positive pressure ventilation (CPAP/BiPAP), which further
33 helps to maintain a patent airway.

1 | ~~In another aspect of the invention, t~~There is provided an apparatus for providing
2 anesthesia to a patient, which comprises, a base having a first side, a second side, a third
3 side, and an adjustable support structure, wherein the base is configured to substantially
4 accommodate a patient's neck and head; wherein a distal end of the base first side
5 comprises either a semi-cylindrical support adjustable in the z-axis, which assists in
6 maintaining the desired sniffing position or a flat surface; a proximal end of the base first
7 side comprises either a slightly inclined or flat surface in order to provide head support to
8 further optimize the sniffing position and is adjustable in the z-axis; the second and third
9 sides of the base can each contain a plurality of protrusions and a mask strap with four
10 sides, wherein the first and second sides include an aperture that is placed over the
11 aperture of the mask, and the third and fourth sides include a narrow extension which
12 include a plurality of holes adapted to attach to one of the four protrusions on sides two
13 and three of the base, or an alternate and preferred design consists clips on each of the
14 second and third side for which the mask cords to attach to; wherein the mask strap is
15 adapted to hold a anesthesia mask strap against the patient's head, mouth and/or nose to
16 maintain the desired sniffing position where the patient's jaw is moved up and forward,
17 thereby preventing the obstruction of the patient's airway; and wherein the mask strap is
18 adapted stabilize the patient's head and neck to the base preventing movement of the
19 patient's head and neck.

20 Other embodiments of the invention include:

21 I. A device for positioning a patient, comprising: a base subassembly comprising
22 a surface for supporting a carriage subassembly, where the first surface of the support
23 arm supports the patients head and is adjustable in the Z-axis, the second surface
24 supports the patient's neck and is adjustable in the z-axis, to place the patient in the
25 desired sniffing position; the surface of the upper arm is lowered until comfortably tight
26 and locked, for constraining the patients head in translation along all three axes; a
27 flexible band for placement over the patient's forehead, for securing it to the sniff
28 subassembly by applying a constant constraining force in the -X direction; a first
29 mandible arm extending vertically from the first surface of the carriage subassembly,
30 wherein the first vertically adjusted portion is lockable in rotation about the Z axis,
31 wherein the first mandible arm is positionable to be in contact with the patient's jaw; and
32 a second mandible arm extending vertically from the third surface of the carriage
33 subassembly, wherein the second vertically adjusted portion is lockable in rotation about
34 the Z axis, wherein the second mandible arm is positionable to be in contact with the

two axes such that the mandible pad is positionable to be in contact with a patient's jaw at one or more points and to maintain a patient in a desired position.

XXV. Also provided is a flexible and soft head restraining device for a patient, comprising:

a first proximal end that attaches to one side of the first side of the base; which can then extend horizontally and come in contact with the patient's head and attach to the opposite side of the first surface of the base; the device is adjustable and able to secure the patient's head to the first surface of the base to prevent the patient from disengaging from the desired position.

XXVI. Also provided is a device for positioning a patient in a sniff position, comprising an adjustable ramp and headrest, wherein as ramp incline is varied, head rest orientation remains parallel, substantially horizontal to the operating table, by changing the head rest angle, θ_x by an opposite amount.

The above device preferably is characterized by one or more of the following features:

(a) wherein adjustment of angles is accomplished by open loop processing based on known or estimated geometries of all known parameters;

(b) wherein adjustment of angles is accomplished by closed loop processing where a current angle is measured relative to an initial angle, and driven back to said initial angle;

(c) wherein adjustment is accomplished upon multiple feedback sensors including but not limited to:

(i) Measurement of angle relative to gravity with an inclinometer; and

(ii) Encoders.

(d) wherein as ramp incline is varied, and / or head rest angle, θ_x are changed to position the patient, ramp linkage length is varied in order to satisfy the conditions that positions of linkages fixed relative to their respective support surfaces;

(e) wherein adjusting of angles is accomplished by:

(i) Open loop processing based on known or estimated geometries of all parameters, or by

(ii) Closed loop processing where the relative positions of one or more linkage termination points are measured and the length d is adjusted under closed loop control driven by sensor feedback to return the measured parameter to their original position with regard to the following geometry, or by

1 Figs. 16A-16C illustrate a pneumatic head or neck rest in accordance with the
2 present invention;

3 Fig. 16D illustrates a patient whose head is restrained by an anterior strap.

4 Figs. 17A-17D and 18A-18~~BD~~ show details of a pneumatic head or neck rest in
5 accordance with the present invention;

6 Fig. 19 is a flow diagram in accordance with one embodiment of the present
7 invention;

8 Figs. 20A, 20B, ~~20C, 20D~~, 22, and 23 show one embodiment of the jaw claw and
9 ramp subassembly in accordance with the present invention;

10 Figs. 21A and 21B and 24A-24D illustrate use of the jaw claw in accordance with
11 the present invention;

12 Fig. 25 is a flow diagram showing the steps for using the jaw claw in accordance
13 with the present invention, taken in conjunction with Fig. 24 and Fig. 26;

14 Fig. 26 illustrates a jaw claw and table assembly in accordance with the present
15 invention;

16 Figs. 27 and 28A and 28B illustrate a mandible structural model, and Fig. 28C
17 shows a skull and mandible coordinate systems on a device in accordance with the
18 present invention;

19 Figs. 29A-29C diagrammatically illustrate a pressure sensing array in accordance
20 with the present invention;

21 Figs. 30A-30B and 31A-31C provide additional details of jaw thrust in
22 accordance with the present invention;

23 Figs. 32A-32D, 33A and 33B illustrate neck and head positioning adjustment
24 capabilities of the device of the present invention;

25 Fig. 34 schematically illustrates a four-bar linkage geometry of the lift
26 mechanism of the present invention;

27 Figs. 35A-35C and 36A-36F diagrammatically illustrate the lift mechanism in
28 accordance with the present invention;

29 Figs. 37 plots linkage lengths, ramp angle and head support angle in accordance
30 with the present invention;

31 Fig. 38 shows a patient in a sniffing position with the jaw thrust device in
32 accordance with the present invention;

1 Fig. 39 is a flow diagram of the use of the device, in order to maintain coincident
2 neck and neck support locations at linkage axis 4 in accordance with the present
3 invention;

1 Figs. 40A-40D, and 41 ~~and 41A~~ illustrate combined nasal and mouth ventilation
2 masks in accordance with yet another embodiment of the present invention; and

3 Figs. 42-45 and 46A-46C illustrate a preferred embodiment of the invention,
4 installed on a conventional operating table.

5 Referring to Figs. 1 and 2 for the lateral decubitus position, an apparatus and the
6 Steps for implementing the sniff position and jaw thrusts are described below.

7 Step 1: A carriage subassembly 10 is translated along the Z axis along a base
8 subassembly rail 12 until the support surface 14, is at a comfortable height for a patient
9 lying on his or her left side.

10 Step 2: A sniff subassembly, surface 16, is adjusted along the Y axis until
11 comfortably aligned with the patient and locked in place.

12 Step 3: The sniff subassembly, surface 16, is adjusted along the X axis until
13 comfortably aligned with the patient and locked in place.

14 Step 4: A head clamp 18 is translated along the carriage subassembly along the Z
15 axis until the patient's head is comfortably constrained.

16 Step 5: A flexible band 20 is placed over the patient's forehead and attached to
17 the back side of the sniff subassembly constraining the patient's head in rotation about
18 the Z axis.

19 Step 6: The vertical adjustment arms of a left and right jaw clamp subassemblies
20 22, 24 are moved along the Z axis until aligned with the patient's mandible.

21 Step 7: Vertical adjustment arms 24, 26 are adjusted radially about the Z axis
22 until in line with engaging the patient's mandible.

23 Step 8: The left and right jaw claw subassemblies 22, 24 are rotated about the Z
24 axis until the mandible is engaged and extended to the desired amount.

25 Step 9: A backboard subassembly 28 height is adjusted along the Z axis until
26 aligned with the center of the back.

27 Step 10: The backboard subassembly 28 position relative to the back is adjusted
28 along the X axis to support maintenance of the patient at a 35° sniff position angle of the
29 head.

30 Step 11: A flexible band 30 is placed around the abdomen of the patient and the
31 back surface of the back board subassembly 28 to constrain the patient in the X-Y plane.

32 The present invention as above described provides several distinct advantages.
33 These include:

1 to enable gas exchange. A second opening can be connected to either an End-tidal CO₂
2 monitor or a portable oxygen supply. A third opening can be used to allow for the use of
3 both supplemental oxygen from an oxygen supply device and used to monitor end-tidal
4 CO₂. The third surface is base surface which may or may not consist of an opening as
5 well as a door, which when the door is opened by engagement of the mouth mask it will
6 allow for bilateral transfer of gases and when it is closed by disengagement of the mouth
7 mask it will prevent gases from escaping from the nasal mask.

8 Referring to Figs. 40C-40D, the top right picture shows a side view of the oral
9 mask and the bottom right picture shows a front view of the oral mask, which also
10 consists of three surfaces; where the first surface is the bottom surface, is open, with a
11 soft, flexible, pneumatic, border that contours to lower lips, cheeks, and upper lips in
12 order to create seal when in contact with the patient's face. The second surface is the top
13 surface. The third surface is the base, which consists of a connector, which when
14 engaged with the nasal mask door, pushes the door open and allows for the bilateral flow
15 of gases and when the connector disengages, it causes the door of the nasal mask to close
16 shut in order to prevent leakage of gases.

17 Figure 41 shows the oral mask connector within the mouth mask engaging with
18 the nasal mask, which causes the nasal mask door to swing open and allow gases to flow
19 into both the mouth and nose bilaterally. When the mouth mask is engaged with the nasal
20 mask, the combination creates the traditional facemask, which can be used for bag-mask
21 ventilation, general anesthesia, respiratory treatment, etc. When the oral mask connector
22 disengages from the nasal mask, the nasal mask door closes, which prevents gases from
23 escaping and now turns the traditional facemask into a nasal mask which can be used for
24 nasal BiPAP/CPAP for sedation cases, ventilation during intubation, general anesthesia,
25 respiratory treatments, can be attached to a portable oxygen supply source and used to
26 deliver oxygen for patient transport, etc. Figure 41 also shows the mask anchor, which
27 can either surround the opening of the nasal mask or be built into the nasal mask (Fig.
28 41A) and attaches to a surface, which secures the nasal mask and/or the nasal-oral mask
29 to the patient's face in order to keep a tight seal, prevent leakage of anesthetic gases, and
30 also maintains the patient's head and neck in the desired position to ensure an open
31 airway.

32 While the invention has been described for use in connection with surgery, the
33 invention also may be used during sedation cases, especially deep sedation or patients
34 with Obstructed Sleep Apnea (OSA) or obesity, where the upper airway of many of these

3 which is the neck height adjustment. If a sensor is provided, the actuator control laws that adjust d would be appropriately modified.

An illustration of the jaw thrust parameters and associated Cartesian coordinate system are provided in Figures 27-29. In a jaw thrust maneuver, the mandible is moved ΔL_{Thrust} , due to the applied force F_{Thrust} . In order to avoid necrosis of the muscle and epidermal tissue, the maximum allowable pressure that can be applied in a thrust is P_{Thrust} . Given the jaw thrust is applied symmetrically on the left and right side of the mandible, the load on each side is $F_{Thrust}/2$. Initial requirements for the jaw thrust maneuver are presented in Table 4.

Table 4, Jaw Thrust Maneuver Top-Level Requirements

	Parameter	Value	Comment
1	Jaw Thrust Displacement, ΔL_{Thrust}	7mm – 10mm @ +22° about the Y_{Shull} Axis	The most optimal protrusion of the mandible is between 7mm-10mm, > 10mm does not increase patency ²⁴
2	Total Jaw Thrust Force, F_{Thrust}	34.07 ± 9.33 N	The mean value of the highest forces to accomplish the jaw thrust maneuver ²⁶
3	Maximum allowable pressure resulting from Jaw Thrust, P_{Thrust}	<66 kPa, 4 hours	Muscle damage occurred at high pressure-short duration ²⁷

An illustration of a simplified mandible structural model is provided in Figures 28A-28C. For the purpose of this illustration, the mandible is assumed to be infinitely stiff with its associated coordinated system X_M , Y_M & Z_M . The back of the skull with its associated coordinate system is tied to ground, with the assumption that it is fixed both in torsion and translation, and the mandible is constrained in all but the thrust axis. Compliance in the mandible is represented by the left and right lateral pterygoid muscle spring stiffness, $K_M/2$, and the effective spring stiffness of the muscle and epidermal tissue below the thrust force, $F_{Thrust}/2$. Note that when the patient is located on the device, the thrust force vector is applied at a nominal 7° angle about the Y_{AS} axis as illustrated in the top right portion of Figure 45A. The jaw thrust force, F_{Thrust} , is transmitted over the area, A_{Thrust} , through the muscle/epidermal tissue spring on each side of the mandible,

1 Claims:

2 1. A disposable anesthesia nasal and oral mask which can be used either as a
3 nasal mask or can be connected together through a connector and used as a combination
4 nasal-oral mask covering and sealing around a patient's mouth and nose, wherein said
5 nasal mask and said oral mask are disconnected, said connector closes to prevent gases
6 from escaping from the nasal mask whereupon the nasal mask may be used alone.

7 2. A nasal and oral mask as claimed in claim 1, further comprising: a first
8 nasal inflatable or non-inflatable cushion that consists of a nasal bridge region, a cheek
9 region, and an upper lip region and a second mouth inflatable or non-inflatable cushion
10 which consists of a lower lip region, a cheek region, and an upper lip region; a first nasal
11 membrane comprising a substantially triangularly shaped frame of resilient material
12 having a first molded inwardly curved rim of said first nasal membrane; a second nasal
13 membrane of resilient material, said second nasal membrane being thinner, as thin, or
14 thicker than said first nasal membrane, said second nasal membrane having a second
15 molded inwardly curved rim, said second nasal membrane curved rim spaced a first
16 distance from said first nasal membrane curved rim in said cheek region and said second
17 nasal membrane curved rim spaced a second distance from said first nasal membrane
18 curved rim in said nasal bridge region, said second distance greater than said first
19 distance, said distances measured when the mask is not in use, a portion of said second
20 membrane curved rim forming a face contacting seal; a first mouth membrane
21 comprising a substantially oval shaped frame of resilient material having a first molded
22 inwardly curved rim of said first mouth membrane; a second mouth membrane of
23 resilient material, said second mouth membrane being thinner, as thin, or thicker than
24 said first mouth membrane, said second mouth membrane having a second molded
25 inwardly curved rim, said second mouth membrane curved rim spaced a first distance
26 from said first mouth membrane curved rim in said cheek region and said second mouth
27 membrane curved rim spaced a second distance from said first mouth membrane curved
28 rim in said mouth region, said second distance greater than said first distance, said
29 distances measured when the mask is not in use, a portion of said second membrane
30 curved rim forming a face contacting seal; an attachment with two apertures; where the
31 first aperture is fixed to the oral mask and can connect to the second aperture, which is
32 fixed to the nasal mask; where when they are connected together it comprises an
33 anesthesia full face mask, covering and sealing around the mouth and nose.

34 3. A nasal and oral mask as claimed in claim 1 or claim 2, characterized by

- 1 one or more of the following features:
- 2 (a) wherein said second molded rim and said first molded rim have a co-
- 3 located notch to accommodate the bridge of a wearer's nose;
- 4 (b) wherein said first nasal membrane molded rim and said second nasal
- 5 membrane molded rim are substantially saddle-shaped;
- 6 (c) wherein said second nasal membrane is shaped so that said seal portion, in
- 7 use, contacts at least a wearer's nose;
- 8 (d) wherein said seal portion, in use, contacts the facial tissue around the
- 9 sides and over the bridge of the nose, and between the base of the nose and the top lip;
- 10 (e) wherein said second rim and seal portion are shaped to generally match
- 11 facial contours in the region of facial tissue around the sides and over the bridge of the
- 12 nose, and between the base of the nose and the upper lip;
- 13 (f) wherein the first and second nasal membranes comprise one molded
- 14 piece, without being adhered together by an adhesive.
- 15 (g) wherein the first molded inwardly curved rim of said first nasal membrane
- 16 is as thick, less thick, or thicker than the second nasal membrane;
- 17 (h) wherein the second molded inwardly curved rim of the second nasal
- 18 membrane is as thick, less thick, or thicker than the first nasal membrane;
- 19 (i) wherein said second molded rim and said first molded rim have a co-
- 20 located notch to accommodate the lips of a wearer's mouth;
- 21 (j) wherein said first mouth membrane molded rim and said second mouth
- 22 membrane molded rim are substantially oval shaped;
- 23 (k) wherein said second mouth membrane is shaped so that said seal portion,
- 24 in use, contacts at least a wearer's upper and lower lip;
- 25 (l) wherein said seal portion, in use, contacts the facial tissue around the
- 26 sides and over the upper and lower lips of the mouth;
- 27 (m) wherein said second rim and seal portion are shaped to generally match
- 28 facial contours in the region of facial tissue around the sides and over the upper and
- 29 lower lip of the mouth;
- 30 (n) wherein the first and second mouth membranes comprise one molded
- 31 piece, without being adhered together by an adhesive;
- 32 (o) wherein the first molded inwardly curved rim of said first mouth
- 33 membrane is as thick, less thick, or thicker than the second mouth membrane, and
- 34 (p) wherein the second molded inwardly curved rim of the second mouth

1 membrane is as thick, less thick, or thicker than the first mouth membrane.

2 4. A nasal mask, oral mask or full face mask, for connection to a wearer's
3 face comprising: a mask body for connection with a supply of breathable gas, whether
4 oxygen, air, anesthetic gases or any other gas; and a nasal inflatable or non-inflatable
5 cushion secured to said mask body, the body and cushion forming a nose-receiving
6 cavity, said cushion including: a nasal bridge region, a cheek region and an upper lip
7 region; a substantially triangularly-shaped first nasal membrane of resilient material
8 having a first molded inwardly curved rim to surround wearer's nose; a second nasal
9 membrane also of resilient material, said second membrane being relatively more
10 flexible than said first nasal membrane, said second nasal membrane having a second
11 molded inwardly curved rim, said second molded rim being of the same general shape as
12 said first molded rim and fixed to and extending away from said first nasal membrane so
13 as to have a second nasal membrane inner surface spaced a first distance from an outer
14 surface of said first molded rim in said cheek region and said second membrane inner
15 surface spaced a second distance from said first nasal membrane outer surface of said
16 first molded rim in said nasal bridge region, said second distance greater than said first
17 distance, said distances measured when the mask is not in use, a portion of said second
18 molded rim forming a face contacting seal; and wherein said seal portion is substantially
19 coterminous with respect to said second molded rim and is resiliently deformable
20 towards said first nasal membrane in use of said mask.

21 5. A nasal mask, oral mask, or full face mask, covering and sealing the
22 mouth and nose, as claimed in claim 4, characterized by one or more of the following
23 features:

24 (a) wherein said a nasal mask, oral mask, or full face mask body includes
25 either integrated head strap attachment points using either an anterior approach or
26 posterior approach or it can have separated head strap attachment points using either an
27 anterior approach or a posterior approach that placed over the nasal mask, oral mask, or
28 full face mask body, which attach to a surface that can secure the nasal mask, oral mask,
29 or full face mask to the wearer's face to ensure a tight seal and to maintain the wearer's
30 head and neck in the desired position to maintain airway patency;

31 (b) further comprising securing straps fixed to said attachment points which
32 can secure the wearer's head to a surface and maintain the wearer's head and neck in the
33 desired position;

34 (c) wherein said second membrane molded rim and said first nasal membrane

1 molded rim each have a co-located notch to accommodate the bridge of a nose;

2 (d) wherein said first and second molded rims are substantially saddle-
3 shaped;

4 (e) wherein said second nasal membrane is shaped so that said seal portion, in
5 use, contacts at least wearer's nose;

6 (f) wherein said seal portion, in use, contacts the facial tissue around the
7 sides and over the bridge of the nose, and between the base of the nose and the upper lip,
8 and

9 (g) wherein said rim and said seal portion are shaped to generally match
10 facial contours in the region of facial tissue around the sides and over the bridge of the
11 nose, and between the base of the nose and the upper lip.

12 6. A nasal noninvasive positive pressure ventilating (CPAP/BiPAP), oral
13 noninvasive positive pressure ventilating (CPAP/BiPAP), or full face mask noninvasive
14 positive pressure ventilating (CPAP/BiPAP) treatment apparatus comprising: a
15 generator for the supply of gas at a pressure below, equal to, or elevated above
16 atmospheric pressure; a gas delivery conduit coupled to said generator; and a nasal mask
17 oral mask, full face mask in turn coupled to said conduit to said nasal mask, oral mask,
18 full face mask including: a mask body for connection with a supply of breathable gas;
19 and a nasal inflatable or non-inflatable cushion secured to said mask body, the body and
20 cushion forming a nose-receiving cavity, the cushion including: a nasal bridge region, a
21 cheek region and a lip region; a substantially triangularly-shaped first nasal membrane of
22 resilient material having a first nasal membrane having a molded inwardly curved rim; a
23 second membrane having a second molded inwardly curved rim also of resilient material,
24 said second nasal membrane being relatively more flexible than said first membrane, and
25 being of the same general shape as said first molded inwardly curved rim and fixed to
26 and extending away from said first nasal membrane so as to have an inner surface spaced
27 a first distance from said first molded rim in said cheek region and said second nasal
28 membrane inner surface spaced a second distance from said first molded rim, said
29 second distance greater than said first distance, said distances measured when the mask
30 is not in use, a portion of said second molded rim forming a face contacting seal; and
31 Wherein said seal portion is generally coterminous with respect to said second molded
32 rim and is resiliently deformable towards said first membrane in use of said mask.

33 7 The non-invasive positive pressure ventilation (BiPAP/CPAP) treatment
34 apparatus as claimed in claim 5, characterized by one or more of the following features:

1 (a) wherein said mask body includes attachment points which can secure the
2 wearer's head to a surface and maintain the wearer's head and neck in position;

3 (b) further comprising securing straps fixed to said attachment points which
4 can secure the wearer's head to a surface and maintain the wearer's head and neck in
5 position;

6 (c) wherein said first and second molded rims each have a co-located notch to
7 accommodate the bridge of a nose;

8 (d) wherein said first and second molded rims are substantially saddle-
9 shaped;

10 (e) wherein said second nasal membrane is shaped so that said seal portion, in
11 use, contacts at least wearer's nose;

12 (f) wherein said seal portion, in use, contacts the facial tissue around the
13 sides and over the bridge of the nose, and facial tissue around the sides and over the
14 bridge of the nose, between the base of the nose and the upper lip, and

15 (g) wherein said second molded rim and said seal portion are shaped to
16 generally match facial contours in the region of facial tissue around the sides and over
17 the bridge of the nose, between the base of the nose and the upper lip.

18 8. An oral mask for connection to a wearer's face comprising: a mask body
19 for connection with a supply of breathable gas; and an inflatable or non-inflatable mouth
20 cushion secured to said mask body, the body and cushion forming a mouth-receiving
21 cavity, said cushion including: a mouth region, a cheek region and an upper and lower lip
22 region; a substantially oval-shaped first mouth membrane of resilient material having a
23 first molded inwardly curved rim to surround a wearer's nose; a second mouth
24 membrane also of resilient material, said second mouth membrane being relatively more
25 flexible than said first mouth membrane, said second mouth membrane having a second
26 molded inwardly curved rim, said second molded rim being of the same general shape as
27 said first molded rim and fixed to and extending away from said first mouth membrane
28 so as to have a second mouth membrane inner surface spaced a first distance from an
29 outer surface of said first molded rim in said cheek region and said second mouth
30 membrane inner surface spaced a second distance from said first mouth membrane outer
31 surface of said first molded rim in said mouth region, said second distance greater than
32 said first distance, said distances measured when the mask is not in use, a portion of said
33 second molded rim forming a face contacting seal; and wherein said seal portion is
34 substantially coterminous with respect to said second molded rim and is resiliently

1 deformable towards said first mouth membrane in use of said mask.

2 9. The mask as claimed in claim 8, characterized by one or more of the
3 following features:

4 (a) wherein said mask body includes attachment points which can secure the
5 wearer's head to a surface and maintain the wearer's head and neck in position;

6 (b) further comprising securing straps fixed to said attachment points which
7 can secure the wearer's head to a surface and maintain the wearer's head and neck in
8 position;

9 (c) wherein said second membrane molded rim and said first mouth
10 membrane molded rim each have a co-located notch to accommodate the mouth;

11 (d) wherein said first and second molded rims are substantially oval-shaped;

12 (e) wherein said second mouth membrane is shaped so that said seal portion,
13 in use, contacts at least wearer's mouth;

14 (f) wherein said seal portion, in use, contacts the facial tissue around the
15 sides and over the mouth, and between the upper and lower lip;

16 (g) wherein said rim and said seal portion are shaped to generally match
17 facial contours in the region of facial tissue around the sides and the mouth, and between
18 the upper and lower lip.

19 10. The nasal mask, oral mask, or full facemask as claimed in claim 4, further
20 patent tubing which has two ends to be used as an gas source to transport patients, where
21 a distal end of the tubing is connected to either a stand alone or a portable generator for
22 the supply of gas at a pressure below, equal to, or elevated above atmospheric pressure; a
23 gas delivery conduit coupled to said generator a portable gas supply and a proximal end
24 is connected to an adaptor, which contains an End-Tidal CO₂ port, a nebulizer port, a
25 PEEP valve port, expiratory port and/or valve, pressure relief valve, which has an
26 aperture which attaches to either the nasal mask, the oral mask, or the full face mask.

27 11. The nasal mask, oral mask or full face mask, as claimed in claim 4,
28 connected to a generator for the supply of gas, where the amount and concentration of
29 gas delivered is controlled by the supply source as well as the expiratory port, and/or
30 used as a scavenger system by connecting the nasal mask and the oral mask
31 simultaneously, where the nasal mask can be used to deliver positive pressure and the
32 oral mask can be connected to a suctioning device to properly store and/or dispose gases.

33 12. The nasal mask, oral mask or full face mask as claimed in claim 4,
34 contoured around the patient's nasal bridge, nose, and upper lip such that it and the

generator gas supply it is connected to does not interfere with the operator's access to the mouth/oral cavity, lips, cheeks, chin, jaw, and neck, and/or connected to a resuscitator bag with or without a gas supply attached to the resuscitator bag.

13. A device for positioning a patient, comprising:

a carriage having a first surface that supports the patients in an inclined position, and is adjustable in the Z-axis, a second surface that supports the patient's head and neck and is adjustable to place the patient in a generally desired sniffing position; and

a pneumatic or mechanical jack, or an expandable bellows, supported on the second surface for independently raising the patient's head relative to the second surface.

14. The device of claim 13, characterized by one or more of the following features:

(a) wherein the expandable bellows comprises a plurality of rigid concentric rings joined by flexible membranes on a rigid base, wherein the third side of the base preferably comprises:

a rigid inclined side with two ends;

a proximal end which is detachable from the distal side of the first side of the base; the desired position can be obtained by different body habitus' by adjusting the height of the first base;

a distal end comprises an extension mechanism to maintain the desired angle to maintain the patient in the desired position;

a resiliently deformable pad that lies on top of the rigid inclined side and comes in contact with the patient's upper back, middle back, and shoulders;

(b) wherein the bellows includes a two-way valve through which air may be added or subtracted; and

(c) wherein the bellows is formed of MRI or Xray compatible material.

15. A method for positioning a patient to facilitate maintenance of a patent airway under anesthesia, comprising providing a device as claimed in claim 13, positioning the patient on the device, adjusting the first surface to support the patient in a desired inclined position;

adjusting the second surface to support the patient's head and neck in a generally desired sniffing position; and

activating the pneumatic or mechanical jack, or inflating the expandable bellows to raise the patient's head relative to the second surface to a desired sniffing position.

1 Claims:

2 1. A nasal mask which can be used separately, or with an oral mask releasably
3 attached to the nasal mask through a closable opening on the nasal mask.

4 2. The nasal mask as claimed in claim 1, wherein when the oral mask is engaged
5 with the nasal mask, the closable opening allows gases to flow bilaterally between the
6 oral mask and the nasal mask.

7 3. The nasal mask as claimed in claim 1 or claim 2, wherein when the oral mask is
8 combined with and engaged with the nasal mask, the combination creates a face mask
9 which can be used for bag-mask ventilation, general anesthesia, deep sedation or
10 respiratory treatment.

11 4. The nasal mask as claimed in any one of claims 1-3, wherein when nasal mask is
12 used by itself, the closable opening automatically closes whereupon the nasal mask may
13 be used for nasal Bipap/CPAP, ventilation during intubation, general anesthesia, deep
14 sedation, respiratory treatment, delivery of oxygen, or treatment of obstructed sleep
15 apnea.

16 5. The nasal mask of any one of claims 1-4, wherein the closable opening comprises
17 a door, and the oral mask includes a connector which when engaged with the nasal mask
18 door, pushes the door open.

19 6. A nasal mask, or combined nasal mask/oral mask full face mask, comprising:
20 a nasal mask body adapted for connection with a supply of breathable gas,
21 preferably oxygen, air, or air anesthetic gas;

22 a cushion secured to said nasal mask body, the body and cushion forming a nose-
23 receiving cavity, said cushion including: a nasal bridge region, a cheek region and an
24 upper lip region;

25 a substantially triangularly-shaped first nasal membrane formed of resilient
26 material having a first molded inwardly curved rim to surround patient's nose;

1 a second nasal membrane formed of resilient material, said second membrane
2 being relatively more flexible than said first nasal membrane, said second nasal
3 membrane having a second molded inwardly curved rim, said second molded rim being
4 of the same general shape as said first molded rim and fixed to and extending away from
5 said first nasal membrane so as to provide a second nasal membrane inner surface spaced
6 a first distance from an outer surface of said first molded rim in said cheek region and
7 said second membrane inner surface spaced a second distance from said first nasal
8 membrane outer surface of said first molded rim in said nasal bridge region, said second
9 distance greater than said first distance, said first and second distances measured when
10 the mask is not in use, a portion of said second molded rim forming a face contacting
11 seal; and

12 wherein said seal portion is substantially coterminous with respect to said second
13 molded rim and is resiliently deformable towards said first nasal membrane when said
14 mask is in use.

15 7. The mask as claimed in claim 6 further comprising tubing for connection to a
16 generator for the supply of gas at a pressure below, equal to, or elevated above
17 atmospheric pressure;

18 a gas delivery conduit having one end for coupling to said supply of gas, and its
19 other end for coupling to an adaptor, which contains an End-Tidal CO₂ port, a nebulizer
20 port, a PEEP valve port, expiratory port and/or valve, pressure relief valve, which has an
21 aperture which attaches to either the nasal mask, the oral mask, or the full face mask.

22 8. The mask as claimed in claim 6 or claim 7, wherein the mask is connectable to a
23 generator for the supply of gas, wherein an amount and concentration of gas delivered is
24 controlled by a supply source as well as the expiratory port, and/or used as a scavenger
25 system by connecting the nasal mask and the oral mask simultaneously, where the nasal

1 mask can be used to deliver positive pressure and the oral mask can be connected to a
2 suctioning device to properly store and/or dispose gases.

3 9. The mask as claimed in any one of claims 6-8, wherein the nasal mask is
4 contoured for the patient's nasal bridge, nose, and upper lip such that when the mask and
5 the generator gas supply are connected and worn by a patient, the mask does not interfere
6 with the operator's access to the mouth/oral cavity, lips, cheeks, chin, jaw, and neck of
7 the patient, and/or connected to a resuscitator bag with or without a gas supply attached
8 to the resuscitator bag.

9 10. The mask as claimed in any one of claims 6-9, wherein said nasal mask body
10 includes either integrated head strap attachment points using either an anterior approach
11 or posterior approach or separate head strap attachment points using either an anterior
12 approach or a posterior approach when placed over the mask, which mask when
13 combined with straps attached to a surface secure the mask to the patient's face to ensure
14 a tight seal and to maintain the patient's head in a desired position to maintain airway
15 patency.

16 11. The mask as claimed in any one of claims 6-10, characterized by one or more of
17 the following features:

18 (a) further comprising securing straps fixed to said attachment points on the
19 mask;

20 (b) wherein said second nasal membrane molded rim and said first nasal
21 membrane molded rim each have co-located notches to accommodate a bridge of a nose
22 of a wearer;

23 (c) wherein said first and second molded rims are substantially saddle-shaped;
24 and

25 (d) wherein said second nasal membrane is shaped so that said seal portion, in

1 use, contacts at least a bridge of a nose of a wearer.

2 12. The mask as claimed in any one of claims 6-11, wherein said seal portion, in use,
3 contacts facial tissue around the sides and over a bridge of the nose of the wearer, and
4 between the base of the wearer's nose and an upper lip of the wearer.

5 13. The mask as claimed in any one of claims 6-12, wherein said rim and said seal
6 portion are shaped to generally match facial contours in the region of facial tissue around
7 sides and over a bridge of a nose of the wearer, and between a base of the nose and an
8 upper lip of the wearer.

9 14. A nasal mask for connection to a patient's face comprising:

10 a mask body for connection with a supply of breathable gas; and a mouth cushion
11 secured to said mask body, the mask body and mouth cushion forming a mouth-receiving
12 cavity, said mouth cushion including: a mouth region, a cheek region and an upper and
13 lower lip region;

14 a substantially oval-shaped first mouth membrane of resilient material having a
15 first molded inwardly curved rim to surround a patient's nose;

16 a second mouth membrane also of resilient material, said second mouth
17 membrane being relatively more flexible than said first mouth membrane, said second
18 mouth membrane having a second molded inwardly curved rim, said second molded rim
19 being of the same general shape as said first molded rim and fixed to and extending away
20 from said first mouth membrane so as to have a second mouth membrane inner surface
21 spaced a first distance from an outer surface of said first molded rim in said cheek region
22 and said second mouth membrane inner surface spaced a second distance from said first
23 mouth membrane outer surface of said first molded rim in said mouth region, said second
24 distance greater than said first distance, said first and second distances measured when
25 the mask is not in use, a portion of said second molded rim forming a face contacting

- 1 seal;
- 2 wherein said seal portion is substantially coterminous with respect to said second
- 3 molded rim and is resiliently deformable towards said first mouth membrane when said
- 4 mask is in use.