

(43) International Publication Date
31 December 2014 (31.12.2014)(51) International Patent Classification:
A61G 13/02 (2006.01)(21) International Application Number:
PCT/US2014/044934(22) International Filing Date:
30 June 2014 (30.06.2014)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:

61/840,980	28 June 2013 (28.06.2013)	US
61/840,997	28 June 2013 (28.06.2013)	US
61/876,093	10 September 2013 (10.09.2013)	US
61/907,938	22 November 2013 (22.11.2013)	US
61/910,648	2 December 2013 (02.12.2013)	US
61/924,114	6 January 2014 (06.01.2014)	US
61/925,089	8 January 2014 (08.01.2014)	US
61/941,206	18 February 2014 (18.02.2014)	US
61/979,912	15 April 2014 (15.04.2014)	US
61/983,941	24 April 2014 (24.04.2014)	US
62/007,802	4 June 2014 (04.06.2014)	US

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(81) Designated States (unless otherwise indicated, for every kind of national protection available): AE, AG, AL, AM, AO, AT, AU, AZ, BA, BB, BG, BH, BN, BR, BW, BY, BZ, CA, CH, CL, CN, CO, CR, CU, CZ, DE, DK, DM, DO, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN, HR, HU, ID, IL, IN, IR, IS, JP, KE, KG, KN, KP, KR, KZ, LA, LC, LK, LR, LS, LT, LU, LY, MA, MD, ME, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM, PA, PE, PG, PH, PL, PT, QA, RO, RS, RU, RW, SA, SC, SD, SE, SG, SK, SL, SM, ST, SV, SY, TH, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, ZA, ZM, ZW.

(84) Designated States (unless otherwise indicated, for every kind of regional protection available): ARIPO (BW, GH,

[Continued on next page]

(54) Title: POSITIONING DEVICE AND METHOD FOR USE WITH A PATIENT UNDER ANESTHESIA

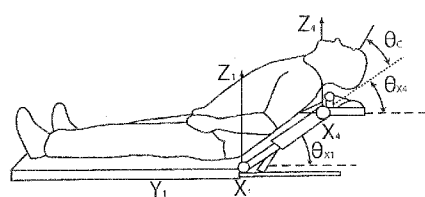
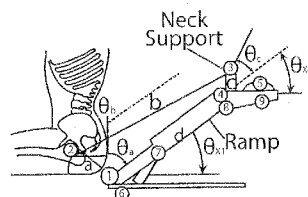


Fig. 32C



4-Bar Linkage (a,b,c,d)
Inclined Position, Angle θ_{x1}
Head Rest Rotated by $\theta_{xc} = -\theta_{x1}$
To maintain head support parallel to Y axis

Fig. 32D

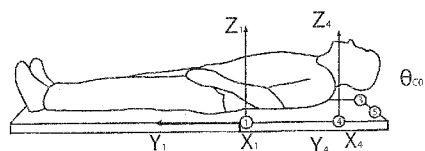
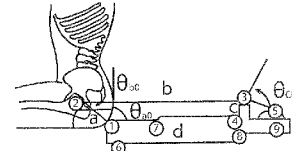


Fig. 32A



4-Bar Linkage (a,b,c,d)
Reclined Position

Fig. 32B

(57) Abstract: An apparatus for supporting the head and neck for airway management and to facilitate the maintenance of a patent airway under anesthesia, for unconscious patients, and for any circumstance requiring a patent airway while the patient is lying on her side. The apparatus includes a head supporting surface, an adjustable neck supporting surface, and two adjustable jaw support arms to protrude the jaw forward and maintain ventilation while the patient is lying on either of his/her sides.



GM, KE, LR, LS, MW, MZ, NA, RW, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, RU, TJ, TM), European (AL, AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HR, HU, IE, IS, IT, LT, LU, LV, MC, MK, MT, NL, NO, PL, PT, RO, RS, SE, SI, SK, SM, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, KM, ML, MR, NE, SN, TD, TG).

Published:

— *without international search report and to be republished upon receipt of that report (Rule 48.2(g))*

1 **POSITIONING DEVICE AND METHOD FOR USE WITH A PATIENT UNDER**
2 **ANESTHESIA**

3 The present invention in one aspect relates to a positioning device and method to
4 facilitate the maintenance of a patent airway while a patient is either unconscious, unable
5 to maintain a patent airway, or under sedation and/or anesthesia, which causes an airway
6 to collapse. In another aspect, the present invention relates to a positioning device to
7 facilitate the maintenance of a patent airway while a patient is either unconscious, unable
8 to maintain a patent airway, or under sedation and/or anesthesia by accurately
9 positioning the patient's head, neck, torso, and jaw and to enable the most optimal view if
10 endotracheal intubation is required by aligning three axes (oropharyngeal, laryngeal,
11 tracheal) prior to placing an endotracheal tube, simultaneously while trying to place an
12 endotracheal tube, and during extubation.. In yet another aspect the present invention
13 relates to an anesthesia nasal mask, full face mask, and combination nasal-oral mask,
14 which can be used for oxygenation and ventilation both prior to intubation, during
15 intubation, and after intubation, can be connected to either a portable oxygen supply
16 source and used to supply oxygen for transport and/or connected to an End-tidal CO₂
17 monitor to measure CO₂ levels, and/or to help maintain patient positioning. In still yet
18 another aspect, the invention relates to a device for facilitating jaw thrust of a patient
19 either unconscious, unable to maintain a patent airway, or undergoing anesthesia.

20 During surgery a patient is usually placed under anesthesia and the most common
21 delivery system consists of canisters containing anesthesia gases and oxygen, a system of
22 regulating the gas flow and the patient's breathing, and a device ensuring the potency of
23 the patient's airway for breathing/ventilation, oxygenation and the delivery of the
24 anesthetic gas mixture. Currently, a full face mask is used to provide oxygen to the
25 patient either before the patient is anesthetized, and to supply oxygen, remove carbon
26 dioxide (CO₂), and supply anesthetic gases while the patient is anesthetized. A few of
27 the drawbacks of current full face mask ventilation is that it first requires constant
28 contact between the provider's hands and the patient's face to hold the mask in place and
29 keep the patient in the so-called sniffing position in order to ensure that oxygen and
30 anesthetic gases do not leak out into the air and that the patient's airway remains patent. If
31 the provider fails to maintain the patient in the sniffing position, a dangerous
32 complication known as upper airway obstruction may occur where the soft palate and/or
33 tongue collapse into the airway. The reason the provider needs to perform continuous
34 mask holding and maneuvering is the human anatomy and physiology. When muscles of

1 the jaw, soft palate, tongue, and upper airway relax due to obstructive sleep apnea,
2 sedatives and/or muscle relaxants given to the patient for sedation and/or anesthesia, the
3 upper airway (mouth, pharynx, larynx) may become partially obstructed and possibly
4 completely closed. When either the head of the patient falls forward or the jaw drops
5 back, either the tongue and/or the soft palate falls back into the airway resulting in
6 snoring (partial obstruction) or apnea (complete inability for oxygen to pass via the upper
7 airway into the lungs). Should this occur, the patient's head and neck should be properly
8 positioned and either non-invasive positive pressure ventilation such as continuous
9 positive airway pressure (CPAP) ventilation or Bilevel positive airway pressure
10 ventilation BiPAP) and/or a so-called "jaw thrust" maneuver should be attempted, as will
11 be discussed below. A second drawback of the current full facemask is that a provider
12 must remove the mask prior to intubation, since the mask covers the patient's mouth and
13 prevents a laryngoscope from entering it. Also, current nasal masks have the anesthesia
14 circuit coming from the right side of the patient and connecting to the nasal mask
15 aperture in the middle of the nasal mask. Since the anesthesia circuit comes from the
16 right side it blocks the provider from being able to intubate, because all intubations are
17 performed on the right side. Also, since the anesthesia circuit connects to the middle
18 aperture of the nasal mask, both the nasal mask connection and the anesthesia circuit
19 obstruct the view of the patient's mouth if a provider was to attempt to intubate a patient.
20 Therefore both the current nasal mask and the full face mask must be removed prior to
21 an intubation attempt is made, the provider can therefore no longer try to oxygenate or
22 ventilate a patient until successful placement of an endotracheal tube occurs. This is also
23 known as the apneic period and one of the most critical events in airway management.
24 The present invention will only cover the patient's nose when attempting direct
25 laryngoscopy and placement of an endotracheal tube, allowing the provider to continue
26 oxygenating and ventilating the patient, and will not obstruct the view of the provider
27 while he/she performs direct laryngoscopy, as the anesthesia circuit connector aperture
28 within the proposed nasal and oral-nasal mask will be located on either the left or right
29 side of the nasal and oral-nasal mask (not sticking straight up) and allow the anesthesia
30 circuit to also be on either the left or right side of the patient, which is out of the way of
31 the provider's view when performing direct laryngoscopy. The present invention
32 essentially eliminates the critical apneic period. A third drawback of the current full
33 facemask is it cannot be used as a source of oxygen for patients during transport unless it
34 is connected to a resuscitator bag. Currently, at the end of each case, anesthesiologists

1 throw the anesthesia mask away since it cannot be used to transport patients to the Post-
2 Anesthesia Care Unit (PACU). The reason why the current nasal mask or full face mask
3 cannot be used for transport is because they only have one aperture which must connect
4 to a non-invasive positive pressure device which has both inspiratory and expiratory
5 valves. These masks do not have a vent to allow for inhalation and exhalation when
6 attached to oxygen supply devices. The present invention has an additional port where
7 either oxygen from an oxygen supply device can attach or an end-tidal CO₂ monitor can
8 attach and the anesthesia circuit aperture can either be used as a vent to prevent excessive
9 pressure from being built up, connected to a resuscitator bag and be used for bag-mask
10 ventilation, or connected to a non-invasive positive pressure ventilation device (CPAP,
11 BiPAP, etc) to assist in ventilation. The present invention's one or more extra port/s
12 (oxygen/CO₂) can also be covered and the anesthesia circuit can be connected to the
13 anesthesia circuit connector aperture to be used for non-invasive positive pressure
14 ventilation. The present invention's one or more extra port/s (oxygen/CO₂) can also be
15 attached to either an oxygen monitor and/or an end-tidal CO₂ monitor and the anesthesia
16 circuit can be connected to the anesthesia circuit connector aperture to be used for non-
17 invasive positive pressure ventilation while being able to measure oxygen levels and
18 CO₂ levels.

19 Another problem exists when a provider fails to administer enough anesthesia or
20 sedation and it begins to wear off and the patient begins to move. This can also cause the
21 patient's airway to obstruct as well since the patient's head and neck position are no longer
22 in the sniffing position. Patient movement during surgery also can be dangerous because
23 it can cause the surgeon to make a mistake, particularly in eye, ear, nose, neck, head, and
24 throat surgery.

25 Also, over the last decade the number of Monitored Anesthesia Care (MAC)
26 cases, especially colonoscopies, have dramatically increased (several million being
27 performed annually just in the U.S.), and unfortunately, so have airway complications
28 resulting in both death and brain damage. MAC cases use sedating medications in order
29 to limit the amount of physical and psychological pain that the patient may experience.
30 However, these sedating medications can cause relaxation of the muscles that help
31 maintain an open airway. Relaxation of these muscles can then lead to the airway
32 becoming obstructed (i.e., upper airway obstruction) and stopping the patient from
33 breathing. Also, if a higher than expected dose of sedating medication is given it can lead
34 to respiratory depression where the patient's brain fails to communicate when to take a

1 breath.

2 Historically, in order to reduce the risk of an upper airway obstruction, a provider
3 would first change the position of the patient's head by lifting the chin or by having the
4 patient lie on their side. Lifting the chin places the patient in the so-called "sniff position"
5 or "sniffing position" and allows the mandible to be slightly displaced anteriorly which
6 removes the tongue from the airway. See Cattano et al, Airway Management and Patient
7 Positioning: A Clinical Perspective, Anesthesiology News Guide to Airway
8 Management, P. 15 (2011). The sniffing position also aligns three axes (oropharyngeal,
9 laryngeal, tracheal) and gives the provider the most optimal view for intubation. Laying a
10 patient on his or her side prevents gravity from forcing the patient's tongue and/or soft
11 palate into the patient's airway and blocking it by allowing the tongue and soft palate to
12 extend forward. However, these two positions only prevent upper airway obstruction in
13 about half of the patients. A new technique that can be used based off of current evidence
14 is to apply nasal CPAP in patients with upper airway obstruction as it is more effective
15 than full face mask CPAP. If these maneuvers fail to relieve the upper airway
16 obstruction, the provider then will perform a jaw thrust maneuver. The jaw thrust
17 maneuver is done with one hand moving the jaw up and forward to move the tongue so
18 that the airway is opened. The jaw thrust is performed while holding a mask over the
19 patient's mouth and nose to deliver oxygen. In order to ventilate the patient while
20 performing a jaw thrust maneuver, the provider is required to hold the mask over the
21 patient's face almost constantly and prevents the ability to perform other tasks during the
22 surgery. An obvious disadvantage of this maneuver is the use of two hands. This can
23 become especially cumbersome when the patient is in the lateral position because the
24 side of the jaw that the patient is lying on cannot be reached.

25 In a 2000 study, 11 % of operations for patients utilizing a full face mask and jaw
26 thrust for airway management had sore-jaw complaints. Currently, 7% of
27 anesthesiologists have lawsuits associated with complications related to anesthesia and
28 jaw-thrust related trauma. Additionally, the requirement to multi-task (perform jaw thrust
29 and other duties) simultaneously results in a significant opportunity for error. This
30 translates into poor patient outcomes and liability for both the anesthesiologist and the
31 facility. This has led to a significant loss of popularity of the mask anesthetics and the
32 increased use of other airway devices, which are more invasive and have greater
33 potential side effects and complications. A successful hands-free jaw thrust device

1 program would benefit more than 13,000,000 patients undergoing anesthesia in the
2 Unites States annually, as well as the doctors and facilities providing the service.

3 Another difficulty that is encountered with the use of a full face mask is
4 maintaining the full face mask on the face of the patient during the procedure, and
5 especially during a long cases since not all faces are the same size or shape and face
6 masks are manufactured in only a few different sizes. Also, patient movement can cause
7 a face mask to fall off, as can incidental contact. In order to maintain a face mask on a
8 patient, the current procedure is to employ a ring and strap member configuration. As
9 best shown in Helling's, U.S. Pat. No. 5,975,079, the ring member typically includes a
10 ring having a central aperture that is sized to interiorly receive a generally cylindrical gas
11 port connector, so that the ring can fit over the cylindrical gas port connector. The ring
12 includes a plurality (usually 4 or 6) radially extending arms that are spaced in intervals
13 around the circumference of a cylindrical part of the ring. An upwardly extending prong
14 is formed on the distal (radially outward most) portion of each of the radially extending
15 arms, and serves as a prong or stud member. This approach have several disadvantages.
16 The first disadvantage is that the prongs are sharp and have been known to cause
17 abrasions to both the provider and the patient. Another disadvantage is that the head strap
18 must be placed beneath the patient's head and the extensions then fixed to the prongs in
19 front. This becomes challenging if the patient has already placed his or her head down on
20 the surface, the provider now has to lift the patient's head up. Also, some patients have
21 difficulty flexing their neck. Additionally, if the patient has long hair, the strap may
22 become tangled in the patient's hair. Another disadvantage is that the strap is bulky,
23 consisting of four long extensions and a very wide head strap. The size and bulkiness of
24 the strap has the potential to create additional clutter around the patient's face, cause
25 corneal abrasions, and may impair a surgeons' or nurses' ability to work on the patient.
26 Yet another disadvantage of the Helling device is that it cannot fix the patient's head to
27 the surface. Thus, even though it is purported to be a hands free approach, since the
28 patient's head is not fixed to the surface, movement of the patient's head or neck can cause
29 obstruction of the patient's airway and prevent oxygen and/or anesthetic gases from being
30 delivered to the patient. Finally, the Helling device is very cumbersome to be used for
31 transport since it tightly covers the nose and mouth causing the patient to feel like they
32 are suffocating and unless they are transported with a resuscitator bag, the current full
33 face mask cannot be connect to an oxygen supply device, since the mask does not
34 contain a vent and or inspiratory/expiratory valves. Other patents which teach systems

1 for stabilizing face masks or binding a person to a stretcher or the like include U.S.
2 Patent Nos. 6,981,503; 7,753,051; 4,905,712; 3,889,668; 3,897,777, and published
3 Applications Nos. 2009/0178682 and 2007/0295335.

4 Another particular and growing problem involves difficulties in ventilation and
5 intubation of obese patients, which problem is becoming more prevalent as the general
6 population is becoming more obese. Obese patients not only have more soft tissue in
7 their upper airways that leads to obstruction, but they also have a significant amount of
8 extra weight that compresses their chest, restricting air exchange. Historically, a health
9 care provider would place sheets or blankets under the patient's back, shoulders, neck,
10 and head in order to allow gravity to relieve the extra weight. This has been shown to be
11 only slightly effective compared to a more rigid structure like a ramp, which has shown
12 to be very effective. Also, if an endotracheal tube is not in place at the start of the case
13 because the patient is only undergoing sedation and during the case the patient goes into
14 respiratory failure and requires endotracheal intubation, there is not enough time to place
15 these sheets under the patient and ensure proper positioning. Moreover, it requires health
16 care personnel to lift these morbidly obese patients in order to position the sheets or
17 blankets underneath the obese patients and to remove the sheets or blankets once the
18 surgery starts. Obviously this greatly increases the risk of work related injuries. Since
19 obese patients are also known to be more difficult intubations, a ramp, in combination
20 with the "sniffing position" and the "ear aligned with sternum position" has been proven to
21 more effective than "sniffing position alone". Although the medical literature specifies
22 the most precise angles for the "sniffing position" which aligns three axes
23 (oropharyngeal, laryngeal, and tracheal) and gives a health care provider the most
24 optimal view for intubation as well as the most optimal patent airway, there currently are
25 no devices that can either assure the provider that the patient's head and neck angles are
26 properly aligned or changed the glottic view in real time during intubation. Accordingly,
27 the health care provider has to "eye ball" these angles which obviously results in errors.

28 The prior art has proposed various devices for facilitating maintenance of a
29 patent airway. For example, U.S. Pat. Publication No. 2012/0180220 shows an
30 apparatus for supporting the head and neck of a user for airway management includes a
31 head-supporting surface dimensioned to receive and support the head of the user and a
32 neck-supporting surface connected to the head-supporting surface, wherein the neck-
33 supporting surface is dimensioned to receive and support the neck of the user; wherein
34 the head-supporting surface and neck-supporting surface are configured so that when the

1 user is lying on his or her side with a side of his or her head positioned on the head-
2 supporting surface and a side of his or her neck on the neck-supporting surface, the user's
3 head and neck are automatically aligned in the sniff position for improved airway
4 management. However, this patent lacks the abilities to independently adjust either the
5 head or the neck as well as adjust them during the most critical point, intubation. It is
6 also unable to custom fit head, neck, and torso positioning or perform a jaw thrust, which
7 is critical in being able to maintain a patent airway. This device also cannot restrain a
8 patient's head during patient movement.

9 U.S. Pat. No. 8,347,889 shows a positioning device to facilitate the maintenance
10 of a patent airway by correctly positioning a patient's head under anesthesia during an
11 operation or procedure comprising at least one adjustable support including a plurality of
12 segments or sections selectively positionable relative to adjacent segments or sections
13 and selectively lockable relative to each other having a patient engaging member coupled
14 to the proximal end portion thereof to engage a portion of the patient's head to maintain
15 the position of the patient's head during an operation or procedure. Although this
16 patented device purportedly has the ability to restrain the patient's head, along with
17 provide chin lift and jaw thrust, it has no adjustability in terms of head and/or neck
18 positioning. This device also cannot displace weight off of an obese patient's chest, which
19 can be crucial for air exchange. Furthermore, this device cannot adjust head and neck
20 positioning in real time and it cannot allow for nasal ventilation during intubation.

21 US Pat. No 8,001,970 provide devices for use with a patient under anesthesia and
22 associated methods. Various embodiments include a device for establishing and
23 maintaining a patient's head and/or jaw in a particular position, including the sniffing
24 position. Embodiments also include a method for positioning a patient comprising the
25 use of a device of the present invention, wherein the device may substantially maintain a
26 patient in a desired position. Although this patented device has the ability to provide chin
27 lift and jaw thrust, it cannot adjust the head and/or neck to provide custom fit
28 positioning. This device also cannot displace weight off of an obese patient's chest which
29 can be crucial for air exchange. Also this device does not allow for nasal mask
30 ventilation during intubation. It also cannot adjust head and neck positioning while the
31 provider is attempting intubation. And, this patented device also is not able to align all 3
32 axes in the lateral decubitous position for intubation, nor does it provide a measuring
33 device to confirm the desired position.

1 US 8,191,553 shows a pair of pads that is held against the ramus of a patient's
2 jaw, to prevent the jaw from slipping back and causing an airway obstruction, while the
3 patient's neck is hyperextended to also cause the patient's airway to stay open. A device
4 including the adjustable jaw pads as well as a triangularly shaped portion over which the
5 patient's neck rests is not required to be attached to the surface on which the patient is
6 lying, and permits the patient to be rolled on either side while still maintaining the
7 patency of the patient's airway. Although this patented device has the ability to provide
8 chin lift and jaw thrust, it cannot adjust the head and/or neck to provide custom fit
9 positioning. This device also cannot displace weight off of an obese patient's chest which
10 can be crucial for air exchange. It also cannot adjust head and neck positioning while the
11 provider is attempting intubation. This patented device also is not able to align all 3 axes
12 in the lateral decubitus position for intubation, nor does it provide a measuring device to
13 confirm the desired position.

14 U.S. Pat. No. 1,131,802 shows a device comprising a frame having a pair of
15 angular adjustable side extensions, a vertically adjustable head rest detachably mounted
16 on the frame with freedom for horizontal adjustment longitudinally of the side extensions
17 a pair of vertically adjustable jaw rests mounted on the side extensions for movement
18 toward and away from the head rest. The objective of this device was to be used to
19 secure a corpses head to a table for embalming, and thus is not designed to maintain a
20 patent airway, nor to displace weight off of a patient's chest to optimize ventilation.

21 U.S. Pat. No. 1,441,817, which relates to an apparatus comprising a base plate
22 and a pair of spaced jaw props adjustable on the base plate at an angle thereto. The jaw
23 props includes the sole projections on the base plate, and the base plate being sufficiently
24 narrow so that it may be placed beneath the neck of a corpse and be adjusted
25 longitudinally of the neck of a corpse while the shoulders of the corpse and the head of
26 the corpse rest upon a head board independently of the base plate. The objective of this
27 patent device is to secure a corpse's head to a table for embalming, and is not designed to
28 maintain a patent airway or to displace weight off of a patient's chest to optimize
29 ventilation.

30 U.S. Pat. No. 1,729,525 teaches a device comprising a vertically adjustable head
31 rest, jaw rests, angularly and lengthwise adjustable supporting means for and carrying
32 the jaw rests carried by the head rest, a supporting structure and head rest having
33 contacting means for latching the head rest in adjusted position, the means including a
34 pair of supports hinged to the head rest and a combined coupling and adjusting device for

1 the supports, the jaw rests being vertically and angularly adjustable with respect to the
2 means, the means further having the forward ends thereof apertured for receiving the jaw
3 rests and carrying at their forward ends clamping devices for maintaining the jaw rests in
4 adjusted position. The objective of this device is to secure a corpse's head to a table for
5 embalming, and is not designed to maintain a patent airway nor to displace weight off of
6 a patient's chest to optimize ventilation.

7 U.S. Pat. No. 1,776,167 shows a device comprising an adjustable head rest
8 element including a pair of oppositely disposed downwardly inclined extensions and a
9 vertical post, an adjustable supporting element including an angle shaped pivoted arm
10 arranged below the head rest element, the supporting element including means for
11 latching the arm, an adjustable coupling device between the post and the arm, a pair of
12 angle shaped oppositely extending jaw rest elements, adjustable coupling devices
13 between the jaw rest elements and the extensions and adjustable shoulder drawing down
14 means pivotally and adjustably connected to the extensions. This patent does not claim to
15 maintain a patent airway, nor does it claim to achieve the desired position, nor displace
16 weight off of a patient's chest to optimize ventilation. Also this device does not allow for
17 nasal mask ventilation during intubation. It also cannot adjust head and neck positioning
18 while the provider is attempting intubation. The device also does not claim to align all 3
19 axes (oropharyngeal, laryngeal, tracheal) in the lateral decubitus position for the optimal
20 view for intubation.

21 U.S. Pat. No. 2,452,816 discloses a jaw supporting device comprising a base
22 member means for securing the base member to and transversely of a table top,
23 abutments upstanding in adjustable spaced opposition from the base member, means for
24 selectively adjusting the abutments longitudinally of the base member. A straight
25 cylindrical stem clampably swiveled to extend upwardly from each abutments upper end,
26 a tubular element telescoped over each stem and slidable axially thereon, means for
27 clamping the tubular element to and in selectively adjusted positions along the stem, a
28 mounting block clampably swiveled to the free end of each tubular element and a jaw
29 engaging cushion removably and replaceably clipped to and in supported relation against
30 each block. The disadvantage to this device is that it requires mandible arms to be
31 engaged in order to achieve the desired position but cannot be used in the lateral
32 decubitous position. This maneuver can be very stimulating and painful to patients that
33 are not deeply anesthetized. Also, it does not provide a mechanism to restrain the head if
34 the patient moves. Obviously if the patient moves the desired position is no longer

1 achieved. This patented device also lacks a way to displace weight off of an obese
2 patient's chest to optimize ventilation, and the patent nowhere teaches or suggests the
3 possibility of aligning all 3 axes in the lateral decubitous position for intubation.

4 U.S. Pat. No. 4,700,691 relates to a restraining and supporting device for the head
5 of a patient comprising a head immobilizing contraption connected to the operating table,
6 arm and hand supports for the surgeon, wherein the hand supports are fixed to the head
7 immobilizing contraption through flexible arms, also provided with elements releasing or
8 tightening the flexible arms, which elements are fitted to one of the fingers of the
9 surgeon's hand, or interconnected with hand and/or foot switch. The head immobilizing
10 contraption consists of nape support provided with a three-point bearing for the head and
11 can be set at an adjustable height. A front support clamps down the head into the nape
12 support and is connected to the nape support through a hinged mechanism. The flexible
13 arms are attached to the front support of the head immobilizing contraption. The main
14 objective of this device is to restrain the head during surgery, it does not have the
15 capability of maintaining a patent airway, nor does it have the ability to perform a jaw
16 thrust. Also, the device cannot displace weight off of an obese patient's chest to optimize
17 ventilation.

18 U.S. Pat. No. 5,524,639 discloses an apparatus intended to maintain or improve a
19 supine patient's airway in a hands-free environment. A frame and detachable pillow
20 device are placed under the patient's head. Mechanisms extend laterally from the frame
21 and provide jaw support members that may be brought under the angles of the jaw. The
22 jaw support members may slide towards and away from the frame, but this sliding
23 movement is regulated by a unidirectional clutch, such as a ratchet and pawl system,
24 which restricts the jaw support members to sliding movement away from the frame only.
25 When the jaw support members are slid away from the frame, they engage the angles of
26 the jaw, and then thrust the jaw forward to maintain or improve the patient's airway.
27 Once the desired anteriorly thrust position of the jaw is achieved, the unidirectional
28 clutch holds the jaw in place until the clutch is released. The weight of the jaw then
29 causes the jaw support members to slide back towards the frame, restoring the jaw to its
30 normal position. This device has several disadvantages, the first being that it can only
31 achieve the desired position by using the jaw support members. Not all patients will
32 require jaw support, and since it is very painful and stimulating, trying a lesser invasive
33 approach first would be ideal. Also, this patent does not teach or suggest aligning all 3
34 axes in the lateral position, and it does not displace weight off of a patient's chest.

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

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

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

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

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

28 For a patient lying on their back (supine position), in yet another aspect of the
29 invention, there is provided a positioning device to facilitate the maintenance of a patient
30 airway by correctly positioning a patient's back, shoulders, neck and head, while the
31 patient is unconscious, unable to maintain a patent airway, sedated, or under anesthesia
32 during an operation or procedure. The present device includes a device including: a base
33 support comprising a first side, a second side, and an inner adjustable support structure.
34 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 back
6 and shoulders to achieve the desired angles. A first support is positioned on the first side
7 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, y
13 and z axis. The first and second proximal parts of the moveable arms are moveable along
14 the x, y and z axis, while the distal parts are rotatable, such that each is positionable to be
15 in contact with the patient's jaw, and maintain a desired position.

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

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

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

1 contact with the patient's anesthesia mask, which creates a seal to the patient's nose and/or
2 face and attaches to the opposite side of the first surface of the base; the device is
3 adjustable and able to secure the patient's head and neck to the first surface of the base.

4 In yet another embodiment, the present invention includes a mandible arm
5 including: a curved portion that consists of an adjustable and lockable mechanism that
6 attach to a mandible pad, wherein the mandible pad is flexible, and wherein the mandible
7 pad has a distal side configured to attach to the curved portion and a proximal side
8 configured to contact a patient's jaw at a plurality of points, which can pivot in all angles
9 at the distal end; and a connector portion which is configured to attach to a support.

10 A further embodiment to the present invention includes an inclined surface that
11 consists of two sides where the proximal side may attach to the first base, and the angle
12 at which the proximal side is positioned can be changed by adjusting the angle of the
13 distal side (either mechanically, actuation, etc). The distal side also has the ability of
14 extending in order to ensure custom fit head, neck, and torso positioning. The inclined
15 surface will have a back and shoulder pad that rests on it to support a patient's upper
16 back, middle back, and shoulders. This support will enable gravity to displace weight off
17 of patient's chest, allowing for a more patent airway.

18 And yet another embodiment to the present invention includes a measuring
19 device to confirm the optimal neck flexion angle of 35° . One embodiment consists of
20 two sides, the first side of which is semi cylindrical and consists of four arms, each of
21 which is located within each of the four corners, each of which makes contact with the
22 patient's neck; the second side consists of a 35° leveled angle.

23 In yet another embodiment the present invention includes a leveling device used
24 to confirm the optimal head extension angle of 15° . This latter embodiment consists of
25 two sides, the first side or which triangular and consists of three arms, each of which is
26 located within each of the three corners, each of which is adjustable in the z-axis, each of
27 which makes contact with the patient's face; the second side consists of a 15° leveled
28 angle.

29 In another embodiment, the present invention includes a method for positioning a
30 patient including the steps of: providing any embodiment of the devices as described
31 herein, placing the patient's upper back, middle back, and shoulders on an inclined
32 surface along with the patient's neck and head substantially on the base of the device;
33 placing the patient's head and neck in the desired position, optionally confirming the
34 position with a measuring device; securing the anesthesia nasal mask, full face mask, or

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 is provided a simple and elegant
7 adjustable head rest neck rest, or combined head-neck rest, which may be a pneumatic
8 jack such as a bellows, or a mechanical jack, that is independently controllable to support
9 a patient's head and/or neck to obtain an optimal sniff position by raising a patient's neck
10 and head independently of the carriage. The head rest and/or head-neck rest can either be
11 fixed to the device or detachable and moved anywhere on either the device, an operating
12 room table, or any other surface used for patient's requiring airway management. The
13 head rest and/or head-neck rest will also have a cover to protect it from blood, saline, and
14 infectious agents that can also either be fixed to the device and reusable or it can be
15 disposable and detachable. The head rest and/or head-neck rest cover will also have
16 attachments for the mask anchor to attach to and be able to secure the patient's head
17 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
2 vice 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 of the
5 invention an apparatus for providing anesthesia to a patient is provided including a base
6 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
20 the head and attaching to the mask in front. The mask strap has four sides, sides one and
21 two which contain an aperture that is placed over the aperture of the mask of side one,
22 and sides three and four which contain one narrow extension each of which include a
23 plurality of holes adapted to attach to one of the protrusions on sides two and three of the
24 base. An alternate and preferred design consists of two cords that are attached to the
25 mask, and the cords can then attach to the support behind the head. These cords can be
26 clipped through friction, hook and loop, etc. on each side of the head. The mask strap is
27 adapted to hold the anesthesia mask against either the patient's nose only, nose, mouth,
28 cheeks, and/or or head to maintain the desired sniffing position where the patient's jaw is
29 moved up and forward, thereby preventing a patient's airway from becoming obstructed.
30 The mask strap is adapted to stabilize the patient's head and/or neck to the base
31 preventing movement of the patient's head and/or neck. The tight seal that the mask strap
32 creates also allows for non-invasive positive pressure ventilation (CPAP/BiPAP), which
33 further helps to maintain a patent airway.

1 In another aspect of the invention, 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

1 patient's jaw; wherein the first mandible arm and the second mandible arm are movable
2 such that each is positionable to be in contact with the patient's jaw and to maintain the
3 patient in a desired position while lying on his or her side and leaving the provider hands
4 free.

5 The above described device preferably is characterized by one or more of the
6 following features

7 (a) wherein the mandible arm is positionable to be in contact with the
8 patient's jaw at a ramus, a body, or an angle of the patient's jaw while the patient is lying
9 on his or her side, wherein each of the first mandible arm and the second mandible arm
10 preferably is positionable in contact with the patient's jaw at two or more of a ramus, a
11 body, or an angle of the patient's jaw while the patient is lying on his or her side, and/or
12 wherein each of the first mandible arm and the second mandible arm preferably is
13 positionable in contact with a patient's jaw at a ramus, a body, and an angle of the
14 patient's jaw while the patient is lying on his or her side;

15 (b) further including a mandible pad on the first and second mandible arms,
16 for contact with the patient's jaw;

17 (c) wherein all surfaces of the carriage subassembly are movable relative to
18 the base, wherein the first and third surfaces of the support arm preferably are movable
19 relative to the base in one axes, and the second surface of the carriage subassembly is
20 movable relative to the base in three axes;

21 (d) wherein the base is rectangular and the carriage subassembly surfaces are
22 c-shaped;

23 (e) wherein the mandible pads preferably are formed of a resiliently
24 deformable material, wherein the mandible pads are formed of foam;

25 (f) wherein the first mandible arm and the second mandible arm are
26 removably connected to the first surface of the carriage subassembly and the third
27 surface of the carriage subassembly, respectively;

28 (g) wherein the first mandible arm is movable relative to the first surface of
29 the carriage subassembly and the second mandible arm is movable relative to the third
30 surface of the carriage subassembly;

31 (h) wherein the desired position is the sniffing position while lying on a side,
32 aligning all 3 axes (oropharyngeal, laryngeal, and tracheal), and/or the jaw thrust
33 maneuver;

- 1 (i) wherein the second surface of the carriage subassembly further comprises
2 a neck rest disposed to provide optimal flexion of the patient's neck and optimal head
3 extension to a acquire the desired position;
- 4 (j) wherein the first and second mandible arms are configured to extend the
5 patient's jaw when rotated in the x-axis;
- 6 (k) wherein the plurality of mandible arms are configured to extend the
7 patient's jaw when rotated in the x-axis;
- 8 (l) wherein the device is formed of MRI or Xray compatible materials;
- 9 (m) wherein the carriage subassembly is reversible, allowing the patient to be
10 placed on an opposite side;
- 11 (n) further including a level for determining a patient's neck flexion angle;
- 12 (o) wherein the base further comprises a distal neck rest disposed on the first
13 surface configured to provide optimal flexion of the patient's neck and a proximal
14 inclined head rest to provide optimal head extension to provide a desired patient position;
15
- 16 (p) wherein the first and second support surfaces and first and second
17 rotatable portions are adjustable while the patient is in contact with the first and second
18 mandible arms;
- 19 (q) wherein the base subassembly comprises:
20 a rigid inclined side with two ends;
21 a proximal end which is detachable from the distal side of the first side of
22 the base; the desired position can be obtained by different body habitus' by adjusting the
23 height of the first base;
24 a distal end comprises an extension mechanism to maintain the desired
25 angle to maintain the patient in the desired position;
26 a foam pad that lies on top of the rigid inclined side and comes in contact
27 with the patient's upper back, middle back, and shoulders;
- 28 (r) wherein the inclined side supports a patient's upper back, middle back, and
29 shoulders, and will enable gravity to displace weight off of the patient's chest, including
30 in obese patients;
- 31 (s) wherein the device is formed of MRI or Xray compatible materials.
- 32 (t) wherein placing the head and neck substantially on the neck rest on a
33 distal end of the inclined side and a head rest on a proximal end of the inclined side
34 places the patient in the desired position within eliciting pain; and

1 (u) wherein the device is adjustable along a y-axis to displace weight off of a
2 patient's chest; is adjustable along a y-axis to align the ear and the sternum horizontally to
3 achieve maximal air exchange in obese patients; and is adjustable along a z-axis for
4 elevating and lowering obese patients without the help of health care workers.

5 II. Also provided is a method for positioning a patient comprising the steps of:
6 providing the above described device, placing the patient's head substantially on
7 the first surface of the carriage subassembly using an adjustable device to place the
8 patient's head and neck in a desired position; moving the first mandible arm to contact
9 the patient's jaw; moving the second mandible arm to contact the patient's jaw; wherein
10 contact of the first mandible arm and the second mandible arm provides sufficient force
11 to substantially maintain the patient's head and/or jaw in a desired position, wherein all
12 three axes (oropharyngeal, laryngeal, tracheal) preferably are aligned for view for
13 intubation.

14 III. Also provided is a mandible arm for positioning a patient, comprising: a rigid
15 lockable arm, wherein the arm has a curved extension which is rotatable in the x-axis; a
16 curved portion, wherein the curved portion is substantially rigid; a mandible pad,
17 wherein the mandible pad is flexible and pivotable, and wherein the mandible pad has a
18 proximal side configured to attach to the curved portion and a distal side configured to
19 contact a patient's jaw at a at least two of a ramus, a body, and an angle of the patient's
20 jaw; and a connector portion, wherein the connector portion is configured to extend from
21 and attach to a rotatable portion of a support, and wherein the connector portion is
22 further configured to attach to a support that is attached to the carriage subassembly
23 comprising a left side and a right side, wherein the carriage subassembly is configured to
24 substantially accommodate a patient's head and wherein the carriage subassembly is
25 movable in one axes such that the mandible pad is positionable to be in contact with a
26 patient's jaw at one or more points and to maintain a patient in a desired position,
27 wherein the carriage subassembly is reversible, allowing the patient to be place on an
28 opposite side.

29 IV. Also provided is a flexible and soft head restraining and anesthesia mask
30 sealing device for positioning a patient, comprising: a first proximal end that attaches to
31 one side of the first side of a base of a carriage subassembly, which can then extend
32 horizontally and come in contact with either the patient's head and attach to the opposite
33 side of the first surface of the base or comes in contact with the anesthesia mask, which
34 then contacts and seals to the patient's face; wherein the device is adjustable and able to

1 secure the patient's head to the first surface of the base to prevent the patient from
2 disengaging from the desired position, wherein the carriage subassembly optionally is
3 reversible, allowing the patient to be placed on an opposite side, and/or wherein the
4 device optionally is formed of MRI or Xray compatible materials.

5 V. Also provided is a flexible and soft back restraining device for positioning a
6 patient, comprising:

7 a first proximal end that attaches to one side of the back board, which can then
8 extend horizontally and come in contact with the patient's abdomen and attach to the
9 opposite side of the back board, wherein the device is adjustable and able to secure the
10 patient's back to the surface of the back board to prevent the patient from disengaging
11 from the desired position.

12 VI. Also provided is a surface for supporting a patient, comprising: a first side
13 that is adjustable to be in contact the patient's back, and a second adjustable side that is
14 adjustable to be in contact with the patient's ribs to prevent patient movement.

15 VII. Also provided is an apparatus for use when providing anesthesia to a
16 patient, comprising:

17 a base having a first side, a second side, a third side, and an adjustable support structure,
18 wherein the base is configured to substantially accommodate a patient's neck and head;
19 wherein a distal end of the base first side comprises either a semi-cylindrical support,
20 adjustable in the z-axis, which assists in maintaining the desired sniffing position or a flat
21 surface also adjustable in the z axis; a proximal end of the base first side comprises either
22 a slightly inclined or flat surface, with or without a cut-out center and is adjustable in the
23 z- axis in order to provide head support to further optimize the sniffing position; the
24 second and third sides of the base each contain a plurality of protrusions; and an
25 anesthesia mask strap with four sides, wherein the first and second sides include an
26 aperture that is placed over an aperture of the mask, and the third and fourth sides
27 include a narrow extension which include a plurality of holes adapted to attach to one of
28 the four protrusions on sides two and thereof the base; wherein the mask strap is adapted
29 to hold an anesthesia mask strap against the patient's nose, cheeks, mouth and/or head to
30 maintain the desired sniffing position where the patient's jaw is moved up and forward,
31 thereby unobstructing the patient's airway; and wherein the mask strap is adapted
32 stabilize the patient's head and neck to the base preventing movement of the patient's head
33 and neck.

1 The above described apparatus preferably is characterized by one or more of the
2 following features:

3 (a) wherein the anesthesia mask strap is formed of a non-static latex free
4 material;

5 (b) wherein at least some of said narrow extensions have respective portions
6 of snap fasteners for attaching the narrow extension to one of the protrusions of the base;

7 (c) wherein the adjustable support is located in the interior of the base;

8 (d) wherein the adjustable support includes a mechanical or a pneumatic
9 adjustment mechanism;

10 (e) wherein the base is substantially rectangular in plan;

11 (f) wherein the desired position is the sniffing position, aligning all three
12 axes, oropharyngeal, laryngeal, and tracheal;

13 (g) wherein the base further comprises a distal adjustable neck rest disposed
14 on the first surface configured to provide optimal flexion of the patient's neck and a
15 proximal inclined head rest to provide optimal head extension to acquire the desired
16 position; or the base comprises only a flat surface if the desired positioned is not
17 necessary;

18 (h) wherein the apparatus is formed of MRI or Xray compatible materials;
19 and

20 (i) wherein the mask strap is formed of a material that is easily disinfected
21 with anti-microbial solutions or is disposable.

22 VIII. Also provided is a method for positioning a patient for administering
23 anesthesia, comprising the steps of: providing the apparatus above described, placing the
24 patient's head and neck substantially on the carriage subassembly; using an adjustable
25 device to place the patient's head and neck in a desired position; placing the mask strap
26 either over the aperture of the anesthesia mask or the patient's head to substantially
27 maintain the patient's head and/or jaw in a desired position.

28 The above method preferably is characterized by one or more of the following
29 features:

30 (a) wherein placing the head and neck substantially on the neck rest on the
31 distal end of the first surface of the base and the head rest on the proximal end of the first
32 side of the base places the patient in the desired position without eliciting pain;

33 (b) wherein placing the head and neck substantially on the neck rest on the
34 distal end of the first surface of the base and the head rest on the proximal end of the first

1 side of the base places the patient in the desired position and restricts the movement of
2 the patient's head and neck; and

3 (c) wherein placing the mask on the patient's face, then placing the mask strap
4 over the mask and attaching it to the base will prevent leakage of anesthetic gases and
5 oxygen into the air.

6 IX. Also provided is an apparatus for use when providing anesthesia to a patient,
7 comprising: means for providing said anesthesia to said patient; mask strap means for
8 holding said mask means against a patient's nose, mouth, cheeks, and or head; a base of
9 which the mask strap attaches to achieve the desired position which raises the patient's
10 jaw up and forward so as to unobstruct the patient's airway.

11 X. Also provided is an apparatus for providing ventilation to a patient lying
12 supine on a support, comprising, a ventilation mask, a mask anchor ring over the
13 ventilation mask, and

14 a plurality of elastomeric straps connecting the mask anchor to the support.
15 Preferably elastomeric straps are fixed to the mask anchor ring spaced 180° around an
16 imaginary circle.

17 XI. Also provided is a device for positioning a patient, comprising: a carriage
18 having a first surface that supports the patients in an inclined position, and is adjustable
19 in the Z-axis, a second surface that supports the patient's head and neck and is adjustable
20 to place the patient in a generally desired sniffing position; and a pneumatic or
21 mechanical jack, or an expandable bellows, supported on the second surface for
22 independently raising the patient's head relative to the second surface.

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

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

28 a rigid inclined side with two ends;

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

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

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

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

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

6 XII. Also provided is a method for positioning a patient to facilitate maintenance
7 of a patient airway under anesthesia, comprising providing a device as above described,
8 positioning the patient on the device, adjusting the first surface to support the patient in a
9 desired inclined position; adjusting the second surface to support the patient's head and
10 neck in a generally desired sniffing position; and activating the pneumatic or mechanical
11 jack, or inflating the expandable bellows to raise the patient's head relative to the second
12 surface to a desired sniffing position.

13 XIII. Also provided is a device for positioning a patient, comprising: a base
14 comprising a first side which supports the patient's head and neck, a second side acting as
15 the foundation, an inner vertically adjustable support structure between the first and
16 second sides, and a detachable third inclined side which supports the upper back, middle
17 back, and shoulders of patient; a first support positioned on the second side of the base
18 and lockably adjustable with respect to the second side of the base in an x and y axes; a
19 second support positioned on the second side of the base and lockably adjustable with
20 respect to the second side of the base in the x and y axes; a first mandible arm extending
21 from a first vertically adjusted portion of the first support, wherein the first vertically
22 adjusted portion is lockable in a z axis to lockably adjust the first mandible arm with
23 respect to the z axis, and wherein the first mandible arm is positionable to be in contact
24 with the patient's jaw; and a second mandible arm extending from a second vertically
25 adjusted portion of the second support, wherein the second vertically adjusted portion is
26 lockable in the z axis to adjust the second mandible arm with respect to the z axis, and
27 wherein the second mandible arm is positionable to be in contact with the patient's jaw;
28 wherein the first mandible arm and the second mandible arm are movable such that each
29 is positionable to be in contact with the patient's jaw and to maintain the patient in a
30 desired position and leaving the provider hands free.

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

33 (a) wherein the mandible arm is positionable to be in contact with the
34 patient's jaw at a ramus, a body, or an angle of the patient's jaw, wherein each of the first

- 1 mandible arm and the second mandible arm preferably is positionable such that the
2 mandible pad, preferably formed of foam, is in contact with the patient's jaw at two or
3 more of a ramus, a body, or an angle of the patient's jaw, or wherein each of the first
4 mandible arm and the second mandible arm preferably is positionable such that the
5 mandible pad is in contact with a patient's jaw at a ramus, a body, and an angle of the
6 patient's jaw;
- 7 (b) wherein the first support is movable relative to the base and the second
8 support is movable relative to the base, wherein the first support preferable is movable
9 relative to the base in two axes and the second support is movable relative to the base in
10 two axes;
- 11 (c) wherein the base is rectangular;
- 12 (d) wherein the first mandible arm and the second mandible arm each
13 comprise a mandible pad;
- 14 (e) wherein the first mandible arm and the second mandible arm are
15 removably connected to the first support and the second support, respectively;
- 16 (f) wherein the first mandible arm is movable relative to the first support and
17 the second mandible arm is movable relative to the second support;
- 18 (g) wherein the desired position is the sniffing position, aligning all 3 axes
19 (oropharyngeal, laryngeal, and tracheal), and/or the jaw thrust maneuver;
- 20 (h) further including a level for determining a patient's neck flexion angle;
- 21 (i) wherein the base further comprises a distal neck rest disposed on the first
22 surface configured to provide optimal flexion of the patient's neck and a proximal
23 inclined head rest to provide optimal head extension to a acquire the desired position;
- 24 (j) wherein the first and second mandible arms are configured to extend the
25 patient's jaw when rotated in the z-axis;
- 26 (k) wherein the plurality of mandible arms are configured to extend the
27 patient's jaw when rotated in the z-axis;
- 28 (l) wherein the first and second supports and first and second rotatable
29 portions are adjustable while the patient is in contact with the first and second mandible
30 arms; and
- 31 (m) wherein the third side of the base will support a patient's upper back,
32 middle back, and shoulders, whereby to enable gravity to displace weight off of the
33 patient's chest, including in obese patients;
- 34 (n) wherein the device is formed of MRI or Xray compatible materials;

1 (o) wherein placing the head and neck substantially on the neck rest on the
2 distal end of the first surface of the base and the head rest on the proximal end of the first
3 side of the base places the patient in the desired position within eliciting pain; and

4 (p) wherein the inner adjustable surface consists of a rigid structure; wherein
5 the device is adjustable along a y-axis to displace weight off of a patient's chest; is
6 adjustable along a y-axis to align the ear and the sternum horizontally to achieve
7 maximal air exchange in obese patients; and is adjustable along a z-axis for elevating and
8 lowering obese patients without the help of health care workers;

9 (q) further comprising a claw for providing an anesthesiologist a tactile
10 interface with the patient in terms of extending the jaw, wherein the position of left and
11 right arms of the claw are maintained by frictional force that is transmitted through the
12 jack assembly, which force may be overcome by the anesthesiologist when rotating the
13 arms about the Z axis, further optionally characterized by one or more of the following
14 features:

15 (i) wherein the position of the left and right arms of the claw are
16 secured by friction about the Y axis;

17 (ii) wherein a fine adjustment for further extending the jaw is
18 provided by a screw which applies additional force in the nominal Z direction by
19 applying a torque to the arms about the Y axis; and

20 (iii) further comprising a torque limiter for limiting force applied to the
21 mandible by the left and right arms in the Z direction to prevent injury to the patient.

22 XIV. Also provided is a mandible arm for use in positioning a patient,
23 comprising: two rigid lockable arms, wherein the upper arm has a curved extension
24 which is rotatable in the z-axis and the lower arm does not provide an extension; a
25 curved portion, wherein the curved portion is substantially rigid; a mandible pad,
26 wherein the mandible pad is flexible and pivotable, and wherein the mandible pad has a
27 proximal side configured to attach to the curved portion and a distal side configured to
28 contact a patient's jaw at a at least two of a ramus, a body, and an angle of the patient's
29 jaw; and a connector portion, wherein the connector portion is configured to extend from
30 and attach to a rotatable portion of a support, and wherein the connector portion is
31 further configured to attach to a support that is attached to a base comprising a left side
32 and a right side, wherein the base is configured to substantially accommodate a patient's
33 head, neck, upper and middle back, and shoulders, and wherein the support is movable in

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

3 XV. Also provided is a first measuring device for use with the device of as above
4 described, comprising two sides: a first rigid semi-cylindrical side with four arm
5 extensions, each of which is located within each of the four corners, and each of which
6 comes into contact with the patient's neck; a second rigid side consists of a 35° incline, of
7 which rests a measuring device used to confirm the neck flexion angle of 35° to achieve
8 the desired position.

9 XVI. Also provided is a second measuring device for use with the device as
10 above described, comprising two sides: a first rigid triangular side with three-arm
11 extensions, each of which is located within each of the three corners, and each of which
12 comes in contact with the patient's head; the arm extensions are each adjustable along the
13 z-axis to achieve the desired position; a second rigid side consists of a 15° incline, of
14 which rests a measuring device used to confirm the head extension angle of 15° to
15 achieve the desired position.

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

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

23 XVIII. Also provided is a method for positioning a patient comprising the steps
24 of:

25 providing a device as described above, placing the patient's head, neck, upper and
26 middle back, and shoulders substantially on the base; using an adjustable device to place
27 the patient's head, neck, upper and middle back, and shoulders in a desired position;
28 optionally using a measuring device to confirm the desired position; moving the first
29 mandible arm to contact the patient's jaw; moving the second mandible arm to contact
30 the patient's jaw; wherein the contact of the first mandible arm and the second mandible
31 arm provides sufficient force to substantially maintain the patient's head and/or jaw in a
32 desired position.

33 The above method preferably is characterized by one or more of the following
34 features:

1 (a) wherein all three axes (oropharyngeal, laryngeal, tracheal) are aligned for
2 the recommended view for intubation;

3 (b) wherein the patient's head height is adjusted with respect to the Z axis by
4 using a jack, and

5 (c) wherein the device includes a squeeze released jaw thrust grip, and
6 including the step of moving the jaw thrust grip in the z direction.

7 XIX. Also provided is a device for positioning a patient, comprising: a base; a
8 ramp subassembly pivotally mounted at a proximal end to the base for supporting the
9 upper back, middle back, and shoulders of the patient, said ramp subassembly being
10 adjustable in length and angle relative to the base; a head support subassembly pivotally
11 mounted to a distal end of the ramp subassembly, said head support subassembly being
12 adjustable in angle relative to the ramp substantially; and a pneumatic or mechanical
13 jack, or an expandable bellows, supported on the head support subassembly for
14 independently raising the patient's head relative to the head support subassembly.

15 XX. Also provided is a first measuring device for use with the device as above
16 described, comprising two sides: a first rigid semi-cylindrical side with four arm
17 extensions, each of which is located within each of the four corners, and each of which
18 comes into contact with the patient's neck; a second rigid side consists of a 35° incline, of
19 which rests a measuring device used to confirm the neck flexion angle of 35° to achieve
20 the desired position.

21 XXI. Also provided is a second measuring device for use with the device as
22 above described, comprising two sides: a first rigid triangular side with three-arm
23 extensions, each of which is located within each of the three corners, and each of which
24 comes in contact with the patient's head; the arm extensions are each adjustable along the
25 z-axis to achieve the desired position; a second rigid side consists of a 15° incline, of
26 which rests a measuring device used to confirm the head extension angle of 15° to
27 achieve the desired position.

28 XXII. Also provided is a method for positioning a patient comprising the steps
29 of:

30 providing the above described device; placing the patient's head, neck, upper and
31 middle back, and shoulders substantially on the base; using an adjustable device to place
32 the patient's head, neck, upper and middle back, and shoulders in a desired position;
33 using a measuring device to confirm the desired position; moving the first mandible arm
34 to contact the patient's jaw; moving the second mandible arm to contact the patient's jaw;

1 wherein the contact of the first mandible arm and the second mandible arm provides
2 sufficient force to substantially maintain the patient's head and/or jaw in a desired
3 position.

4 The above method preferably is characterized by one or more of the following
5 features:

6 (a) wherein all three axes (oropharyngeal, laryngeal, tracheal) are aligned for
7 the recommended view for intubation;

8 (b) wherein the patient's head height is adjusted with respect to the Z axis by
9 using a jack;

10 (c) wherein the device includes a squeeze released jaw thrust grip, and
11 including the step of moving the jaw thrust grip in the z direction;

12 (d) including a neck interface and a head interface which are independently
13 adjustable in one or more of the x, y and z positions, and

14 (e) wherein the detachable third incline side is rotatably adjustable about each
15 y axis.

16 XXIII. Also provided is a method for positioning a patient to facilitate
17 maintenance of a patent airway under anesthesia, comprising: providing a device as
18 above described: positioning the patient on the device; adjusting the ramp subassembly
19 to support the patient in a desired inclined position; adjusting the head subassembly to
20 support the patient's head and neck in a generally desired sniffing position; and activating
21 the pneumatic or mechanical jack, or inflating the expandable bellows to raise the
22 patient's head relative to the second surface to a desired sniffing position.

23 XXIV. Also provided is a mandible arm for use in positioning a patient,
24 comprising: two rigid lockable arms, wherein the upper arm has a curved extension
25 which is rotatable in the z-axis and the lower arm does not provide an extension; a
26 curved portion, wherein the curved portion is substantially rigid; a mandible pad,
27 wherein the mandible pad is flexible and pivotable, and wherein the mandible pad has a
28 proximal side configured to attach to the curved portion and a distal side configured to
29 contact a patient's jaw at a at least two of a ramus, a body, and an angle of the patient's
30 jaw; and a connector portion, wherein the connector portion is configured to extend from
31 and attach to a rotatable portion of a support, and wherein the connector portion is
32 further configured to attach to a support that is attached to a base comprising a left side
33 and a right side, wherein the base is configured to substantially accommodate a patient's
34 head, neck, upper and middle back, and shoulders, and wherein the support is movable in

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

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

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

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

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

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

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

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

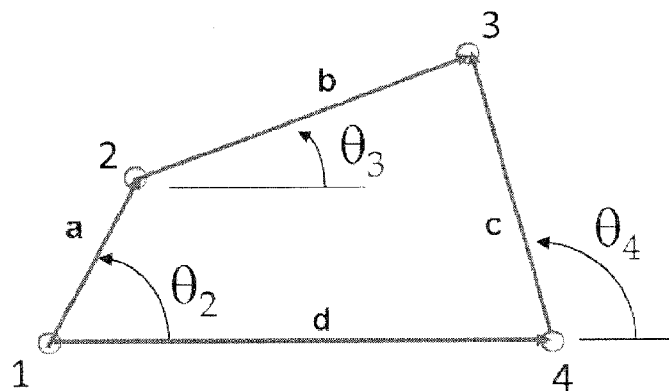
23 (i) Measurement of angle relative to gravity with an inclinometer; and
24 (ii) Encoders.

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

28 (e) wherein adjusting of angles is accomplished by:

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

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



- 1
2 (a) Point 2 of linkage a's position relative to point 1;
3 (b) Point 3 of linkage c's position relative to point 4;
4 (c) Alternate Linkage Axis Point 3 where the patient head meets the head
5 rest; and
6 (d) feedback sensors monitoring relative position of the points that
7 define the linkage length including position measurement sensors selected from
8 the group consisting of: hall effect sensors; magneto-resistive sensors; optical
9 sensors, including encoders, interferometers and/or positional sensing detectors;
10 and stress / strain / force / torque monitoring sensors located at the point
11 interfaces that minimize those parameters by adjusting linkage length d under
12 closed loop control.
- 13 XXVII. Also provided is a disposable anesthesia nasal and oral mask which can
14 be used either separately as a nasal mask or a oral mask or can be attached together and
15 can be used as a combination nasal-oral mask, which can also be used to sealingly
16 connect a mask to a wearer's face; two cushions comprising: a first nasal inflatable or
17 non-inflatable cushion that consists of a nasal bridge region, a cheek region, and an
18 upper lip region and a second mouth inflatable or non-inflatable cushion which consists
19 of a lower lip region, a cheek region, and an upper lip region; a first nasal membrane
20 comprising a substantially triangularly shaped frame of resilient material having a first
21 molded inwardly curved rim of said first nasal membrane; a second nasal membrane of
22 resilient material, said second nasal membrane being thinner, as thin, or thicker than said
23 first nasal membrane, said second nasal membrane having a second molded inwardly
24 curved rim, said second nasal membrane curved rim spaced a first distance from said
25 first nasal membrane curved rim in said cheek region and said second nasal membrane
26 curved rim spaced a second distance from said first nasal membrane curved rim in said

1 nasal bridge region, said second distance greater than said first distance, said distances
2 measured when the mask is not in use, a portion of said second membrane curved rim
3 forming a face contacting seal; a first mouth membrane comprising a substantially oval
4 shaped frame of resilient material having a first molded inwardly curved rim of said first
5 mouth membrane; a second mouth membrane of resilient material, said second mouth
6 membrane being thinner, as thin, or thicker than said first mouth membrane, said second
7 mouth membrane having a second molded inwardly curved rim, said second mouth
8 membrane curved rim spaced a first distance from said first mouth membrane curved rim
9 in said cheek region and said second mouth membrane curved rim spaced a second
10 distance from said first mouth membrane curved rim in said mouth region, said second
11 distance greater than said first distance, said distances measured when the mask is not in
12 use, a portion of said second membrane curved rim forming a face contacting seal; an
13 attachment with two apertures; where the first aperture is fixed to the oral mask and can
14 connect to the second aperture, which is fixed to the nasal mask; where when they are
15 connected together it comprises an anesthesia full face mask, covering and sealing
16 around the mouth and nose; yet either the mouth mask or the nasal mask can detach so
17 that the mask can be used for nasal non-invasive positive pressure ventilation
18 (CPAP/BiPAP) alone or oral non-invasive positive pressure ventilation (CPAP/BiPAP)
19 alone.

20 An above described nasal and oral mask preferably is characterized by one or
21 more of the following features:

- 22 (a) wherein said second molded rim and said first molded rim have a co-
23 located notch to accommodate the bridge of a wearer's nose;
- 24 (b) wherein said first nasal membrane molded rim and said second nasal
25 membrane molded rim are substantially saddle-shaped;
- 26 (c) wherein said second nasal membrane is shaped so that said seal portion, in
27 use, contacts at least a wearer's nose;
- 28 (d) wherein said seal portion, in use, contacts the facial tissue around the
29 sides and over the bridge of the nose, and between the base of the nose and the top lip;
- 30 (e) wherein said second rim and seal portion are shaped to generally match
31 facial contours in the region of facial tissue around the sides and over the bridge of the
32 nose, and between the base of the nose and the upper lip;
- 33 (f) wherein the first and second nasal membranes comprise one molded
34 piece, without being adhered together by an adhesive.

- 1 (g) wherein the first molded inwardly curved rim of said first nasal membrane
2 is as thick, less thick, or thicker than the second nasal membrane;
- 3 (h) wherein the second molded inwardly curved rim of the second nasal
4 membrane is as thick, less thick, or thicker than the first nasal membrane;
- 5 (i) wherein said second molded rim and said first molded rim have a co-
6 located notch to accommodate the lips a wearer's mouth;
- 7 (j) wherein said first mouth membrane molded rim and said second mouth
8 membrane molded rim are substantially oval shaped;
- 9 (k) wherein said second mouth membrane is shaped so that said seal portion,
10 in use, contacts at least a wearer's upper and lower lip;
- 11 (l) wherein said seal portion, in use, contacts the facial tissue around the
12 sides and over the upper and lower lips of the mouth;
- 13 (m) wherein said second rim and seal portion are shaped to generally match
14 facial contours in the region of facial tissue around the sides and over the upper and
15 lower lip of the mouth;
- 16 (n) wherein the first and second mouth membranes comprise one molded
17 piece, without being adhered together by an adhesive;
- 18 (o) wherein the first molded inwardly curved rim of said first mouth
19 membrane is as thick, less thick, or thicker than the second mouth membrane, and
- 20 (p) wherein the second molded inwardly curved rim of the second mouth
21 membrane is as thick, less thick, or thicker than the first mouth membrane.

22 XXIII. Also provided is a nasal mask, oral mask or full face mask, for connection
23 to a wearer's face comprising: a mask body for connection with a supply of breathable
24 gas, whether oxygen, air, anesthetic gases or any other gas; and a nasal inflatable or non-
25 inflatable cushion secured to said mask body, the body and cushion forming a nose-
26 receiving cavity, said cushion including: a nasal bridge region, a cheek region and an
27 upper lip region; a substantially triangularly-shaped first nasal membrane of resilient
28 material having a first molded inwardly curved rim to surround wearer's nose; a second
29 nasal membrane also of resilient material, said second membrane being relatively more
30 flexible than said first nasal membrane, said second nasal membrane having a second
31 molded inwardly curved rim, said second molded rim being of the same general shape as
32 said first molded rim and fixed to and extending away from said first nasal membrane so
33 as to have a second nasal membrane inner surface spaced a first distance from an outer
34 surface of said first molded rim in said cheek region and said second membrane inner

1 surface spaced a second distance from said first nasal membrane outer surface of said
2 first molded rim in said nasal bridge region, said second distance greater than said first
3 distance, said distances measured when the mask is not in use, a portion of said second
4 molded rim forming a face contacting seal; and wherein said seal portion is substantially
5 coterminous with respect to said second molded rim and is resiliently deformable
6 towards said first nasal membrane in use of said mask.

7 The above described nasal mask, oral mask, or full face mask, covering and
8 sealing the mouth and nose, preferably is characterized by one or more of the following
9 features:

10 (a) wherein said a nasal mask, oral mask, or full face mask body includes
11 either integrated head strap attachment points using either an anterior approach or
12 posterior approach or it can have separated head strap attachment points using either an
13 anterior approach or a posterior approach that placed over the nasal mask, oral mask, or
14 full face mask body, which attach to a surface that can secure the nasal mask, oral mask,
15 or full face mask to the wearer's face to ensure a tight seal and to maintain the wearer's
16 head and neck in the desired position to maintain airway patency;

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

20 (c) wherein said second membrane molded rim and said first nasal membrane
21 molded rim each have a co-located notch to accommodate the bridge of a nose;

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

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

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

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

32 XXIX. Also provided is a nasal noninvasive positive pressure ventilating
33 (CPAP/BiPAP), oral noninvasive positive pressure ventilating (CPAP/BiPAP), or full
34 face mask noninvasive positive pressure ventilating (CPAP/BiPAP) treatment apparatus

1 comprising: a generator for the supply of gas at a pressure below, equal to, or elevated
2 above atmospheric pressure; a gas delivery conduit coupled to said generator; and a nasal
3 mask oral mask, full face mask in turn coupled to said conduit to said nasal mask, oral
4 mask, full face mask including: a mask body for connection with a supply of breathable
5 gas; and a nasal inflatable or non-inflatable cushion secured to said mask body, the body
6 and cushion forming a nose-receiving cavity, the cushion including: a nasal bridge
7 region, a cheek region and a lip region; a substantially triangularly-shaped first nasal
8 membrane of resilient material having a first nasal membrane having a molded inwardly
9 curved rim; a second membrane having a second molded inwardly curved rim also of
10 resilient material, said second nasal membrane being relatively more flexible than said
11 first membrane, and being of the same general shape as said first molded inwardly
12 curved rim and fixed to and extending away from said first nasal membrane so as to have
13 an inner surface spaced a first distance from said first molded rim in said cheek region
14 and said second nasal membrane inner surface spaced a second distance from said first
15 molded rim, said second distance greater than said first distance, said distances measured
16 when the mask is not in use, a portion of said second molded rim forming a face
17 contacting seal; and Wherein said seal portion is generally coterminous with respect to
18 said second molded rim and is resiliently deformable towards said first membrane in use
19 of said mask.

20 The above described non-invasive positive pressure ventilation (BiPAP/CPAP)
21 treatment apparatus preferably is characterized by one or more of the following features:

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

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

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

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

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

33 (f) wherein said seal portion, in use, contacts the facial tissue around the
34 sides and over the bridge of the nose, and facial tissue around the sides and over the

1 bridge of the nose, between the base of the nose and the upper lip and between the base
2 of the nose and the upper lip, and

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

7 XXX. Also provided is an oral mask for connection to a wearer's face comprising:
8 a mask body for connection with a supply of breathable gas; and an inflatable or non-
9 inflatable mouth cushion secured to said mask body, the body and cushion forming a
10 mouth-receiving cavity, said cushion including: a mouth region, a cheek region and an
11 upper and lower lip region; a substantially oval-shaped first mouth membrane of resilient
12 material having a first molded inwardly curved rim to surround a wearer's nose; a second
13 mouth membrane also of resilient material, said second mouth membrane being
14 relatively more flexible than said first mouth membrane, said second mouth membrane
15 having a second molded inwardly curved rim, said second molded rim being of the same
16 general shape as said first molded rim and fixed to and extending away from said first
17 mouth membrane so as to have a second mouth membrane inner surface spaced a first
18 distance from an outer surface of said first molded rim in said cheek region and said
19 second mouth membrane inner surface spaced a second distance from said first mouth
20 membrane outer surface of said first molded rim in said mouth region, said second
21 distance greater than said first distance, said distances measured when the mask is not in
22 use, a portion of said second molded rim forming a face contacting seal; and wherein
23 said seal portion is substantially coterminous with respect to said second molded rim and
24 is resiliently deformable towards said first mouth membrane in use of said mask.

25 The above described mask preferably is characterized by one or more of the
26 following features:

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

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

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

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

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

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

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

8 The above described nasal mask, oral mask, or full facemask, further preferably
9 comprises tubing which has two ends to be used as an gas source to transport patients,
10 where a distal end of the tubing is connected to either a stand alone or a portable
11 generator for the supply of gas at a pressure below, equal to, or elevated above
12 atmospheric pressure; a gas delivery conduit coupled to said generator a portable gas
13 supply and a proximal end is connected to an adaptor, which contains an End-Tidal CO₂
14 port, a nebulizer port, a PEEP valve port, expiratory port and/or valve, pressure relief
15 valve, which has an aperture which attaches to either the nasal mask, the oral mask, or
16 the full face mask.

17 The above described nasal mask, oral mask or full face mask, also preferably may
18 be connected to a generator for the supply of gas, where the amount and concentration of
19 gas delivered is controlled by the supply source as well as the expiratory port, and/or
20 used as a scavenger system by connecting the nasal mask and the oral mask
21 simultaneously, where the nasal mask can be used to deliver positive pressure and the
22 oral mask can be connected to a suctioning device to properly store and/or dispose gases.

23 The above described nasal mask, oral mask or full face mask also preferably is
24 contoured around the patient's nasal bridge, nose, and upper lip such that it and the
25 generator gas supply it is connected to does not interfere with the operator's access to the
26 mouth/oral cavity, lips, cheeks, chin, jaw, and neck, and/or connected to a resuscitator
27 bag with or without a gas supply attached to the resuscitator bag.

28 XXXI. Also provided is an operating table having a positioning device as above
29 described, and one or more pads having a thickness approximating that of the positioning
30 device, on the operating table.

31 In the above described operating table preferably at least one of the pads is slatted
32 or pleated to facilitate bending. Also, the above described operating table preferably
33 further includes a base spacer having a plurality of rollers located under a main pad.

1 Further features and advantages of the present invention will be seen by the
2 following detailed description, taking in conjunction with the accompanying drawings,
3 wherein:

4 Fig. 1 is a side elevational view showing a lateral positioning device in
5 accordance with one embodiment of the present invention and illustrates a patient lying
6 on his or her side (lateral decubitus position) in order to displace weight off his or her
7 chest to assist in ventilation; and

8 Fig. 2 is the lateral device with x,y, and z views in the lateral decubitus position.

9 Figs. 3A and 3B diagrammatically illustrate the apparatus and method for
10 positioning a patient in accordance with the present invention for the supine position.

11 Figs. 3A-3C are front and rear perspective views and side elevational views of
12 yet another embodiment, the supine positioning device in accordance with the present
13 invention;

14 Figs. 4A and 4B are top perspective and side elevational views of the current
15 embodiment shown in a lowered position;

16 Figs. 5 and 6 is a side elevational view of the Fig. 4A-4B positioning device
17 retrofitted to existing operating tables in the raised and lowered positions respectively;

18 Figs. 7A and 7B are views similar to Fig. 6, of an alternative embodiment of the
19 invention showing the head and neck independent supports mounted on the lift support;

20 Fig. 8 shows a traditional patient mask strap in accordance with the prior art;

21 Figs. 9A and 9B show a mask strap in accordance with an embodiment of the
22 present invention;

23 Figs. 10-12 show another embodiment of mask strap in accordance with the
24 present invention;

25 Fig. 13 shows a head restraint in accordance with the present invention;

26 Figs. 14A-14C show a mask anchor ring in accordance with the present
27 invention;

28 Fig. 14D shows a ring part of the mask and how the posterior straps attach;

29 Fig. 14D shows a ring part of the mask and how posterior straps will attach;

30 Figs. 15A-15C illustrate use of a mask anchor ring in accordance with the present
31 invention, and Fig. 15D illustrates a mask in which the mask anchor ring or mask anchor
32 straps are built into the mask;

33 Figs. 15E and 44F are top and bottom plan views of yet another aspect of mask in
34 accordance with the present invention;

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-18D 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 Figs. 27 and 28A and 28B illustrate a mandible structural model, and Fig. 28C
15 shows a skull and mandible coordinate systems on a device in accordance with the
16 present invention;
17 Figs. 29A-29C diagrammatically illustrate a pressure sensing array in accordance
18 with the present invention;
19 Figs. 30A-30B and 31A-31C provide additional details of jaw thrust in
20 accordance with the present invention;
21 Figs. 32A-32D, 33A and 33B illustrate neck and head positioning adjustment
22 capabilities of the device of the present invention;
23 Fig. 34 schematically illustrates a four-bar linkage geometry of the lift
24 mechanism of the present invention;
25 Figs. 35A-35C and 36A-36F diagrammatically illustrate the lift mechanism in
26 accordance with the present invention;
27 Figs. 37 plots linkage lengths, ramp angle and head support angle in accordance
28 with the present invention;
29 Fig. 38 shows a patient in a sniffing position with the jaw thrust device in
30 accordance with the present invention;
31 Fig. 39 is a flow diagram of the use of the device, in order to maintain coincident
32 neck and neck support locations at linkage axis 4 in accordance with the present
33 invention;

1 Figs. 40A-40D, 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 the
17 back side of the sniff subassembly constraining the patient's head in rotation about the Z
18 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 (1) Achieving a desired position also known as the sniffing position or chin-
2 lift (35° of neck flexion and 15° of head extension) without the use of jaw support
3 members that may cause stimulation, and that is comfortable for the patient while in the
4 lateral decubitus position;
- 5 (2) Alignment of 3 axes (oropharyngeal, laryngeal, tracheal) to provide the
6 most optimal view for intubation in the lateral decubitus;
- 7 (3) Restrain of the patient's head from moving and disengaging the patient
8 from a desired position;
- 9 (4) Provides an easy, user friendly mechanism for the jaw thrust maneuver to
10 be performed in a hands free fashion while the patient lies on either of his/her side;
- 11 (5) A durable device with inexpensive disposable parts that may come in
12 contact with the patient;
- 13 (6) A device that is easily disinfected;
- 14 (7) A device that is MRI or Xray compatible; and
- 15 (8) Provides the most amount of exposure to the surgical field.

16 Still yet other embodiments of the invention for the supine position are shown in
17 Figs. 3-7. Referring next to Figs. 3A-3C, a patient positioning device is provided which
18 includes:

- 19 1. An adjustable ramp 50 that fits the torso of the patient. Ramp 50 includes a
20 base 52 which attaches to the operating room table 54. A pivot axis 56 allows the ramp
21 to rotate relative to the operating table 54 at the base.
- 22 2. A lift top 58 that accommodates the neck and head of the patient, and includes
23 a pivot axis 60 that allows the lift top to rotate relative to the ramp
- 24 3. Linear actuators that extend or retract along the indicated axes. The linear
25 actuators include a first linear actuator 62 that connects between base 51 attached to
26 operating table 54 and the back of the ramp 50. Ramp 50 is hingedly attached to the base
27 51. One or more actuators can be used to provide the required force. Actuation results in
28 a change in actuator length L_{A1} . A second linear actuator 64 connects between back of
29 the ramp 50 and the back of the lift top 58, via a hinge 55 between the ramp 50 top and
30 the lift top 58. One or more actuators can be used to provide the required force.
31 Actuation results in a change in actuator length L_{A2} . A third linear actuator 66 attached
32 to ramp 50 is used to extend and retract ramp length to meet a required patient torso
33 length. One or more actuators can be used to provide the required force. Actuation
34 results in a change in actuator length.

1 Figs. 4A-4B show the device of Figs. 3A-3C in a lowered position.

2 In yet another embodiment, the positioning device may be incorporated into an
3 operating table, or retrofit to an existing operating table. In this later embodiment:

4 1. The device can retrofit to an existing operating table 68 or be incorporated into
5 the design of a new table as shown in Figure 5.

6 2. The ramp is raised and lowered relative to the operating table through the
7 respective extension or contraction of linear actuator 62. The ramp pivots about the X_R
8 axis resulting in a change in θ_R as shown in Figures 5 and 6.

9 3. The lift top (LT) is rotated relative to the ramp about the X_{LT} axis as shown in
10 shown in Figure 5 and Figure 6 when the linear actuator 64 is extended or retracted.

11 4. The extension of the linear actuator 64 can be operated independent of lift
12 actuator 62 to result in an inclined position of the lift top about the X_{LT} axis. The
13 extension or retraction of linear actuator 64 can also be coordinated with the extension or
14 retraction of linear actuator 62 to maintain the angle of the lift top relative to the
15 operating table constant as the angle θ_R is varied due to the change in length of linear
16 actuator 62 as illustrated in Figure 6 and Figure 7 where the lift top remains parallel to
17 the top of the operating table.

18 5. The ramp length, L_R , can be controlled by the extension or retraction of linear
19 actuator 62.

20 6. If desired, a jaw claw as will be described in detail hereinafter can be integrated
21 into the lift top of the system.

22 Yet another embodiment, illustrated in Figs. 7A-7B the apparatus includes a lift
23 top 70 which interfaces with a patient's head and neck. Lift top 70 comprises two
24 elements 72, 74 that adjust in the Z direction to interface optimally with the neck and
25 head as shown in Figures 7A-7B. The neck and head adjustments are independently
26 adjustable in the Z direction from the nominal location and comprise pneumatically
27 driven pillows or mechanically driven pads. Another option is to have only the neck or
28 head portions adjust and the corresponding head or neck regions be stationary pads. The
29 nominal and extended ranges for each are illustrated.

30 The present invention also addresses problems encountered with the use of a face
31 mask, including maintaining the face mask on the face of the patient during a procedure,
32 and especially during a long term respiratory event. Also, patient movement can cause a
33 face mask to fall off, as can incidental contact.

1 Referring to Fig. 8, a conventional patient mask strap 102 is illustrated. The
2 mask strap 102 comprises one or two straps 104, 106 which are designed to be tied to the
3 back of the patient's head. Referring to Figs. 9A-9B, the present invention provides a
4 mask 107 in which straps 108, 110 (Fig. 9A) or conjoined straps 111 (Fig. 9B) are
5 placed over the mask and anchored to a base plate 112 under the patient's head. In a case
6 where the ventilation hose has already been attached to the mask, the mask 107 may be
7 split at one side 113 to accommodate the ventilation hose 115, and still allow the
8 attachment of the mask to the base as illustrated in Figures 10 and 11.

9 In a situation where the oxygen hose has yet to be attached to the mask, an
10 unseparated mask strap can be attached to the mask, then to the hose, then to the patient
11 as illustrated in Figure 12.

12 In addition to strapping a patient and mask to the base, other parts of the patients
13 head can be attached to the base if the head needs to be constrained as illustrated in
14 Figure 13.

15 Figures 14A-14D illustrate yet another embodiment of our invention, in which
16 the ventilation mask 120 is attached with a strap 122 from the front to a base such as a
17 patient support, where the strap consists of elastomeric straps that may vary in diameter
18 of from, e.g., 0.125" to 0.25". A mask anchor ring 124 kinematically interfaces with the
19 mask at a plurality of interface points, preferably three, on the mask anchor ring,
20 resulting in more evenly applied force to the mask, as shown in Figures 15A-15C or the
21 mask can have the mask anchor straps (one or more on each side of the mask) built into
22 the mask, where the mask anchor ring would not be needed (see Figure 15D). Preferably
23 one or more elastomeric straps 125, 127 are affixed to a mask anchor ring 124 or built
24 into the mask (Figure 15D, straps 125A, 127A), spaced at any number of degrees apart
25 an imaginary circle, for example if four straps were used then they would be spaced 90°
26 apart, where each strap would secure each of the four sides of the mask (the right side,
27 left side, forehead side, chin side). The mask is attached over the nose only or the nose
28 and mouth of the patient by a force, F_{Strap} applied by the elongated straps that connect to
29 a head support.

30 A single mask anchor strap 125, 127 on each side configuration is shown in
31 Figures 15A-15C. Each mask anchor strap attaches posteriorly behind the head to a
32 respective mask anchor clip 129, 131 attached to the head support with a friction
33 connection. Alternatively, the straps may include a plurality of holes for attachment to

1 prongs on the head support. This connection results in an essentially airtight seal
2 between the ventilation mask and the patient's face.

3 An advantage of the mask strap of the current invention over conventional masks
4 is that it allows a doctor to approach a patient from in front of the patient's face, place
5 either the nasal mask, full face mask, or combined nasal-oral mask and then attach either
6 of the masks to the surface so that the patient's head is resting on a surface and it prevents
7 the patient's head from moving out of the desired position. Thus, if the patient's head is
8 already on the surface, the provider will not have to lift the patient's head in order to strap
9 the mask to the patient's face. Also, this approach places the patient in the desired
10 position and fixes their head and neck in this position to maintain a patent airway. The
11 mask strap of the current invention is smaller than a conventional mask and only
12 comprises two surfaces of which an aperture is in the center that is placed on the face
13 mask and two arm extensions with a plurality of holes that connect to a surface. It does
14 not contain a wide rectangular head rest that wraps around the patient's head as in the
15 case of conventional masks. It also does not require prongs on the face mask, and thus
16 eliminates the risk of injury to the provider and patient.

17 Another advantage of the present invention is that it both maintains the sniffing
18 position by fixing the patient's head to the table and is placed in front of the patient's face.
19 Therefore if the patient lies down the strap can be applied without having to lift the
20 patient's head off of the table.

21 In another aspect of the invention there is provided either a disposable or re-
22 usable nasal mask with an off-centered aperture for ventilation and / or one for Oxygen
23 or a combined but detachable and either disposable or re-usable nasal mask and oral
24 mask, which can be used either uniformly as a full facemask to ventilate a patient either
25 prior to endotracheal intubation or during general anesthesia (GA), or the mouth mask
26 can be separated from the nasal mask and the nasal mask can be used to apply nasal non-
27 invasive positive pressure ventilation (BiPAP—Bilevel Positive Airway Pressure/CPAP -
28 continuous positive airway pressure) to help maintain a patent airway and ventilate a
29 patient while the anesthesiologist is attempting intubation, which will significantly
30 prolong the time until the patient begins to desaturate. More specifically, the present
31 invention also provides a facemask, which is capable of functioning as an improved
32 anesthesia mask compared to the prior art masks because it uniquely combines the
33 following advantages:

34 (1) the ability to deliver and evacuate gas(es) while being sealed on the patient's

1 face,

2 (2) the provision of either a full face mask having a separate nasal mask or a
3 nasal mask alone to apply nasal non-invasive positive pressure ventilation
4 (BiPAP/CPAP) and/or oxygenation during apneic periods (time when patient is not
5 breathing on their own), sedation cases, general anesthesia (GA), and for respiratory
6 therapy, and it has a separate mouth mask, which when attached to the nasal mask is
7 essentially a traditional full facemask used for oxygenation and ventilation during bag-
8 mask ventilation, GA, and respiratory treatments, or the mouth mask can be detached in
9 order to provide the anesthesiologists with access to the airway for intubation and
10 fiberoptic intubation,

11 (3) secure the nasal mask and nasal-oral mask not only to the patient's face but
12 also secure the patient's head and neck in position to maintain airway patency, and
13 stabilize the mask on the patient's face without affecting its sealing capability, and

14 (4) detach the oral mask or use the stand alone nasal mask and attach the nasal
15 mask and use the head rest and/or neck rest cover with the mask strap to clip onto the
16 nasal masks from the front and secure the nasal masks to the patient's face and attach the
17 nasal mask to a portable oxygen supply source and use the nasal mask to supply oxygen
18 during patient transport.

19 (5) another advantage is that the off-center port or ports will minimize the
20 obstruction of the anesthesiologist's glottic view during the intubation process. On-center
21 ports will partially or completely obstruct the glottic view.

22 Referring to Figs. 40A-40B, the top left picture shows a side view of the nasal
23 mask and the bottom left picture shows a front view, which consists of three surfaces;
24 where the first surface is the bottom surface, is open, with a soft, flexible, pneumatic,
25 border that contours to nose bridge, side of the nose, cheeks, and upper lip in order to
26 create seal when in contact with the patient's face. The bottom surface also has a plurality
27 of holes on each side, which allow straps to be either attached to or detachable and used
28 to secure the mask to the patient's face and the patient's head and/or neck in the desired
29 position. Built into these plurality of holes are clips which allow a mask strap to attach to
30 when the mask strap comes from behind the patient's head and attaches to these clips in
31 front. The second surface is the top surface of the nasal mask and contains one or more
32 openings, the first of, which can be either off-centered left or right and connects to either
33 an anesthesia circuit, BiPAP/CPAP machine, or resuscitation bag, in order to prevent
34 obstruction of the glottic view or it can be centered and connects to the breathing circuit

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

1 patients becomes obstructed and prevents them from breathing. The oral mask of the
2 current invention can be separated from the nasal mask and the nasal mask or just the
3 stand alone nasal mask can be used to apply BiPAP and/or continuous positive airway
4 pressure (CPAP) to help relieve the upper airway obstruction, maintain a patent airway,
5 and assist in ventilation during the case. Another advantage of the current invention as
6 opposed to existing nasal masks is in situations where a nasal mask is not sufficient to
7 ventilate the patient. The proposed invention has the ability to reattach the oral mask and
8 now the mask can be used for traditional bag-mask ventilation. Another advantage of the
9 invention is the ability to apply nasal BiPAP/CPAP during semi-awake fiberoptic
10 intubations, where being able to maintain a patient's oxygen saturation levels are also
11 critical. Another advantage of the current nasal mask and/or nasal-oral mask is the ability
12 to connect it to a portable oxygen supply of needed and used to transport the patient with
13 oxygen. It can also attach to both a supplement oxygen supply source as well as a
14 resuscitator bag simultaneously in order to provide simultaneous oxygenation and
15 ventilation. The final advantage that the present invention has over the prior anesthesia
16 mask art is the ability to secure not only the combined nasal mask and oral mask to the
17 patient's face allowing for hands-free ventilation, but it also secures the patient's head and
18 neck in place by attaching to a surface and maintaining the patient in a position that
19 ensures a patent airway, which is critical for oxygenation and ventilation.

20 In yet another aspect, the present invention provides improvement over the
21 system described in our aforesaid parent applications, by providing a simple and elegant
22 head/neck rest that comprises a compliant adjustable head and neck rest (ie: bellows,
23 mechanical) that is independently controllable to support a patient's head/neck to obtain
24 an optimal sniff position by raising a patient's neck and head independently of the
25 carriage.

26 Referring to Figs. 16-18, another feature and advantage of the present invention
27 is to provide a head/neck support 302 that may be independently controlled to support
28 the optimum sniff position by raising a patient's head and neck independently of the
29 ramp, whereby to improve the glottic view in real time. More particularly, in accordance
30 with the present invention, there is provided an adjustable head/neck support mechanism
31 that permits adjustment in the z-axis. In one embodiment the adjustable head/neck
32 support mechanism consists of a pneumatic jack such as a compliant bellows 304 that is
33 fixed or located on top surface of lift top 70. Alternatively, as will be described below
34 the adjustable head/neck support may comprise a mechanical jack.

1 Referring again to Figs. 16-18, pneumatic head/neck support 302 in accordance
2 with the present invention comprises an inflatable bladder or bellows 304 comprising a
3 plurality of rigid concentric rings 320, 322, 324, 326 joined by flexible membranes 330,
4 332, 334 on a rigid base 336. The bellows includes a two-way valve 338 through which
5 air may be added or subtracted in order to inflate the bellows and increase internal
6 pressure and bellows height. The relative (height) position of a patient's head or neck,
7 and achievement of an optimal sniff position, may be controlled by regulating the
8 pressure within the bellows. Thus, when air is flowed into the bellows, the head/neck
9 bellows 304 raises, and when air flows out of the bellows, the head/neck bellows 304
10 lowers. A feature and advantage of the present invention is that the inflatable bellows
11 provide a relatively low-cost highly-adjustable device that readily may be sterilized.
12 However, the device also is sufficiently low cost that it could be used once, and then
13 discarded. Moreover, lateral movement of the head/neck rest is significantly more
14 constrained than if the head/neck rest were made of a purely compliant bellows for
15 raising and or lowering the head/neck.

16 Referring to Fig. 19, the present invention also provides methods for positioning
17 a patient. The methods include the steps of: providing a device according to the
18 invention as described herein, placing the patient's head substantially on the top of the
19 adjustable mechanism (bellows), elevating the ramp and then adjusting the mechanism
20 so that the patient is in a sniff position.

21 Referring in particular to Figures 20A and 20B of the drawings, in another aspect,
22 the present invention provides a device comprising:

23 a base 400 comprising a first side which supports the patients head and neck, a
24 second side acting as the foundation, inner vertically adjustable support structures 406
25 between the first and second sides, and a detachable third inclined side or ramp 408
26 which supports the upper back, middle back, and shoulders of a patient and is rotatable
27 and adjustable in the x axis;

28 a first support 410 positioned on the second side of the base and lockably
29 adjustable with respect to the second side of the base in an x and y axes;

30 a second support 412 positioned on the second side of the base and lockably
31 adjustable with respect to the second side of the base in the x and y axes;

32 a first mandible arm 414 extending from a first vertically adjusted portion of the
33 first support 410, wherein the first vertically adjusted portion is lockable in a z axis to

1 lockably adjust the first mandible arm with respect to the z axis, and wherein the first
2 mandible arm 414 is positionable to be in contact with the patient's jaw; and
3 a second mandible arm 416 extending from a second vertically adjusted portion
4 of the second support 412, wherein the second vertically adjusted portion is lockable in
5 the z axis to adjust the second mandible arm 416 with respect to the z axis, and wherein
6 the second mandible arm 416 is positionable to be in contact with the patient's jaw;
7 wherein the first mandible arm 414 and the second mandible arm 416 are
8 movable such that each is positionable to be in contact with the patient's jaw and to
9 maintain the patient in a desired position. In such case, preferably the sniffing position,
10 aligning all 3 axes (oropharyngeal, laryngeal, tracheal), and/or in the jaw thrust
11 maneuver, and leaving the provider hands free.

12 In a preferred embodiment, the base 400 is rectangular.

13 In one embodiment, the mandible arms 414, 416 are positionable to be in contact
14 with the patient's jaw at three points. The most distal end of the mandible arms can pivot
15 in three degrees in order to conform to the angle of the mandible.

16 The first mandible arm 414 and second mandible arm 416 each include a
17 mandible pad 420, 422 which preferably are formed of a resiliently deformable material
18 such as foam. In yet another embodiment, the first mandible arm 414 and second
19 mandible arm 416 are removeably connected to the first support 410 and second support
20 412, respectively; and the most distal end of the first and second mandible arms 414, 416
21 are removeably connected to the distal end of the first and second supports 410, 412.

22 In yet another embodiment, the first mandible arm 414 is moveable relative to the
23 first support 410, and the second mandible arm 416 is moveable to the second support
24 412.

25 In further embodiments, the mandible arms 414, 416 are positionable such that
26 the mandible pads 420, 422 are in contact with the patient's jaw at one or more points.

27 In some embodiments, the mandible arms 414, 416 are positionable such that the
28 mandible pads 420, 422 are in contact with the patient's jaw at three points, and in yet
29 other embodiments the first support 410 is moveable relative to the base 400 and the
30 second support 412 is moveable relative to the base 400.

31 In various embodiments the first support 410 is moveable relative to the base 400
32 on the X and Y axis, and the second support 412 is movable relative to the base 400 on
33 the X and Y axis.

1 Referring in particular to Figs. 21A and 21B, in one embodiment of the present
2 invention, the mandible arms each include a curved portion 430 that consists of an
3 adjustable and lockable mechanism 432 that attach to a respective mandible pad 420,
4 422, wherein the mandible pads 420, 422 are flexible, and wherein the mandible pads
5 have a distal side configured to attach to the curved portion and a proximal side
6 configured to contact a patient's jaw at a plurality of points, which can pivot in all angles
7 at the distal end; and a connector portion which is configured to attach to a support.

8 Referring to Figs. 22-24, in yet other embodiment, a connector portion 450, is
9 configured to attach to a support 452 that is attached to a base 454 comprising a left side
10 and a right side, wherein the base 454 is configured to substantially accommodate a
11 patient's neck and head, and wherein the support 452 is moveable in three axis such that
12 the mandible pads 420, 422 are positionable to be in contact with the patient's jaw at one
13 or more points and to maintain a desired position.

14 A further embodiment to the present invention includes a detachable inclined
15 surface 500 that may attach to the base 454, and the angle at which the inclined surface
16 500 is positioned can be changed, while also having the ability of extending further
17 distance in order to maintain the same angle which assists in supporting larger patients.
18 The inclined surface will have a back and shoulder bar 502 that rests on it which will
19 support a patient's upper back, middle back, and shoulders. This support will enable
20 gravity to displace weight off of patient's chest, allowing for a more patent airway.

21 In yet another embodiment of the present invention, there optionally is included a
22 measuring device 530 such as a level to confirm the optimal neck flexion angle of 35° .
23 One embodiment consists of two sides, the first side 532 of which is semi cylindrical and
24 consists of four arms 554, 556, 558, 560, each of which is located within each of the four
25 corners, each of which makes contact with the patient's neck; the second side 562 which
26 consists of a 35° leveled angle.

27 In yet another embodiment the present invention optionally includes a leveling
28 device 564 used to confirm the optimal head extension angle of 15° . This latter
29 embodiment consists of two sides, the first side 566 or triangular side which consists of
30 three arms 568, 570, 572, each of which is located within each of the three corners, each
31 of which is adjustable in the z-axis, each of which makes contact with the patient's face;
32 and the second side 574 which consists of a 15° leveled angle.

33 Referring now to Fig. 25, in yet another embodiment, the present invention
34 includes a method for positioning a patient including the steps of: placing the patient's

1 upper back, middle back, and shoulders on an inclined surface along with the patient's
2 neck and head substantially on the base of the device; placing the patient's head and neck
3 in the desired position, confirming the position with a measuring device; restraining the
4 patient's head to prevent the patient from being dislodged from the desired position;
5 moving a first mandible arm to contact the patient's jaw; moving the second mandible
6 arm to contact the patient's jaw; wherein the contact of the first mandible arm and the
7 second mandible arm provides sufficient force to substantially maintain the patient's
8 head, neck, and/or jaw in a desired position.

9 The invention will be further illustrated with reference to Figures 22-26 which
10 illustrate the Steps for implementing the Sniff position and Jaw thrusts using the above
11 described device as follows:

12 Step 1: Adjust Head Height in z with Jack Subassembly to Achieve 35° Angle by
13 rotating handle 600 and engaging the acme screw.

14 Step 2: Adjust Ramp Length.

15 Step 3: With correct radius Head Rest in place, constrain forehead to Jack
16 Subassembly with flexible band to achieve 15° angle.

17 Step 4: Attach the Jaw-Claw-Based Subassembly to the top portion of the Jack
18 Subassembly as illustrated in Figure 4 with the Claws separated (by rotating opposite one
19 another along the Z axis) and tilted below the plane of the head (Rotated about the Y
20 axis). Nominally position the left and right padded elements of the Claw below their
21 respective mandible locations (by rotating them towards each other about the Z axis) and
22 slide the Claw assembly along the X axis and lock the Claw assembly in position to the
23 top of the Jack subassembly. Adjust the Left and Right Jaw Thrust Subassemblies by
24 sliding them along the y axis along the Jaw Thrust Slide towards the patient's head and
25 squeezing the Jaw Thrust Grip causing it to rotate about the x axis, resulting in a
26 translation in the positive z direction until the Jaw Thrust Shelf is lightly engaged below
27 the mandible, and locked into position.

28 Step 5: With the claw subassembly locked in place on the Jack Subassembly,
29 Rotate, about the Z axis, the left and right arms of the Claw subassembly until the
30 padded portions are engaged with their respective left and right mandible of the jaw.
31 After the pads are securely engaged with the mandible, rotate both left and right arms of
32 the claw about the -Y direction of the Y axis until the Jaw is extended by the desired
33 amount in the Z direction. Extend Mandible by required amount by squeezing the Left

1 and Right Jaw Claw Grips simultaneously resulting in a rotation of the Jaw Claw and
2 engagement with an extension of the mandible.

3 Lock the Left and Right Jaw Thrust Assemblies to the Jaw Thrust Slide by
4 rotating the Jaw Thrust Lock about the x axis. This fixes the Jaw Thrust Assembly
5 position in the x-y Plane. Proceed to engage the Left and Right Jaw thrust shelf to
6 extend the mandible by the required amount of squeezing the Jaw Thrust Grip, causing it
7 to rotate about the x axis, resulting in a translation in the positive z direction until the
8 Jaw is properly extended and the Airway is open.

9 The foregoing steps:

10 (1) achieve a desired position also known as the sniffing position or chin-lift
11 (35° of neck flexion and 15° of head extension) without the use of jaw support members
12 that may cause stimulation and that is comfortable for the patient;

13 (2) Restrains the patient's head from moving and disengaging the patient from
14 the desired position;

15 (3) Achieves a position in obese patients where the ear and the sternum are
16 aligned in horizontally to achieve maximal air exchange;

17 (4) Provides an easy, user friendly mechanism for the jaw thrust maneuver to
18 be performed in a hands free fashion;

19 (5) Displaces weight off of a patient's chest with the help of gravity by using
20 an inclined surface;

21 (6) Provides a mechanism of elevating and lowering obese patients without
22 the use of health care workers to limit work related injuries;

23 (7) Provides a measuring device to confirm the optimal angles of the desired
24 position;

25 (8) Aligns 3 axes (oropharyngeal, laryngeal, tracheal) to provide the most
26 optimal view for intubation; and

27 The present invention is believed to be first of its kind to maximize ventilation in
28 a hands free fashion by being able to perform a jaw thrust maneuver, along with the
29 ability to displace weight off of a patient's chest by utilizing an elevating device. The
30 invention also is believed to be the first to utilize a measuring device (i.e.: a level) on the
31 body in order to reassure the provider that the patients head and neck are properly
32 aligned in the sniffing position. This invention also gives the provider the ability to first
33 try a much lesser invasive way of maintaining a patent airway by placing the patient in
34 the proper sniffing position without eliciting any painful stimuli. The provider can then

1 restrain the patient's head to prevent the patient from being displaced from the desired
 2 position. If the patient's airway is not yet patent, the provider can use 2 clamps with
 3 ratchet capability, each applied to each side of the mandible to displace the jaw forward.
 4 If the patient still cannot maintain a patent airway, this invention, by placing the patient
 5 in the desired position, aligns all 3 axes in order to achieve the best possible view to
 6 intubate the patient. See Figs. 27-31.

7 Yet another embodiment of the invention is shown in Figs. 32A-32D, and 33A
 8 and 33B which show the positioning device of the present invention with a patient
 9 initially horizontal on the OR table, and raised to an inclined position. When the device
 10 is raised and lowered, it pivots about the X axis, Point 1, by an amount θ_{X1} . As the device
 11 is raised or lowered, the head support, containing the independently adjustable head and
 12 neck actuators that position the head and neck for optimal intubation view, is maintained
 13 nominally parallel to the Y axis by rotating about point 4 along the X axis an amount θ_{Z4} ,
 14 where $\theta_{X4} = -\theta_{X1}$. The patient is intubated while in the inclined position and then
 15 repositioned to the reclined position for the operation. The device and patient create a 4-
 16 bar linkage (Fig. 34) as defined in Table 1 below.

17 *Table 1*

Linkage	Linkage Description	Comment
a	Connects Ramp Pivot Point 1, to Patients Hip Pivot (Trochanterion), Point 2	Fixed Length, a
b	Connects Hip Pivot, Point 2, to Top of Neck actuator (Head / Neck Pivot location) , Point 3	Fixed Length, b
c	Connects Head / Neck Pivot location, Point 3, to Head Support Pivot, Point 4	Fixed Length, c
d	Connects Head Support Pivot, Point 4, to Ramp Pivot, Point 1	Adjustable Length, d

18
 19 Generalized geometry for the lifting linkage is illustrated in Figs. 35A-37, and the
 20 associated known variables as well as equations for θ_2 as a function of ramp angle θ_{X1} , θ_4
 21 as a function of head support angle θ_{X4} , and unknown variables θ_3 and d are defined as
 22 follows:

- 23 • a, b, c, θ_2 , and θ_4 are known

1 1. $\theta_2 = \theta'_2 - \theta_{x1}$ where θ'_2 is for the reclined position and θ_{x1} is the ramp pivot angle
 2 about point 1

3 2. $\theta_4 = \theta'_4 + \theta_{x4}$ where θ'_4 is for the reclined position and θ_{x4} is the head support
 4 pivot angle about point 2

5 3. $\theta_3 = \text{asin} [(c \sin \theta_4 - a \sin \theta_2)] / b$

6 4. $d = a \cos \theta_2 + b \cos \theta_3 - c \cos \theta_4$

7 The problem is that as the ramp is raised and, or the head support is rotated about its
 8 pivot axes, one or more of the linkage lengths must change or the patient will be forced
 9 to slide along the device surface and operating table. The sliding effectively changes
 10 linkage lengths a and c, given lengths b and d are fixed. What is desired is to maintain
 11 the lengths and positions of linkage a, θ_a and c, θ_c fixed relative to their support surfaces
 12 as the ramp angle, θ_{x1} , and head support angle, θ_{x4} , are adjusted. The present invention
 13 accomplishes this requirement by changing the length of the ramp, linkage d, as a
 14 function of the initial patient geometry, ramp angle θ_{x1} and head rest angle θ_{x4} .

15 Referring again to Figs. 36A-36F and 37, as ramp incline is varied, θ_{x1} , the head
 16 rest orientation remains parallel, in most cases horizontal to the operating table, by
 17 changing head rest angle, θ_{x4} by the opposite amount. This can be accomplished in the
 18 following manner:

19 a. Open loop based on known or estimated geometries of all parameters; or
 20 b. Closed loop where the current angle
 21 θ_{x4} is measured relative to an initial angle, θ'_{x4} and driven back to that initial angle.
 22 This could be accomplished with multiple feedback sensors including but not limited to:

23 i. Measurement of angle relative to gravity with an inclinometer
 24 ii. Encoder

25 Referring in particular to Fig. 37, as ramp incline is varied, θ_{z1} , and / or head rest
 26 angle, θ_{z4} are changed to position the patient, ramp (linkage d) length is varied in order
 27 to satisfy the conditions that positions of linkage a, θ_a and c, θ_c fixed relative to their
 28 support surfaces. This prevents the patient from sliding along the operating table surface
 29 as the ramp and head rest angles are adjusted. This can be accomplished in the following
 30 manner:

31 a. Open loop based on known or estimated geometries of all parameters
 32 i. Equations 1-4 provide the analytical solution to calculated and control
 33 length d; or

- 1 b. Closed loop where the relative positions of one or more of the following linkage
 2 termination points are measured and the length d is adjusted under closed loop control
 3 driven by sensor feedback to return the measured parameter to their original position.
- 4 i. Point 2 of linkage a's position relative to point 1
 5 ii. Point 3 of linkage c's position relative to point 4
 6 iii. Alternate Point 3 where the patient head meets the head rest
- 7 a. The feedback sensors monitoring relative position of the points that define the
 8 linkage length could include:
- 9 i. Position measurement sensors including but not limited to:
- 10 1. Hall effect sensors
 11 2. Magneto-resistive sensors
 12 3. Optical sensors
 13 a. Encoder
 14 b. Interferometric
 15 c. Position sensing detectors
- 16 ii. Stress / strain / force / torque monitoring sensors located at the point
 17 interfaces that minimize those parameters by adjusting linkage length d under closed
 18 loop control.
- 19 Referring again to Figs. 36A-36F, in a preferred exemplary embodiment, the
 20 device includes linear actuator linkage d that adjusts the length of the ramp to
 21 accommodate the patient, Linkage g that raises the ramp about the Z axis, pivot axis 1,
 22 and linkage j that maintains the head support parallel to the X axis by counter rotating
 23 about the Z axis along Pivot Axis 4. The device and patient create a 4-bar linkage as
 24 defined in Table 1. The associated initial reclined position and relational equations for
 25 the angles and actuators d and j as a function of actuators, linkage g length, that drive
 26 ramp angle θ_{Z1} are also defined in Table 2 below.

27 Table 2. Patient 4-Bar Linkage & Actuator Linkages
 28

Initial Conditions when Reclined									
X-Axis Linkage Pivot Point Definitions									
Reclined (Initial) Location	Associated Actuator	Minimum Adjustment	Patient Adjustment	Distance from Neck CM to Hip Pivot (cm)	Function	Defining Equations			
Axis Point Y (cm)	Z (cm)	d		59.9	Ramp Pivot Axis	$\theta_{p_2} = \theta_{p_1} - \theta_{p_0}$			
1	0.00	0.00			Hip Pivot	$\theta_{p_2} = \theta_{p_1} - \theta_{p_0}$			
2	-11.95	6.90			Neck Pivot & Y Neck Adjustment				
3	45.44	6.90	0		Head Support Pivot Axis	$\theta_{p_2} = \theta_{p_1}$			
4	42.50	0.00	33.4		Head Y Adjustment				
5	9.50	-3.52							
6	26.14	0.00							
7	40.00	-3.40							
8	65.68	-1.28							
9									
Linkage Definitions									
Linkage	First Axis	Second Axis	Length cm	Linkage / Opposite Angle	Linkage / Opposite Angle Value	Linkage / Opposite Angle Value	Actuator?	Function	
3	1	2	13.80	θ_3	2.6183	130.00			$\theta_3 = \theta_2 - \theta_{p_1}$
b	2	3	59.95	θ_b	0.0000	C.00			$\theta_b = \sin[(\sin \theta_2 - \sin \theta_3)] / b$
c	3	4	7.35	θ_c	1.2186	69.73			$\theta_c = \theta_3 + \theta_{p_1}$
d	1	4	45.50	θ_d	0.0000	230.00	Determined Ramp Linear Actuator		$d = 2 \cos \theta_1 + b \cos \theta_3 - c \cos \theta_4$
e	1	6	10.21	θ_e	0.2594	12.00			$\theta_e = \cos[(\theta_1^2 + \theta_6^2 - e^2) / 2\theta_6]$
f	1	7	26.14	θ_f	2.5800	147.82			$\theta_f = \cos[(\theta_1^2 + \theta_7^2 - f^2) / 2\theta_7]$
g	6	7	16.93	θ_g	0.3521	20.17	Determined Ramp Linear Actuator		$\theta_g = \cos[(\theta_6^2 + \theta_7^2 - g^2) / 2\theta_7]$
h	4	8	3.57	θ_h	0.1512	8.66			$\theta_h = \cos[(\theta_4^2 + \theta_8^2 - h^2) / 2\theta_8]$
i	4	9	22.82	θ_i	1.8485	105.91			$\theta_i = \cos[(\theta_4^2 + \theta_9^2 - i^2) / 2\theta_9]$
j	8	9	21.58	θ_j	1.1415	65.43	Determined Head Support Linear Actuator		$\theta_j = \cos[(\theta_8^2 + \theta_9^2 - j^2) / 2\theta_9]$

- 1
2 An illustration in Figure 32A–32D for a mid-sized male patient with Neck Pivot
3 distance to Hip Pivot distance of 59.9 cm and hip pivot, axis 2, to ramp pivot, axis 2, is
4 provided. The associated Table 3 provides angles and linkage lengths as a function of
5 driving linkage g from a length of 16.75 cm to 22 cm. A plot of Linkage lengths d and j

1 as well as ramp angle θ_{x1} and head support angle θ_{x4} as a function of linkage length g is
 2 provided in Figures 36A-36F.

3 *Table 3, Linkage length commands for d and j as a function of linkage g*

Linkage g (cm)	θ_{x1} (Degrees)	θ_{x1} (Rad)	θ_{x4} (Degrees)	θ_{x4} (Rad)	Linkage d (cm)	θ_d (Rad)	θ_d (Rad)	θ_d (Rad)	θ_d (Rad)	Linkage j (cm)	θ_j (Rad)
16.75	-1.98079995	-0.0346	-1.98079995	0.0346	45.27	2.6526	0.0070	1.2180	0.3175	21.70	1.1765
17.00	0.72721933	0.0127	-0.72721933	-0.0127	45.50	2.6033	-0.0031	1.2053	0.3648	21.53	1.1292
17.25	3.16885085	0.0553	-3.16885085	-0.0553	45.52	2.5627	-0.0134	1.1627	0.4074	21.39	1.0866
17.50	5.42111121	0.0946	-5.42111121	-0.0946	45.55	2.5234	-0.0228	1.1234	0.4467	21.26	1.0473
17.75	7.53086323	0.1314	-7.53086323	-0.1314	45.59	2.4866	-0.0317	1.0866	0.4836	21.13	1.0105
18.00	9.52910796	0.1663	-9.52910796	-0.1663	45.65	2.4517	-0.0400	1.0517	0.5184	21.02	0.9756
18.25	11.43760228	0.1996	-11.43760228	-0.1996	45.72	2.4184	-0.0479	1.0184	0.5517	20.92	0.9423
18.50	13.27230674	0.2316	-13.27230674	-0.2316	45.79	2.3863	-0.0555	0.9864	0.5838	20.82	0.9103
18.75	15.04534012	0.2626	-15.04534012	-0.2626	45.88	2.3554	-0.0627	0.9554	0.6147	20.72	0.8793
19.00	16.76616329	0.2926	-16.76616329	-0.2926	45.97	2.3254	-0.0697	0.9254	0.6447	20.63	0.8493
19.25	18.44233307	0.3219	-18.44233307	-0.3219	46.07	2.2961	-0.0765	0.8961	0.6740	20.54	0.8201
19.50	20.08000305	0.3505	-20.08000305	-0.3505	46.17	2.2675	-0.0830	0.8676	0.7026	20.46	0.7915
19.75	21.68426774	0.3785	-21.68426774	-0.3785	46.29	2.2395	-0.0894	0.8396	0.7306	20.38	0.7635
20.00	23.25940615	0.4060	-23.25940615	-0.4060	46.40	2.2120	-0.0955	0.8121	0.7581	20.31	0.7360
20.25	24.80905851	0.4330	-24.80905851	-0.4330	46.53	2.1850	-0.1015	0.7850	0.7851	20.24	0.7089
20.50	26.33635727	0.4597	-26.33635727	-0.4597	46.66	2.1583	-0.1074	0.7584	0.8118	20.17	0.6823
20.75	27.66406041	0.4828	-27.66406041	-0.4828	46.78	2.1352	-0.1124	0.7352	0.8349	20.11	0.6591
21.00	29.33445565	0.5120	-29.33445565	-0.5120	46.94	2.1060	-0.1186	0.7060	0.8641	20.04	0.6300
21.25	30.80976336	0.5377	-30.80976336	-0.5377	47.08	2.0803	-0.1240	0.6803	0.8899	19.98	0.6042
21.50	32.27183984	0.5632	-32.27183984	-0.5632	47.24	2.0547	-0.1293	0.6548	0.9154	19.92	0.5787
21.75	33.7223866	0.5886	-33.7223866	-0.5886	47.40	2.0294	-0.1345	0.6294	0.9407	19.86	0.5534
22.00	35.16294644	0.6137	-35.16294644	-0.6137	47.56	2.0043	-0.1395	0.6043	0.9658	19.81	0.5282

4
 5 The control steps for the device initialization and operation are outlined in Figure
 6 39. Optionally, if desired, a sensor may be provided for measuring the Y location of axis

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 $K_{E\&M}$. A_{Thrust} is determined by the necrosis pressure limit, P_{Thrust} , and time period that the
 2 thrust is applied. See Table 5 below.

3 *Table 5, Biomechanically Accurate Mandible Model Requirements*

	Parameter	Value	Comment
1	Mandible muscle spring stiffness, K_M	4.86 N/mm	Based on Median thrust force of 34N and extension of 7 mm ^{24,26}
2	Minimum thrust area, A_{Thrust}	> 6.6 cm ²	Area required with thrust force of 43.4N and maximum pressure level allowed, P_{Thrust} of <66 kPa, 4 hours ²⁷
3	Muscle/epidermal tissue spring on each side of the mandible, $K_{E\&M}$	11 N/mm	Based on Young's Modulus of 101.20 kPa, 3 mm thickness and $A_{Thrust}/2$ Area ²⁸

4
 5 The patient is positioned on the device with the neck flexion angle at 35° and the
 6 plane of the face is -15° to the horizontal. As a result the coordinate system of the skull is
 7 rotated about the Y_{Skull} axis and the device y axis, Y_{AS} , by -15° as shown in Figure 28C.
 8 As a result, the nominal jaw thrust force vector is applied at a 7° angle relative to the Y_{AS}
 9 axis. Note the thrust angle is 22° relative to the Y_{Skull} axis.

10 Referring again to Figs. 29A-29C, a mandible base is connected to structural
 11 ground, by a six-degree-of-freedom (DOF) load cell measuring reaction forces and
 12 moments. The mandible slides along the base, constrained in all but the ΔL_{Thrust} axis as
 13 shown (7° about the Y_{AS} axis). Stiffness of the left and right lateral pterygoid muscle that
 14 provides the thrust resistance, is represented by spring stiffness K_M . The simulated
 15 mandible consists of an "infinitely" stiff mandible bone covered by an elastomeric material
 16 shown in green (silicone rubber is the initial choice due to its similarity in mechanical
 17 properties to the skin³⁰). With an elastic modulus of 100 kPa, the effective spring
 18 stiffness when a pressure is applied over the area $A_{Thrust}/2$ with a thickness of 3mm is
 19 $K_{E\&M}$ (Epidermis and muscle). Jaw thrust forces are applied to the left and right side of
 20 the mandible as shown, or in shear along the sides of the mandible. A pressure sensing
 21 grid will be applied to the outer surface of the mandible in order to measure the pressure
 22 field when a jaw thrust is applied to the mandible model. Displacement of the mandible
 23 along the mandible base will be measured with a dial indicator or other distance

1 measuring device. Details of the load cell and pressure measurement array are provided
2 below.

3 Multiple jaw thrust approaches can be employed. Two approaches include the
4 jaw thrust approach shown in Figures 28A-28C where a thrust moment, M_{Thrust} , applied
5 about the Y_{AS} axis results in a thrust force, $F_{Thrust}/2$ on the left and right side of the
6 mandible. In this approach the hands-free jaw thrust device is detached from the device
7 base, and jaw cups that interface with the mandible, are shown in Figures 29A-29C. A
8 second approach interfaces to the side of the mandible through suction cups providing a
9 shear thrust force. The benefit of a suction cup approach is that there is a larger area to
10 interface on the side, as opposed to the back of the mandible, resulting in lower pressure
11 being required to apply the thrust and reduce the possibility of skin or muscle damage.
12 There is precedence in using vacuum to reduce bruising or other damage, as is the case in
13 vacuum assisted delivery during pregnancy. In all cases, thrust force, due to an applied
14 force or moment and mandible displacement will be measured and the thrust provided
15 under closed loop control of the jaw thrust device.

16 The jaw thrust force provided by the device will be provided under closed loop
17 feedback measuring P_{Thrust} directly or indirectly, as measured either by pressure array
18 sensors located in the Jaw Cup/Suction Cup-Mandible interface, similar to this used in
19 the mandible model, or in a load cell measuring the applied force F_{Thrust} or moment
20 M_{Thrust} . This feedback will determine the applied thrust force required for the jaw thrust
21 maneuver.

22 Testing of the Mandible Model with the hands-free jaw thrust device of the
23 present invention involved thrusting the mandible incremental distances of 5mm–15mm
24 (In 1 mm steps) at angles about Y_{AS} of 5° – 10° . (In 1° steps). Four parameters were be
25 simultaneously measured and recorded as a function of time during testing as illustrated
26 in Figures 29A-29C. These include:

- 27 1. Thrust pressure field at the mandible interface as measured in the Mandible
28 reference frame, $P_{Thrust}(X_M, Y_M, Z_M)$.
- 29 2. Reaction forces and moments as transferred through the mandible, to the skull, to
30 the device mechanical ground plane, $F(X_{AS}, Y_{AS}, Z_{AS})$ and $M(X_{AS}, Y_{AS}, Z_{AS})$.
- 31 3. Displacement of the mandible relative to the device reference frame, ΔL .
- 32 4. Jaw thrust maneuver force, F_{Thrust} , applied by the hands-free jaw thrust device to
33 the mandible, as measured at the hands-free jaw thrust device, $F(X_{JC}, Y_{JC}, Z_{JC})$
34 and $M(X_{JC}, Y_{JC}, Z_{JC})$. Note these are assumed to be the similar to 2.

1 Table 6 provides the measurement parameters, requirements and measurement approach
 2 for testing. The last column identifies sensor solutions and provides a basis for the
 3 requirement.

4 *Table 6, Test Measurement Parameters, Requirements & Approach*

	Parameter	Requirement	Candidate Sensor / Basis of Requirement
1	Pressure Field Sensor, $P_{\text{Thrust}} (X_M, Y_M, Z_M) @$ Mandible Interface		Reference Table, TekScan 4205 is a candidate sensor http://www.tekscan.com/4205-pressure-sensor
1.1	Range	0–100 kPa	<66 kPa, 4 hours is the preliminary requirement ²⁷
1.2	Pressure Measurement Accuracy	0.7 kPa	Place holder, 1/100 of preliminary requirement
1.3	Pressure Measurement Precision	0.5 kPa	Place holder, 1/100 of range
1.4	Pressure Measurement Sensor Area	$1.5 \times 10^{-3} \text{ m}^2 /$ $6.0 \times 10^{-3} \text{ m}^2$	Approximate area for rear and side of right and left of mandible
1.5	Pressure Grid spatial resolution	< 2mm in X & Y	Placeholder
1.6	Pressure Array Minimum Surface Radius	“TBD”	
1.7	Pressure Measurement Bandwidth	> 10 Hz	Placeholder
2 & 4	Reaction Force / Moment Sensor, $F (X_{AS}, Y_{AS}, Z_{AS})$ and $M (X_{AS}, Y_{AS}, Z_{AS})$		Reference Table, Candidate SRI 3702A is a candidate sensor, http://www.srisensor.com/pdf/m3202.pdf
2.1	Force Range	-50N - +50N	$34.07 \pm 9.33 \text{ N}$ is expected jaw thrust force ²⁶
2.2	Moment Range	-0.75N-m to +0.75 N-m	Placeholder
2.3	Force Accuracy	< 1N, 1σ	Placeholder
2.4	Force Precision	0.05N, 1σ	Placeholder
2.5	Measurement Bandwidth	> 10 Hz	Placeholder

3	Mandible Displacement Sensor		Reference Table, Candidate sensor is 'TBD'
3.1	Length of Jaw Thrust displacement, θ_{L_Thrust}	0.7mm–10.0 mm	Distance required to achieve airway opening and acceptable glottic view ²⁴
3.2	Measurement Accuracy	0.01 mm, 1σ	
3.3	Measurement Precision	0.005 mm, 1σ	Placeholder
3.4	Measurement Bandwidth	> 10 Hz	Placeholder

1

2 The present invention is believed to be the first of its kind to combine several
3 different mechanisms to maximize ventilation in a hands-free fashion. The device is also
4 novel in that it is the only patient positioning device that can adjust head and/or neck
5 position in real time during intubation. This is essential because the sniffing position is
6 not the optimal intubating position for every patient, although it is for most. The
7 invention being described has the ability to accommodate for those patients whose glottis
8 is not in view in the sniffing position by being able to adjust the head and/or the neck
9 until the glottis is in view.

10 The device is also novel because it is the only patient positioning device that
11 secures a patient's head and neck in optimal ventilating and intubating position and can
12 provide nasal continuous positive pressure ventilation while simultaneously attempting
13 intubation. This helps significantly prolong the short yet critical time period between the
14 patient's last breath and securing of the endotracheal tube.

15 The present invention also has an ability to perform a jaw thrust maneuver in the
16 lateral position, along with the ability to displace weight off of a patient's chest by
17 utilizing a lateral decubitus position, along with placing the patient in the sniffing
18 position which aligns all 3 axes (oropharyngeal, laryngeal, tracheal). The invention also
19 gives the provider the ability to first try a much lesser invasive way of maintaining a
20 patent airway by placing the patient in the proper sniffing position without eliciting any
21 painful stimuli. The provider can then restrain the patient's head to prevent the patient
22 from being displaced from the desired position. If the patient's airway is not yet patent,
23 the provider can adjust the mandibular arms with ratchet capability, each applied to each
24 side of the mandible to displace the jaw forward. If the patient still cannot maintain a
25 patent airway, the present invention, by placing the patient in the desired position, aligns
26 all 3 axes in order to achieve the best possible view to intubate the patient.

1 Figures 42-46C illustrate another and preferred embodiment of the positioning
2 device 1002 of the present invention installed on a conventional operating table 1004.
3 More particularly, there is shown an alternate method of maintaining the patient's head
4 and head support, linkages axis 3, in a collocated position as the device is raised or
5 lowered or as the lift support is raised and lowered is to allow the hip axis 2 (X_2) to be
6 allowed to translate along the Y and Z axis as illustrated in Figures 46A-46C. The
7 alternate method consists of connecting the top cushion on which the patient is lying to
8 the slide back support and allowing the top cushion to slide relative to the anchored back
9 support if that length is adjusted and on the roller assembly along the Y axis.
10 Additionally, as the lift support rotates about the X axis, the head, on the head support
11 slides along the Y axis to compensate for the change in angle and linkage length between
12 axis 3 and 4.

13 Figure 46A shows the patient lying in a supine position with the head and head
14 support collocated at linkage axis 3. As the ramp is raised to an incline position by
15 rotating about the X_1 axis, the patient on the top cushion both slide on the device along
16 the Y axis, Figure 46B. The head and head support remain collocated and the hip axis 2
17 is allowed to move.

18 Referring first to Fig. 42, a foot spacer 1006 and a base spacer 1008, each having
19 a thickness equal to the thickness of the positioning device 1002, are placed on the
20 operating table so as to provide a level surface. Foot spacer 1006 is formed, for example,
21 of a high density foam. Base spacer 1008 preferably includes a plurality of rollers 1010
22 to permit the main pad 1012 (Fig. 44) to roll back and forth as the positioning ramp is
23 raised and lowered or extended as previously described. A foot pad 1014 is also
24 provided, and main pad 1012 and foot pad 1014 are of the same thickness so as to
25 approximate the height of the head and neck support 1016 of the positioning device.
26 Referring also to Fig. 43, the main pad 1012 includes a slatted or pleated base pad 1018
27 which allow the support structure to bend to support the elevation of the ramp over the
28 range of the ramp extension. The assembled unit is shown in Fig. 45. Also, if desired,
29 additional spacer pads 1020 may be inserted between the foot pad 1014 and the main
30 pad 1012 when the positioning device 1002 is extended, to support taller patients. See
31 also Figs. 46A-46C.

32 While the invention has been described in detail with reference to exemplary
33 embodiments thereof, various changes can be made, and equivalents employed, without
34 departing from the scope of the invention. By way of example, the nasal mask, oral mask,

1 and/or full facemask can be used for nebulizer treatments. Also, the nasal mask, oral mask, and
2 full facemask can be used to measure End-Tidal CO₂ (EtCO₂) or capnography. Additionally,
3 the nasal mask, oral mask, and full facemask also consists of patent tubing which consists of two
4 ends to be used as an gas source to transport patients, where the distal end of the tubing is
5 connected to either a stand alone or a portable generator for the supply of gas at a pressure
6 below, equal to, or elevated above atmospheric pressure; a gas delivery conduit coupled to said
7 generator a portable gas supply (oxygen, anesthetic gases, air, or any other gases) and the
8 proximal end is connected to an adaptor, which contains an End-Tidal CO₂ port, a nebulizer port,
9 a PEEP valve port, expiratory port and/or valve, pressure relief valve, which has an aperture
10 which attaches to either the nasal mask, the oral mask, or the full face mask.

11 In yet other embodiments the nasal mask, oral mask, and/or full face mask can be
12 connected to a generator for the supply of gas, where the amount and concentration of gas
13 delivered is controlled by the supply source as well as the expiratory port.

14 In yet other embodiments the nasal mask, oral mask, and/or full face mask can be
15 used as a scavenger system by connecting the nasal mask and the oral mask
16 simultaneously, where the nasal mask can be used to deliver positive pressure and the
17 oral mask can be connected to a suctioning device to properly store and/or dispose gases.

18 A feature and advantage of the present invention is that the nasal mask will
19 contour around the nasal bridge, nose, and upper lip in such a way that it and the
20 generator gas supply it is connected to does not interfere with the operator's access to the
21 mouth/oral cavity, lips, cheeks, chin, jaw, and neck.

22 Also, the nasal mask and full face mask can be connected to a resuscitator bag
23 with or without a gas supply attached to the resuscitator bag. Still other modifications are
24 possible. Still other features and advantages of the present invention include:

- 25 • Neck and head flexion for optimizing the view as well as achieving the Sniff
26 position can be accomplished with one or some combination of the following:
 - 27 a. Neck Support Lift translation along the Z axis
 - 28 b. Head Support Lift translation along the Z axis
 - 29 c. Lift Support rotation about Linkage Axis 4 (X axis) (The head support
30 lift and neck support lift are attached to the Lift Support)
 - 31 d. Note one embodiment may not have the Neck Support Lift
- 32 • The mask anchor anterior strap may have 2 or more straps with one strap
33 securing the chin.
- 34 • The mask anchor straps attach to the top surface of the head support lift, that also
35 contains a soft gel-like doughnut to support the head, with friction wedge.

- 1 • The top of the head support lift with a soft doughnut-like gel that supports the
2 head is detachable from the Lift base. This allows the top of the head support lift
3 with the gel doughnut and mask anchor to be secured to the patient if there is the
4 need to move the patient to a different part of the OR table without the patient
5 positioning device.
- 6 • The top of the head support lift is covered with a disposable barrier. The top of
7 this barrier has an elastic strap taped to it that can be removed and posteriorly
8 attach to the mask that also has an oxygen port. The ventilation port serves as a
9 CO2 exhaust port when the oxygen line is attached to the oxygen port that
10 supplies O2 to the patient. This allows the mask to also be used as an oxygen
11 supply mask postoperatively.
- 12 • The mask anchor connection that holds the anterior mask straps as well as the
13 posterior elastic strap wedge can be integrally part of the mask, as opposed to a
14 separate component that was shown in other embodiments.
- 15 The foregoing description of the preferred embodiments of the invention has been
16 presented for purposes of illustration and description. It is not intended to be exhaustive
17 or to limit the invention to the precise form disclosed, and modifications and variations
18 are possible in light of the above teachings or may be acquired from practice of the
19 invention. The embodiments were chosen and described in order to explain the principles
20 of the invention and its practical application to enable one skilled in the art to utilize the
21 invention in various embodiments as are suited to the particular use contemplated. It is
22 intended that the scope of the invention be defined by the claims appended hereto, and
23 their equivalents. The entirety of each of the aforementioned documents is incorporated
24 by reference herein.
25

1 Claims:

2 1. A device for positioning a patient, comprising:

3 a base; a ramp subassembly pivotally mounted at a proximal end to the base for
4 supporting the upper back, middle back, and shoulders of the patient, said ramp
5 subassembly being adjustable in length and angle relative to the base;6 a head support subassembly pivotally mounted to a distal end of the ramp
7 subassembly, said head support subassembly being adjustable in angle relative to the
8 ramp substantially; and9 a pneumatic or mechanical jack, or an expandable bellows, supported on the head
10 support subassembly for independently raising the patient's head relative to the head
11 support subassembly.12 2. A method for positioning a patient to facilitate maintenance of a patent
13 airway under anesthesia, comprising:

14 providing a device as claimed in claim 1;

15 positioning the patient on the device;

16 adjusting the ramp subassembly to support the patient in a desired inclined
17 position;18 adjusting the head subassembly to support the patient's head and neck in a
19 generally desired sniffing position; and20 activating the pneumatic or mechanical jack, or inflating the expandable bellows
21 to raise the patient's head relative to the second surface to a desired sniffing position.22 3. A first measuring device for use with the device of claim 1, comprising
23 two sides:24 a first rigid semi-cylindrical side with four arm extensions, each of which is
25 located within each of the four corners, and each of which comes into contact with the
26 patient's neck;27 a second rigid side consists of a 35° incline, of which rests a measuring device
28 used to confirm the neck flexion angle of 35° to achieve the desired position.29 4. A second measuring device for use with the device of claim 1, comprising
30 two sides:31 a first rigid triangular side with three-arm extensions, each of which is located
32 within each of the three corners, and each of which comes in contact with the patient's
33 head; the arm extensions are each adjustable along the z-axis to achieve the desired
34 position;

1 a second rigid side consists of a 15^0 incline, of which rests a measuring device
2 used to confirm the head extension angle of 15^0 to achieve the desired position.

3 5. A method for positioning a patient comprising the steps of:

4 providing the device of claim 1;

5 placing the patient's head, neck, upper and middle back, and shoulders

6 substantially on the base; using an adjustable device to place the patient's head, neck,

7 upper and middle back, and shoulders in a desired position; using a measuring device to

8 confirm the desired position; moving the first mandible arm to contact the patient's jaw;

9 moving the second mandible arm to contact the patient's jaw; wherein the contact of the

10 first mandible arm and the second mandible arm provides sufficient force to substantially

11 maintain the patient's head and/or jaw in a desired position.

12 6. The method of claim 5, characterized by one or more of the following
13 features:

14 (a) wherein all three axes (oropharyngeal, laryngeal, tracheal) are aligned for
15 the recommended view for intubation;

16 (b) wherein the patient's head height is adjusted with respect to the Z axis by
17 using a jack;

18 (c) wherein the device includes a squeeze released jaw thrust grip, and
19 including the step of moving the jaw thrust grip in the z direction;

20 (d) including a neck interface and a head interface which are independently
21 adjustable in one or more of the x, y and z positions, and

22 (e) wherein the detachable third incline side is rotatably adjustable about each
23 y axis.

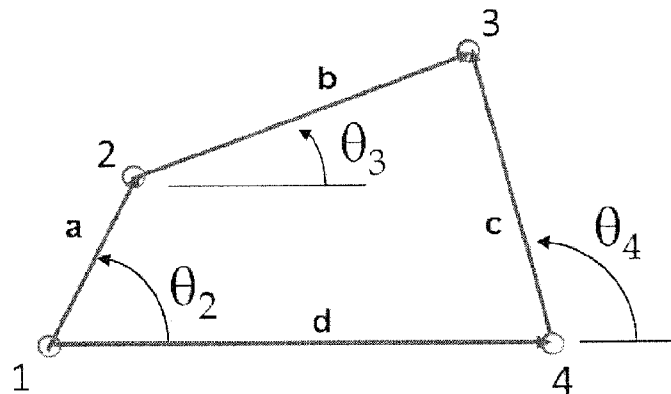
24 7. A device for positioning a patient in a sniff position, comprising an
25 adjustable ramp and headrest, wherein as ramp incline is varied, head rest orientation
26 remains parallel, substantially horizontal to the operating table, by changing the head rest
27 angle, θ_x by an opposite amount.

28 8. The device of claim 7, characterized by one or more of the following
29 features:

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

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

- 1 (c) wherein adjustment is accomplished upon multiple feedback sensors
 2 including but not limited to:
 3 (i) Measurement of angle relative to gravity with an inclinometer; and
 4 (ii) Encoders.
 5 (d) wherein as ramp incline is varied, and / or head rest angle, θ are changed
 6 to position the patient, ramp linkage length is varied in order to satisfy the conditions that
 7 positions of linkages fixed relative to their respective support surfaces;
 8 (e) wherein adjusting of angles is accomplished by:
 9 (i) Open loop processing based on known or estimated geometries of
 10 all parameters, or by
 11 (ii) Closed loop processing where the relative positions of one or
 12 more linkage termination points are measured and the length d is adjusted under closed
 13 loop control driven by sensor feedback to return the measured parameter to their original
 14 position with regard to the following geometry, or by



- 15
 16 (a) Point 2 of linkage a's position relative to point 1;
 17 (b) Point 3 of linkage c's position relative to point 4;
 18 (c) Alternate Point 3 where the patient head meets the head rest; and
 19 (d) feedback sensors monitoring relative position of the points that
 20 define the linkage length including position measurement sensors selected from
 21 the group consisting of: hall effect sensors; magneto-resistive sensors; optical
 22 sensors, including encoders, interferometers and/or positional sensing detectors;
 23 and stress / strain / force / torque monitoring sensors located at the point
 24 interfaces that minimize those parameters by adjusting linkage length d under
 25 closed loop control.
 26 9. A disposable anesthesia nasal and oral mask which can be used either

1 separately as a nasal mask or an oral mask or can be attached together and can be used as
2 a combination nasal-oral mask, which can also be used to sealingly connect a mask to a
3 wearer's face; two cushions comprising: a first nasal inflatable or non-inflatable cushion
4 that consists of a nasal bridge region, a cheek region, and an upper lip region and a
5 second mouth inflatable or non-inflatable cushion which consists of a lower lip region, a
6 cheek region, and an upper lip region; a first nasal membrane comprising a substantially
7 triangularly shaped frame of resilient material having a first molded inwardly curved rim
8 of said first nasal membrane; a second nasal membrane of resilient material, said second
9 nasal membrane being thinner, as thin, or thicker than said first nasal membrane, said
10 second nasal membrane having a second molded inwardly curved rim, said second nasal
11 membrane curved rim spaced a first distance from said first nasal membrane curved rim
12 in said cheek region and said second nasal membrane curved rim spaced a second
13 distance from said first nasal membrane curved rim in said nasal bridge region, said
14 second distance greater than said first distance, said distances measured when the mask
15 is not in use, a portion of said second membrane curved rim forming a face contacting
16 seal; a first mouth membrane comprising a substantially oval shaped frame of resilient
17 material having a first molded inwardly curved rim of said first mouth membrane; a
18 second mouth membrane of resilient material, said second mouth membrane being
19 thinner, as thin, or thicker than said first mouth membrane, said second mouth membrane
20 having a second molded inwardly curved rim, said second mouth membrane curved rim
21 spaced a first distance from said first mouth membrane curved rim in said cheek region
22 and said second mouth membrane curved rim spaced a second distance from said first
23 mouth membrane curved rim in said mouth region, said second distance greater than said
24 first distance, said distances measured when the mask is not in use, a portion of said
25 second membrane curved rim forming a face contacting seal; an attachment with two
26 apertures; where the first aperture is fixed to the oral mask and can connect to the second
27 aperture, which is fixed to the nasal mask; where when they are connected together it
28 comprises an anesthesia full face mask, covering and sealing around the mouth and nose;
29 yet either the mouth mask or the nasal mask can detach so that the mask can be used for
30 nasal non-invasive positive pressure ventilation (CPAP/BiPAP) alone or oral non-
31 invasive positive pressure ventilation (CPAP/BiPAP) alone.

32 10. A nasal and oral mask as claimed in claim 9, characterized by one or more
33 of the following features:

34 (a) wherein said second molded rim and said first molded rim have a co-

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

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

19 12. A nasal mask, oral mask, or full face mask, covering and sealing the
20 mouth and nose, as claimed in claim 11, characterized by one or more of the following
21 features:

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

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

32 (c) wherein said second membrane molded rim and said first nasal membrane
33 molded rim each have a co-located notch to accommodate the bridge of a nose;

34 (d) wherein said first and second molded rims are substantially saddle-

1 shaped;

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

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

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

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

31 14 The non-invasive positive pressure ventilation (BiPAP/CPAP) treatment
32 apparatus as claimed in claim 13, characterized by one or more of the following features:

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

- 1 (b) further comprising securing straps fixed to said attachment points which
2 can secure the wearer's head to a surface and maintain the wearer's head and neck in
3 position;
- 4 (c) wherein said first and second molded rims each have a co-located notch to
5 accommodate the bridge of a nose;
- 6 (d) wherein said first and second molded rims are substantially saddle-
7 shaped;
- 8 (e) wherein said second nasal membrane is shaped so that said seal portion, in
9 use, contacts at least wearer's nose;
- 10 (f) wherein said seal portion, in use, contacts the facial tissue around the
11 sides and over the bridge of the nose, and facial tissue around the sides and over the
12 bridge of the nose, between the base of the nose and the upper lip and between the base
13 of the nose and the upper lip, and
- 14 (g) wherein said second molded rim and said seal portion are shaped to
15 generally match facial contours in the region of facial tissue around the sides and over
16 the bridge of the nose, between the base of the nose and the upper lip and between the
17 base of the nose and the upper lip.

18 15. 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 membrane
24 also of resilient material, said second mouth membrane being relatively more flexible
25 than said first mouth membrane, said second mouth membrane having a second molded
26 inwardly curved rim, said second molded rim being of the same general shape as said
27 first molded rim and fixed to and extending away from said first mouth membrane so as
28 to have a second mouth membrane inner surface spaced a first distance from an outer
29 surface of said first molded rim in said cheek region and said second mouth membrane
30 inner surface spaced a second distance from said first mouth membrane outer surface of
31 said first molded rim in said mouth region, said second distance greater than said first
32 distance, said distances measured when the mask is not in use, a portion of said second
33 molded rim forming a face contacting seal; and wherein said seal portion is substantially
34 coterminous with respect to said second molded rim and is resiliently deformable

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

2 16. The mask as claimed in claim 15, 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 17. The nasal mask, oral mask, or full facemask as claimed in claim 11,
20 further patent tubing which has two ends to be used as an gas source to transport patients,
21 where a distal end of the tubing is connected to either a stand alone or a portable
22 generator for the supply of gas at a pressure below, equal to, or elevated above
23 atmospheric pressure; a gas delivery conduit coupled to said generator a portable gas
24 supply and a proximal end is connected to an adaptor, which contains an End-Tidal CO2
25 port, a nebulizer port, a PEEP valve port, expiratory port and/or valve, pressure relief
26 valve, which has an aperture which attaches to either the nasal mask, the oral mask, or
27 the full face mask.

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

34 19. The nasal mask, oral mask or full face mask as claimed in claim 11,

1 contoured around the patient's nasal bridge, nose, and upper lip such that it and the
2 generator gas supply it is connected to does not interfere with the operator's access to the
3 mouth/oral cavity, lips, cheeks, chin, jaw, and neck, and/or connected to a resuscitator
4 bag with or without a gas supply attached to the resuscitator bag.

5 20. An operating table having a positioning device as claimed in claim 1, and
6 one or more pads having a thickness approximating that of the positioning device, on the
7 operating table.

8 21. The operating table in claim 20, wherein at least one of the pads is slatted
9 or pleated to facilitate bending.

10 22. The operating table of claim 20, further including the base spacer having a
11 plurality of rollers located under a main pad.

12 23. A flexible and soft head restraining device for a patient, comprising:
13 a first proximal end that attaches to one side of the first side of the base; which
14 can then extend horizontally and come in contact with the patient's head and attach to the
15 opposite side of the first surface of the base; the device is adjustable and able to secure
16 the patient's head to the first surface of the base to prevent the patient from disengaging
17 from the desired position.

18 24. A mandible arm for use in positioning a patient, comprising:
19 two rigid lockable arms, wherein the upper arm has a curved extension which is
20 rotatable in the z-axis and the lower arm does not provide an extension;

21 a curved portion, wherein the curved portion is substantially rigid;

22 a mandible pad, wherein the mandible pad is flexible and pivotable, and wherein
23 the mandible pad has a proximal side configured to attach to the curved portion and a
24 distal side configured to contact a patient's jaw at a at least two of a ramus, a body, and
25 an angle of the patient's jaw; and

26 a connector portion, wherein the connector portion is configured to extend from
27 and attach to a rotatable portion of a support, and wherein the connector portion is
28 further configured to attach to a support that is attached to a base comprising a left side
29 and a right side, wherein the base is configured to substantially accommodate a patient's
30 head, neck, upper and middle back, and shoulders, and wherein the support is movable in
31 two axes such that the mandible pad is positionable to be in contact with a patient's jaw
32 at one or more points and to maintain a patient in a desired position.

33 25. A flexible and soft head restraining and anesthesia mask sealing device
34 for positioning a patient, comprising:

1 a first proximal end that attaches to one side of the first side of a base of a
2 carriage subassembly, which can then extend horizontally and come in contact with
3 either the patient's head and attach to the opposite side of the first surface of the base or
4 comes in contact with the anesthesia mask, which then contacts and seals to the patient's
5 face; wherein the device is adjustable and able to secure the patient's head to the first
6 surface of the base to prevent the patient from disengaging from the desired position,
7 wherein the carriage subassembly optionally is reversible, allowing the patient to be
8 placed on an opposite side, and/or wherein the device optionally is formed of MRI or
9 Xray compatible materials.

10 26. A flexible and soft back restraining device for positioning a patient,
11 comprising:

12 a first proximal end that attaches to one side of the back board, which can then
13 extend horizontally and come in contact with the patient's abdomen and attach to the
14 opposite side of the back board, wherein the device is adjustable and able to secure the
15 patient's back to the surface of the back board to prevent the patient from disengaging
16 from the desired position.

17 27. A surface for supporting a patient, comprising:

18 a first side that is adjustable to be in contact the patient's back, and a second
19 adjustable side that is adjustable to be in contact with the patient's ribs to prevent patient
20 movement.

21 28. An apparatus for use when providing anesthesia to a patient, comprising,
22 a base having a first side, a second side, a third side, and an adjustable support
23 structure, wherein the base is configured to substantially accommodate a patient's neck
24 and head;

25 wherein a distal end of the base first side comprises either a semi-cylindrical
26 support, adjustable in the z-axis, which assists in maintaining the desired sniffing
27 position or a flat surface also adjustable in the z axis;

28 a proximal end of the base first side comprises either a slightly inclined or flat
29 surface, with or without a cut-out center and is adjustable in the z- axis in order to
30 provide head support to further optimize the sniffing position;

31 the second and third sides of the base each contain a plurality of protrusions; and

32 an anesthesia mask strap with four sides, wherein the first and second sides
33 include an aperture that is placed over an aperture of the mask, and the third and fourth

1 sides include a narrow extension which include a plurality of holes adapted to attach to
2 one of the four protrusions on sides two and thereof the base;
3 wherein the mask strap is adapted to hold an anesthesia mask strap against the
4 patient's nose, cheeks, mouth and/or head to maintain the desired sniffing position where
5 the patient's jaw is moved up and forward, thereby unobstructing the patient's airway; and
6 wherein the mask strap is adapted stabilize the patient's head and neck to the base
7 preventing movement of the patient's head and neck.

8 29. The apparatus according to claim 28, characterized by one or more of the
9 following features:

- 10 (a) wherein the anesthesia mask strap is formed of a non-static latex free
11 material;
12 (b) wherein at least some of said narrow extensions have respective portions
13 of snap fasteners for attaching the narrow extension to one of the protrusions of the base;
14 (c) wherein the adjustable support is located in the interior of the base;
15 (d) wherein the adjustable support includes a mechanical or a pneumatic
16 adjustment mechanism;
17 (e) wherein the base is substantially rectangular in plan;
18 (f) wherein the desired position is the sniffing position, aligning all three
19 axes, oropharyngeal, laryngeal, and tracheal;
20 (g) wherein the base further comprises a distal adjustable neck rest disposed
21 on the first surface configured to provide optimal flexion of the patient's neck and a
22 proximal inclined head rest to provide optimal head extension to acquire the desired
23 position; or the base comprises only a flat surface if the desired positioned is not
24 necessary;
25 (h) wherein the apparatus is formed of MRI or Xray compatible materials;
26 and
27 (i) wherein the mask strap is formed of a material that is easily disinfected
28 with anti-microbial solutions or is disposable.

29 30. An apparatus for use when providing anesthesia to a patient, comprising:
30 means for providing said anesthesia to said patient; mask strap means for holding said
31 mask means against a patient's nose, mouth, cheeks, and or head; a base of which the
32 mask strap attaches to achieve the desired position which raises the patient's jaw up and
33 forward so as to unobstruct the patient's airway.

1 31. A method for positioning a patient for administering anesthesia,
2 comprising the steps of: providing the device of claim 28; placing the patient's head and
3 neck substantially on the carriage subassembly; using an adjustable device to place the
4 patient's head and neck in a desired position; placing the mask strap either over the
5 aperture of the anesthesia mask or the patient's head to substantially maintain the patient's
6 head and/or jaw in a desired position.

7 32. The method of claim 31, characterized by one or more of the following
8 features:

9 (a) wherein placing the head and neck substantially on the neck rest on the
10 distal end of the first surface of the base and the head rest on the proximal end of the first
11 side of the base places the patient in the desired position without eliciting pain;

12 (b) wherein placing the head and neck substantially on the neck rest on the
13 distal end of the first surface of the base and the head rest on the proximal end of the first
14 side of the base places the patient in the desired position and restricts the movement of
15 the patient's head and neck; and

16 (c) wherein placing the mask on the patient's face, then placing the mask strap
17 over the mask and attaching it to the base will prevent leakage of anesthetic gases and
18 oxygen into the air.

19 33. An apparatus for providing ventilation to a patient lying supine on a
20 support, comprising,

21 a ventilation mask,

22 a mask anchor ring over the ventilation mask, and

23 a plurality of elastomeric cords connecting the mask anchor to the support.

24 34. The apparatus according to claim 33, wherein the elastomeric straps are
25 fixed to the mask anchor ring spaced 180° around an imaginary circle.

26 35. A device for positioning a patient, comprising:

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

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

32 36. The device of claim 35, characterized by one or more of the following
33 features:

- 1 (a) wherein the expandable bellows comprises a plurality of rigid concentric
2 rings joined by flexible membranes on a rigid base, wherein the third side of the base
3 preferably comprises:
4 a rigid inclined side with two ends;
5 a proximal end which is detachable from the distal side of the first side of the
6 best; the desired position can be obtained by different body habitus' by adjusting the
7 height of the first base;
8 a distal end comprises an extension mechanism to maintain the desired angle to
9 maintain the patient in the desired position;
10 a resiliently deformable pad that lies on top of the rigid inclined side and comes
11 in contact with the patient's upper back, middle back, and shoulders;
12 (b) wherein the bellows includes a two-way valve through which air may be
13 added or subtracted; and
14 (c) wherein the bellows is formed of MRI or Xray compatible material.
15 37. A method for positioning a patient to facilitate maintenance of a patient
16 airway under anesthesia, comprising providing a device as claimed in claim 35,
17 positioning the patient on the device, adjusting the first surface to support the patient in a
18 desired inclined position;
19 adjusting the second surface to support the patient's head and neck in a generally
20 desired sniffing position; and
21 activating the pneumatic or mechanical jack, or inflating the expandable bellows
22 to raise the patient's head relative to the second surface to a desired sniffing position.
23 38. A device for positioning a patient, comprising:
24 a base comprising a first side which supports the patients head and neck, a second
25 side acting as the foundation, an inner vertically adjustable support structure between the
26 first and second sides, and a detachable third inclined side which support the upper back,
27 middle back, and shoulders of patient;
28 a first support positioned on the second side of the base and lockably adjustable
29 with respect to the second side of the base in an x and y axes;
30 a second support positioned on the second side of the base and lockably
31 adjustable with respect to the second side of the base in the x and y axes;
32 a first mandible arm extending from a first vertically adjusted portion of the first
33 support, wherein the first vertically adjusted portion is lockable in a z axis to lockably

1 adjust the first mandible arm with respect to the z axis, and wherein the first mandible
2 arm is positionable to be in contact with the patient's jaw; and

3 a second mandible arm extending from a second vertically adjusted portion of the
4 second support, wherein the second vertically adjusted portion is lockable in the z axis to
5 adjust the second mandible arm with respect to the z axis, and wherein the second
6 mandible arm is positionable to be in contact with the patient's jaw;

7 wherein the first mandible arm and the second mandible arm are movable such
8 that each is positionable to be in contact with the patient's jaw and to maintain the patient
9 in a desired position and leaving the provider hands free.

10 39. The device of claim 38, characterized by one or more of the following
11 features:

12 (a) wherein the mandible arm is positionable to be in contact with the
13 patient's jaw at a ramus, a body, or an angle of the patient's jaw, wherein each of the first
14 mandible arm and the second mandible arm preferably is positionable such that the
15 mandible pad, preferably formed of foam, is in contact with the patient's jaw at two or
16 more of a ramus, a body, or an angle of the patient's jaw, or wherein each of the first
17 mandible arm and the second mandible arm preferably is positionable such that the
18 mandible pad is in contact with a patient's jaw at a ramus, a body, and an angle of the
19 patient's jaw;

20 (b) wherein the first support is movable relative to the base and the second
21 support is movable relative to the base, wherein the first support preferable is movable
22 relative to the base in two axes and the second support is movable relative to the base in
23 two axes;

24 (c) wherein the base is rectangular;

25 (d) wherein the first mandible arm and the second mandible arm each
26 comprise a mandible pad;

27 (e) wherein the first mandible arm and the second mandible arm are
28 removably connected to the first support and the second support, respectively;

29 (f) wherein the first mandible arm is movable relative to the first support and
30 the second mandible arm is movable relative to the second support;

31 (g) wherein the desired position is the sniffing position, aligning all 3 axes
32 (oropharyngeal, laryngeal, and tracheal), and/or the jaw thrust maneuver;

33 (h) further including a level for determining a patient's neck flexion angle;

- 1 (i) wherein the base further comprises a distal neck rest disposed on the first
2 surface configured to provide optimal flexion of the patient's neck and a proximal
3 inclined head rest to provide optimal head extension to a acquire the desired position;
- 4 (j) wherein the first and second mandible arms are configured to extend the
5 patient's jaw when rotated in the z-axis;
- 6 (k) wherein the plurality of mandible arms are configured to extend the
7 patient's jaw when rotated in the z-axis;
- 8 (l) wherein the first and second supports and first and second rotatable
9 portions are adjustable while the patient is in contact with the first and second mandible
10 arms; and
- 11 (m) wherein the third side of the base will support a patient's upper back,
12 middle back, and shoulders, whereby to enable gravity to displace weight off of the
13 patient's chest, including in obese patients;
- 14 (n) wherein the device is formed of MRI or Xray compatible materials;
- 15 (o) wherein placing the head and neck substantially on the neck rest on the
16 distal end of the first surface of the base and the head rest on the proximal end of the first
17 side of the base places the patient in the desired position within eliciting pain; and
- 18 (p) wherein the inner adjustable surface consists of a rigid structure; wherein
19 the device is adjustable along a y-axis to displace weight off of a patient's chest; is
20 adjustable along a y-axis to align the ear and the sternum horizontally to achieve
21 maximal air exchange in obese patients; and is adjustable along a z-axis for elevating and
22 lowering obese patients without the help of health care workers;
- 23 (q) further comprising a claw for providing an anesthesiologist a tactile
24 interface with the patient in terms of extending the jaw, wherein the position of left and
25 right arms of the claw are maintained by frictional force that is transmitted through the
26 jack assembly, which force may be overcome by the anesthesiologist when rotating the
27 arms about the Z axis, further optionally characterized by one or more of the following
28 features:
- 29 (i) wherein the position of the left and right arms of the claw are
30 secured by friction about the Y axis;
- 31 (ii) wherein a fine adjustment for further extending the jaw is
32 provided by a screw which applies additional force in the nominal Z direction by
33 applying a torque to the arms about the Y axis; and

1 (iii) further comprising a torque limiter for limiting force applied to the
2 mandible by the left and right arms in the Z direction to prevent injury to the patient.

3 40. A mandible arm for use in positioning a patient, comprising:
4 two rigid lockable arms, wherein the upper arm has a curved extension which is
5 rotatable in the z-axis and the lower arm does not provide an extension;
6 a curved portion, wherein the curved portion is substantially rigid;
7 a mandible pad, wherein the mandible pad is flexible and pivotable, and wherein
8 the mandible pad has a proximal side configured to attach to the curved portion and a
9 distal side configured to contact a patient's jaw at a at least two of a ramus, a body, and
10 an angle of the patient's jaw; and
11 a connector portion, wherein the connector portion is configured to extend from
12 and attach to a rotatable portion of a support, and wherein the connector portion is
13 further configured to attach to a support that is attached to a base comprising a left side
14 and a right side, wherein the base is configured to substantially accommodate a patient's
15 head, neck, upper and middle back, and shoulders, and wherein the support is movable in
16 two axes such that the mandible pad is positionable to be in contact with a patient's jaw
17 at one or more points and to maintain a patient in a desired position.

18 41. A first measuring device for use with the device of claim 38, comprising
19 two sides:

20 a first rigid side with four arm extensions, each of which is located within each of
21 the four corners, and each of which comes into contact with the patient's neck;
22 a second rigid side consists of a 35° incline, of which rests a measuring device
23 used to confirm the neck flexion angle of 35° to achieve the desired position.

24 42. A second measuring device for use with the device of claim 38,
25 comprising two sides:

26 a first rigid triangular side with three-arm extensions, each of which is located
27 within each of the three corners, and each of which comes in contact with the patient's
28 head; the arm extensions are each adjustable along the z-axis to achieve the desired
29 position;

30 a second rigid side consists of a 15° incline, of which rests a measuring device
31 used to confirm the head extension angle of 15° to achieve the desired position.

32 43. A flexible and soft head restraining device for a patient, comprising:

33 a first proximal end that attaches to one side of the first side of the base; which
34 can then extend horizontally and come in contact with the patient's head and attach to the

1 opposite side of the first surface of the base; the device is adjustable and able to secure
2 the patient's head to the first surface of the base to prevent the patient from disengaging
3 from the desired position.

4 44. A method for positioning a patient comprising the steps of:
5 providing the device of claim 38;
6 placing the patient's head, neck, upper and middle back, and shoulders
7 substantially on the base; using an adjustable device to place the patient's head, neck,
8 upper and middle back, and shoulders in a desired position; optionally using a measuring
9 device to confirm the desired position; moving the first mandible arm to contact the
10 patient's jaw; moving the second mandible arm to contact the patient's jaw; wherein the
11 contact of the first mandible arm and the second mandible arm provides sufficient force
12 to substantially maintain the patient's head and/or jaw in a desired position.

13 45. The method of claim 44, characterized by one or more of the following
14 features:

15 (a) wherein all three axes (oropharyngeal, laryngeal, tracheal) are aligned for
16 the recommended view for intubation;

17 (b) wherein the patient's head height is adjusted with respect to the Z axis by
18 using a jack, and

19 (c) wherein the device includes a squeeze released jaw thrust grip, and
20 including the step of moving the jaw thrust grip in the z direction.

21 46. A device for positioning a patient, comprising:

22 a base subassembly comprising a surface for supporting a carriage subassembly,
23 where the first surface of the support arm supports the patients head and is adjustable in
24 the Z-axis, the second surface supports the patient's neck and is adjustable in the z-axis,
25 to place the patient in the desired sniffing position;

26 the surface of the upper arm is lowered until comfortably tight and locked, for
27 constraining the patients head in translation along all three axes;

28 a flexible band for placement over the patient's forehead, for securing it to the
29 sniff subassembly by applying a constant constraining force in the-X direction;

30 a first mandible arm extending vertically from the first surface of the carriage
31 subassembly, wherein the first vertically adjusted portion is lockable in rotation about the
32 Z axis, wherein the first mandible arm is positionable to be in contact with the patient's
33 jaw; and

1 a second mandible arm extending vertically from the third surface of the carriage
2 subassembly, wherein the second vertically adjusted portion is lockable in rotation about
3 the Z axis, wherein the second mandible arm is positionable to be in contact with the
4 patient's jaw;

5 wherein the first mandible arm and the second mandible arm are movable such
6 that each is positionable to be in contact with the patient's jaw and to maintain the patient
7 in a desired position while lying on his or her side and leaving the provider hands free.

8 47. The device of claim 46, characterized by one or more of the following
9 features

10 (a) wherein the mandible arm is positionable to be in contact with the
11 patient's jaw at a ramus, a body, or an angle of the patient's jaw while the patient is lying
12 on his or her side, wherein each of the first mandible arm and the second mandible arm
13 preferably is positionable in contact with the patient's jaw at two or more of a ramus, a
14 body, or an angle of the patient's jaw while the patient is lying on his or her side, and/or
15 wherein each of the first mandible arm and the second mandible arm preferably is
16 positionable in contact with a patient's jaw at a ramus, a body, and an angle of the
17 patient's jaw while the patient is lying on his or her side;

18 (b) further including a mandible pad on the first and second mandible arms,
19 for contact with the patient's jaw;

20 (c) wherein all surfaces of the carriage subassembly are movable relative to
21 the base, wherein the first and third surfaces of the support arm preferably are movable
22 relative to the base in one axes, and the second surface of the carriage subassembly is
23 movable relative to the base in three axes;

24 (d) wherein the base is rectangular and the carriage subassembly surfaces are
25 c-shaped;

26 (e) wherein the mandible pads preferably are formed of a resiliently
27 deformable material, wherein the mandible pads are formed of foam;

28 (f) wherein the first mandible arm and the second mandible arm are
29 removably connected to the first surface of the carriage subassembly and the third
30 surface of the carriage subassembly, respectively;

31 (g) wherein the first mandible arm is movable relative to the first surface of
32 the carriage subassembly and the second mandible arm is movable relative to the third
33 surface of the carriage subassembly;

- 1 (h) wherein the desired position is the sniffing position while lying on a side,
2 aligning all 3 axes (oropharyngeal, laryngeal, and tracheal), and/or the jaw thrust
3 maneuver;
- 4 (i) wherein the second surface of the carriage subassembly further comprises
5 a neck rest disposed to provide optimal flexion of the patient's neck and optimal head
6 extension to a acquire the desired position;
- 7 (j) wherein the first and second mandible arms are configured to extend the
8 patient's jaw when rotated in the x-axis;
- 9 (k) wherein the plurality of mandible arms are configured to extend the
10 patient's jaw when rotated in the x-axis;
- 11 (l) wherein the device is formed of MRI or Xray compatible materials;
- 12 (m) wherein the carriage subassembly is reversible, allowing the patient to be
13 placed on an opposite side;
- 14 (n) further including a level for determining a patient's neck flexion angle;
- 15 (o) wherein the base further comprises a distal neck rest disposed on the first
16 surface configured to provide optimal flexion of the patient's neck and a proximal
17 inclined head rest to provide optimal head extension to provide a desired patient position;
18
- 19 (p) wherein the first and second support surfaces and first and second
20 rotatable portions are adjustable while the patient is in contact with the first and second
21 mandible arms;
- 22 (q) wherein the base subassembly comprises:
23 a rigid inclined side with two ends;
24 a proximal end which is detachable from the distal side of the first side of
25 the base; the desired position can be obtained by different body habitus' by adjusting the
26 height of the first base;
27 a distal end comprises an extension mechanism to maintain the desired
28 angle to maintain the patient in the desired position;
29 a foam pad that lies on top of the rigid inclined side and comes in contact
30 with the patient's upper back, middle back, and shoulders;
- 31 (r) wherein the inclined side supports a patient's upper back, middle back, and
32 shoulders, and will enable gravity to displace weight off of the patient's chest, including
33 in obese patients;
- 34 (s) wherein the device is formed of MRI or Xray compatible materials.

1 (t) wherein placing the head and neck substantially on the neck rest on a
2 distal end of the inclined side and a head rest on a proximal end of the inclined side
3 places the patient in the desired position within eliciting pain; and

4 (u) wherein the device is adjustable along a y-axis to displace weight off of a
5 patient's chest; is adjustable along a y-axis to align the ear and the sternum horizontally to
6 achieve maximal air exchange in obese patients; and is adjustable along a z-axis for
7 elevating and lowering obese patients without the help of health care workers.

8 48. A method for positioning a patient comprising the steps of:
9 providing the device of claim 46;
10 placing the patient's head substantially on the first surface of the carriage
11 subassembly using an adjustable device to place the patient's head and neck in a desired
12 position; moving the first mandible arm to contact the patient's jaw; moving the second
13 mandible arm to contact the patient's jaw; wherein contact of the first mandible arm and
14 the second mandible arm provides sufficient force to substantially maintain the patient's
15 head and/or jaw in a desired position.

16 49. The method of claim 48, wherein all three axes (oropharyngeal,
17 laryngeal, tracheal) are aligned for view for intubation.

18 50. A mandible arm for positioning a patient, comprising:
19 a rigid lockable arm, wherein the arm has a curved extension which is rotatable in
20 the x-axis;

21 a curved portion, wherein the curved portion is substantially rigid;

22 a mandible pad, wherein the mandible pad is flexible and pivotable, and wherein
23 the mandible pad has a proximal side configured to attach to the curved portion and a
24 distal side configured to contact a patient's jaw at a at least two of a ramus, a body, and
25 an angle of the patient's jaw; and

26 a connector portion, wherein the connector portion is configured to extend from
27 and attach to a rotatable portion of a support, and wherein the connector portion is
28 further

29 configured to attach to a support that is attached to the carriage subassembly comprising
30 a left side and a right side, wherein the carriage subassembly is configured to
31 substantially accommodate a patient's head and wherein the carriage subassembly is
32 movable in one axes such that the mandible pad is positionable to be in contact with a
33 patient's jaw at one or more points and to maintain a patient in a desired position,

- 1 wherein the carriage subassembly is reversible, allowing the patient to be place on an
- 2 opposite side.
- 3

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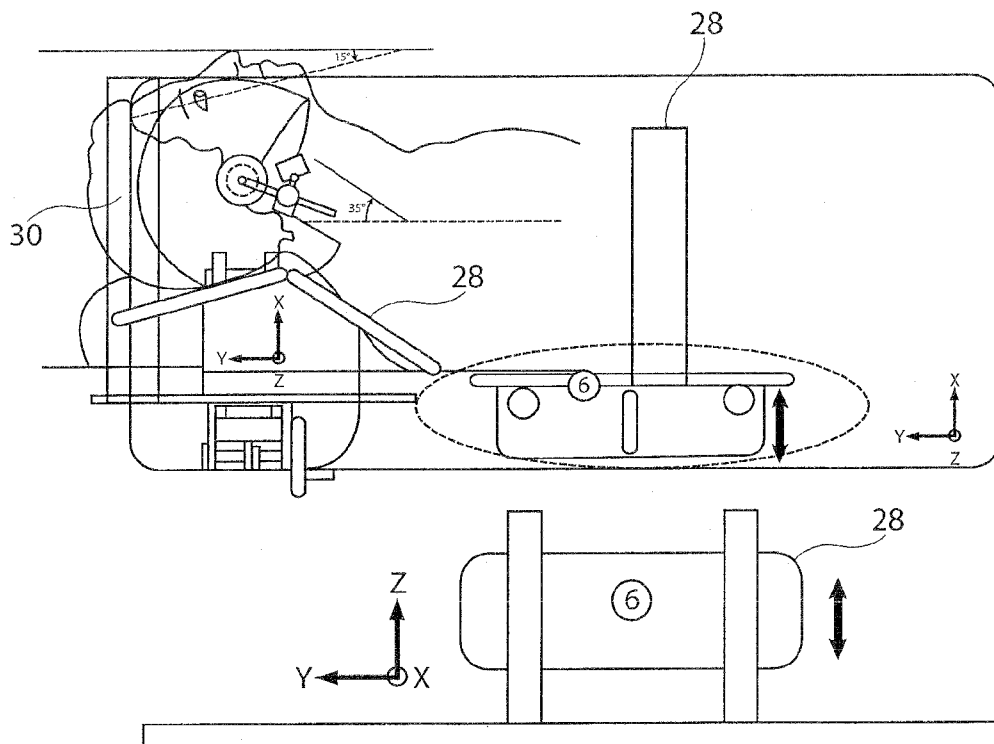


Fig. 1

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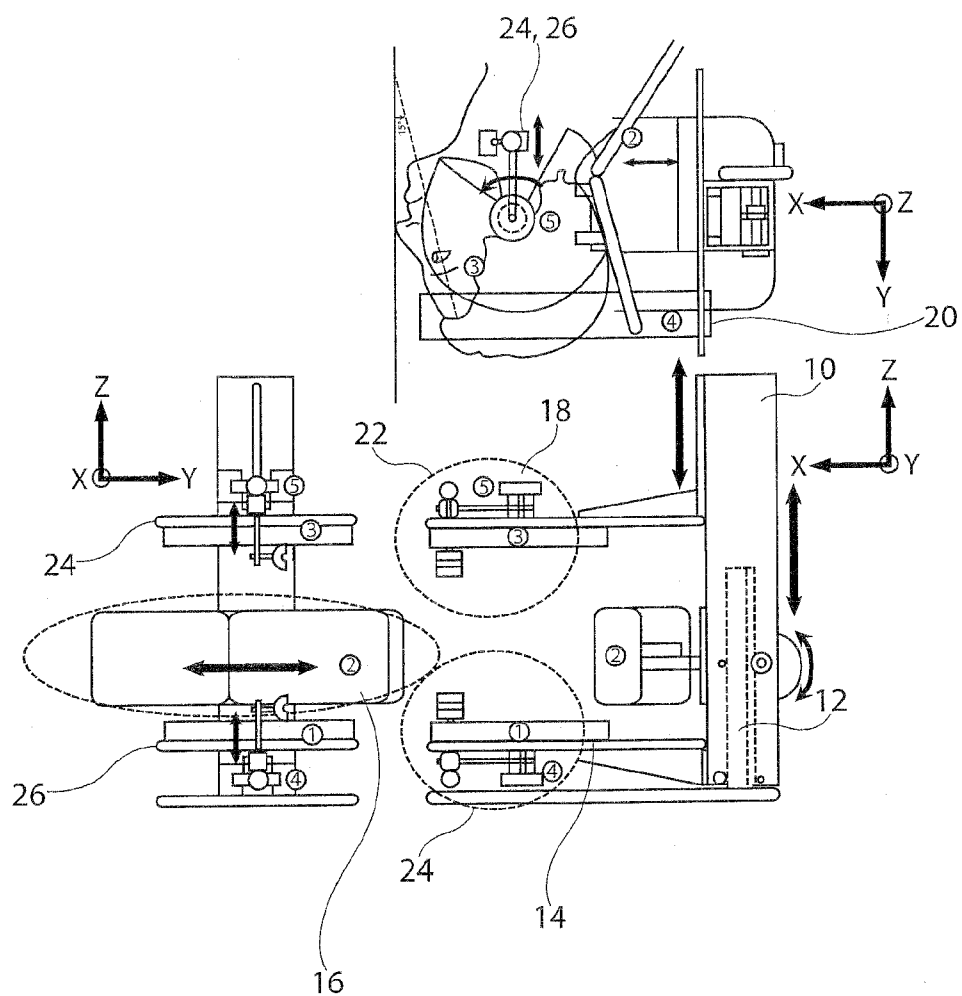
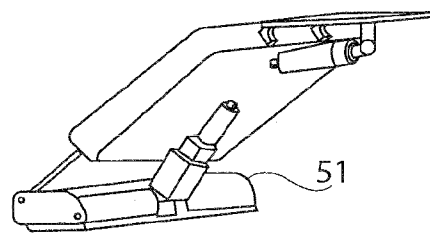
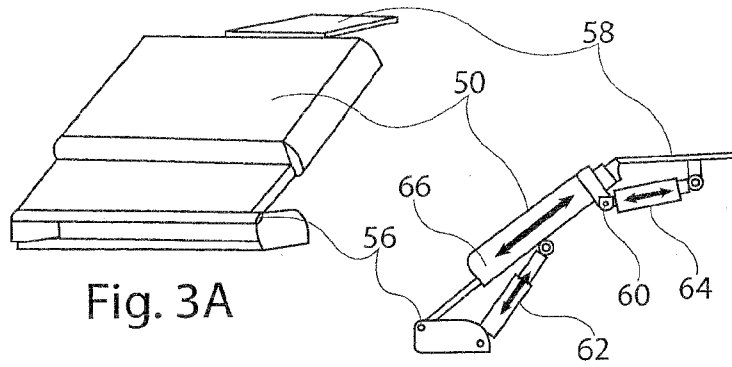


Fig. 2

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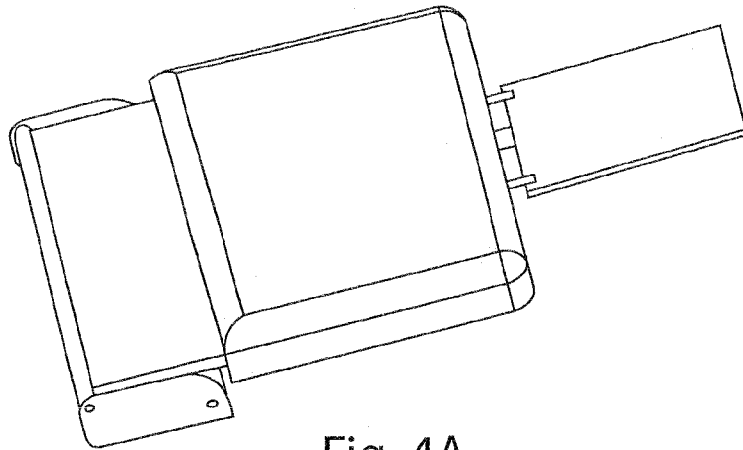


Fig. 4A

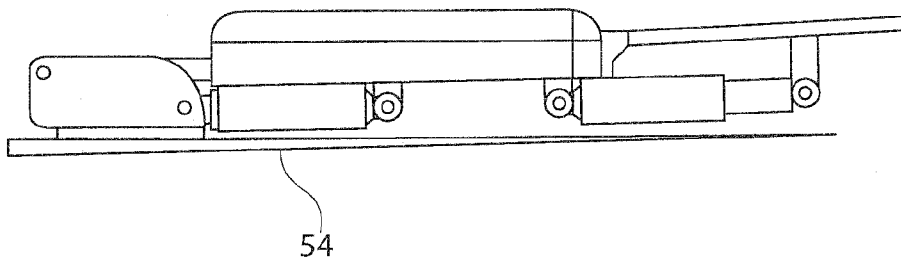


Fig. 4B

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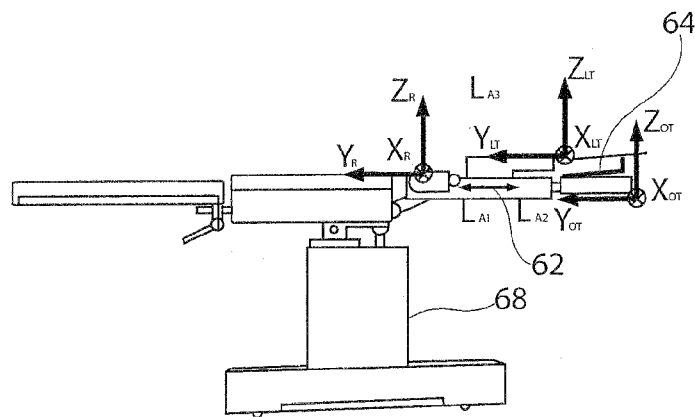
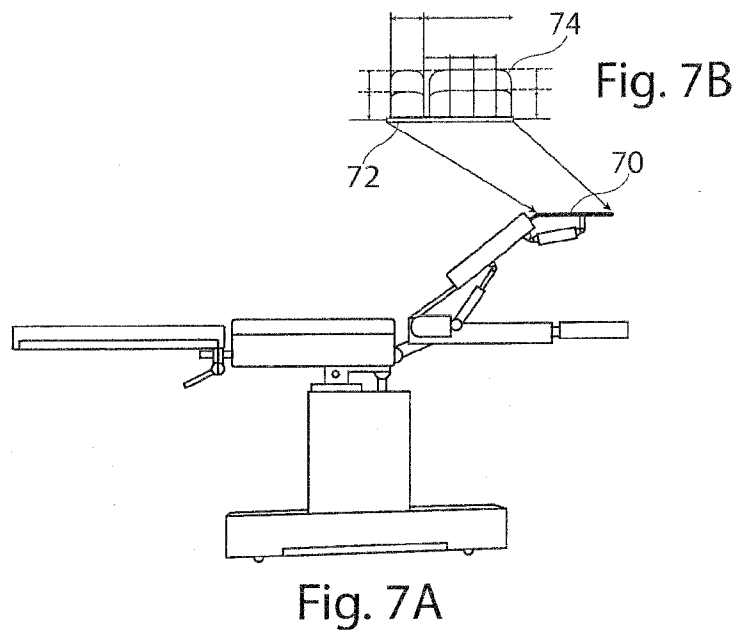


Fig. 6

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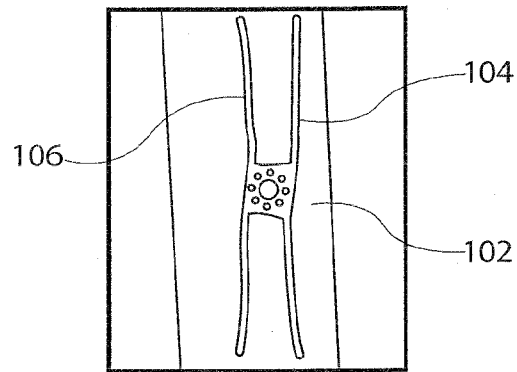


Fig. 8
Prior Art

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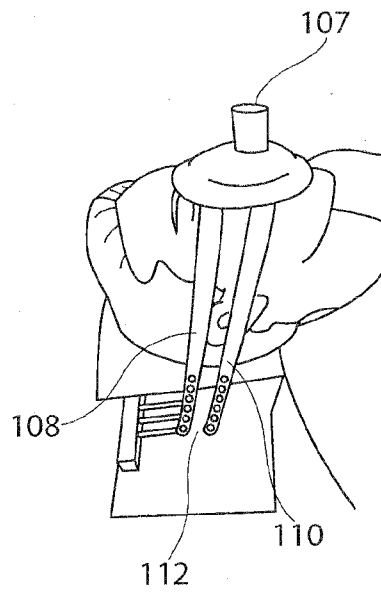


Fig. 9B

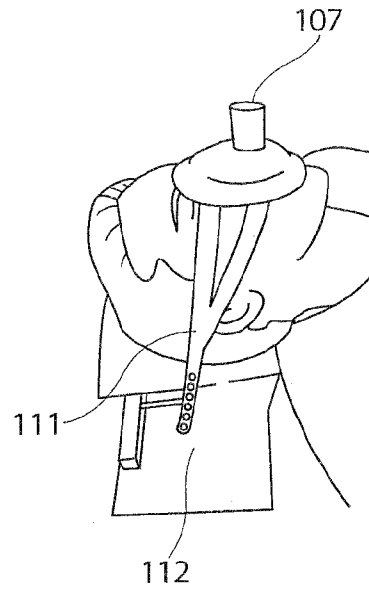


Fig. 9A

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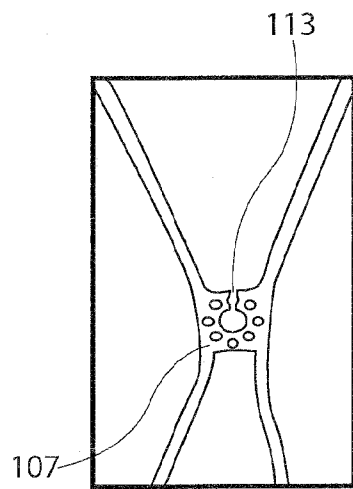


Fig. 10

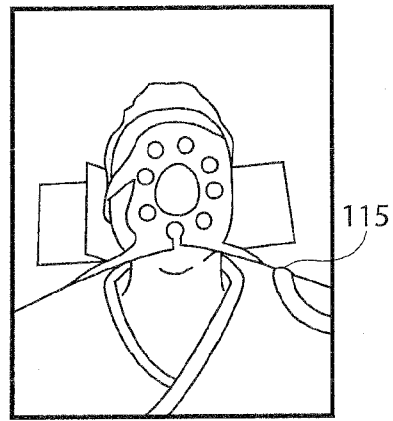


Fig. 11

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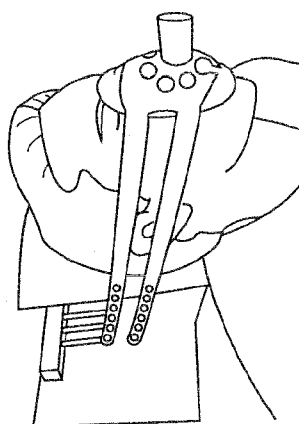


Fig. 12

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Fig. 13

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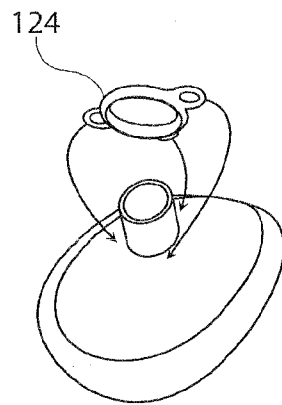


Fig. 14A

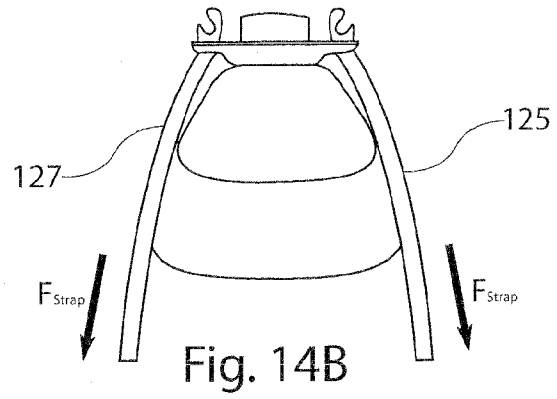


Fig. 14B

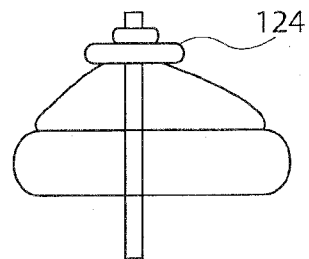


Fig. 14C

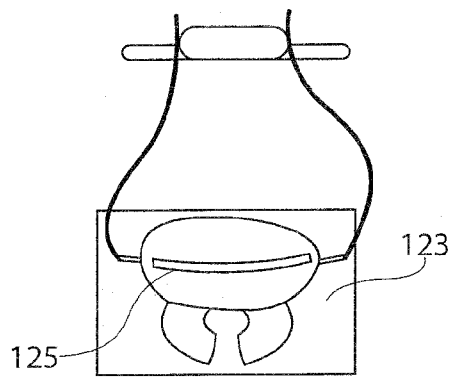
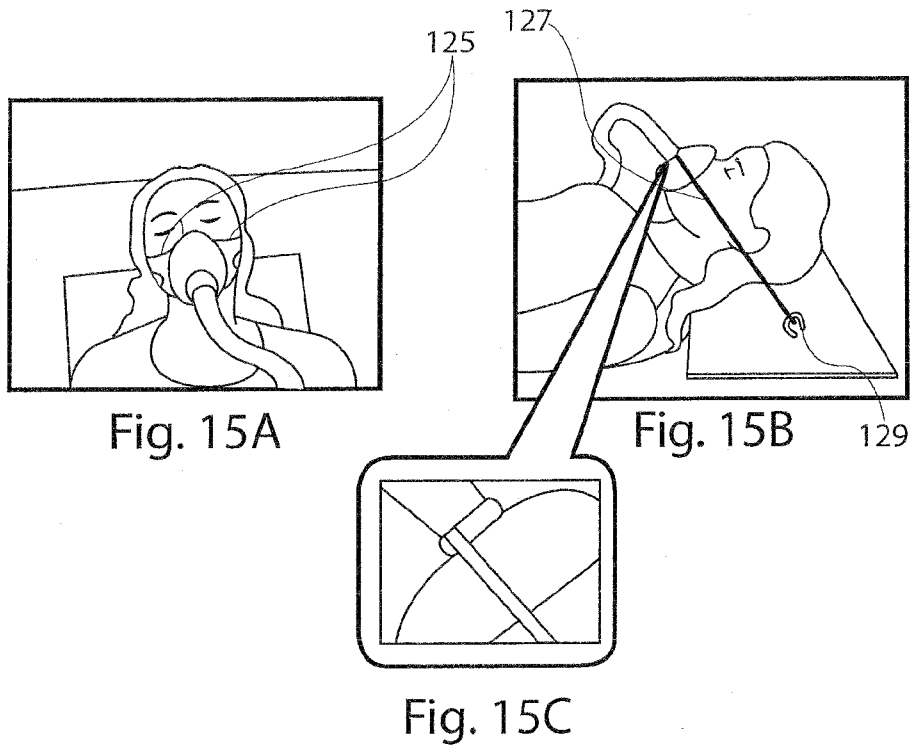


Fig. 14D

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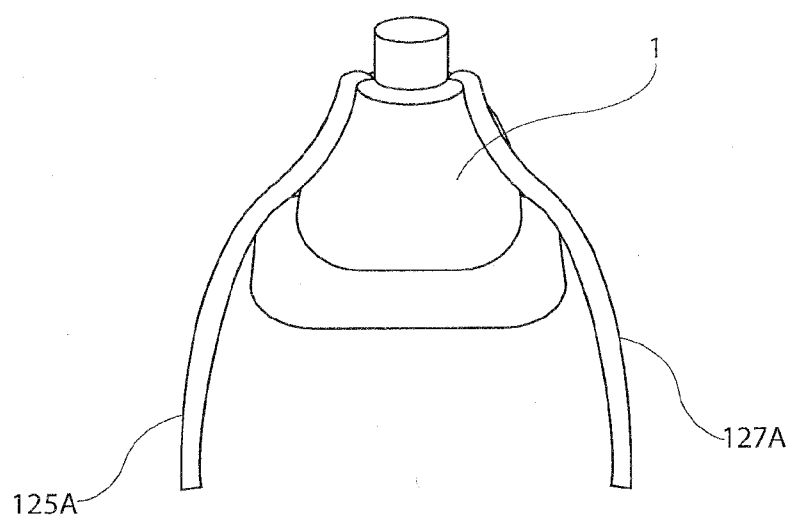


Fig. 15D

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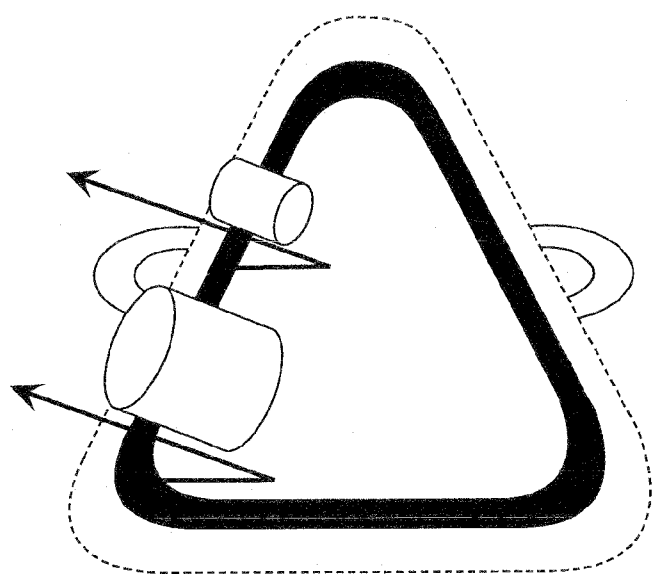


Fig. 15E

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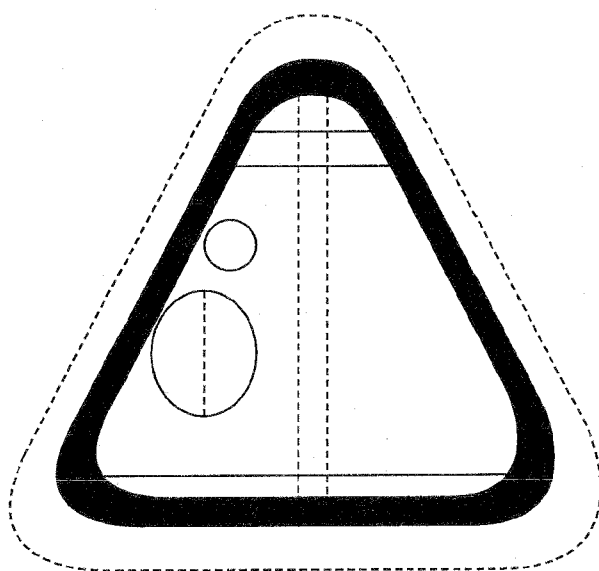


Fig. 15F

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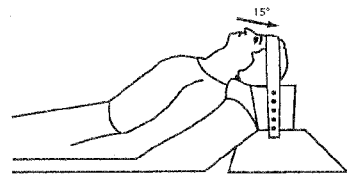


Fig. 16D

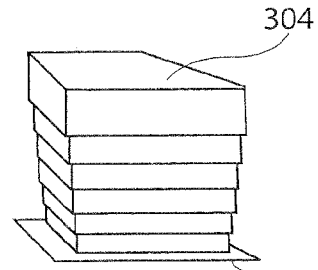


Fig. 16A

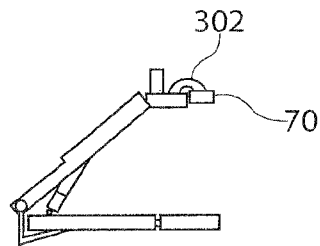


Fig. 16C

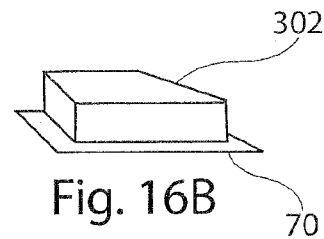


Fig. 16B

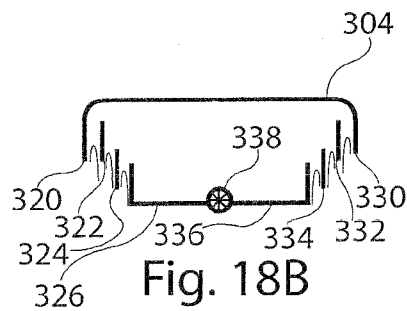


Fig. 18B



Fig. 18A

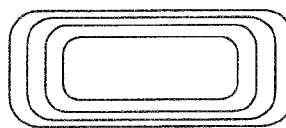


Fig. 17A

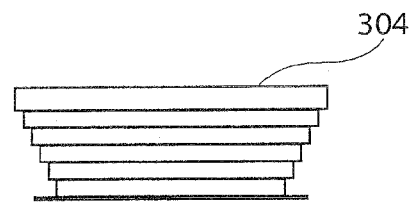


Fig. 17D

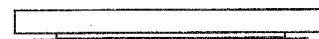


Fig. 17C



Fig. 17B

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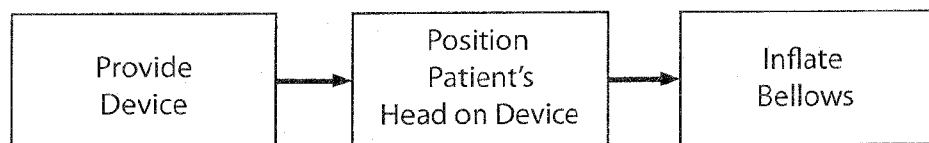


Fig. 19

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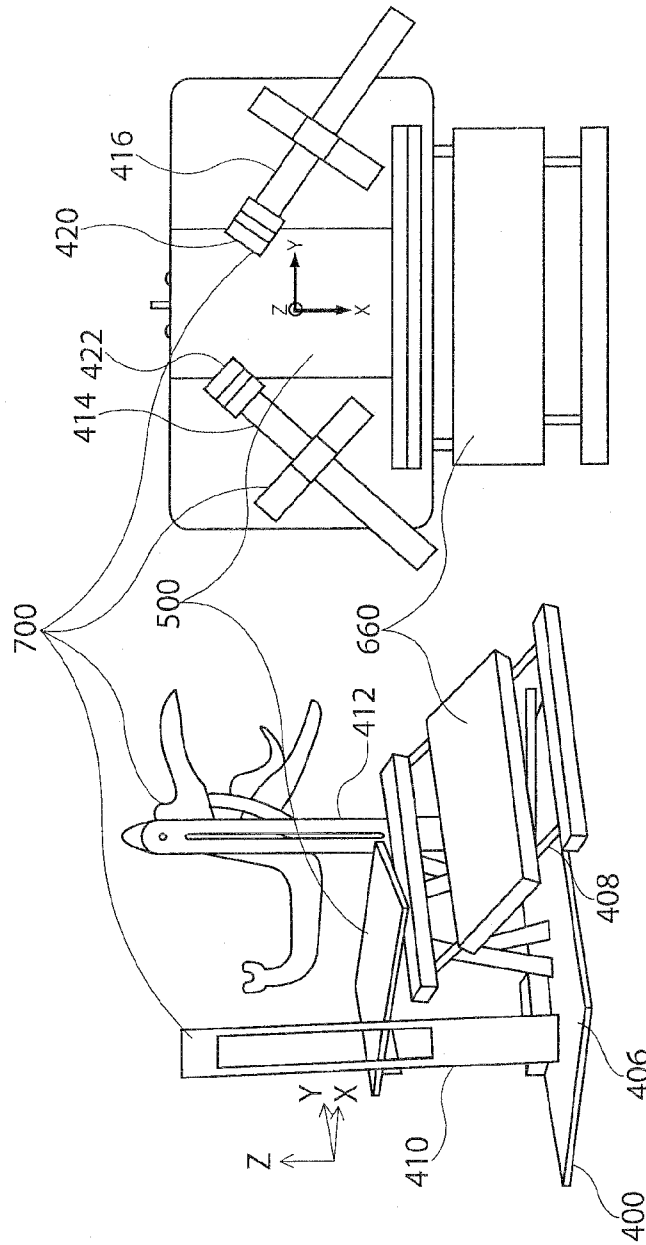


Fig. 20B

Fig. 20A

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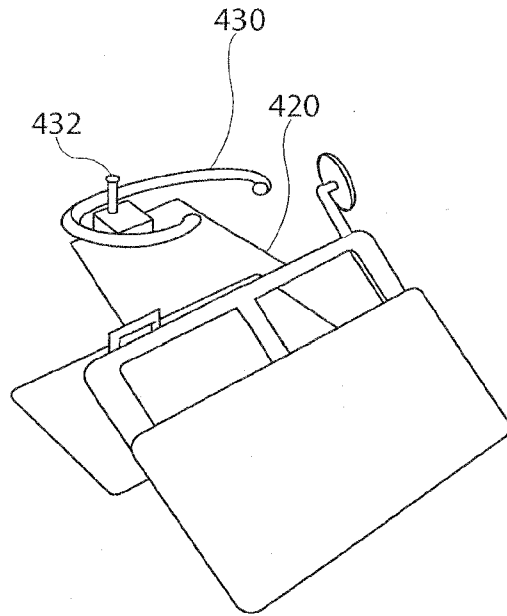


Fig. 21A

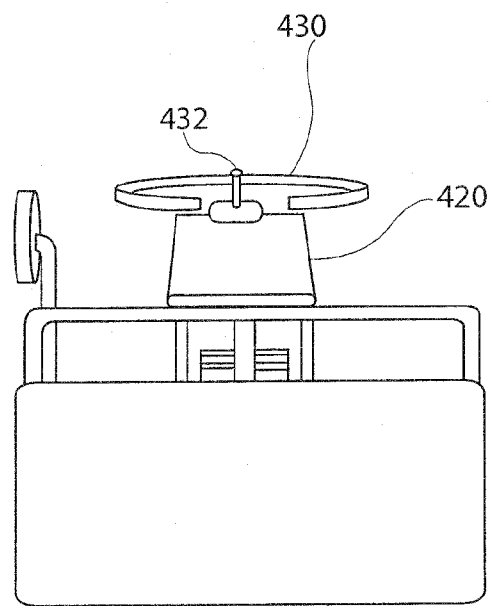
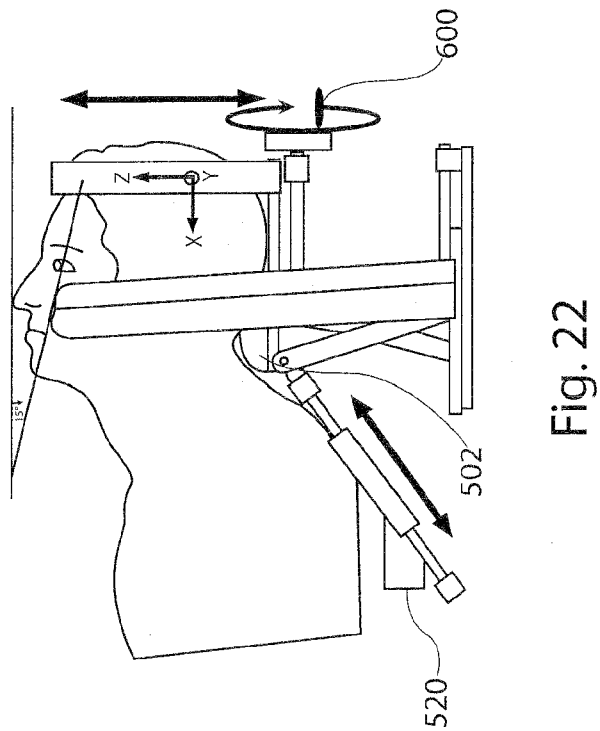
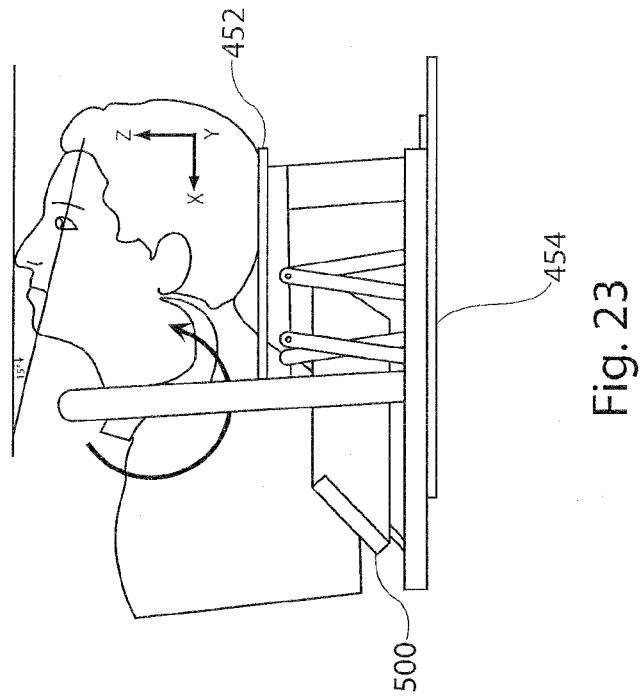


Fig. 21B

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Figures 24A-24D, Steps 4 & 5

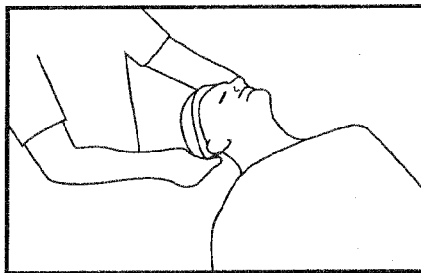


Fig. 24C

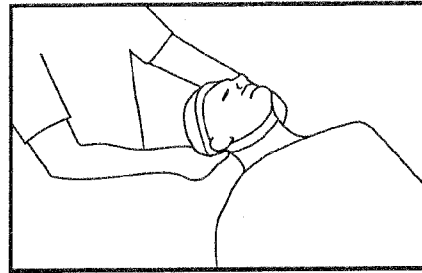


Fig. 24A

Step 4

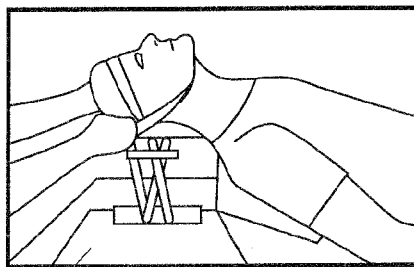


Fig. 24D

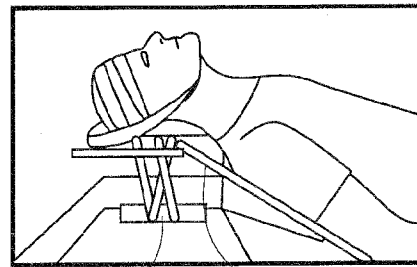


Fig. 24B

Step 5

450

454

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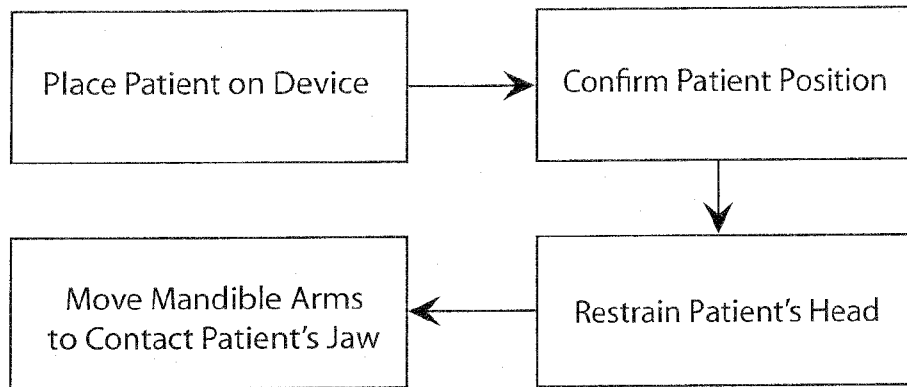


Fig. 25

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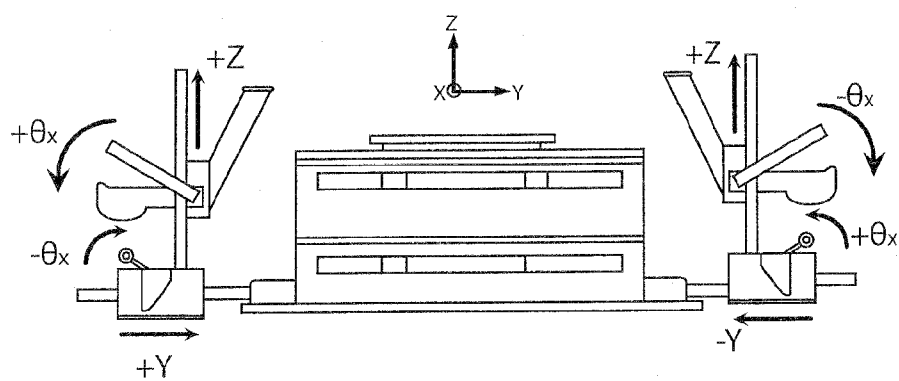


Fig. 26

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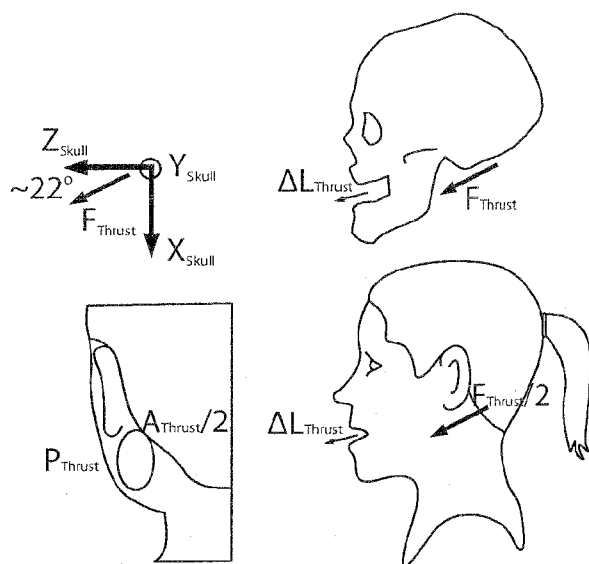


Fig. 27, Mandible Jaw Thrust
Maneuver Vector Definitions
PRIOR ART

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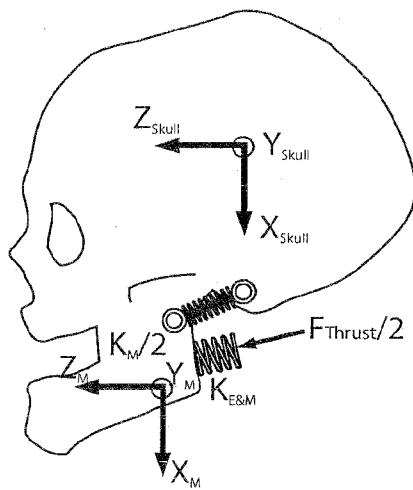


Fig. 28A

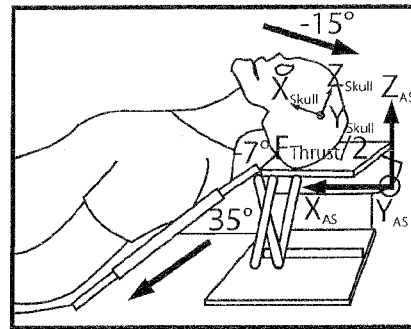


Fig. 28C

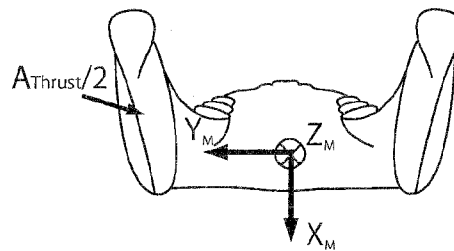


Fig. 28B

Fig. 28A-28C Mandible Structural Model

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Figures 29A-29C, Biomechanically Accurate Mandible Model

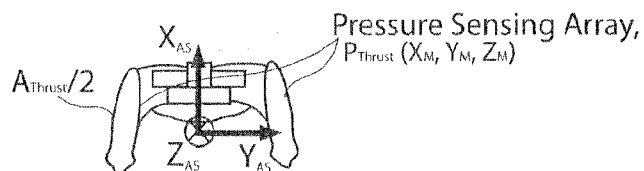
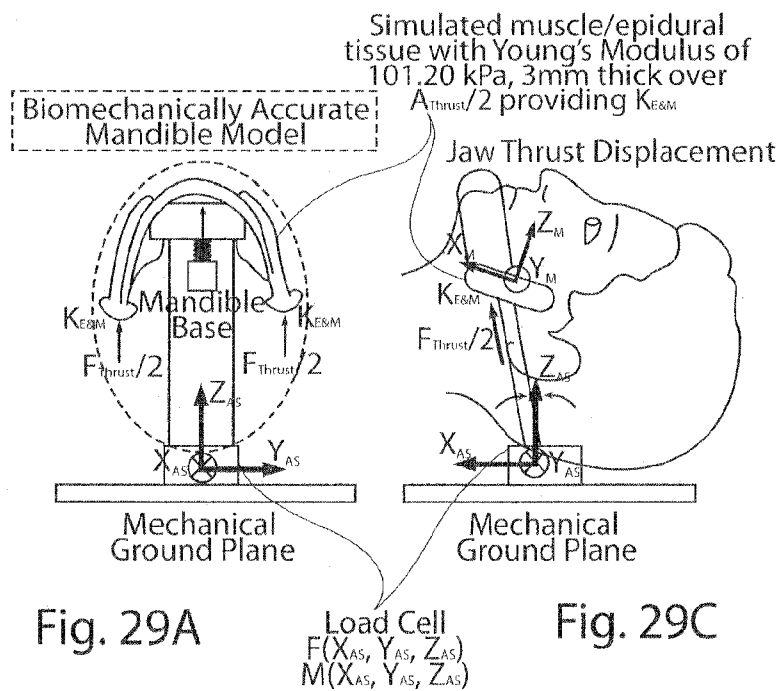


Fig. 29B

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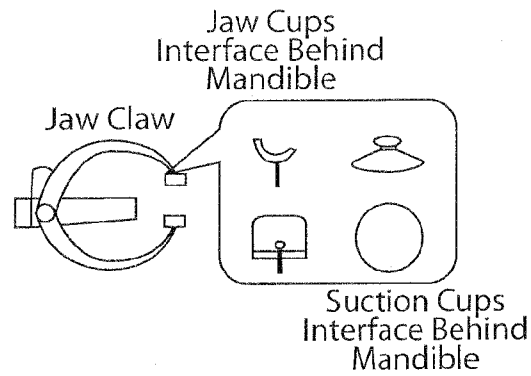


Fig. 30A

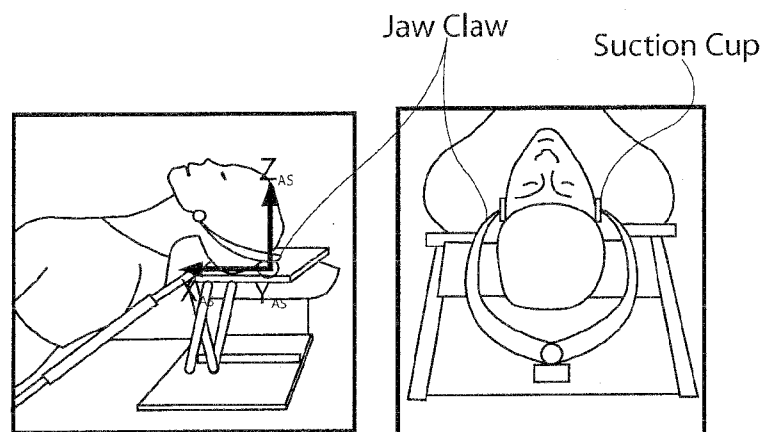
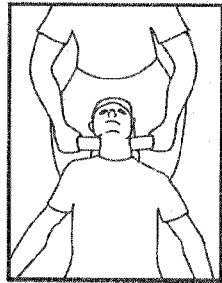


Fig. 30B

Figures 30A-30B Jaw Claw with
Jaw Cup or Suction Cup

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Patient on Supine Assembly



Proceed to engage the Left and Right Jaw thrust shelf to extend the mandible by the required amount by squeezing the Jaw Thrust Grip, causing it to rotate about the X axis, resulting in a translation in the positive Z direction until the Jaw is properly extended and the Airway is open

Fig. 31A

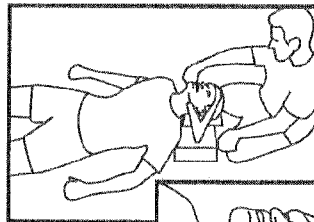
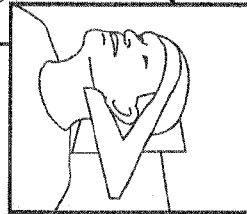


Fig. 31B



Jaw is properly extended as a result of translating the Jaw Thrust Subassembly along the Z axis

Fig. 31C

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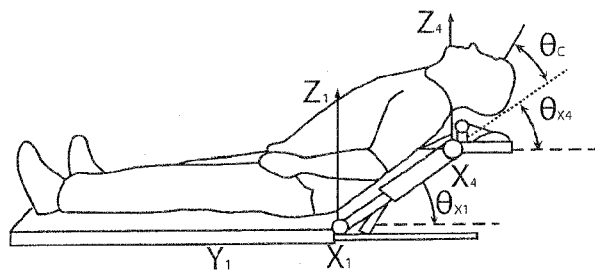
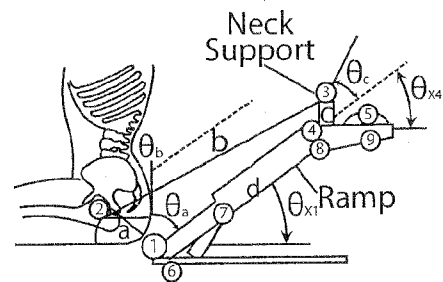
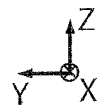


Fig. 32C



4-Bar Linkage (a,b,c,d)
Inclined Position, Angle θ_{x1}
Head Rest Rotated by $\theta_{x4} = -\theta_{x1}$
To maintain head support parallel to Y axis

Fig. 32D

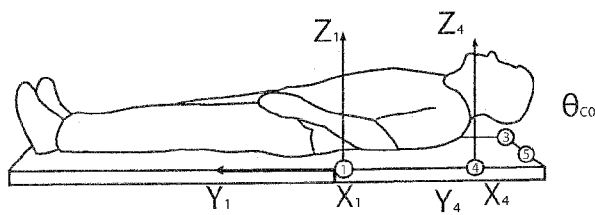
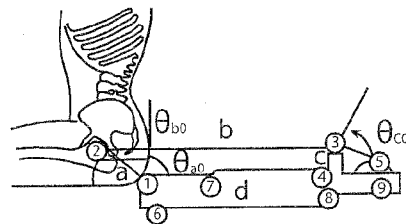


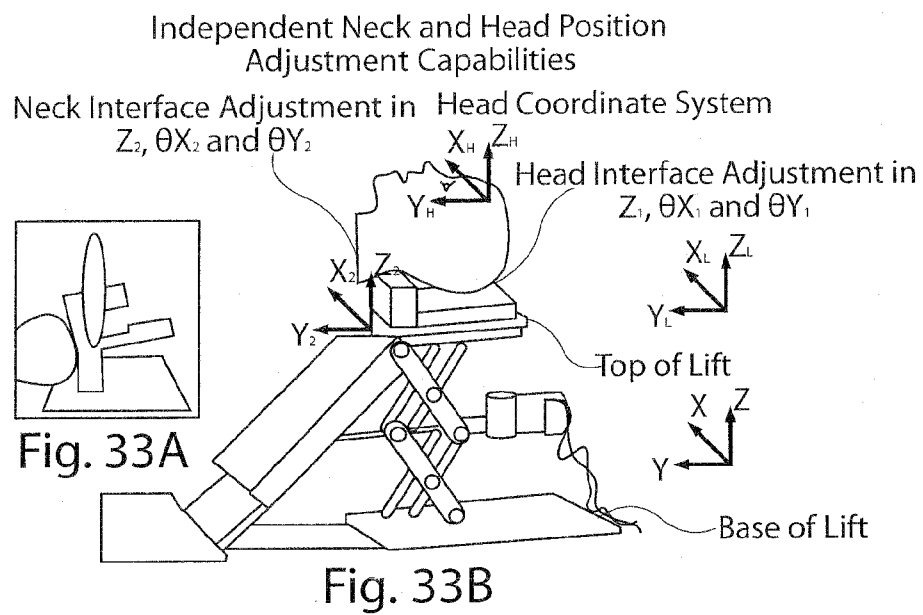
Fig. 32A



4-Bar Linkage (a,b,c,d)
Reclined Position

Fig. 32B

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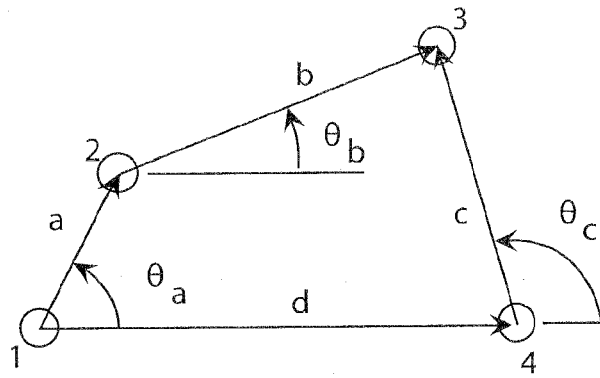


Fig. 34

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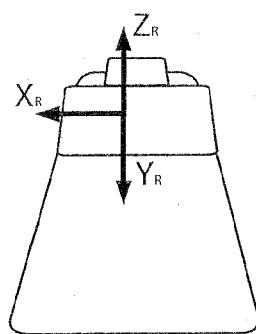


Fig. 35B

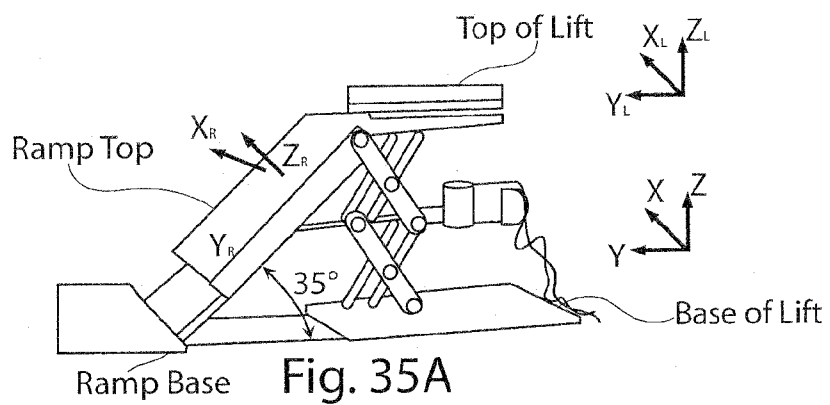


Fig. 35A

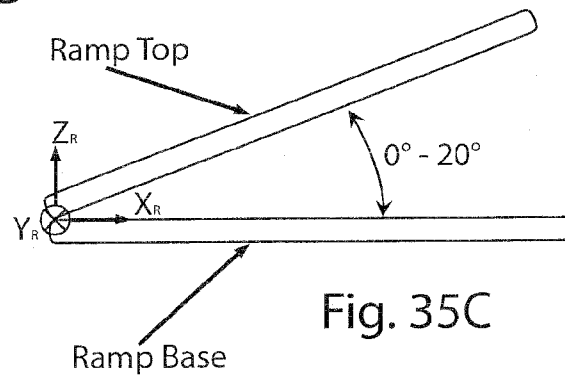
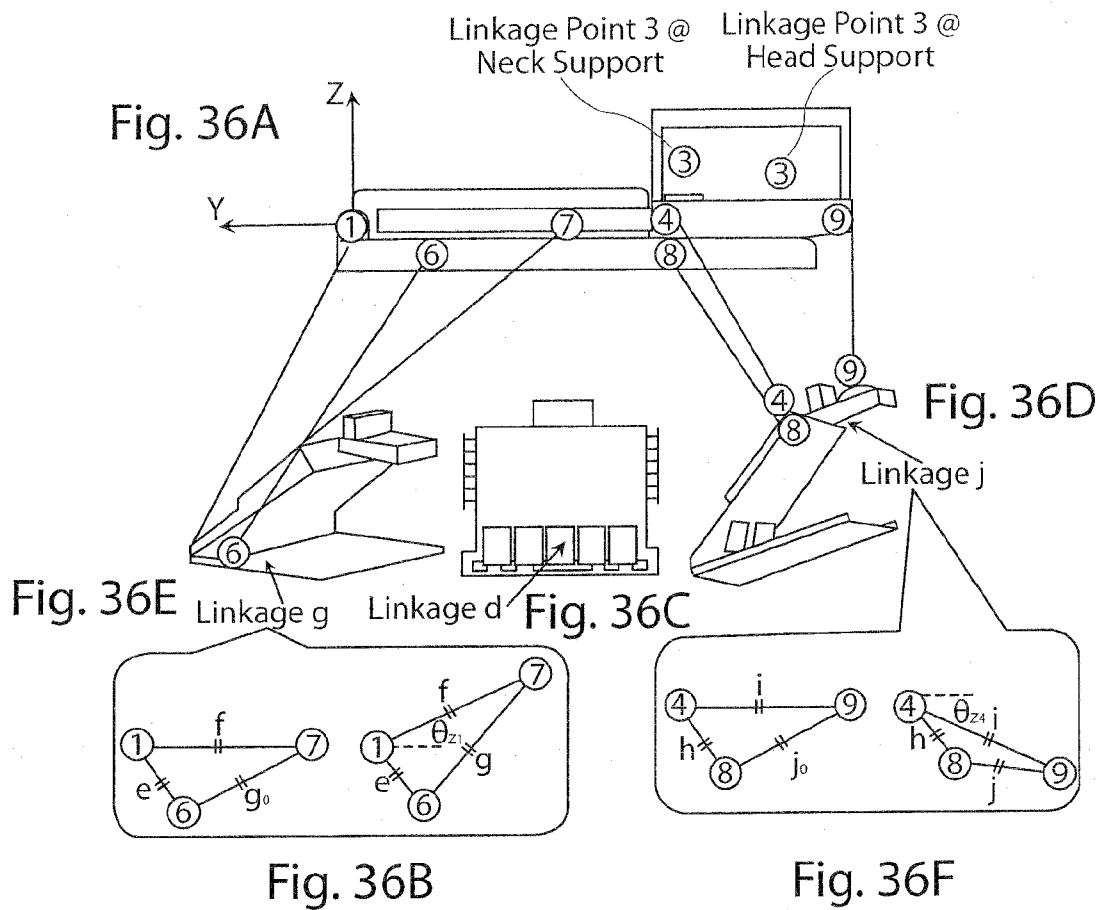


Fig. 35C

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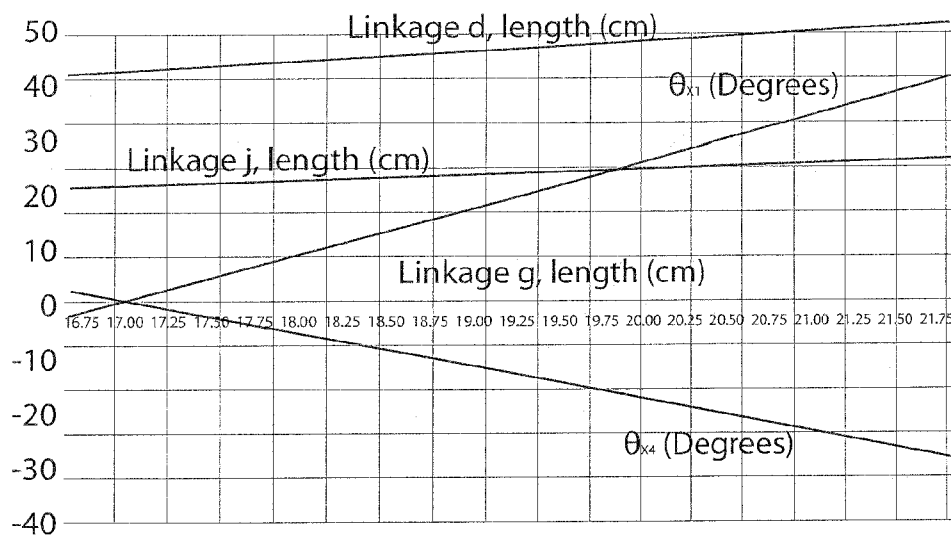


Figure 37
Linkage Lengths d and j, Ramp Angle θ_{x1}
and Head Support Angle θ_{x4}

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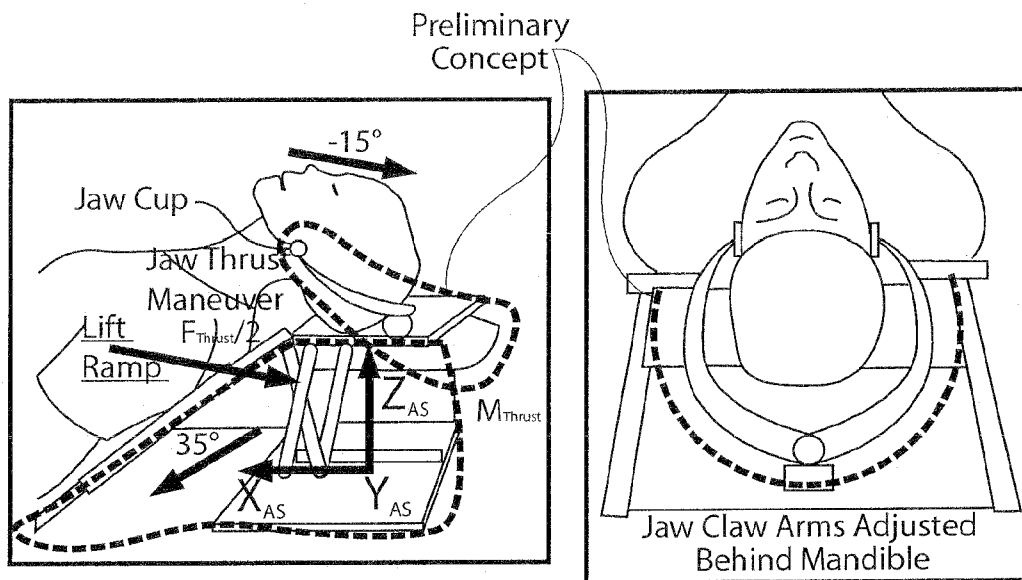


Figure 38

Air Sniffing Position and Chin Elevation

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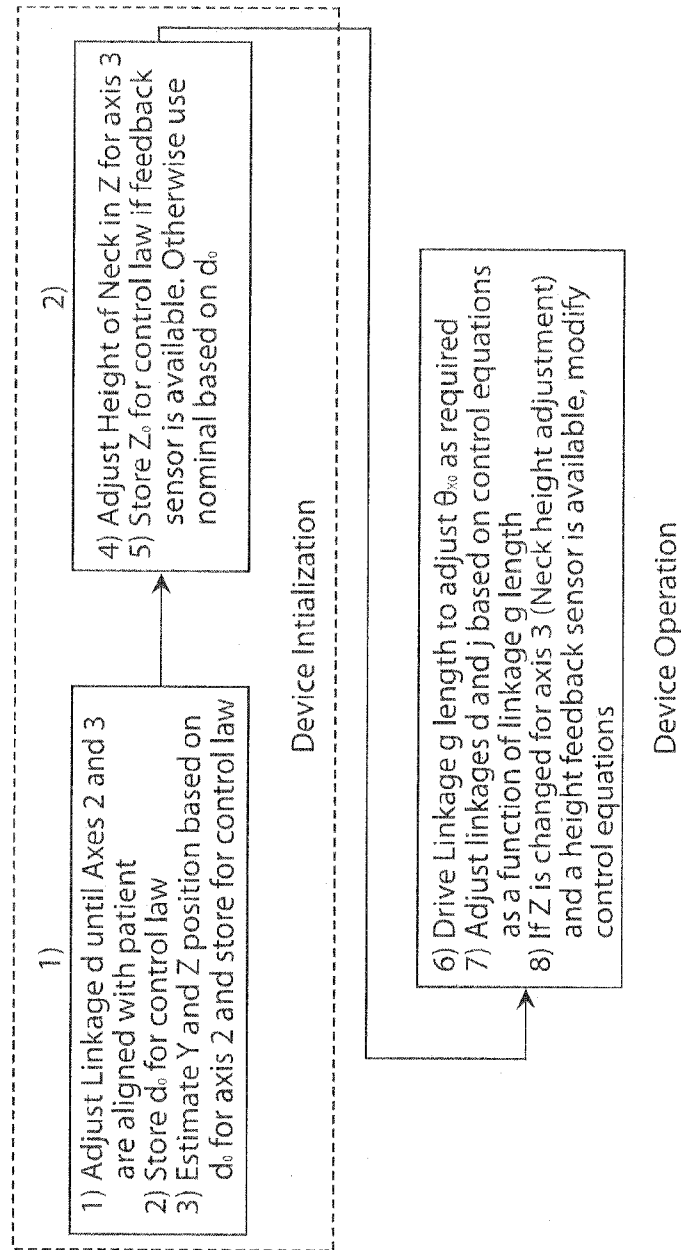
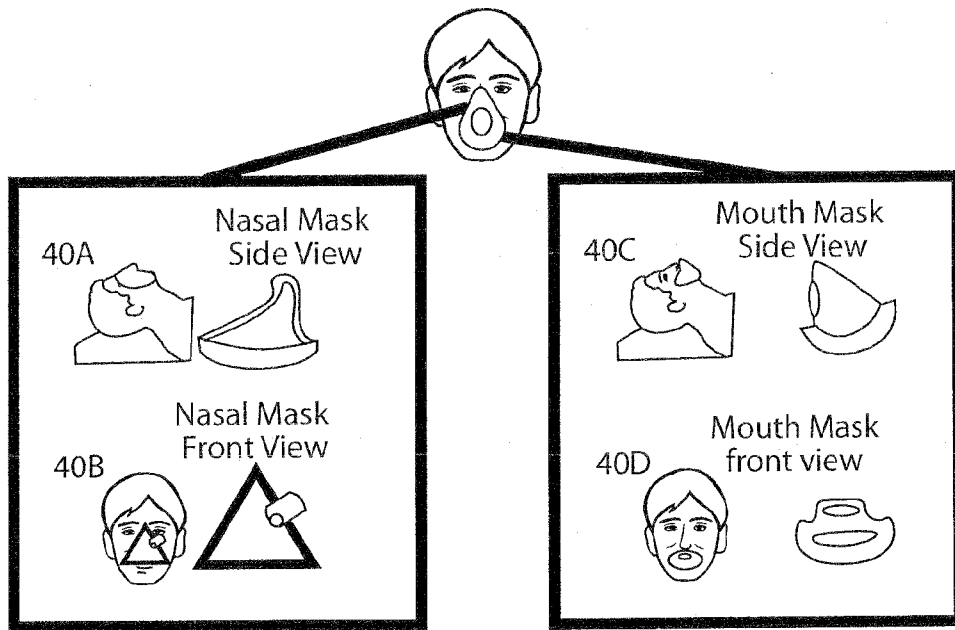


Fig. 39

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Combined Nasal and Mouth Ventilation Mask

Fig. 40

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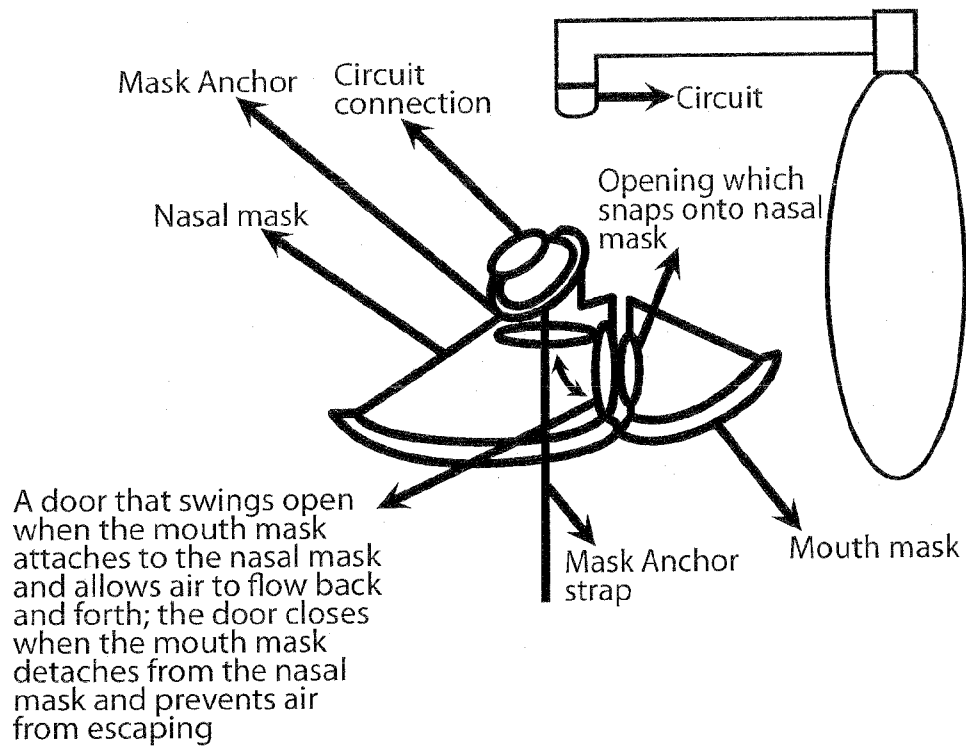


Figure 41

Combined Nasal and Mouth Ventilation Mask
 Cross Section Secured by the Mask
 Anchor and Connected to a Ventilation Circuit

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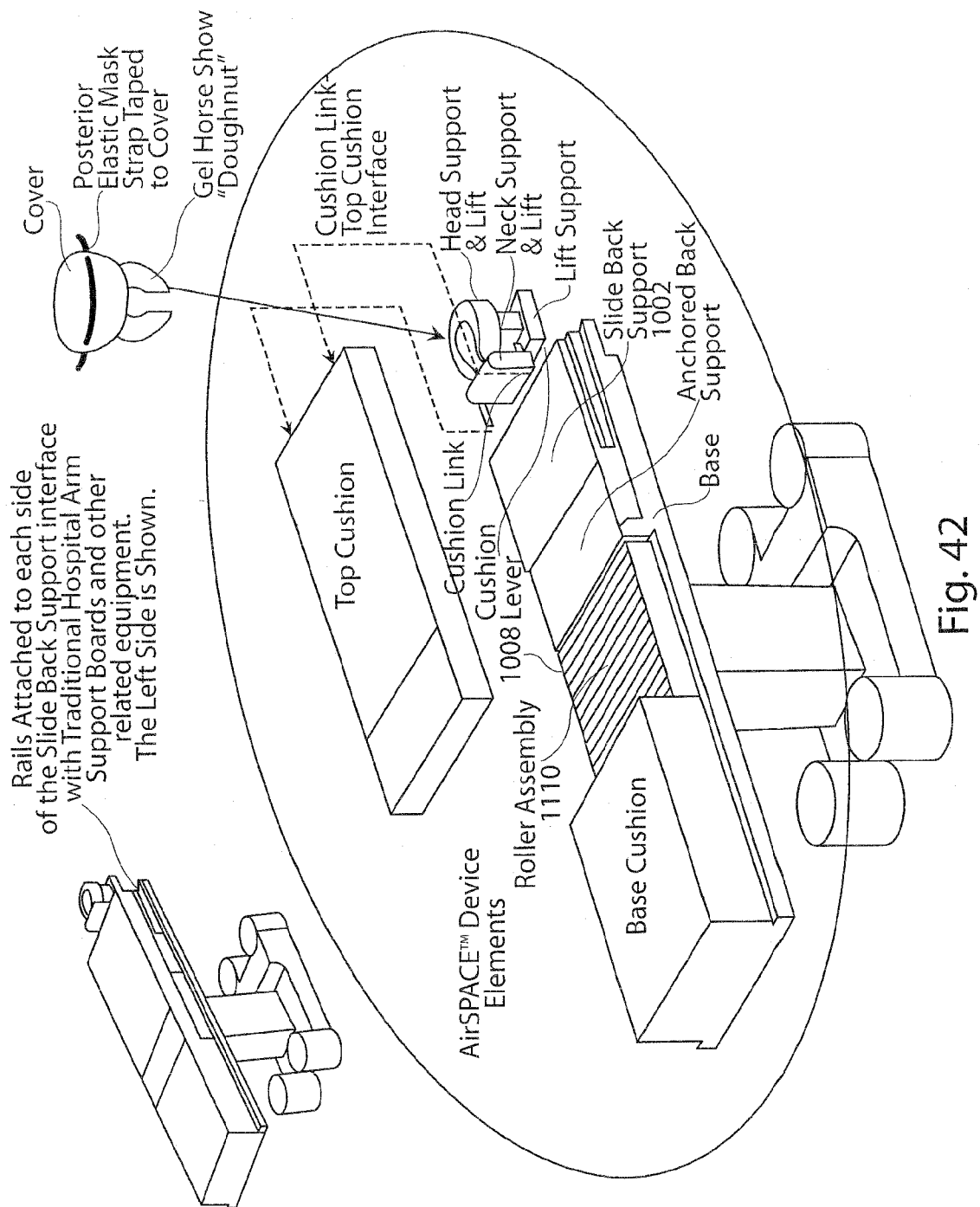


Fig. 42

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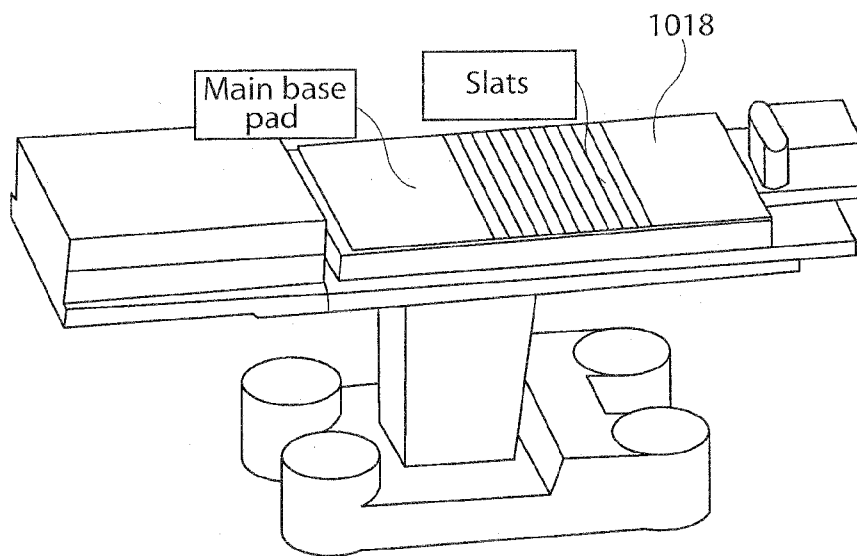


Figure 43

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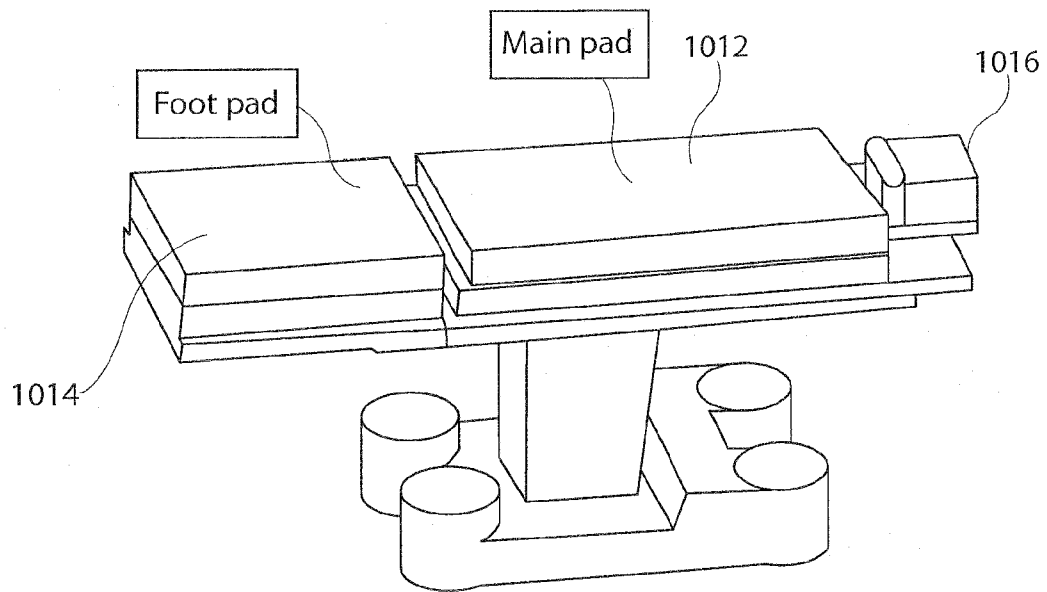


Figure 44

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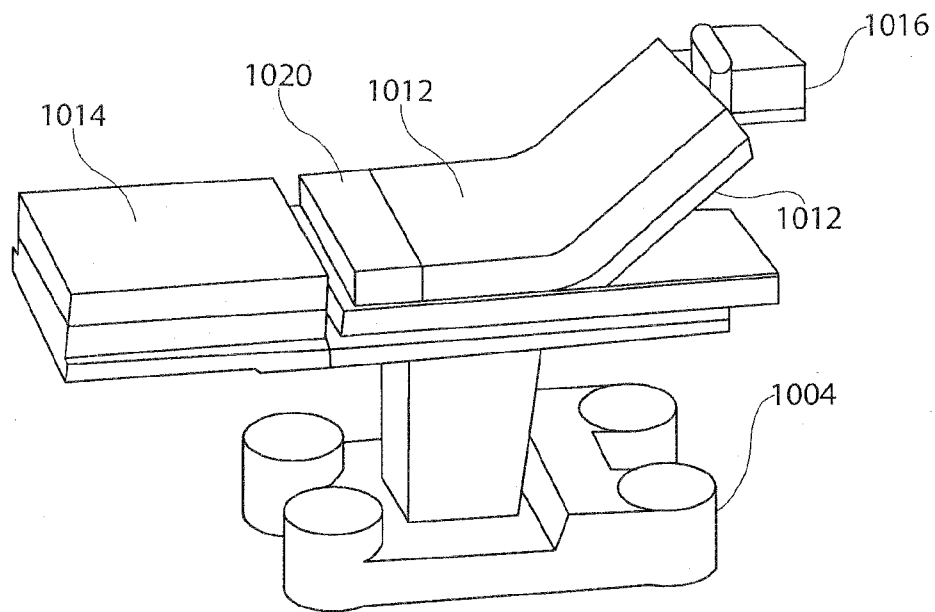


Figure 45

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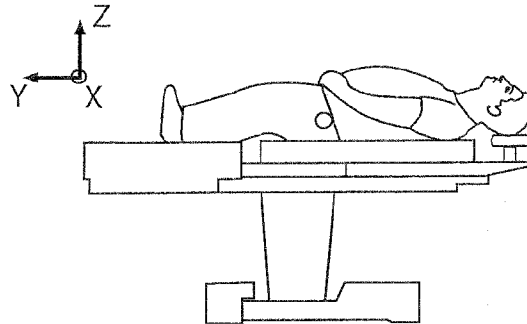


Fig. 46A

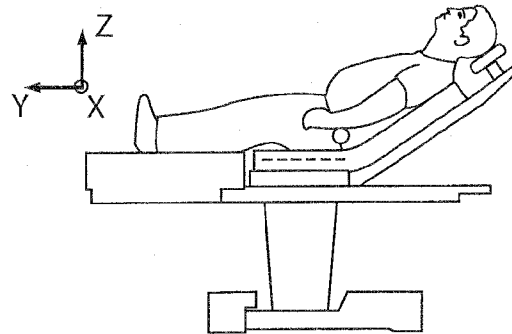


Fig. 46B

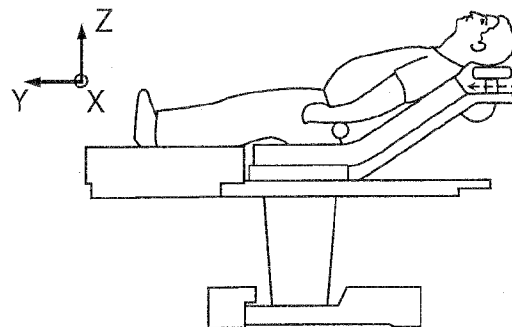


Fig. 46C

(43) International Publication Date
31 December 2014 (31.12.2014)

- (51) International Patent Classification:
A47B 7/00 (2006.01) *A62B 18/02* (2006.01)
- (21) International Application Number:
PCT/US2014/044934
- (22) International Filing Date:
30 June 2014 (30.06.2014)
- (25) Filing Language: English
- (26) Publication Language: English
- (30) Priority Data:
- | | | |
|------------|--------------------------------|----|
| 61/840,980 | 28 June 2013 (28.06.2013) | US |
| 61/840,997 | 28 June 2013 (28.06.2013) | US |
| 61/876,093 | 10 September 2013 (10.09.2013) | US |
| 61/907,938 | 22 November 2013 (22.11.2013) | US |
| 61/910,648 | 2 December 2013 (02.12.2013) | US |
| 61/924,114 | 6 January 2014 (06.01.2014) | US |
| 61/925,089 | 8 January 2014 (08.01.2014) | US |
| 61/941,206 | 18 February 2014 (18.02.2014) | US |
| 61/979,912 | 15 April 2014 (15.04.2014) | US |
| 61/983,941 | 24 April 2014 (24.04.2014) | US |
| 62/007,802 | 4 June 2014 (04.06.2014) | US |
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(81) Designated States (unless otherwise indicated, for every kind of national protection available): AE, AG, AL, AM, AO, AT, AU, AZ, BA, BB, BG, BH, BN, BR, BW, BY, BZ, CA, CH, CL, CN, CO, CR, CU, CZ, DE, DK, DM, DO, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN, HR, HU, ID, IL, IN, IR, IS, JP, KE, KG, KN, KP, KR, KZ, LA, LC, LK, LR, LS, LT, LU, LY, MA, MD, ME, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM, PA, PE, PG, PH, PL, PT, QA, RO, RS, RU, RW, SA, SC, SD, SE, SG, SK, SL, SM, ST, SV, SY, TH, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, ZA, ZM, ZW.

(84) Designated States (unless otherwise indicated, for every kind of regional protection available): ARIPO (BW, GH,

[Continued on next page]

(54) Title: POSITIONING DEVICE AND METHOD FOR USE WITH A PATIENT UNDER ANESTHESIA

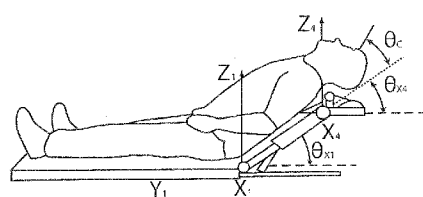
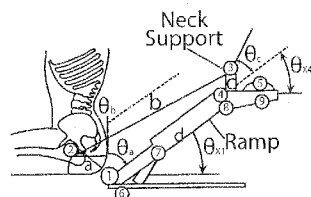


Fig. 32C



4-Bar Linkage (a,b,c,d)
Inclined Position, Angle θ_{x1}
Head Rest Rotated by $\theta_{xc} = -\theta_{x1}$
To maintain head support parallel to Y axis

Fig. 32D

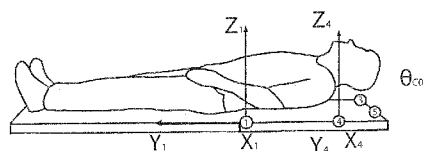
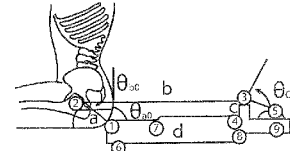


Fig. 32A



4-Bar Linkage (a,b,c,d)
Reclined Position

Fig. 32B

(57) Abstract: An apparatus for supporting the head and neck for airway management and to facilitate the maintenance of a patent airway under anesthesia, for unconscious patients, and for any circumstance requiring a patent airway while the patient is lying on her side. The apparatus includes a head supporting surface, an adjustable neck supporting surface, and two adjustable jaw support arms to protrude the jaw forward and maintain ventilation while the patient is lying on either of his/her sides.



GM, KE, LR, LS, MW, MZ, NA, RW, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, RU, TJ, TM), European (AL, AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HR, HU, IE, IS, IT, LT, LU, LV, MC, MK, MT, NL, NO, PL, PT, RO, RS, SE, SI, SK, SM, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, KM, ML, MR, NE, SN, TD, TG).

Published:

— *with international search report (Art. 21(3))*

(88) Date of publication of the international search report:

29 October 2015

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US 14/44934

Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:

2. ☐ Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:
This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1. In order for all inventions to be examined, the appropriate additional examination fees must be paid.

Group I: Claims 1, 20-22 directed to a device for positioning a patient.
Group II: Claims 3, 41 directed to a measuring device.
Group III: Claim 4, 42 directed to a measuring device.
Group IV: Claims 2, 5-6 directed to a method for positioning a patient.
Group V: Claims 7-8 directed to a device for positioning a patient in a sniff position
Group VI: Claims 9-19 directed to a mask.
Group VII: Claims 23, 25, 43 directed to a head restraint
Group VIII: Claims 24, 40, 50 directed to a mandible arm

----Continued on Supplemental Page----

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying additional fees, this Authority did not invite payment of additional fees.
3. ☒ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:
1, 9-22
4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.
- ☐ The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.
- ☐ No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US 14/44934

A. CLASSIFICATION OF SUBJECT MATTER

IPC(8) - A47B 7/00; A62B 18/02 (2014.01)

CPC - A61G 13/12; A61M 16/06

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)
CPC: A61G 13/12; A61M 16/06 IPC(8): A47B 7/00; A62B 18/02 (2014.01)Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched
USPC: 5/624; 128/205.25, 206.21, 206.28, 207.13, 204.18 (keyword limited; terms below)

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

PatBase; Google Patents; Google

Search Terms Used: combin*, oral, nasal, mask%, patient, interface, detach*, separa*, modular, convert*, combin*, cpap, patient, rest, head, support, position*, adjust*, length, bellow%, pneumatic, inflat*, neck, back, bladder%

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X ----- Y	US 2012/0144588 A1 (HEIMBROCK et al) 14 June 2012 (14.06.2012) fig 3-5, 6, 8, para [0033], [0038]-[0039]	1, 20 ----- 21-22
X ----- Y	US 5,560,354 A (BERTHON-JONES et al) 01 October 1996 (01.10.1996) fig 2, 4b, col 2, ln 18-29, col 5, ln 37-41, col 6, ln 25-32, col 6, ln 65 to col 7, ln 10	9-17, 19 ----- 18
Y	US 2009/0133696 A1 (REMMERS et al) 28 May 2009 (28.05.2009) abstract	18
Y	US 2006/0168730 A1 (MENKEDICK et al) 03 August 2006 (03.08.2006) fig 112, 113, para [0523]	21
Y	US 6,459,923 B1 (PLEWES et al) 01 October 2002 (01.10.2002) fig 2, 4	22

☐ Further documents are listed in the continuation of Box C.

* Special categories of cited documents:

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier application or patent but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search

18 December 2014 (18.12.2014)

Date of mailing of the international search report

02 JAN 2015

Name and mailing address of the ISA/US

Mail Stop PCT, Attn: ISA/US, Commissioner for Patents
P.O. Box 1450, Alexandria, Virginia 22313-1450

Facsimile No. 571-273-3201

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PCT Helpdesk: 571-272-4300
PCT OSP: 571-272-7774

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US 14/44934

Continuation of Box III: Observations where unity of invention is lacking

Group IX: Claim 26 directed to a back restraint.
 Group X: Claim 27 directed to a patient support.
 Group XI: Claims 28-32 directed to an apparatus and a method of using the apparatus.
 Group XII: Claim 33-34 directed to an apparatus for providing ventilation to a patient lying supine on a support
 Group XIII: Claims 35-37 directed to a device for positioning a patient and a method of using the apparatus.
 Group XIV: Claims 38-39, 44-49 directed to a positioning system and a method of using the positioning system.

The inventions listed as Groups I-XIV do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

SPECIAL TECHNICAL FEATURES

The invention of Group I includes the special technical feature of an adjustable ramp, not required by the claims of Groups II-XIII.

The invention of Group II includes the special technical feature of a side with four arm extensions, not required by the claims of Groups I or III-XIV.

The invention of Group III includes the special technical feature of a triangular side with three arm extensions, not required by the claims of Groups I-II or IV-XIV.

The invention of Group IV includes the special technical feature of a method for positioning a patient comprising the steps of: placing the patient's head, neck, upper and middle back, and shoulders substantially on the base; using an adjustable device to place the patient's head, neck, upper and middle back, and shoulders in a desired position; using a measuring device to confirm the desired position; moving the first mandible arm to contact the patient's jaw; moving the second mandible arm to contact the patient's jaw; wherein the contact of the first mandible arm and the second mandible arm provides sufficient force to substantially maintain the patient's head and/or jaw in a desired position, not required by the claims of Groups I-III, or V-XIV.

The invention of Group V includes the special technical feature of wherein as ramp incline is varied, head rest orientation remains parallel, substantially horizontal to the operating table, by changing the head rest angle by an opposite amount, not required by the claims of Groups I-IV, or VI-XIV.

The invention of Group VI includes the special technical feature of a first nasal inflatable or non-inflatable cushion, not required by the claims of Groups I-V, or VII-XIV.

The invention of Group VII includes the special technical feature of 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 patients head and attach to the opposite side of the first surface of the base, not required by the claims of Groups I-VI or VIII-XIV.

The invention of Group VIII includes the special technical feature of a mandible pad, wherein the mandible pad is flexible and pivotable, and wherein the mandible pad has a proximal side configured to attach to the curved portion and a distal side configured to contact a patient's jaw at least two of a ramus, a body, and an angle of the patient's jaw, not required by the claims of Groups I-VII or IX-XIV.

The invention of Group IX includes the special technical feature of a first proximal end that attaches to one side of the back board, which can then extend horizontally and come in contact with the patient's abdomen and attach to the opposite side of the back board, not required by the claims of Groups I-VIII or X-XIV.

The invention of Group X includes the special technical feature of a first side that is adjustable to be in contact the patient's back, and a second adjustable side that is adjustable to be in contact with the patient's ribs to prevent patient movement, not required by the claims of Groups I-IX or XI-XIV.

The invention of Group XI includes the special technical feature of an anesthesia mask strap, not required by the claims of Groups I-X or XII-XIV.

The invention of Group XI includes the special technical feature of a mask anchor ring over the ventilation mask, not required by the claims of Groups I-X or XII-XIV.

The invention of Group XIII includes the special technical feature of a sa carriage having a first surface that supports the patients in an inclined position, and is adjustable in the Z-axis, not required by the claims of Groups I-XII, XIV.

The invention of Group XIV includes the special technical feature of a second mandible arm extending from a second vertically adjusted portion of the second support, wherein the second vertically adjusted portion is lockable in the z axis to adjust the second mandible arm with respect to the z axis, and wherein the second mandible arm is positionable to be in contact with the patient's jaw, not required by the claims of Groups I-XIII.

-----Continued on Supplemental Page-----

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US 14/44934

Continuation of Box III: Observations where unity of invention is lacking

COMMON TECHNICAL FEATURES

Groups I and IV share the common technical features of claim 1. However, these shared technical feature do not represent a contribution over prior art as being anticipated by US 2012/0144588 A1 to Heimbrock, et al. (hereinafter 'Heimbrock').

Heimbrock discloses a device for positioning a patient (abstract), comprising:

a base (14, fig 1);

a ramp subassembly (20, 98, fig 5 shows portion of 98 inclined) pivotally mounted at a proximal end to the base (at 96, fig 3) for supporting the upper back, middle back, and shoulders of the patient (intended use), said ramp subassembly being adjustable in length and angle relative to the base (fig 3-5, para [0033]);

a head support subassembly (78, para [0038]) pivotally mounted to a distal end of the ramp subassembly (subassembly 78 is shown pivoting and sliding along rod connected to ramp subassembly, fig 8), said head support subassembly being adjustable in angle relative to the ramp subassembly (fig 8); and

a pneumatic or mechanical jack, or an expandable bellows (40), supported on the head support subassembly for independently raising the patient's head relative to the head support subassembly (fig 8, para [0039]).

Groups I and V share the common technical features of an adjustable ramp and headrest. However, these shared technical feature do not represent a contribution over prior art as being anticipated by Heimbrock, which discloses a ramp (98, fig 5) and a headrest (78, fig 8, para [0038]).

Groups VIII and XIV share the common technical feature of a mandible arm. However, this shared technical feature does not represent a contribution over prior art as being anticipated by US 2011/0253150 A1 to King, et al. (hereinafter 'King'), which discloses a mandible arm (120, fig 1, para [0027]).

Groups I and XI share the common technical feature of a base. However, this shared technical feature does not represent a contribution over prior art as being anticipated by King, which discloses a base (10, fig 1, para [0027]).

Groups I and XIII share the common technical features of a carriage having a first surface that supports the patients in an inclined position, and a second surface that supports the patient's head and neck. However, these shared technical features do not represent a contribution over the prior art as being anticipated by Heimbrock, which discloses a first surface (20, 98) that supports the patients in an inclined position (fig 5 shows portion of 98 in inclined position), and a second surface (78, fig 8) that supports the patient's head and neck (para [0038]).

Groups VI and XII share the common technical feature of a ventilation mask. However, this shared technical feature does not represent a contribution over prior art as being anticipated by King, which teaches a ventilation mask (para [0031]).

As the common technical features were known in the art at the time of the invention, these cannot be considered special technical feature that would otherwise unify the groups.

Therefore, Groups I-XIV lack unity under PCT Rule 13 because they do not share a same or corresponding special technical feature.



(12) 发明专利申请

(10) 申请公布号 CN 105451603 A

(43) 申请公布日 2016. 03. 30

(21) 申请号 201480042735. 9

(22) 申请日 2014. 06. 30

(30) 优先权数据

61/840, 980 2013. 06. 28 US

61/840, 997 2013. 06. 28 US

61/876, 093 2013. 09. 10 US

61/907, 938 2013. 11. 22 US

61/910, 648 2013. 12. 02 US

61/924, 114 2014. 01. 06 US

61/925, 089 2014. 01. 08 US

61/941, 206 2014. 02. 18 US

61/979, 912 2014. 04. 15 US

61/983, 941 2014. 04. 24 US

62/007, 802 2014. 06. 04 US

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代理人 周蕾

(51) Int. Cl.

A47B 7/00(2006. 01)

A62B 18/02(2006. 01)

(85) PCT国际申请进入国家阶段日

2016. 01. 28

(86) PCT国际申请的申请数据

PCT/US2014/044934 2014. 06. 30

(87) PCT国际申请的公布数据

W02014/210606 EN 2014. 12. 31

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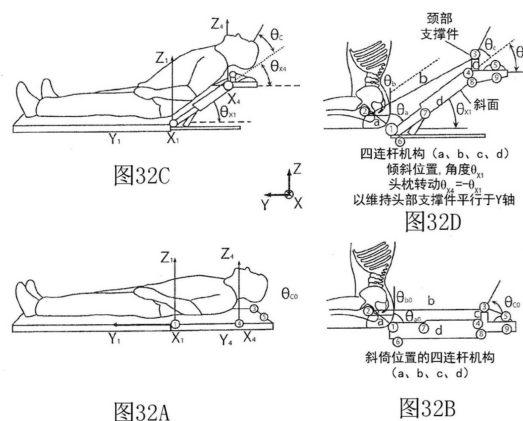
权利要求书13页 说明书39页 附图27页

(54) 发明名称

用于麻醉状态下的患者的定位装置和方法

(57) 摘要

一种用于支撑头部和颈部的装置用于管理呼吸道且当患者侧躺时,对于无意识的患者和对于需要呼吸道通畅的任何情况以促进维持在麻醉状态下呼吸道通畅。该装置包括:头部支撑表面,可调节的颈部支撑表面,以及两个可调节的下颌支撑臂以当患者侧躺时使下颌向前突出并维持畅通。



1. 用于定位患者的装置,包括:

基部;枢转地安装在基部的近端上的斜面组件,用于支撑患者的上背部、中间背部和肩部,所述斜面组件可调整长度和相对于基部的角度;

枢转地安装到斜面组件的远端上的头部支撑分组合件,所述头部支撑分组合件可调整相对于所述斜面组件的角度;以及

气动或机械千斤顶,或者可张开的风箱,支撑在头部支撑分组合件上用于独立地相对于头部支撑分组合件来提升患者的头部。

2. 用于定位患者以促进维持在麻醉状态下呼吸道通畅的方法,包括

提供权利要求1中所要求的装置;

将患者定位在该装置上;

调节斜面组件以支撑患者在所期望的倾斜位置上;

调节头部支撑分组合件以支撑患者头部和颈部在大致期望的嗅探位置上;以及

激活气动或机械千斤顶,或给可张开的风箱充气以相对于第二表面提升患者的头部到期望的嗅探位置。

3. 第一测量装置,用于权利要求1所述的装置,包括两个侧面:

具有四个臂伸出部分的第一刚性半圆柱形侧面,四个臂伸出部分的每一个位于四个角的每一个中,并且其每一个接触患者的颈部;

第二刚性侧面包括 35° 的斜面,其搁置测量装置用于确认 35° 的颈部弯曲角度,以实现所期望的位置。

4. 用于权利要求1所述的装置的第二测量装置,包括两个侧面:

具有三臂伸出部分的第一刚性三角形侧面,其中的每一个位于三个角的每一内,并且其每一个接触患者的头部;所述臂伸出部分各自沿z轴调节以实现所期望的位置;

第二刚性侧面包括 15° 的斜面,其搁置测量装置用于确认 15° 的头部伸展角度,以实现所期望的位置。

5. 用于定位患者的方法,包括以下步骤:

提供权利要求1所述的装置;

将患者的头部、颈部、上部和中间背部以及肩部基本放置在基部上;使用可调节的装置将患者的头部、颈部、上部和中间背部以及肩部放置在所期望的位置上;使用测量装置以确认所期望的位置;移动第一下颌骨臂接触患者的下颌;移动第二下颌骨臂接触患者的下颌;其中第一下颌骨臂和第二下颌骨臂的接触提供了足够的力以充分地维持患者的头部和/或下颌在所期望的位置上。

6. 根据权利要求5所述的方法,特征在于以下一个或多个特征:

(a) 其中对准所有三条轴线(口咽、喉、气管)用于气管插管的推荐视野;

(b) 其中通过使用千斤顶调整所述患者的头部相对于所述Z轴的高度;

(c) 其中该装置包括释放挤压的托下颌握把,并且包括在z方向上移动该托下颌握把的步骤;

(d) 包括颈部接口和头部接口,其独立地在一个或多个x、y和z位置上是可调节的,以及

(e) 其中可拆卸的第三倾斜侧面围绕每个y轴是可旋转调节的。

7. 用于定位患者在嗅位的装置,包括可调节的斜面 and 头枕,其中随着斜面的坡度改变,

通过改变相反量的头枕角度 θ_x ,头枕方向保持基本上横向地平行于手术台。

8. 根据权利要求7所述的装置,特征在于一个或多个下列特征:

(a) 其中调整角度是通过基于已知或估计的所有已知参数的几何形状的开环处理来完成的;

(b) 其中调整角度是通过闭环处理来完成的,其中当前角度是相对于初始角度测量的,并返回到所述初始角度;

(c) 其中调整是根据多个反馈传感器来完成的,包括但不限于:

(1) 利用倾角仪相对于重力测量角度;以及

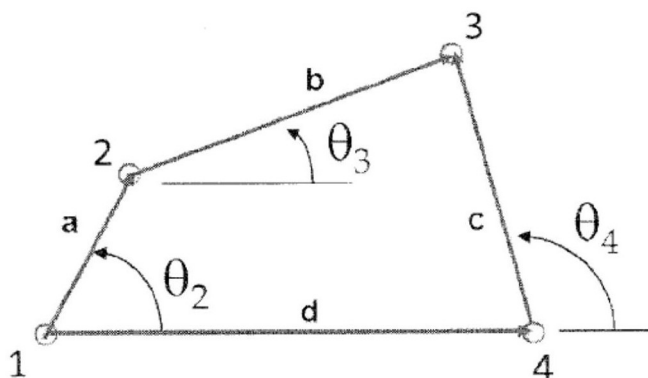
(2) 编码器。

(d) 其中随着斜面的坡度改变,和/或头枕的角度变为定位所述患者,改变斜面联动长度,以满足条件:固定的联动相对于它们各自的支撑表面的位置;

(e) 其中调整角度通过以下来完成:

(1) 基于已知或估计的所有参数的几何形状的开环处理,或通过

(2) 闭环处理,其中在通过传感器反馈驱动的闭环控制下测量一个或多个联动端点的相对位置并调节长度 d ,以将所测量的参数返回到关于下列几何形状的它们原来的位置,或通过



(a) 联动 a 的点2是相对于点1的位置;

(b) 联动 c 的点3是相对于点4的位置;

(c) 替换点3,其中患者的头部满足头枕;以及

(d) 反馈传感器监测所述点的相对位置,其定义了联动长度,包括选自下组的位置测量传感器:霍尔效应传感器、磁阻传感器、光学传感器,包括编码器、干涉仪和/或位置感测检测器以及位于点接口上的应力/应变/力/扭矩监测传感器,所述点接口是通过在闭环控制下调节联动长度 d 使这些参数最小化。

9. 一次性的麻醉鼻腔和口腔面罩,其可单独地用作鼻罩或口腔面罩,或可附接在一起并可作为组合鼻口面罩,其也可用来密封地连接面罩和佩戴者的面部;两个衬垫,包括:充气或不可充气的第二鼻腔衬垫,其由鼻梁区域、脸颊区域和上唇区域组成,以及充气或不可充气的第二口腔衬垫,其由下唇区域、脸颊区域和上唇区域组成;第一鼻膜,包括弹性材料的大致三角形框架,具有所述第一鼻膜的第一模制向内弯曲凸缘;弹性材料的第二鼻膜,所述第二鼻膜比所述第一鼻膜更薄、一样薄或更厚,所述第二鼻膜具有第二模制向内弯曲凸缘,所述第二鼻膜弯曲凸缘与所述第一鼻膜弯曲凸缘在所述脸颊区域上间隔开第一距离,并且所述第二鼻膜弯曲凸缘与所述第一鼻膜弯曲凸缘在所述鼻梁区域上间隔开第二距离,

所述第二距离大于所述第一距离,当不使用面罩时测量所述距离,所述第二膜弯曲凸缘的一部分形成面部接触密封;第一口膜,包括弹性材料的大致椭圆形的框架,具有所述第一口膜的第一模制向内弯曲凸缘;弹性材料的第二口膜,所述第二口膜比所述第一口膜更薄、一样薄或更厚,所述第二口膜具有第二模制向内弯曲凸缘,所述第二口膜弯曲凸缘与所述第一口膜弯曲凸缘在所述脸颊区域上间隔开第一距离,而所述第二口膜弯曲凸缘与所述第一口膜弯曲凸缘在口部区域上间隔开第二距离,所述第二距离大于所述第一距离,当不使用面罩时测量所述距离,所述第二膜弯曲凸缘的一部分形成面部接触密封;附件具有两个孔;其中第一个孔固定在口腔面罩上并且可连接第二个孔,其固定到鼻腔面罩上;其中当它们连接在一起时,它包括麻醉全面罩,在口和鼻子周围覆盖和密封;然而无论是口腔面罩还是鼻腔面罩都可分离,使得该面罩可单独用于鼻腔无创正压通气(CPAP/BiPAP)或单独用于口腔无创正压通气(CPAP/BiPAP)。

10. 根据权利要求9所述的鼻腔和口腔面罩,特征在于以下一个或多个特征:

(a) 其中所述第二模制凸缘和所述第一模制凸缘具有协同定位的缺口,以容纳佩戴者的鼻梁;

(b) 其中所述第一鼻膜模制凸缘和所述第二鼻膜模制凸缘大致为鞍形;

(c) 其中所述第二鼻膜成形为使得所述密封部在使用中至少接触佩戴者的鼻子;

(d) 其中所述密封部在使用中接触围绕鼻梁的侧面和在鼻梁上以及在鼻子的底部和上唇之间的面部组织;

(e) 其中所述第二凸缘和密封部成形为大体上匹配围绕鼻梁的侧面和在鼻梁上以及在鼻子的底部和上唇之间的面部组织的区域中的面部轮廓;

(f) 其中第一和第二鼻膜包括模制件,不通过粘合剂粘附在一起;

(g) 其中所述第一鼻膜的第一模制向内弯曲凸缘与所述第二鼻膜一样厚、更薄或更厚;

(h) 其中所述第二鼻膜的第二模制向内弯曲凸缘与所述第一鼻膜一样厚、更薄或更厚;

(i) 其中所述第二模制凸缘和所述第一模制凸缘具有协同定位的缺口,以容纳佩戴者的嘴唇;

(j) 其中所述第一口膜模制凸缘和所述第二口膜模制凸缘大致为椭圆形;

(k) 其中所述第二口膜成形为使得所述密封部在使用中至少接触佩戴者的上下嘴唇;

(l) 其中所述密封部在使用中接触围绕上下嘴唇的侧面以及在其上的面部组织;

(m) 其中所述第二凸缘和密封部成形为大体上匹配围绕上下嘴唇的侧面以及在其上的面部组织的区域中的面部轮廓;

(n) 其中第一和第二口膜包括件,不通过粘合剂粘附在一起;

(o) 其中所述第一口膜的第一模制向内弯曲凸缘与所述第二口膜一样厚、更薄或更厚;以及

(p) 其中所述第二口膜的第二模制向内弯曲凸缘与所述第一口膜一样厚、更薄或更厚。

11. 鼻腔面罩、口腔面罩或全面罩,用于连接到佩戴者的面部,包括:用于连接吸入气体供应的面罩主体,无论是氧气、空气、麻醉气体或任何其它气体;以及固定到所述面罩主体上的充气或不可充气的鼻腔衬垫,主体和衬垫形成鼻接收腔,所述衬垫包括:鼻梁区域、脸颊区域和上唇区域;弹性材料的大致三角形形状的第一鼻膜具有第一模制向内弯曲凸缘以围绕佩戴者的鼻子;也是弹性材料的第二鼻膜,所述第二膜比所述第一鼻膜相对更有弹性,

所述第二鼻膜具有第二模制向内弯曲凸缘,所述第二模制凸缘具有与所述第一模制凸缘相同的一般形状,并固定到和远离所述第一鼻膜延伸,以便使第二鼻膜内表面与所述第一模制凸缘的外表面在所述脸颊区域内间隔开第一距离,并且所述第二膜内表面与所述第一模制凸缘的所述第一鼻膜外表面在所述鼻梁区域内间隔开第二距离,所述第二距离大于所述第一距离,在不使用面罩时测量所述距离,所述第二模制凸缘的一部分形成面部接触密封;并且其中所述密封部基本上相对于所述第二模制凸缘毗连,并且在使用所述面罩时朝向所述第一鼻膜弹性变形。

12. 根据权利要求11所述的鼻腔面罩、口腔面罩或全面罩,覆盖并密封口和鼻子,特征在于一个或多个下列特征:

(a) 其中所述鼻腔面罩、口腔面罩或全面罩主体包括使用前路手术或后路手术的集成头带附接点,或者它可具有使用前路手术或后路手术的分离头带附接点,其放置在所述鼻腔面罩、口腔面罩或全面罩主体上,其附接到可将鼻腔面罩、口腔面罩或全面罩固定到佩戴者面部的表面上,以确保紧密密封并保持佩戴者的头部和颈部在期望的位置上,以保持呼吸道通畅;

(b) 还包括固定到所述附接点上的固定带,其可将佩戴者的头部固定到表面上并保持佩戴者的头部和颈部在期望的位置上;

(c) 其中所述第二膜模制凸缘和所述第一鼻膜模制凸缘各具有协同定位的缺口,以容纳鼻梁;

(d) 其中所述第一和第二模制凸缘大致为鞍形;

(e) 其中所述第二鼻膜成形为使得所述密封部在使用中至少接触佩戴者的鼻子;

(f) 其中所述密封部在使用中接触围绕鼻梁的侧面和在鼻梁上以及在鼻子的底部和上唇之间的面部组织,以及

(g) 其中所述凸缘和密封部成形为大体上匹配围绕鼻梁的侧面和在鼻梁上以及在鼻子的底部和上唇之间的面部组织的区域中的面部轮廓。

13. 鼻腔无创正压通气(CPAP/BiPAP)、口腔无创正压通气(CPAP/BiPAP)或全面罩无创正压通气(CPAP/BiPAP)的治疗装置,包括:用于在低于、等于或高于大气压的压力时供应气体的发生器;接合到所述发生器的气体运送导管;以及反过来接合到所述导管的鼻腔面罩、口腔面罩、全面罩,所述鼻腔面罩、口腔面罩、全面罩包括:用于连接吸入气体供应的面罩主体;以及固定到所述面罩主体上的充气或不可充气的鼻腔衬垫,主体和衬垫形成鼻接收腔,所述衬垫包括:鼻梁区域、脸颊区域和嘴唇区域;弹性材料的大致三角形形状的第一鼻膜具有模制向内弯曲凸缘;也是弹性材料的第二鼻膜具有第二模制向内弯曲凸缘,所述第二鼻膜比所述第一膜相对更有弹性,并具有与所述第一模制向内弯曲凸缘相同的一般形状,并固定到和远离所述第一鼻膜延伸,以便使内表面与所述第一模制凸缘在所述脸颊区域内间隔开第一距离,并且所述第二鼻膜内表面与所述第一模制凸缘间隔开第二距离,所述第二距离大于所述第一距离,在不使用面罩时测量所述距离,所述第二模制凸缘的一部分形成面部接触密封;并且其中所述密封部基本上相对于所述第二模制凸缘毗连,并且在使用所述面罩时朝向所述第一膜弹性变形。

14. 根据权利要求13所述的无创正压通气(BiPAP/CPAP)的治疗装置,特征在于一个或多个下列特征:

(a)其中所述面罩主体包括附接点,其可将佩戴者的头部固定到表面上并保持佩戴者的头部和颈部在适当的位置;

(b)还包括固定到所述附接点上的固定带,其可将佩戴者的头部固定到表面上并保持佩戴者的头部和颈部在适当的位置;

(c)其中所述第一和第二模制凸缘各具有协同定位的缺口,以容纳鼻梁;

(d)其中所述第一和第二模制凸缘大致为鞍形;

(e)其中所述第二鼻膜成形为使得所述密封部在使用中至少接触佩戴者的鼻子;

(f)其中所述密封部在使用中接触围绕鼻梁的侧面和在鼻梁上的面部组织,以及接触围绕鼻梁的侧面和在鼻梁上、在鼻子的底部和上唇之间的面部组织,以及接触在鼻子的底部和上唇之间的面部组织,以及

(g)其中所述第二模制凸缘和所述密封部成形为大体上匹配围绕鼻梁的侧面和在鼻梁上以及在鼻子的底部和上唇之间的面部组织以及在鼻子的底部和上唇之间的面部组织的区域中的面部轮廓。

15.口腔面罩,用于连接到佩戴者的面部,包括:用于连接吸入气体供应的面罩主体;以及固定到所述面罩主体上的充气或不可充气的口腔衬垫,主体和衬垫形成口接收腔,所述衬垫包括:嘴部区域、脸颊区域和上下嘴唇区域;弹性材料的大致椭圆形状的第一口膜具有第一模制向内弯曲凸缘以围绕佩戴者的鼻子;也是弹性材料的第二口膜,所述第二口膜比所述第一口膜相对更有弹性,所述第二口膜具有第二模制向内弯曲凸缘,所述第二模制凸缘具有与所述第一模制凸缘相同的一般形状,并固定到和远离所述第一口膜延伸,以便使第二口膜内表面与所述第一模制凸缘的外表面在所述脸颊区域内间隔开第一距离,并且所述第二口膜内表面与所述第一模制凸缘的所述第一口膜外表面在所述嘴部区域内间隔开第二距离,所述第二距离大于所述第一距离,在不使用面罩时测量所述距离,所述第二模制凸缘的一部分形成面部接触密封;并且其中所述密封部基本上相对于所述第二模制凸缘毗连,并且在使用所述面罩时朝向所述第一口膜弹性变形。

16.根据权利要求15所述的面罩,特征在于以下一个或多个特征:

(a)其中所述面罩主体包括附接点,其可将佩戴者的头部固定到表面上并保持佩戴者的头部和颈部在适当的位置;

(b)还包括固定到所述附接点上的固定带,其可将佩戴者的头部固定到表面上并保持佩戴者的头部和颈部在适当的位置;

(c)其中所述第二膜模制凸缘和所述第一口膜模制凸缘各具有协同定位的缺口,以容纳嘴部;

(d)其中所述第一和第二模制凸缘大致为椭圆形;

(e)其中所述第二口膜成形为使得所述密封部在使用中至少接触佩戴者的嘴部;

(f)其中所述密封部在使用中接触围绕嘴部的侧面和在其上以及上下嘴唇之间的面部组织;

(g)其中所述凸缘和所述密封部成形为大体上匹配围绕嘴部的侧面以及上下嘴唇之间的面部组织的区域中的面部轮廓。

17.如权利要求11所要求的鼻腔面罩、口腔面罩或全面罩,进一步的明显配管具有两端,用作输送给患者的气体源,其中该配管的远端连接到单独的或便携式发生器,用于在低

于、等于或高于大气压的压力时供应气体；气体输送导管接合到所述便携式气体供应的发生器，且近端连接到适配器，其包含呼气末CO₂端口、喷雾器端口、PEEP阀口、呼气端口和/或阀、泄压阀，其具有孔连接到或者鼻腔面罩、口腔面罩或者全面罩。

18. 如权利要求11所要求的鼻腔面罩、口腔面罩或全面罩，可连接到发生器，用于气体的供应，其中运送的气体量和浓度通过供给源以及呼气端口来控制，和/或通过同时连接鼻腔面罩和口腔面罩用作换气系统，其中鼻腔面罩可用于提供正压，并且口腔面罩可连接到抽吸装置以正确地储存和/或处理气体。

19. 如权利要求11所要求的鼻腔面罩、口腔面罩或全面罩，是围绕患者的鼻梁、鼻子和上唇的轮廓，使得它和气体供给发生器连接，而不干涉操作者接触嘴/口腔、嘴唇、脸颊、下巴，下颌、颈部，和/或连接到复苏气囊，其具有或不具有附接到该复苏气囊的气体供给。

20. 具有如权利要求11所要求的定位装置的手术台，以及一个或多个与定位装置的厚度接近的垫，其在手术台上。

21. 根据权利要求20所述的手术台，其中至少一个垫是板条做的或起褶的，以便于弯曲。

22. 根据权利要求20所述的手术台，还包括基垫片，具有多个位于主垫之下的辊。

23. 用于患者的有弹性的和柔软的头颈部限制装置，包括：

第一近端，附接到基部的第一侧面的一侧上，然后其可沿水平方向延伸并接触患者的头部且附接到所述基部的第一表面的相反侧上；该装置是可调的并能够将患者的头部固定在基部的第一表面上，以防止患者从所期望的位置脱落。

24. 用于定位患者的下颌骨臂，包括：

两个刚性可锁定臂，其中上臂具有在z轴上可转动的弯曲伸出部分，以及下臂不提供伸出部分；

弯曲部分，其中所述弯曲部分基本上是刚性的；

下颌骨垫，其中下颌骨垫是柔性的和可枢转的，并且其中所述下颌骨垫具有配置为附接到所述弯曲部分的近端侧以及配置为在至少两个分支、身体和患者下颌的角度上接触患者下颌的远端侧；以及

连接器部分，其中所述连接器部分配置为延伸并附接到支撑件的可旋转部分上，并且其中所述连接器部分进一步配置为连接到附接到基部的支撑件上，该基部包括左侧和右侧，其中基部配置为基本上容纳患者的头部、颈部、上部和中间背部以及肩部，并且其中所述支撑件在两个轴上是可移动的，使得所述下颌骨垫可定位成在一个或多个点上接触患者的下颌，以保持患者在所期望的位置上。

25. 有弹性的和柔软的头颈部限制和麻醉面罩密封装置，用于定位患者，包括：第一近端，附接到托架分组合件的基部的第一侧面的一侧上，然后其可沿水平方向延伸并接触患者的头部且附接到所述基部的第一表面的相反侧上，或者接触麻醉面罩，然后其接触并密封患者的面部；其中该装置是可调的并能够将患者的头部固定在基部的第一表面上，以防止患者从所期望的位置脱落，其中所述托架分组合件任选是可逆的，允许将患者放置在相反侧上，和/或其中所述装置任选地由MRI或X光兼容材料形成。

26. 有弹性的和柔软的上背部限制装置，用于定位患者，包括：

第一近端，其可附接到背板的一侧上，然后可沿水平方向延伸并接触患者的腹部且附

接到背板的相反侧上,其中所述装置是可调节的,并能够将患者的背部固定到背板的表面上以防止患者从所期望的位置上脱落。

27.用于支撑患者的表面,包括:

第一侧面,其可调整为接触患者的背部,以及第二侧面,其可调整为接触患者的肋部以防止患者移动。

28.向患者提供麻醉时使用的装置,包括:

具有第一侧面、第二侧面、第三侧面和可调整支撑结构的基部,其中所述基部配置为基本上容纳患者的颈部和头部;

其中基部第一侧面的远端包括半圆柱形的支撑件,其可在z轴上调节,这有助于保持所期望的嗅探位置,或也可在z轴上调节的平面;

基部第一侧面的近端包括稍微倾斜的或平坦的表面,具有或不具有切口中心,并在z轴上是可调节的,以提供头部支持,进一步优化该嗅探位置;

基部的第二和第三侧面各包含多个突起;以及

麻醉面罩条带有四个侧面,其中第一和第二侧面包括放置在面罩的孔之上的孔,并且第三和第四侧面包括窄的伸出部分,其包括多个孔,均适于附接到其基部和两个侧面上的四个突起中的一个;

其中面罩条带适于靠住患者的鼻子、面颊、口和/或头部来将麻醉面罩保持在所期望的嗅探位置,其中患者的下颌向上和向前移动,从而不会阻塞患者的呼吸道;并且其中面罩条带适于将患者的头部和/或颈部稳定到基部上,防止患者的头部和/或颈部的移动。

29.根据权利要求28所述的装置,特征在于以下一个或多个特征:

(a)其中所述麻醉面罩由非静态乳胶自由材料形成;

(b)其中至少一些所述窄的伸出部分具有相应的按扣部分,用于将窄的伸出部分附接到基部的一个突出部上;

(c)其中所述可调节的支撑件位于基部的内部;

(d)其中所述可调节的支撑件包括机械或气动调节机构;

(e)其中所述基部的平面图是大致矩形的;

(f)其中所期望的位置是嗅探位置,对准所有三条轴线,口咽、喉、气管;

(g)其中所述基部还包括设置在第一表面上并配置为提供患者颈部的最佳弯曲的远端可调节颈枕,以及提供最佳的头部伸展来获得所期望的位置的近端倾斜头枕;或如果所期望的位置是没有必要的,所述基部仅包括平面;

(h)其中所述装置由MRI或X光兼容材料形成;以及

(i)其中所述面罩由用抗微生物溶液很容易消毒的材料形成或是一次性的。

30.在向患者提供麻醉时使用的装置,包括:用于向所述患者提供所述麻醉的装置;用于保持所述面罩装置靠住患者的鼻子、口、面颊和或头部的面罩条带装置;面罩条带附接到其基部上实现所期望的位置,这向上和向前提升了患者的下颌,以便不阻塞患者的呼吸道。

31.用于定位患者来执行麻醉的方法,包括以下步骤:提供根据权利要求28所述的装置,将患者的头部和颈部基本放置在托架分组合件上;使用可调节的装置将患者的头部和颈部放置在所期望的位置上;将面罩条带放置在麻醉面罩的孔之上或患者的头部之上,以基本维持患者的头部和/或下颌在所期望的位置上。

32. 根据权利要求31所述的方法, 特征在于以下一个或多个特征:

(a) 其中基本放置头部和颈部在基部第一表面的远端上的颈枕上以及在基部第一侧面的近端上的头枕上将未引发疼痛的患者放置在所期望的位置上;

(b) 其中基本放置头部和颈部在基部第一表面的远端上的颈枕上以及在基部第一侧面的近端上的头枕上是将患者放置在所期望的位置上并限制患者的头部和颈部移动; 以及

(c) 其中将面罩放置在患者的面部上, 然后将面罩条带放置在面罩上并将其附接到基部上, 将防止麻醉气体和氧气泄漏到空气中。

33. 用于向仰卧在支撑件上的患者提供通气的装置, 包括,

通气面罩,

通气面罩上的面罩锚环, 以及

多个弹性体条带, 连接该面罩锚到支撑件上。

34. 根据权利要求33所述的装置, 其中弹性体条带围绕假想的圆圈间隔开180°固定到该面罩锚环上。

35. 用于定位患者的装置, 包括:

托架, 具有第一表面, 支撑患者在倾斜的位置上, 并且在z轴上是可调节的, 第二表面, 支撑患者的头部和颈部并且是可调节的, 以将患者放置在大致所期望的嗅探位置上; 以及

气动或机械千斤顶, 或者可张开的风箱, 支撑在第二表面上用于独立地相对于所述第二表面提升患者的头部。

36. 根据权利要求35所述的装置, 特征在于以下一个或多个特征:

(a) 其中所述可张开的风箱包括多个由在刚性基部上的柔性膜连接的刚性同心环, 其中所述基部的第三侧面优选包括:

具有两个端部的刚性倾斜侧面;

可从基部的第一侧的远端侧拆卸的近端; 所期望的位置可由不同的体型通过调整第一基部的高度来获得;

远端, 包括伸展机构来维持所期望的角度, 以维持患者在期望的位置上;

可弹性变形垫, 位于该刚性倾斜侧面的顶部上并且接触患者的上背部、中间背部和肩部;

(b) 其中所述风箱包括双向阀, 通过它可增加或减少空气; 以及

(c) 其中所述风箱由MRI或X光兼容材料形成。

37. 用于定位患者以促进维持在麻醉状态下的患者呼吸道的方法, 包括提供根据权利要求35所要求的装置, 将患者定位在该装置上, 调节第一表面以支撑患者在所期望的倾斜位置上;

调节第二表面以支撑患者头部和颈部在大致期望的嗅探位置上; 以及

激活气动或机械千斤顶, 或给可张开的风箱充气以相对于第二表面提升患者的头部到期望的嗅探位置。

38. 用于定位患者的装置, 包括:

基部, 其包括支撑患者的头部和颈部的第一侧面, 作为基础的第二侧面, 在第一和第二侧面之间的内垂直可调节支撑结构, 以及可拆卸的第三倾斜侧面, 其支撑患者的上背部、中间背部和肩部;

定位在基部的第二侧面上的第一支撑件,并且相对于基部的第二侧面在x轴和y轴上是可锁定地调节;

定位在基部的第二侧面上的第二支撑件,并且相对于基部的第二侧面在x轴和y轴上是可锁定地调节;

第一下颌骨臂从第一支撑件的第一垂直可调节部分延伸,其中所述第一垂直可调节部分在z轴上是可锁定的,以相对于z轴可锁定地调节第一下颌骨臂,并且其中所述第一下颌骨臂定位成与患者的下颌接触;以及

第二下颌骨臂从第二支撑件的第二垂直可调节部分延伸,其中第二垂直可调节部分是可锁定在z轴上以相对于z轴调节第二下颌骨臂,并且其中所述第二下颌骨臂定位成接触患者的下颌;

其中,第一下颌骨臂和第二臂颌骨是可移动的,使得每一个可定位成接触患者的下颌并维持患者在所期望的位置上,并使服务人员免持。

39. 根据权利要求38所述的装置,特征在于以下一个或多个特征:

(a) 其中所述下颌骨臂可定位成在分支、身体或患者的下颌角度上接触患者的下颌,其中所述第一下颌骨臂和第二下颌骨臂的每一个优选的可定位使得优选由泡沫形成的下颌骨垫在两个或多个分支、身体或患者的下颌角度上接触患者的下颌,或其中所述第一下颌骨臂和第二下颌骨臂的每一个优选的可定位使得优选由泡沫形成的下颌骨垫在分支、身体或患者的下颌角度上接触患者的下颌;

(b) 其中所述第一支撑件可相对于所述基部移动,并且所述第二支撑件可相对于所述基部移动,其中所述第一支撑件优选是在两个轴上可相对于基部移动,并且第二支撑件是在两个轴上可相对于基部移动;

(c) 其中所述基部是矩形的;

(d) 其中所述第一下颌骨臂和第二下颌骨臂各自包括下颌骨垫;

(e) 其中所述第一下颌骨臂和第二下颌骨臂分别可拆卸地连接到第一支撑件和第二支撑件上;

(f) 其中第一下颌骨臂可相对于第一支撑件移动,并且第二下颌骨臂可相对于所述第二支撑件移动;

(g) 其中所期望的位置是嗅探位置、对齐所有三条轴线(口咽、喉和气管)和/或托下颌手法;

(h) 进一步包括水平仪,用于确定患者的颈部弯曲角度;

(i) 其中所述基部还包括设置在第一表面上配置为提供患者颈部的最佳弯曲的远端颈枕以及近端倾斜头枕,以提供最佳的头部伸展来获得所期望的位置;

(j) 其中第一和第二下颌骨臂配置为当在z轴上旋转时伸展患者的下颌;

(k) 其中多个下颌骨臂配置为当在z轴上旋转时伸展患者的下颌;

(l) 其中第一和第二支撑件以及第一和第二旋转部分是可调节的,而患者与第一和第二下颌骨臂接触;以及

(m) 其中该基部的第三侧面支撑患者的上背部、中间背部和肩部,从而使重力来取代减轻患者的胸部重量,包括肥胖患者;

(n) 其中该装置由MRI或X光兼容材料形成;

(o)其中基本上放置头部和颈部在基部的第一表面的远端上的颈枕上以及在基部的第一侧面的近端上的头枕上将引发疼痛的患者放置在所期望的位置上;以及

(p)其中所述内可调节表面由刚性结构组成;其中该装置沿y轴是可调节的,以取代减轻患者的胸部重量;沿y轴是可调节的,以水平地对齐耳朵和胸骨来实现肥胖患者的最大量的换气;并沿z轴是可调节的,用于升降肥胖患者而不需要医护人员的帮助;

(q)还包括卡爪,用于根据延伸所述下颌提供给麻醉师与患者的触觉界面,其中所述卡爪的左右臂位置由摩擦力来维持,其通过千斤顶组件来传递,该力可由麻醉师在绕z轴转动所述臂时克服,进一步任选地特征在于一个或多个下列特征:

(1)其中所述卡爪的左右臂位置是由摩擦力绕Y轴固定;

(2)其中由螺杆提供微调,用于进一步伸展下颌,所述螺杆通过围绕Y轴将扭矩施加至所述臂上以将附加力施加至标称Z轴方向上;以及

(3)还包括扭矩限制器,用于限制通过在Z方向上的左右臂施加到下颌骨上的力,以防止患者受伤。

40. 用于定位患者的下颌骨臂,包括:

两个刚性可锁定臂,其中上臂具有在z轴上可转动的弯曲伸出部分,以及下臂不提供伸出部分;

弯曲部分,其中所述弯曲部分基本上是刚性的;

下颌骨垫,其中下颌骨垫是柔性的和可枢转的,并且其中所述下颌骨垫具有配置为附接到所述弯曲部分的近端侧以及配置为在至少两个分支、身体和患者下颌的角度上接触患者下颌的远端侧;以及

连接器部分,其中所述连接器部分配置为延伸并附接到支撑件的可旋转部分上,并且其中所述连接器部分进一步配置为连接到附接到底部的支撑件上,该底部包括左侧和右侧,其中底部配置为基本上容纳患者的头部、颈部、上部和中间背部以及肩部,并且其中所述支撑件在两个轴上是可移动的,使得所述下颌骨垫可定位成在一个或多个点上接触患者的下颌,以保持患者在所期望的位置上。

41. 用于根据权利要求38所述的装置的第一测量装置,包括两个侧面:

具有四个臂伸出部分的第一刚性侧面,四个臂伸出部分的每一个位于四个角的每一个中,并且其每一个接触患者的颈部;

第二刚性侧面包括35°的斜面,其搁置测量装置用于确认35°的颈部弯曲角度,以实现所期望的位置。

42. 用于根据权利要求38所述的装置的第二测量装置,包括两个侧面:

具有三臂伸出部分的第一刚性三角形侧面,其中的每一个位于三个角的每一个内,并且其每一个接触患者的头部;所述臂伸出部分各自沿z轴调节以实现所期望的位置;

第二刚性侧面包括15°的斜面,其搁置测量装置用于确认15°的头部伸展角度,以实现所期望的位置。

43. 有弹性的和柔软的头限制装置,用于定位患者,包括:

第一近端,附接到基部的第一侧面的一侧上,然后其可沿水平方向延伸并接触患者的头部且附接到所述基部的第一表面的相反侧上;该装置是可调的并能够将患者的头部固定在基部的第一表面上,以防止患者从所期望的位置脱落。

44. 用于定位患者的方法,包括以下步骤:

提供根据权利要求38所述的装置;

将患者的头部、颈部、上部和中间背部以及肩部基本放置在基部上;使用可调节的装置将患者的头部、颈部、上部和中间背部以及肩部放置在所期望的位置上;任选地使用测量装置以确认所期望的位置;移动第一下颌骨臂接触患者的下颌;移动第二下颌骨臂接触患者的下颌;其中第一下颌骨臂和第二下颌骨臂的接触提供了足够的力以充分地维持患者的头部和/或下颌在所期望的位置上。

45. 根据权利要求44所述的方法,特征在于以下一个或多个特征:

(a) 对准其中所有三条轴线(口咽、喉、气管)用于气管插管的推荐视野;

(b) 其中通过使用千斤顶调整所述患者的头部相对于所述Z轴的高度,以及

(c) 其中该装置包括释放挤压的托下颌握把,并且包括在z方向上移动该托下颌握把的步骤。

46. 用于定位患者的装置,包括:

基部分组合件,包括用于支撑托架分组合件的表面,其中支撑臂的第一表面支撑患者头部并且在Z轴上是可调的,第二表面支撑患者的颈部并且在Z轴上是可调的,以将患者放置在所期望的嗅探位置上;

降低上臂的表面直至舒适地紧密并锁定,用于约束患者的头部沿着所有三条轴线平移;

柔性带放置在患者的前额上,用于通过在X方向上施加恒定的约束力将患者的前额固定到嗅探位置上;

第一下颌骨臂从托架分组合件的第一表面垂直地延伸,其中第一垂直调整部分可绕Z轴旋转锁定,其中第一下颌骨臂可定位成与患者的下颌接触;并且

第二下颌骨臂从托架分组合件的第三表面垂直延伸,其中第二垂直调整部分可绕Z轴旋转锁定,其中第二下颌骨臂可定位成与患者的下颌接触旋转;

其中第一下颌骨臂和第二臂颌骨是可移动的,使得每个可定位成与患者的下颌接触,并在患者侧躺时使服务人员免持来维持患者在期望的位置上。

47. 根据权利要求46所述的装置,特征在于以下一个或多个特征:

(a) 其中下颌骨臂可定位成在患者侧躺时在分支、主体或患者下颌的角度上接触患者的下颌,其中每个所述第一下颌骨臂和第二下颌骨臂优选地可定位成在患者侧躺时在两个或多个分支、主体或患者下颌的角度上接触患者的下颌,和/或其中每个第一下颌骨臂和第二下颌骨臂优选地可定位成在患者侧躺时在分支、主体或患者下颌的角度上接触患者的下颌;

(b) 还包括在第一和第二下颌骨臂上的下颌骨垫,用于接触患者的下颌;

(c) 其中所述托架分组合件的所有表面相对于基部移动,其中所述支撑臂的第一和第三表面优选地在一个轴上相对于基部是可移动的,并且托架分组合件的第二表面在三个轴上相对于基部是可移动的;

(d) 其中所述基部是矩形的,并且托架分组合件的表面是c形的;

(e) 其中所述下颌骨垫优选地由弹性的变形材料形成,其中所述下颌骨垫由泡沫形成;

(f) 其中第一下颌骨臂和第二下颌骨臂分别可拆卸地连接到托架分组合件的第一表面

和第三表面上；

(g)其中第一下颌骨臂相对于托架分组合件的第一表面是可移动的，并且第二下颌骨臂相对于托架分组合件的第三表面是可移动的；

(h)其中所期望的位置是侧躺、对准所有3条轴线轴(口咽、喉和气管)和/或托下颌手法时的嗅探位置；

(i)其中所述托架分组合件的第二表面还包括颈枕，其布置为提供患者颈部的最佳弯曲和最优的头部伸展来获得所期望的位置；

(j)其中第一和第二下颌骨臂配置为在X轴上旋转时延伸患者的下颌；

(k)其中多个下颌骨臂配置为在X轴上旋转时延伸患者的下颌；

(l)其中所述装置由MRI或X光兼容材料形成；

(m)其中所述托架分组合件是可逆的，允许将患者放置在相反侧上；

(n)进一步包括水平仪，用于确定患者的颈部弯曲角度；

(o)其中所述基部还包括设置在第一表面上配置为提供患者颈部的最佳弯曲的远端颈枕以及近端倾斜头枕，以提供最佳的头部伸展来提供所期望的患者位置；

(p)其中第一和第二支撑表面以及第一和第二旋转部分是可调节的，而患者与第一和第二下颌骨臂接触；

(q)其中所述基部分组合件包括：

具有两个端部的刚性倾斜侧面；

可从基部的第一侧的远端侧拆卸的近端；所期望的位置可由不同的体型通过调整第一基部的高度来获得；

远端，包括伸展机构来维持所期望的角度，以维持患者在期望的位置上；

泡沫垫，位于该刚性倾斜侧面的顶部上并且接触患者的上背部、中间背部和肩部；

(r)其中该倾斜侧面支撑患者的上背部、中间背部和肩部，并使重力来取代减轻患者的胸部重量，包括肥胖患者；

(s)其中该装置由MRI或X光兼容材料形成。

(t)其中基本上放置头部和颈部在倾斜侧面的远端上的颈枕上以及倾斜侧面的近端上的头枕上将引发疼痛的患者放置在所期望的位置上；以及

(u)其中所述装置沿y轴是可调节的，以取代减轻患者的胸部重量；沿y轴是可调节的，以水平地对齐耳朵和胸骨来实现肥胖患者的最大量的换气；并沿z轴是可调节的，用于升降肥胖患者而不需要医护人员的帮助。

48. 用于定位患者的方法，包括以下步骤：

提供根据权利要求46所述的装置；

使用可调节装置将患者的头部基本放置在托架分组合件的第一表面上，以将患者的头部和颈部放置在所期望的位置上；移动第一下颌骨臂接触患者的下颌；移动第二下颌骨臂接触患者的下颌；其中第一下颌骨臂和第二下颌骨臂的接触提供了足够的力以充分维持患者的头部和/或下颌在所期望的位置上。

49. 根据权利要求48所述的方法，其中对准所有的三条轴线(口咽、喉、气管)用于插管视野。

50. 用于定位患者的下颌骨臂，包括：

刚性可锁定臂,其中所述臂具有在X轴上可旋转的弯曲伸出部分;

弯曲部,其中所述弯曲部基本上是刚性的;

下颌骨垫,其中所述下颌骨垫是柔性的和可枢转的,并且其中所述下颌骨垫具有配置为附接到该弯曲部的近端侧以及配置为在至少两个分支、主体以及患者下颌的角度上接触患者下颌的远端侧;以及

连接器部分,其中所述连接器部分配置为延伸并附接到支撑件的可旋转部分上,并且其中所述连接器部分进一步配置为连接到附接到托架分组合件的支撑件上,该托架分组合件包括左侧和右侧,其中托架分组合件配置为基本上容纳患者的头部,并且其中所述托架分组合件在一个轴上是可移动的,使得所述下颌骨垫可定位成在一个或多个点上接触患者的下颌,并保持患者在所期望的位置上,其中所述托架分组合件是可逆的,允许将患者放置在相反侧上。

用于麻醉状态下的患者的定位装置和方法

发明内容

[0001] 本发明的一个方面涉及定位装置和方法,以在患者或者是无意识、无法保持呼吸道通畅或者在镇静和/或麻醉状态时促进保持呼吸道通畅,患者或者无意识、无法保持呼吸道通畅或者在镇静和/或麻醉状态将导致呼吸道塌陷。在另一方面,本发明涉及定位装置,以在患者或者是无意识、无法保持呼吸道通畅或者在镇静和/或麻醉状态时通过准确地定位患者的头部、脖子、躯体和下颌来促进保持呼吸道通畅,并且如果在放置气管插管之前气管插管需要对齐三条轴线(口咽、喉、气管)、同时在试图放置气管插管时以及在拔管过程中能实现最优的视野。在又一方面,本发明涉及麻醉鼻罩、全面罩以及组合口鼻面罩,其可在气管插管前、插管时以及插管后用于充氧和透气,可连接到便携式氧气供给源并用来运输供应氧气,和/或连接到呼气末CO₂监测器以测量CO₂等级,和/或帮助维持患者定位。还有另一方面,本发明涉及用于促进托住患者下颌的装置,所述患者或者是无意识、无法保持患者的呼吸道通畅或者是接受麻醉。

[0002] 在手术过程中患者通常是在麻醉状态下,并且最常见的运送系统包含含有麻醉气体和氧气的滤毒罐、调节气体流量和患者呼吸的系统以及确保患者的呼吸道用于呼吸/透气、充氧的效力和运送麻醉气体混合物的装置。目前,全面罩用来在患者被麻醉之前向患者提供氧气,并且用来当患者在麻醉状态时提供氧气、除去二氧化碳(CO₂)并提供麻醉气体。当前全面罩透气的一些缺点是首先需要在服务人员的手和患者的脸之间进行经常接触以保持面罩在适当的位置,并且保持患者在所谓的嗅探位置,以便确保氧气和麻醉气体不会泄漏到空气中,并且使患者的呼吸道保持通畅。如果服务人员不能维持患者在嗅探位置,可能发生称为上呼吸道阻塞的危险并发症,其中软腭和/或舌头塌陷到呼吸道中。服务人员需要进行连续的面罩固定和操作的原因是人体解剖学和生理学。由于阻塞性睡眠呼吸暂停,当下颌、软腭、舌头和上呼吸道的肌肉放松时,给予患者镇静剂和/或肌肉松弛剂用于镇静和/或麻醉,上呼吸道(口腔、咽、喉)可能会部分地阻塞并可能完全关闭。当患者的头部前倒或是下颌回落时,舌头和/或软腭落回到呼吸道造成打鼾(部分阻塞)或呼吸暂停(完全不能使氧气通过上呼吸道进入肺部)。如果发生这种情况,患者的头部和颈部应妥善放置,应该尝试无创正压通气,例如持续呼吸道正压(CPAP)通气或双相气道正压(BiPAP)通气和/或所谓的“双手托颌法操作”,如下面将要讨论的。当前全面罩的第二个缺点是服务人员在插管之前必须去除面罩,因为面罩覆盖了患者的口腔且阻止了喉镜进入口腔。此外,当前鼻罩具有来自患者右侧的环封式麻醉,并且连接到鼻罩中部的鼻罩孔。因为环封式麻醉来自右侧,它阻止了服务人员插管,因为所有的插管都在右侧进行。另外,因为环封式麻醉连接到鼻罩的中间孔,如果服务人员试图给患者插管,无论是鼻罩连接还是该环封式麻醉都妨碍了观察患者的嘴部。因此,当前的鼻罩和全面罩必须在尝试插管之前去除,因此服务人员可以不再尝试给患者充氧或透气,直到发生了气管插管的成功放置。这也被称为呼吸暂停期间,以及是呼吸道管理中最关键的事件之一。当试图直接喉镜检查并放置气管插管时,本发明将仅盖住患者的鼻子,允许服务人员继续给患者充氧和透气,在他/她进行直接喉镜检查时不会阻碍服务人员的观察,因为在所提出的鼻罩和口鼻面罩内的环封式麻醉连接器孔将位

于鼻罩和口鼻面罩的左侧或右侧(不是竖直往上伸出),并允许环封式麻醉也在患者的左侧或右侧,当进行直接喉镜检查时不挡住服务人员的视线。本发明基本上消除了临界呼吸暂停期。当前全面罩的第三个缺点是在运送过程中它不能用作患者的氧气源,除非它连接到复苏气囊。目前,在每种情况结束时,麻醉师丢弃麻醉面罩,因为它不能用来将病人运送至麻醉后监护室(PACU)。当前鼻罩或全面罩不能用于运送的原因是因为他们只有一个孔,该孔必须连接到无创正压装置,它同时具有吸入和呼气阀。这些面罩不具有通气孔,以允许附连到氧气供应装置时进行吸气和呼气。本发明具有附加端口,其中或可附连来自氧气供应装置的氧气或可附连呼气末CO₂监视器,并且环封式麻醉孔径或可用作通气口,以防止建立过大的压力,连接到复苏气囊并用于面罩通气,或连接到无创正压通气装置(CPAP、BiPAP等)以协助通气。本发明的一个或多个额外端口(氧气/CO₂)也可是盖住的,并且环封式麻醉可连接到环封式麻醉连接器孔用于无创正压通气。本发明的一个或多个额外端口(氧气/CO₂)也可连接到任何一个氧气监视器和/或呼气末CO₂监视器,并且环封式麻醉可连接到环封式麻醉连接器孔用于无创正压通气,同时能够测量氧气等级和CO₂等级。

[0003] 存在另一个问题,当服务人员没有给予足够的麻醉或镇静时,它开始逐渐减弱并且病人开始移动。这也可能导致患者的呼吸道阻塞,因为患者的头部和颈部位置不再是在嗅探位置。在手术过程中患者的移动也很危险,因为它可能会导致外科医生犯错误,特别是在眼、耳、鼻、颈、头和喉咙的手术中。

[0004] 此外,在过去十年中,监测麻醉护理(MAC)病例,特别是结肠镜检查的人数有显著增加(仅在美国每年进行数百万例),不幸的是出现了呼吸道并发症导致死亡和脑损伤。MAC病例使用镇静药物以限制患者可能遭受到的生理和心理的疼痛量。然而,这些镇静药物可能会导致肌肉的松弛,所述肌肉帮助维持呼吸道通畅。这些肌肉松弛则可导致呼吸道阻塞(即上呼吸道阻塞)并停止患者呼吸。此外,如果给予比预期剂量更高的镇静药物可导致呼吸抑制,其中当深呼吸时病人的大脑无法沟通。

[0005] 在历史上,为了减少上呼吸道阻塞的风险,服务人员将首先通过抬起下巴或通过使患者侧躺而改变患者的头部位置。抬起下巴将患者放置在所谓的“吸气位置”或“嗅探位置”,并允许下颌骨稍向前移位,这从呼吸道中移走了舌头。参见Cattano等人的Airway Management and Patient Positioning: A Clinical Perspective, Anesthesiology News Guide to Airway Management, 第15页(2011)。该嗅探位置还对准三条轴线(口咽、喉、气管),并为服务人员的气管插管提供了最优的视野。使患者朝他或她的一面侧躺防止了重力迫使患者的舌头和/或软腭进入到患者的呼吸道中,并通过允许舌头和软腭向前延伸而防止阻塞它。然而,这两个位置仅防止了大约一半患者的上呼吸道阻塞。基于现有证据而采用的新技术是对上呼吸道阻塞的患者应用正压呼吸器,因为它比全面罩持续气道正压通气更有效。如果这些操作不能缓解上呼吸道阻塞,则服务人员将进行托下颌手法。完成托下颌手法是用一只手向上和向前移动下颌来移动舌头使得呼吸道打开。进行该托下颌的同时保持面罩在患者的嘴和鼻子上以运送氧气。为了患者透气的同时进行托下颌手法,服务人员需要几乎不间断地保持面罩在患者的脸上,并防止在手术期间能够进行其它任务。这种手法的明显缺点是使用两只手。这在患者处于侧卧位时可能变得特别麻烦,因为无法够到该患者侧躺时的下颌侧。

[0006] 在2000例的研究中,11%的使用全面罩和托下颌用于呼吸道管理的患者手术有下

颌疼痛的投诉。目前,7%的麻醉医师有与并发症相关的诉讼,这些并发症涉及麻醉和托下颌相关的创伤。此外,多重任务(进行托下颌和其它任务)的要求同时导致了相当大的错误机会。这转化为差的患者治疗效果以及对于麻醉师和设施差的责任。这导致面罩麻醉普及的显著损失,并增加了其它的呼吸道装置的使用,这更有侵入性并有较大的潜在副作用和并发症。成功的免托托下颌装置方案将惠及美国每年超过1300万的接受麻醉的患者,以及医生和提供服务的设施。

[0007] 另一个困难是遇到使用全面罩要在程序过程中保持全面罩在患者的面部上,尤其是在长期情况下,因为不是所有的面部有相同的尺寸或形状,并且面罩只能制造为几个不同的尺寸。此外,患者移动可引起面罩脱落,如可以偶然接触。为了保持面罩在患者之上,当前的程序是采用环带部件的配置。最好如Helling的US专利号5975079所示,环部件通常包括具有中心孔的环,其尺寸适于在内部接收大致圆柱形的气体端口连接器,以使所述环能安装在该圆柱形的气体端口连接器上。所述环包括多个(通常为4个或6个)径向延伸臂,其围绕所述环的圆柱形部分的圆周以间距间隔开。向上延伸的尖头形成在每个所述径向延伸臂的远端(径向最向外)部分,并用作尖头或双头螺栓构件。这种做法有几个缺点。第一个缺点是该尖头是锐利的,已经知道会导致擦伤服务人员和患者。另一个缺点是头带必须置于患者的头部下方,然后向前扩展固定到尖头上。如果患者已经将他或她的头部倒置在表面上这将变得具有挑战性,服务人员现在必须将患者的头部抬起。此外,部分患者扭脖子有困难。另外,如果患者有长头发,所述条带可能缠结患者的头发。另一个缺点是条带很笨重,由四个长伸出部分和非常宽的头带组成。所述条带的尺寸和蓬松度可能造成围绕患者面部的额外混乱,引起角膜擦伤,并可能削弱外科医生或护士对患者的工作。Helling装置的另一缺点是它不能将患者的头部固定到表面上。因此,即使它声称是免提方式,但由于患者的头部不能固定到表面上,患者头部或颈部的运动可引起患者呼吸道的阻塞,并阻止氧气和/或麻醉气体运送给患者。最后,Helling装置用于运送很麻烦,因为它紧密地覆盖口鼻,造成患者觉得他们是窒息的,除非他们用复苏气囊运送,当前的全面罩不能连接到氧气供应装置,因为面罩不包含通风口和或吸气/呼气阀。教导用于稳定面罩或将人绑定到担架上等的系统的其它专利包括美国专利号6,981,503、7,753,051、4,905,712、3,889,668、3,897,777以及公布申请号2009/0178682和2007/0295335。

[0008] 另外的特定和日益严重的问题涉及肥胖患者的通气和气管插管困难,该问题随着普通大众越来越肥胖而变得更加普遍。肥胖患者不仅在他们们的上呼吸道具有更多的软组织导致阻塞,而且他们还具有大量的额外重量压缩其胸部,限制气体交换。从历史上看,医疗服务人员在患者的背部、肩部、颈部和头部下放置片材或毯子,以允许重力来减轻额外的重量。这已被证明相比于更刚性的结构例如斜面仅略微有效,这已证明是非常有效的。此外,如果在开始时的情况下气管插管不到位,因为病人仅经受镇静并在该情况下病人进入呼吸衰竭并且需要气管插管,则没有足够的时间来将这些片材放置在患者下面并确保正确定位。此外,需要医护人员把这些过度肥胖患者抬起以将这些片材或毯子定位在肥胖患者的下面,并且一旦手术开始要去除片材或毯子。显然,这大大增加了工伤的风险。因为已知的肥胖患者的插管比较困难,已经证明斜面结合“嗅探位置”和“耳朵与胸骨对齐的位置”比“单独嗅探位置”更有效。尽管医学文献详细说明了对于“嗅探位置”的最精确角度,其对准三条轴线(口咽、喉、气管)并为医疗服务人员提供了进行气管插管以及最优化的呼吸道通

畅的最优化视野,当前没有设备在插管期间或者可以确保服务人员正确对准患者头部和颈部的角度,或者实时改变声门视野。因此,医疗服务人员必须“盯着”会明显导致错误的这些角度。

[0009] 现有技术已经提出了用于促进维持呼吸道通畅的各种设备。例如,美国专利公开号2012/0180220示出了支撑使用者的头部和颈部用于呼吸道管理的装置,包括头部支撑表面,尺寸为容纳和支撑使用者的头部,以及连接到该头部支撑表面的颈部支撑表面,其中所述颈部支撑表面的尺寸为容纳和支撑使用者的颈部;其中,该头部支撑表面和颈部支撑表面配置为使得当使用者在他或她的一侧侧躺,他或她的头部一侧设置在头部支撑表面上,且他或她的颈部一侧在该颈部支撑表面上时,使用者的头部和颈部自动在嗅位对准用于改善呼吸道管理。然而,该专利缺乏在最关键的点、插管过程中独立地调整头部或颈部以及调整两者的能力。也无法自定义配合头部、颈部和躯干定位或进行托下颌,这是能够保持呼吸道通畅所的关键。该装置也不能在患者移动过程中限制患者的头部。

[0010] 美国专利号8,347,889示出了定位装置,通过在操作或过程期间在麻醉状态下正确定位患者的头部来促进保持呼吸道通畅,其包括至少一个可调整的支架,包括多个区段或部分,可选择性地相对于相邻区段或部分定位,并选择性地相对于彼此可锁定,具有患者接合构件,其联接到其近端部分,以在操作或过程期间接合患者头部的一部分来维持患者的头部位置。虽然此专利的装置加上抬下巴和托下颌据称具有能够限制患者的头部,但是它在头部和/或颈部定位方面没有调节性。该装置也不能取代减轻对于气体交换至关重要的肥胖患者的胸部重量。此外,该装置不能实时调整头部和颈部定位,而且不容许在插管过程中鼻腔通气。

[0011] 美国专利号8,001,970提供了在麻醉状态下的患者使用的装置和相关的方法。各种实施方式包括用于建立和保持患者的头部和/或下颌在特定位置,包括嗅探位置的装置。实施方式还包括用于定位患者的方法,包括使用本发明的装置,其中该装置可基本上保持患者在希望的位置。虽然该专利的装置能够提供抬下巴和托下颌,但它不能调整头部和/或颈部来提供习惯的配合定位。该装置也不能取代减轻对于气体交换至关重要的肥胖患者的胸部重量。另外,该装置不允许在插管过程中鼻面罩通气。在服务人员试图插管时它也不能调整头部和颈部定位。并且,该专利的装置也不能对准在侧卧位的所有3条轴线用于气管插管,也没有提供测量装置来确认所希望的位置。

[0012] 美国专利号8,191,553示出了一对衬垫,其抵靠患者的下颌分支,以防止下颌后滑并引起呼吸道阻塞,而患者的颈部过度伸展也导致患者的呼吸道继续开放。一种包括可调整的下颌衬垫以及三角形部分的装置,在其上患者的颈部不需要附接在患者躺着的表面上,且该装置允许患者往任一侧翻转而仍然保持患者的呼吸道通畅。虽然这个专利的装置能够提供抬下巴和托下颌,但它不能调整头部和/或颈部来提供习惯的配合定位。该装置也不能取代减轻对于气体交换至关重要的肥胖患者的胸部重量。在服务人员试图插管时它也不能调整头部和颈部定位。该专利的装置也不能对准在侧卧位的所有3条轴线用于气管插管,也没有提供测量装置来确认所希望的位置。

[0013] 美国专利号1,131,802示出了一种装置,包括具有一对角度可调节的侧伸出部分的框架,利用纵向上所述侧伸出部分的水平调整的自由性可拆卸地安装在所述框架上的垂直可调的头枕,一对安装在侧伸出部分上用于朝向和远离该头枕运动的垂直可调的下颌支

架。该装置的目的是用来将尸体头部固定到桌子上用于防腐,并且因此没有设计为保持呼吸道通畅,也不取代减轻患者的胸部重量以优化通气。

[0014] 美国专利号1,441,817涉及一种装置,包括基板和一对间隔开的支颌器,其在该基板上于此以一定角度可调。该支颌器包括在基板上的唯一突出物,并且该基板足够窄,以便它可放置在尸体的颈部下方,并可纵向地调整尸体的颈部而尸体的肩部和头部放置在独立于该基板的护顶板上。该发明装置的目的是将尸体头部固定到桌子上用于防腐,并且因此没有设计为保持呼吸道通畅,也不取代减轻患者的胸部重量以优化通气。

[0015] 美国专利号1,729,525教导了一种设备,包括垂直可调的头枕、支颌器、用于承载由该头枕承载的支颌器的角度和长度可调的支撑装置、具有用于将头枕锁定在可调位置的接触装置的支撑结构和头枕,所述装置包括一对铰接到头枕上的支撑件以及用于该支撑件的组合连结和调整设备,支颌器相对于该装置是上下和角度可调整的,该装置还具有前端,其开孔用于容纳支颌器并在它们的前端承载用于保持支颌器在调整位置的夹紧设备。该装置的目的是将尸体头部固定到桌子上用于防腐,并且因此没有设计为保持呼吸道通畅,也不取代减轻患者的胸部重量以优化通气。

[0016] 美国专利号1,776,167示出了包括可调整头枕元件、可调整支撑元件、可调整接合装置、一对角度相反成形的延伸支颌器元件以及可调整肩部拉伸装置的设备,该可调整头枕元件包括一对相对设置向下倾斜的伸出部分和立柱,该可调整支撑元件包括设置在该头枕元件下方的角度成形的回转臂,该支撑元件包括用于锁定所述臂的装置,该可调整接合装置在立柱和臂之间,可调整接合装置在该支颌器元件和该伸出部分之间,该可调整肩部拉伸装置沿中心轴旋转地和可调整地连接到该伸出部分上。该专利没有要求保持呼吸道通畅,也不要求以实现所希望的位置,也不要求取代减轻患者的胸部重量以优化通气。另外,该设备不允许在插管过程中鼻面罩通气。在服务人员试图插管时它也不能调整头部和颈部定位。该设备也不要求对准在侧卧位的所有3条轴线(口咽、喉、气管)用于气管插管的最佳视野。

[0017] 美国专利号2,452,816公开了下颌支撑设备,包括基部构件装置,用于将基部构件固定到桌面上并横向于该桌面,与所述基部构件可调整间隔开的直立基台,用于选择性地调整纵向于所述基部构件的基台的装置。直圆柱形阀杆可夹持地回转以从每个基台的上端向上延伸,管状元件在每一个阀杆上是套叠的,并在其上轴向地滑动,用于夹紧管状元件并沿着该阀杆在选择性的可调整位置上的装置,安装块可回转地夹持在每个管状元件的自由端,并且下颌接合衬垫可移除地和可更换地夹持在每个块上,并以支撑关系抵靠每个块。该设备的缺点是它需要接合下颌骨臂以达到所希望的位置,但不能在侧卧位使用。这个动作对于没有深度麻醉的患者是非常刺激和疼痛的。而且,如果患者移动它不能提供限制头部的机械装置。显然,如果患者移动则不再能达到所希望的位置。该专利的装置还缺少取代减轻肥胖患者的胸部重量以优化通气的方法,以及该专利任何地方都没有教导或建议对准在侧卧位的所有3条轴线用于气管插管的可能性。

[0018] 美国专利号4,700,691涉及用于患者头部的限制和支撑设备,包括连接到手术台的头部固定装置、用于外科医生的胳膊和手支持件,其中所述手支撑件通过柔性臂固定于头部固定装置,还设置有元件来释放或紧固该柔性臂,该元件装配到外科医生的一个手指上,或与手和/或脚开关互连。该头部固定装置包括颈背支撑件,其设置有助于头部的三点

支撑,并且可设置在可调整的高度上。前支撑件在头部下方夹持到颈背支撑件中并通过铰接机构连接到颈背支撑件上。该柔性臂附接到在头部固定装置的前支撑件上。该装置的主要目的是在手术过程中限制头部,它不具有保持呼吸道通畅的能力,也不能进行托下颌。此外,该设备不能取代减轻患者的胸部重量以优化通气。

[0019] 美国专利号5,524,639公开了一种装置,意在免持环境中保持或改善仰卧患者的呼吸道。框架和可拆卸的枕头设备放置在患者的头部之下。机械装置从框架横向延伸并提供支颌器元件,其可设置在下颌的角度下。该支颌器元件可朝向和远离所述框架滑动,但这种滑动移动是通过单向离合器来控制,例如棘轮和棘爪系统,其仅限制了支颌器元件远离该框架的滑动。当支颌器元件远离框架滑动时,它们啮合下颌的角度,并随后把下颌往前推以维持或改善患者的呼吸道。一旦达到下颌的所需先前的推力位置,单向离合器保持下颌就位,直到释放离合器。下颌的重量则使支颌器元件朝向框架向后滑动,使下颌恢复到其正常位置。该设备有几个缺点,首先是它只能通过使用支颌器元件达到所需的位置。并不是所有的患者都需要支颌器,因为它是非常痛苦和刺激的,首先尝试较小的侵入性方法将是理想的。此外,该专利没有教导或建议对准在侧卧位的所有3条轴线。并且它不能取代减轻患者的胸部重量。

[0020] 本发明的一个方面涉及一种定位装置,它或可改造到现有的手术室台上或内置于将来的手术室台,以通过正确定位患者的颈部、头部和身体促进维持呼吸道通畅,此时的患者或者无意识,没有能力保持呼吸道畅通,或者是在手术或过程期间处于麻醉状态下,同时患者朝其任何一侧侧躺。虽然设计了一些枕头来将使用者的头部放置在嗅位,同时使用者平躺,但很多程序需要患者侧躺,即所谓的“侧卧位”。虽然目前存在一个枕头(美国专利2012/0180220)要求当患者在其侧卧位侧躺时将患者放置在嗅探位置(对准三条轴线,口咽、气管、喉),但需要服务人员必须在出现紧急情况下可以选择以免持方式执行托下颌,其中需要推送药物或进一步管理。还参见美国专利7,467,431,其中描述了患者倾斜装置,其包括倾斜的斜面以及位于基部构件上的中心线脊椎支撑件。该倾斜的斜面支撑患者的上身和头部,使得上身和头部相对于所述基部构件升高。所述中心线支撑件位于临近该倾斜的斜面,用于接触患者背部的位于临近脊椎的中央部分以提升该中央背部。根据一个实施方式,可调整该倾斜的斜面以及中心线脊椎支撑件以习惯配合于患者的身体。该脊椎支撑件的宽度小于所述倾斜的斜面宽度以沿中心线支撑件的相对侧限定横向空间,以容纳患者的胳膊和侧部,用于胸廓的横向延伸。也参见美国专利8,336,142。

[0021] 对于在侧卧位的患者,本发明还提供了改进现有技术的定位装置,其使能够在嗅探位置、鼻和全面罩无创正压通气CPAP、BiPAP、插管时通气、在运送患者的过程中氧合作用、托下颌,并且包括具有第一表面和第二表面的基底,该第一表面用于支撑可调整的斜面和用于支撑患者背部的托架,该第二表面用于支撑其上的患者头部,其可调节两条轴线X和Y以将患者放置在希望的嗅探位置上。

[0022] 更具体地,本发明在一个方面提供了包括用于支撑托架分组合件的基底的装置,所述托架分组合件包括三个表面,第一表面、第二表面和第三表面,均沿Z轴并沿所述基底分组合件是可调整的。每个基底表面具有一个侧面,其中所述基底配置为基本上支撑所述托架分组合件臂。托架分组合件包括连接到所述第二表面并可沿Z轴移动的第一表面。托架分组合件的第一表面包括两个表面,第一表面或斜面,其有助于维持患者的身体在倾斜的

位置,以及第二表面,其提供了头部支撑表面,用于支撑患者在所期望的位置,即嗅探位置。

[0023] 在本发明的另一个实施方式中提供了背部限制装置,包括背板,其包含与患者背部接触并且在y轴上是可调节的刚性表面;弹性和柔软背部限制装置具有第一近端,其附接在背板的一侧上,然后可沿水平方向延伸并接触患者的腹部且附接在背板的相对侧上。该装置是可调的,并能够将患者的背部固定到背板上。

[0024] 在本发明的又一个实施方式中,当患者处于侧卧位时提供了头部/颈部支撑件,其可独立地控制以通过独立于斜面提高头部与颈部而支撑所期望的位置,即嗅探位置,或者如果病人在右侧或左侧的侧卧位,该头部和颈部支撑件可以调整,以保证正确对准颈椎、胸椎和腰椎。更具体地,提供了气动或机械的头部/颈部支撑件,其由机械千斤顶或柔性波纹管组成,固定或者位于头部/颈部支架的顶表面上。

[0025] 本发明还提供了用于定位患者的方法。该方法包括以下步骤:提供具有背板和支撑臂的装置;将患者的头部放置在该装置的支撑臂的第一表面上;调节所述支撑臂的第二表面以实现与所述患者的颈部接触,移动并放置所述患者的头部和颈部在所期望的位置上,连同将颈椎、胸椎、腰椎和所期望的位置对准;抑制患者的头部防止从所期望的位置脱落;移动第一下颌骨臂来接触患者的下颌;以及移动第二下颌骨臂接触患者下颌;其中第一下颌骨臂和第二下颌骨臂的接触提供了足够的力来充分地维持患者的头部、颈部和/或下颌在期望的位置上。然后可调节背板成与所述患者的背部接触,并限制病人的背部防止患者从所期望的位置脱落。

[0026] 在另外的实施方式中,本发明包括下颌骨臂,包括:由附接到下颌骨垫的可调节和可锁定的机构组成的弯曲部,其中该下颌骨垫是柔性的,并且其中所述下颌骨垫具有配置为附接到该弯曲部的远端侧和配置为在多个点接触患者下颌的近端侧,其可在远端侧以全角度枢转。设置有连接器部分,其配置为附接到支撑件上。优选地,所述连接器部分配置为附接到与包括左侧和右侧的基底相附接的支撑件上,其中所述基底配置为充分地容纳患者的颈部和头部,并且其中所述支撑件在三条轴线上是可移动的,使得下颌骨垫可定位成在一个或多个点与患者的下颌接触,并保持在所期望的位置。

[0027] 本发明还提供了用于定位患者的方法,包括以下步骤:提供具有在z轴上可调节机构的装置(即,其可以是气动千斤顶,例如波纹管或机械千斤顶等),将患者的头部基本放置在可调节机构的顶部上,提升该斜面然后调节在z轴上的该可调节机构以及具有在垂直方向上的可调节机构的装置,(即,气动千斤顶,例如波纹管或机械千斤顶等),将患者的颈部基本放置在可调节机构的顶部上,然后调节所述在Z轴上的可调节机构,使得患者最初在嗅位或“耳朵到胸骨的切迹位置”。

[0028] 在另一方面,本发明提供了用于定位患者的方法,包括提供如上所述的装置,将患者的头部和颈部基本放置在托架的第一表面上,并利用一个或多个可调节装置将患者的头部和颈部放置在所期望的位置上。然后移动第一下颌骨臂和第二下颌骨臂来接触患者的下颌,其中该第一下颌骨臂和第二下颌骨臂的接触提供了足够的力来充分地维持患者的头部和/或下颌在期望的嗅探位置上。

[0029] 对于患者平躺(仰卧位)来说,在本发明的另一个方面提供了定位装置,通过正确定位患者的背部、肩部、颈部和头部来促进维持呼吸道通畅,此时患者在手术或过程期间在镇静或麻醉状态下是无意识的、无法保持呼吸道通畅。本装置包括一种装置,包括:包含第

一侧和第二侧的基部支撑件以及内部可调节的支撑结构。第一侧基部配置为基本上容纳患者的颈部和头部。第一基部的远端支撑患者的颈部,并由在Z轴上的可调节支撑件组成,这有助于保持所期望的嗅探位置。基部的近端由在Z方向上可调节的稍微倾斜或平的表面组成,具有或不具有切口中心,这提供了头部支撑以进一步优化嗅探位置。可调节的斜面可放置在患者的背部和肩部下面以获得所期望的角度。第一支撑件定位在基部的第一侧上,并且第二支撑件定位在基部的第二侧上。提供在基部的内部的可调节支撑结构以机械地调整斜面的高度和长度,以习惯的配合于患者。第一下颌骨臂配置为接触患者下颌的一侧,并且第二下颌骨臂定位在第二支撑件上并配置为接触患者下颌的另一侧。下颌骨臂的第一和第二支撑件可在X、Y和Z轴上移动。可移动臂的第一和第二近端部分沿X、Y和Z轴移动,而远端部分是可旋转的,使得每个可定位成与患者的下颌接触并保持在所期望的位置。

[0030] 本发明还提供了改进现有技术的定位装置,使能够保持在嗅位和托下颌,并包括具有用于支撑托架的表面的基部,该托架用于在Z轴上调节的支撑患者的头部,在第一表面或第二表面上支撑患者的颈部,其在Z轴上是可调节的,以将患者放置在所期望的嗅探位置上。上臂限制了患者的头部沿着所有三条轴线平移。提供从所述第一表面延伸的第一和第二下颌骨臂用于与病人的下颌接触,以便保持患者在其平躺的期望位置上。

[0031] 在另一个方面,本发明提供了用于定位患者的方法,提供如上所述的装置,将患者的头部基本放置在托架的第一表面上,并使用可调节装置将患者的头部和/或颈部放置在所期望的位置上。然后移动第一下颌骨臂和第二下颌骨臂接触患者的下颌,其中通过服务人员或机械的第一下颌骨臂和第二下颌骨臂的接触提供了足够的力来充分维持患者的头部、颈部和/或下颌在所期望的嗅探位置上。

[0032] 在另外其它的实施方式中,提供了弹性的和柔软的头颈部限制装置,其可附接或内置在麻醉全面罩、鼻罩、鼻口面罩中,包括两个端部;第一近端附接到基部的第一表面一侧上,然后其可沿水平方向延伸并接触患者的麻醉面罩,这产生了对患者的鼻子和/或面部的密封,并且附接到基部的第一表面的相对侧上;该装置是可调节的并且能够将患者的头部和颈部固定到基部的第一表面上。

[0033] 在又一个实施方式中,本发明包括下颌骨臂,其包括:由附接到下颌骨垫的可调节和可锁定的机构组成的弯曲部,其中该下颌骨垫是柔性的,并且其中所述下颌骨垫具有配置为附接到该弯曲部的远端侧和配置为在多个点接触患者下颌的近端侧,其可在远端以所有角度枢转;以及连接器部分,其配置为附接到支撑件上。

[0034] 本发明进一步的实施方式包括倾斜表面,其由两个侧面组成,其中所述近端侧可附接到第一基部上,并且该近端侧定位的角度可通过调节远端侧的角度来改变(或者机械地致动等)。该远端侧还能够延伸以确保习惯的配合头部、颈部和身体的定位。倾斜表面将具有背部和肩部垫,将其搁置以支撑患者的上背部、中间背部和肩部。这种支撑能使重力取代减轻患者的胸部重量,允许呼吸道更通畅。

[0035] 本发明的又一实施方式包括测量装置,以确认35°的最佳颈部屈曲角度。一个实施方式包括两个侧面,其中其第一侧面是半圆柱形的并且由四个臂组成,其每一个位于四个角的每一个内,其每一个接触患者的颈部;第二侧面包括35°的水平转角。

[0036] 在又一个实施方式中,本发明包括用于确认15°的最佳头部伸展角度的调平装置。这后一种实施方式包括两个侧面,其第一侧面是三角形的,包括三个臂,其每一个位于三个

角的每一个内,其中每一个在Z轴上是可调节的,其每一个接触患者的面部;第二侧面包括15°的水平转角度。

[0037] 在另一个实施方式中,本发明包括用于定位患者的方法,包括以下步骤:提供如本文所述的装置的任何实施方式,在该装置的基部上基本上连同患者的头部和颈部将患者的上背部、中间背部和肩部放置在倾斜表面上;将患者的头部和颈部放置在所期望的位置上,利用测量装置任选地确认该位置;将麻醉鼻罩、全面罩、或鼻口面罩固定到患者的鼻子或面部上,限制患者的头部以防止患者从所期望的位置脱落;移动第一和第二下颌骨臂接触患者的下颌;其中第一下颌骨臂和第二下颌骨臂的接触提供了足够的力来充分地维持患者的头部、颈部和/或下颌在所期望的位置上。

[0038] 在本发明的又一方面,提供了简单而优雅可调的头枕颈枕,或组合的头颈枕,其可以是气动千斤顶例如波纹管或机械千斤顶,其是独立控制的以支撑患者的头和/或颈部来通过独立于所述托架提升患者的颈部和头部获得最佳的嗅位。头枕和/或头颈枕可以是固定到装置上或是可拆卸的,并在装置上、手术室台或用于需要呼吸道管理的患者的其它表面任意移动。头枕和/或头颈枕还具有盖,以保护它防止血液、生理盐水和传染性病原体进入,该盖也可固定到该装置上并可重复使用,或者它可以是一次性的和可拆卸的。头枕和/或头颈枕的盖还具有附件,用于面罩附接并能够将患者的头部和/或颈部固定在装置上、手术室台或用于需要呼吸道管理的患者的任何其它表面上的任何位置。头枕和/或颈枕的盖还具有第二鼻罩、全面罩或鼻口面罩条带,其可以是重复使用的并附接到所述盖上,或是可拆卸的和一次性的,并且来自患者头部的后面并在前面附接到麻醉面罩上。具有附接的或可拆卸的条带的头枕和/或颈枕的盖是新颖的,允许患者头部和/或颈部保持在所期望的位置上,而麻醉面罩密封患者面部在装置上,手术室台或用于需要呼吸道管理的患者的其它表面上的任意位置。

[0039] 在又一实施方式中,附接的或从头枕和/或颈枕的盖可拆卸的面罩条带包括具有一个或多个侧面的基部。第一侧面可用于从正面遇到麻醉面罩并在相对侧面上附接到该基部上,以产生鼻罩、全面罩或鼻口面罩与患者的面部之间的紧密密封。在又一实施方式中,面罩条带具有附接到所述麻醉面罩左侧的一个侧面,而第二侧面附接到右侧,或反之亦然,以产生鼻罩、全面罩或鼻口面罩与患者的面部之间的紧密密封。在又一实施方式中,面罩条带具有三个侧面,其中一个侧面附接到所述麻醉面罩的左侧,而第二侧面附接到右侧,或反之亦然,并且第三侧面越过患者的头部附接到麻醉面罩的顶部,以产生鼻罩、全面罩或鼻口面罩与患者的面部之间的紧密密封。在本发明的又一方面,提供了用于为患者提供麻醉的装置,包括基部,其包括第一侧面、第二侧面、第三侧面和内部可调节的支撑结构。基部的第一侧面配置为基本容纳患者的颈部和头部。第一基部的远端支撑患者的颈部,包括有助于保持所需的嗅探位置的大致半圆柱形的支撑件或大致平坦的表面,这两者在Z轴上都是可调节的。第一基部的近端包括稍微倾斜的或大致平坦的表面,具有或不具有切口中心,在Z轴上也是可调节的,以提供头部支持,以进一步优化该嗅探位置。在所述基部的内部提供了调节的支撑结构,以机械地调整患者的高度以及使患者的头部、颈部和身体与该表面习惯地配合以优化该定位。基部的第二和第三侧面各包含多个突起,优选地是四个突起。该麻醉面罩从前透视角度附接到患者,伴随着条带从患者的头部后面附接到连接支撑件的面罩。当前的条带从后面使用,所述条带从头部后面开始,在前面附接到面罩上。面罩条带有四个侧

面,第一和第二侧面含有放置在面罩的第一侧面的孔之上的孔,第三和第四侧面含有一个窄的伸出部分,其每一个包括多个孔,均适于附接到基部的第二和第三侧面上的突起中的一个。可选择和优选的设计包括附接到面罩上的两条细绳,然后所述细绳可在头部后面附接到所述支撑件上。这些细绳在头部的每一侧面可通过摩擦、钩和毛圈搭扣等裁剪。面罩条带仅适于靠住患者的鼻子、鼻子、口、面颊和/或头部来保持麻醉面罩,以维持所期望的嗅探位置,其中患者的下颌向上和向前移动,从而防止患者的呼吸道变得阻塞。面罩条带适于将患者的头部和/或颈部稳定到基部上以防止患者的头部和/或颈部的移动。该面罩条带产生的紧密密封也允许无创正压通气(CPAP/BiPAP),其进一步有助于维持呼吸道通畅。

[0040] 在本发明的另一方面,提供了用于为患者提供麻醉的装置,包括基部,其包括第一侧面、第二侧面、第三侧面和可调节的支撑结构,其中基部配置为基本容纳患者的颈部和头部;其中基部第一侧面的远端包括有助于保持所需的嗅探位置的在Z轴上可调的大致半圆柱形的支撑件或平坦的表面;基部第一侧面的近端包括稍微倾斜的或平坦的表面,以提供头部支持,以进一步优化该嗅探位置,并且在Z轴上是可调的;基部的第二和第三侧面可各包含多个突起以及具有四个侧面的面罩条,其中第一和第二侧面包括放置在面罩的孔之上的孔,第三和第四侧面包括窄的伸出部分,其包括多个孔,均适于附接到基部的第二和第三侧面上的四个突起中的一个,或可选择和优选的设计包括在第二和第三侧面的每一个上的夹子,面罩的细绳附接在夹子上;其中面罩条带适于靠住患者的头部、口和/或鼻子来保持麻醉面罩,以维持所期望的嗅探位置,其中患者的下颌向上和向前移动,从而防止患者的呼吸道变得阻塞;并且其中面罩条带适于将患者的头部和/或颈部稳定到基部上以防止患者的头部和/或颈部移动。

[0041] 本发明的其它实施方式包括:

[0042] 一、用于定位患者的装置,包括:基部分组零件,包括用于支撑托架分组合件的表面,其中支撑臂的第一表面支撑患者头部并且在Z轴上是可调的,第二表面支撑患者的颈部并且在Z轴上是可调的,以将患者放置在所期望的嗅探位置上;降低上臂的表面直至适于紧密并锁定,用于约束患者的头部沿着所有三条轴线平移;柔性绷带放置在患者的前额上,用于通过在X方向上施加恒定的约束力将患者的前额固定到嗅探组件上;第一下颌骨臂从托架分组合件的第一表面垂直地延伸,其中第一垂直调整部分可绕Z轴旋转锁定,其中第一下颌骨臂可定位成与患者的下颌接触;并且第二下颌骨臂从托架分组合件的第三表面垂直延伸,其中第二垂直调整部分可绕Z轴旋转锁定,其中第二下颌骨臂可定位成与患者的下颌接触;其中第一下颌骨臂和第二臂颌骨是可移动的,使得每个可定位成与患者的下颌接触,并在患者侧躺时使服务人员免持来维持患者在期望的位置上。

[0043] 上述装置优选的特征在于以下一个或多个特征:

[0044] (a)其中下颌骨臂可定位成在患者侧躺时在分支、主体或患者下颌的角度上接触患者的下颌,其中每个所述第一下颌骨臂和第二下颌骨臂优选地可定位成在患者侧躺时在两个或多个分支、主体或患者下颌的角度上接触患者的下颌,和/或其中每个第一下颌骨臂和第二下颌骨臂优选地可定位成在患者侧躺时在分支、主体或患者下颌的角度上接触患者的下颌;

[0045] (b)还包括在第一和第二下颌骨臂上的下颌骨垫,用于接触患者的下颌;

[0046] (c)其中所述托架分组合件的所有表面相对于基部移动,其中所述支撑臂的第一

和第三表面优选地在一个轴上相对于基部是可移动的,并且托架分组合件的第二表面在三个轴上相对于基部是可移动的;

[0047] (d)其中所述基部是矩形的,并且托架分组合件的表面是c形的;

[0048] (e)其中所述下颌骨垫优选地由弹性的变形材料形成,其中所述下颌骨垫由泡沫形成;

[0049] (f)其中第一下颌骨臂和第二下颌骨臂分别可拆卸地连接到托架分组合件的第一表面和第三表面上;

[0050] (g)其中第一下颌骨臂相对于托架分组合件的第一表面是可移动的,并且第二下颌骨臂相对于托架分组合件的第三表面是可移动的;

[0051] (h)其中所期望的位置是侧躺、对准所有3条轴线轴(口咽、喉和气管)和/或托下颌手法时的嗅探位置;

[0052] (i)其中所述托架分组合件的第二表面还包括颈枕,其布置为提供患者颈部的最佳弯曲和最优的头部伸展来获得所期望的位置;

[0053] (j)其中第一和第二下颌骨臂配置为在X轴上旋转时延伸患者的下颌;

[0054] (k)其中多个下颌骨臂配置为在X轴上旋转时延伸患者的下颌;

[0055] (l)其中所述装置由MRI或X光兼容材料形成;

[0056] (m)其中所述托架分组合件是可逆的,允许将患者放置在相反侧上;

[0057] (n)进一步包括水平仪,用于确定患者的颈部弯曲角度;

[0058] (o)其中所述基部还包括设置在第一表面上配置为提供患者颈部的最佳弯曲的远端颈枕以及近端倾斜头枕,以提供最佳的头部伸展来提供所期望的患者位置;

[0059] (p)其中当患者与第一和第二下颌骨臂接触时,第一和第二支撑表面以及第一和第二旋转部分是可调节的;

[0060] (q)其中所述基部分组合件包括:

[0061] 具有两个端部的刚性倾斜侧面;

[0062] 可从基部的第一侧的远端侧拆卸的近端;所期望的位置可由不同的体型通过调整第一基部的高度来获得;

[0063] 远端,包括伸展机构来维持所期望的角度,以保持患者在期望的位置上;

[0064] 泡沫垫,位于该刚性倾斜侧面的顶部上并且接触患者的上背部、中间背部和肩部;

[0065] (r)其中该倾斜侧面支撑患者的上背部、中间背部和肩部,并使重力来取代减轻患者的胸部重量,包括肥胖患者;

[0066] (s)其中该装置由MRI或X光兼容材料形成;

[0067] (t)其中基本上放置头部和颈部在倾斜侧面的远端上的颈枕上以及倾斜侧面的近端上的头枕上使将引发疼痛的患者放置在所期望的位置上;以及

[0068] (u)其中所述装置沿y轴是可调节的,以取代减轻患者的胸部重量;沿y轴是可调节的,以水平地对齐耳朵和胸骨来实现肥胖患者的最大量的换气;并沿z轴是可调节的,用于升降肥胖患者而不需要医护人员的帮助。

[0069] 二、还提供了用于定位患者的方法,包括以下步骤:

[0070] 提供上述装置,使用可调节装置将患者的头部基本放置在托架分组合件的第一表面上,以将患者的头部和颈部放置在所期望的位置上;移动第一下颌骨臂接触患者的下颌;

移动第二下颌骨臂接触患者的下颌;其中,第一下颌骨臂和第二下颌骨臂的接触提供了足够的力以充分维持患者的头部和/或下颌在所期望的位置上,其中所有的三条轴线(口咽、喉、气管)优选地对准用于插管视野。

[0071] 三、还提供了下颌骨臂用于定位患者,包括:刚性可锁定臂,其中所述臂具有在X轴上可旋转的弯曲伸出部分;弯曲部,其中所述弯曲部基本上是刚性的;下颌骨垫,其中所述下颌骨垫是柔性的和可枢转的,并且其中所述下颌骨垫具有配置为附接到该弯曲部的近端侧以及配置为在至少两个分支、主体以及患者下颌的角度上接触患者下颌的远端侧;以及连接器部分,其中所述连接器部分配置为延伸并附接到支撑件的可旋转部分上,并且其中所述连接器部分进一步配置为连接到附接到托架分组合件的支撑件上,该托架分组合件包括左侧和右侧,其中托架分组合件配置为基本上容纳患者的头部,并且其中所述托架分组合件在一个轴上是可移动的,使得所述下颌骨垫可定位成在一个或多个点上接触患者的下颌,并保持患者在所期望的位置上,其中所述托架分组合件是可逆的,允许将患者放置在相反侧上。

[0072] 四、还提供了有弹性的和柔软的头限制和麻醉面罩密封装置,用于定位患者,包括:第一近端,附接到托架分组合件的基部的第一表面的一侧上,然后其可沿水平方向延伸并接触患者的头部且附接到所述基部的第一表面的相反侧上,或者接触麻醉面罩,然后其接触并密封患者的面部;其中该装置是可调的并能够将患者的头部固定在基部的第一表面上,以防止患者从所期望的位置脱落,其中所述托架分组合件任选是可逆的,允许将患者放置在相反侧上,和/或其中所述装置任选地由MRI或X光兼容材料形成。

[0073] 五、还提供了弹性的和柔软背部限制装置,用于定位患者,包括:

[0074] 第一近端,其附接到背板的一侧上,然后可沿水平方向延伸并接触患者的腹部且附接到背板的相反侧上,其中所述装置是可调节的,并能够将患者的背部固定到背板上以防止患者从所期望的位置上脱落。

[0075] 六、还提供了用于支撑患者的表面,包括:第一侧面,其可调整为接触患者的背部,以及第二侧面,其可调整为接触患者的肋骨以防止患者移动。

[0076] 七、还提供了向患者提供麻醉时使用的装置,包括:

[0077] 具有第一侧面、第二侧面、第三侧面和可调整支撑结构的基部,其中所述基部配置为基本上容纳患者的颈部和头部;其中基部第一侧面的远端包括半圆柱形的支撑件,其可在z轴上调节,这有助于保持所期望的嗅探位置,或也可在z轴上调节的平面;基部第一侧面的近端包括稍微倾斜的或平坦的表面,具有或不具有切口中心,并在z轴上是可调节的,以提供头部支持,进一步优化该嗅探位置;基部的第二和第三侧面各包含多个突起;以及麻醉面罩条带有四个侧面,其中第一和第二侧面包括放置在面罩的孔之上的孔,并且第三和第四侧面包括窄的伸出部分,其包括多个孔,均适于附接到基部的第二和第三侧面上的四个突起中的一个;其中面罩条带适于保持麻醉面罩条带抵靠在患者的鼻子、面颊、口和/或头部来维持所期望的嗅探位置,其中患者的下颌向上和向前移动,从而不会阻塞患者的呼吸道;并且其中面罩条带适于将患者的头部和/或颈部稳定到基部上,以防止患者的头部和/或颈部的移动。

[0078] 上述装置优选的特征在于以下一个或多个特征:

[0079] (a)其中所述麻醉面罩由非静态乳胶自由材料形成;

[0080] (b)其中至少一些所述窄的伸出部分具有相应的按扣部分,用于将窄的伸出部分附接到基部的一个突出部上;

[0081] (c)其中所述可调节的支撑件位于基部的内部;

[0082] (d)其中所述可调节的支撑件包括机械或气动调节机构;

[0083] (e)其中所述基部的平面图是大致矩形的;

[0084] (f)其中所期望的位置是嗅探位置,对准所有三条轴线,口咽、喉、气管;

[0085] (g)其中所述基部还包括设置在第一表面上并配置为提供患者颈部的最佳弯曲的远端可调节颈枕,以及提供最佳的头部伸展来获得所期望的位置的近端倾斜头枕;或如果所期望的位置是没有必要的,所述基部仅包括平面;

[0086] (h)其中所述装置由MRI或X光兼容材料形成;以及

[0087] (i)其中所述面罩由用抗微生物溶液很容易消毒的材料形成或是一次性的。

[0088] 八、还提供了用于定位患者来执行麻醉的方法,包括以下步骤:提供上述的装置,将患者的头部和颈部基本放置在托架分组合件上;使用可调节的装置将患者的头部和颈部放置在所期望的位置上;将面罩条带放置在麻醉面罩的孔之上或患者的头部之上,以基本保持患者的头部和/或下颌在所期望的位置上。

[0089] 上述方法优选的特征在于以下一个或多个特征:

[0090] (a)其中基本放置头部和颈部在基部第一表面的远端上的颈枕上以及在基部第一侧面的近端上的头枕上使将未引发疼痛的患者放置在所期望的位置上;

[0091] (b)其中基本放置头部和颈部在基部第一表面的远端上的颈枕上以及在基部第一侧面的近端上的头枕上使将患者放置在所期望的位置上并限制患者的头部和颈部移动;以及

[0092] (c)其中将面罩放置在患者的面部上,然后将面罩条带放置在面罩上并将其附接到基部上,将防止麻醉气体和氧气泄漏到空气中。

[0093] 九、还提供了在向患者提供麻醉时使用的装置,包括:用于向所述患者提供所述麻醉的装置;用于保持所述面罩装置靠住患者的鼻子、口、面颊和/或头部的面罩条带装置;面罩条带附接到其基部上实现所期望的位置,这向上和向前提升了患者的下颌,以便不阻塞患者的呼吸道。

[0094] 十、还提供了用于向仰卧在支撑件上的患者提供通气的装置,包括通气面罩、通气面罩上的面罩锚环,以及

[0095] 多个弹性体条带,连接该面罩锚到支撑件上。优选的,弹性体条带围绕假想的圆圈间隔开180°固定到该面罩锚环上。

[0096] 十一、还提供了用于定位患者的装置,包括:托架,其具有第一表面,支撑患者在倾斜的位置上,并且在z轴上是可调节的,第二表面,其支撑患者的头部和颈部并且是可调节的,以将患者放置在大致所期望的嗅探位置上;以及气动或机械千斤顶,或者可张开的风箱,支撑在第二表面上用于独立地相对于所述第二表面提升患者的头部。

[0097] 上述装置优选的特征在于以下一个或多个特征:

[0098] (a)其中所述可张开的风箱包括多个由在刚性基部上的柔性膜连接的刚性同心环,其中所述基部的第三侧面优选包括:

[0099] 具有两个端部的刚性倾斜侧面;

[0100] 可从基部的第一侧面的远端侧拆卸的近端;所期望的位置可由不同的体型通过调整第一基部的高度来获得;

[0101] 远端,包括伸展机构来维持所期望的角度,以维持患者在期望的位置上;

[0102] 可弹性变形垫,其位于该刚性倾斜侧面的顶部上并且接触患者的上背部、中间背部和肩部;

[0103] (b)其中所述风箱包括双向阀,通过它可增加或减少空气;以及

[0104] (c)其中所述风箱由MRI或X光兼容材料形成。

[0105] 十二、还提供了用于定位患者以促进维持在麻醉状态下的患者呼吸道的方法,包括提供如上所述的装置,将患者定位在该装置上,调节第一表面以支撑患者在所期望的倾斜位置上;调节第二表面以支撑患者头部和颈部在大致期望的嗅探位置上;以及激活气动或机械千斤顶,或给可张开的风箱充气以相对于第二表面提升患者的头部到期望的嗅探位置。

[0106] 十三、还提供了用于定位患者的装置,包括:基部,其包括支撑患者的头部和颈部的第一侧面,作为基础的第二侧面,在第一和第二侧面之间的内部垂直可调节支撑结构,以及可拆卸的第三倾斜侧面,其支撑患者的上背部、中间背部和肩部;定位在基部的第二侧面上的第一支撑件,并且相对于基部的第二侧面在x轴和y轴上是可锁定地调节;定位在基部的第二侧面上的第二支撑件,并且相对于基部的第二侧面在x轴和y轴上是可锁定地调节;第一下颌骨臂从第一支撑件的第一垂直可调节部分延伸,其中所述第一垂直可调节部分在z轴上是可锁定的,以相对于z轴可锁定地调节第一下颌骨臂,并且其中所述第一下颌骨臂定位成与患者的下颌接触;以及第二下颌骨臂从第二支撑件的第二垂直可调节部分延伸,其中第二垂直可调节部分是可锁定在z轴上以相对于z轴调节第二下颌骨臂,并且其中所述第二下颌骨臂定位成接触患者的下颌;其中,第一下颌骨臂和第二臂颌骨是可移动的,使得每一个可定位成接触患者的下颌并维持患者在所期望的位置上,并使服务人员免持。

[0107] 上述装置优选的特征在于以下一个或多个特征:

[0108] (a)其中所述下颌骨臂可定位成在分支、身体或患者的下颌角度上接触患者的下颌,其中所述第一下颌骨臂和第二下颌骨臂的每一个优选的可定位使得优选由泡沫形成的下颌骨垫在两个或多个分支、身体或患者的下颌角度上接触患者的下颌,或其中所述第一下颌骨臂和第二下颌骨臂的每一个优选的可定位使得下颌骨垫在分支、身体或患者的下颌角度上接触患者的下颌;

[0109] (b)其中所述第一支撑件可相对于所述基部移动,并且所述第二支撑件可相对于所述基部移动,其中所述第一支撑件优选是在两个轴上可相对于基部移动,并且第二支撑件优选是在两个轴上可相对于基部移动;

[0110] (c)其中所述基部是矩形的;

[0111] (d)其中所述第一下颌骨臂和第二下颌骨臂各自包括下颌骨垫;

[0112] (e)其中所述第一下颌骨臂和第二下颌骨臂分别可拆卸地连接到第一支撑件和第二支撑件上;

[0113] (f)其中第一下颌骨臂可相对于第一支撑件移动,并且第二下颌骨臂可相对于所述第二支撑件移动;

[0114] (g)其中所期望的位置是嗅探位置、对齐所有三条轴线(口咽、喉和气管)和/或托

下颌手法；

[0115] (h)进一步包括水平仪,用于确定患者的颈部弯曲角度；

[0116] (i)其中所述基部还包括设置在第一表面上配置为提供患者颈部的最佳弯曲的远端颈枕以及近端倾斜头枕,以提供最佳的头部伸展来获得所期望的位置；

[0117] (j)其中第一和第二下颌骨臂配置为当在z轴上旋转时伸展患者的下颌；

[0118] (k)其中多个下颌骨臂配置为当在z轴上旋转时伸展患者的下颌；

[0119] (l)其中当患者与第一和第二下颌骨臂接触时,第一和第二支撑件以及第一和第二旋转部分是可调节的；以及

[0120] (m)其中该基部的第三侧面支撑患者的上背部、中间背部和肩部,从而使重力来取代减轻患者的胸部重量,包括肥胖患者；

[0121] (n)其中该装置由MRI或X光兼容材料形成；

[0122] (o)其中基本上放置头部和颈部在基部的第一表面的远端上的颈枕上以及在基部的第一侧面的近端上的头枕上是将引发疼痛的患者放置在所期望的位置上；以及

[0123] (p)其中所述内部可调节表面由刚性结构组成；其中该装置沿y轴是可调节的,以取代减轻患者的胸部重量；沿y轴是可调节的以水平地对齐耳朵和胸骨来实现肥胖患者的最大量的换气；并沿z轴是可调节的用于升降肥胖患者而不需要医护人员的帮助；

[0124] (q)还包括卡爪,用于根据延伸所述下颌提供给麻醉师与患者的触觉界面,其中,所述卡爪的左右臂位置由摩擦力来维持,其通过千斤顶组件来传递,该力可由麻醉师在绕z轴转动所述臂时克服,进一步任选地特征在于一个或多个下列特征：

[0125] (1)其中所述卡爪的左右臂位置是由摩擦力绕Y轴固定；

[0126] (2)其中由螺杆提供微调,用于进一步伸展下颌,所述螺杆通过围绕Y轴将扭矩施加至所述臂上以将附加力施加至标称Z轴方向上；以及

[0127] (3)还包括扭矩限制器,用于限制通过在Z方向上的左右臂施加到下颌骨上的力,以防止患者受伤。

[0128] 十四、还提供了用于定位患者的下颌骨臂,包括:两个刚性可锁定臂,其中上臂具有在z轴上可转动的弯曲伸出部分,并且下臂不提供伸出部分；弯曲部分,其中所述弯曲部分基本上是刚性的；下颌骨垫,其中下颌骨垫是柔性的和可枢转的,并且其中所述下颌骨垫具有配置为附接到所述弯曲部分的近端侧以及配置为在至少两个分支、身体和患者下颌的角度上接触患者下颌的远端侧；以及连接器部分,其中所述连接器部分配置为延伸并附接到支撑件的可旋转部分上,并且其中所述连接器部分进一步配置为连接到附接到基部的支撑件上,该基部包括左侧和右侧,其中基部配置为基本上容纳患者的头部、颈部、上部和中间背部以及肩部,并且其中所述支撑件在两个轴上是可移动的,使得所述下颌骨垫可定位成在一个或多个点上接触患者的下颌,以保持患者在所期望的位置上。

[0129] 十五、还提供了用于如上所述的装置的第一测量装置,包括两个侧面:具有四个臂伸出部分的第一刚性半圆柱形侧面,四个臂伸出部分的每一个位于四个角的每一个中,并且其每一个接触患者的颈部；第二刚性侧面包括35°的斜面,其搁置测量装置用于确认35°的颈部弯曲角度,以实现所期望的位置。

[0130] 十六、还提供了用于如上所述的装置的第二测量装置,包括两个侧面:具有三臂伸出部分的第一刚性三角形侧面,其中的每一个位于三个角的每一个内,并且其每一个接触

患者的头部;所述臂伸出部分各自沿z轴调节以实现所期望的位置;第二刚性侧面包括15°的斜面,其搁置测量装置用于确认15°的头部伸展角度,以实现所期望的位置。

[0131] 十七、还提供了用于患者的弹性的和柔软的头限制装置,包括:

[0132] 第一近端,其附接到基部的第一侧面的一侧上,然后其可沿水平方向延伸并接触患者的头部且附接到所述基部的第一表面的相反侧上;该装置是可调的并能够将患者的头部固定在基部的第一表面上,以防止患者从所期望的位置脱落。

[0133] 十八、还提供了用于定位患者的方法,包括以下步骤:

[0134] 提供如上所述的装置,将患者的头部、颈部、上部和中间背部以及肩部基本放置在基部上;使用可调节的装置将患者的头部、颈部、上部和中间背部以及肩部放置在所期望的位置上;任选地使用测量装置以确认所期望的位置;移动第一下颌骨臂接触患者的下颌;移动第二下颌骨臂接触患者的下颌;其中第一下颌骨臂和第二下颌骨臂的接触提供了足够的力以充分地维持患者的头部和/或下颌在所期望的位置上。

[0135] 上述方法优选的特征在于以下一个或多个特征:

[0136] (a)对准其中所有三条轴线(口咽、喉、气管)用于气管插管的推荐视野;

[0137] (b)其中通过使用千斤顶调整所述患者的头部相对于所述Z轴的高度,以及

[0138] (c)其中该装置包括释放挤压的托下颌握把,并且包括在z方向上移动该托下颌握把的步骤。

[0139] 十九、还提供了用于定位患者的装置,包括:基部;枢转地安装在基部的近端上的斜面组件,用于支撑患者的上背部、中间背部和肩部,所述斜面组件可调整长度和相对于基部的角度;枢转地安装到斜面组件的远端上的头部支撑分组合件,所述头部支撑分组合件可调整相对于所述斜面组件的角度;以及气动或机械千斤顶,或者可张开的风箱,支撑在头部支撑分组合件上用于独立地相对于头部支撑分组合件来提升患者的头部。

[0140] 二十、还提供了第一测量装置,用于如上所述的装置,包括两个侧面:具有四个臂伸出部分的第一刚性半圆柱形侧面,四个臂伸出部分的每一个位于四个角的每一个中,并且其每一个接触患者的颈部;第二刚性侧面包括35°的斜面,其搁置测量装置用于确认35°的颈部弯曲角度,以实现所期望的位置。

[0141] 二十一、还提供了用于如上所述的装置的第二测量装置,包括两个侧面:具有三臂伸出部分的第一刚性三角形侧面,其中的每一个位于三个角的每一个内,并且其每一个接触患者的头部;所述臂伸出部分各自沿z轴调节以实现所期望的位置;第二刚性侧面包括15°的斜面,其搁置测量装置用于确认15°的头部伸展角度,以实现所期望的位置。

[0142] 二十二、还提供了用于定位患者的方法,包括以下步骤:

[0143] 提供如上所述的装置,将患者的头部、颈部、上部和中间背部以及肩部基本放置在基部上;使用可调节的装置将患者的头部、颈部、上部和中间背部以及肩部放置在所期望的位置上;使用测量装置以确认所期望的位置;移动第一下颌骨臂接触患者的下颌;移动第二下颌骨臂接触患者的下颌;其中第一下颌骨臂和第二下颌骨臂的接触提供了足够的力以充分地维持患者的头部和/或下颌在所期望的位置上。

[0144] 上述方法优选的特征在于以下一个或多个特征:

[0145] (a)对准其中所有三条轴线(口咽、喉、气管)用于气管插管的推荐视野;

[0146] (b)其中通过使用千斤顶调整所述患者的头部相对于所述Z轴的高度;

[0147] (c)其中该装置包括释放挤压的托下颌握把,并且包括在z轴方向上移动该托下颌握把的步骤。

[0148] (d)包括颈部接口和头部接口,其独立地在一个或多个x、y和z位置上是可调节的,以及

[0149] (e)其中可拆卸的第三倾斜侧面围绕每个y轴是可旋转调节的。

[0150] 二十三、还提供了用于定位患者以促进维持在麻醉状态下呼吸道通畅的方法,包括提供如上所述的装置,将患者定位在该装置上,调节斜面组件以支撑患者在所期望的倾斜位置上;调节头部支撑分组合件以支撑患者头部和颈部在大致期望的嗅探位置上;以及激活气动或机械千斤顶,或给可张开的风箱充气以相对于第二表面提升患者的头部到期望的嗅探位置。

[0151] 二十四、还提供了用于定位患者的下颌骨臂,包括:两个刚性可锁定臂,其中上臂具有在z轴上可转动的弯曲伸出部分,且下臂不提供伸出部分;弯曲部分,其中所述弯曲部分基本上是刚性的;下颌骨垫,其中下颌骨垫是柔性的和可枢转的,并且其中所述下颌骨垫具有配置为附接到所述弯曲部分的近端侧以及配置为在至少两个分支、身体和患者下颌的角度上接触患者下颌的远端侧;以及连接器部分,其中所述连接器部分配置为延伸并附接到支撑件的可旋转部分上,并且其中所述连接器部分进一步配置为连接到附接到基部的支撑件上,该基部包括左侧和右侧,其中基部配置为基本上容纳患者的头部、颈部、上部和中间背部以及肩部,并且其中所述支撑件在两个轴上是可移动的,使得所述下颌骨垫可定位成在一个或多个点上接触患者的下颌,以保持患者在所期望的位置上。

[0152] 二十五、还提供了用于患者的弹性的和柔软的头限制装置,包括:

[0153] 第一近端,附接到基部的第一侧面的一侧上,然后其可沿水平方向延伸并接触患者的头部且附接到所述基部的第一表面的相反侧上;该装置是可调的并能够将患者的头部固定在基部的第一表面上,以防止患者从所期望的位置脱开。

[0154] 二十六、还提供了用于定位患者在嗅位的装置,包括可调节的斜面和头枕,其中随着斜面的坡度改变,通过改变相反量的头枕角度 θ_x ,头枕方向保持基本上横向地平行于手术台。

[0155] 上述装置优选的特征在于一个或多个下列特征:

[0156] (a)其中调整角度是通过基于已知或估计的所有已知参数的几何形状的开环处理来完成的;

[0157] (b)其中调整角度是通过闭环处理来完成的,其中当前角度是相对于初始角度测量的,并返回到所述初始角度;

[0158] (c)其中调整是根据多个反馈传感器来完成的,包括但不限于:

[0159] (1)利用倾角仪相对于重力测量角度;以及

[0160] (2)编码器。

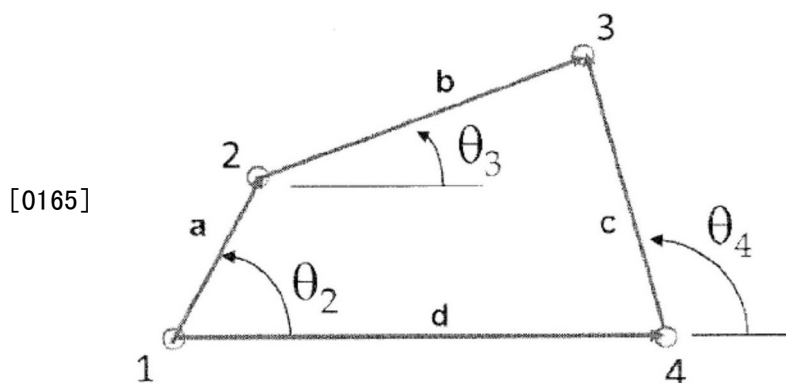
[0161] (d)其中随着斜面的坡度改变,和/或头枕的角度,改变以定位所述患者,改变斜面连杆长度,以满足条件:连杆的位置相对于它们各自的支撑表面的固定;

[0162] (e)其中调整角度通过以下来完成:

[0163] (1)基于已知或估计的所有参数的几何形状的开环处理,或通过

[0164] (2)闭环处理,其中在通过传感器反馈驱动的闭环控制下测量一个或多个连杆端

点的相对位置并调节长度d,以将所测量的参数返回到关于下列几何形状的它们原来的位置,或通过



[0166] (a)连杆a的点2是相对于点1的位置;

[0167] (b)连杆c的点3是相对于点4的位置;

[0168] (c)替换连杆轴点3,其中患者的头部满足头枕;以及

[0169] (d)反馈传感器监测所述点的相对位置,其定义了连杆长度,包括选自下组的位置测量传感器:霍尔效应传感器、磁阻传感器、光学传感器,包括编码器、干涉仪和/或位置感测检测器以及位于点接口上的应力/应变/力/扭矩监测传感器,所述点接口是通过在闭环控制下调节连杆长度d使这些参数最小化。

[0170] 二十七、还提供了一次性的麻醉鼻腔和口腔面罩,其可单独地用作鼻罩或口腔面罩,或可附接在一起并可作为组合鼻口面罩,其也可用来密封地连接面具和佩戴者的面部;两个衬垫,包括:充气或不可充气的第二鼻腔衬垫,其由鼻梁区域、脸颊区域和上唇区域组成,以及充气或不可充气的第二口腔衬垫,其由下唇区域、脸颊区域和上唇区域组成;第一鼻膜,包括弹性材料的大致三角形框架,具有所述第一鼻膜的第一模制向内弯曲凸缘;弹性材料的第二鼻膜,所述第二鼻膜比所述第一鼻膜更薄、一样薄或更厚,所述第二鼻膜具有第二模制向内弯曲凸缘,所述第二鼻膜弯曲凸缘与所述第一鼻膜弯曲凸缘在所述脸颊区域上间隔开第一距离,并且所述第二鼻膜弯曲凸缘与所述第一鼻膜弯曲凸缘在所述鼻梁区域上间隔开第二距离,所述第二距离大于所述第一距离,当不使用面罩时测量所述距离,所述第二膜弯曲凸缘的一部分形成面部接触密封;第一口膜,包括弹性材料的大致椭圆形的框架,具有所述第一口膜的第一模制向内弯曲凸缘;弹性材料的第二口膜,所述第二口膜比所述第一口膜更薄、一样薄或更厚,所述第二口膜具有第二模制向内弯曲凸缘,所述第二口膜弯曲凸缘与所述第一口膜弯曲凸缘在所述脸颊区域上间隔开第一距离,而所述第二口膜弯曲凸缘与所述第一口膜弯曲凸缘在口部区域上间隔开第二距离,所述第二距离大于所述第一距离,当不使用面罩时测量所述距离,所述第二膜弯曲凸缘的一部分形成面部接触密封;附件具有两个孔;其中第一个孔固定在口腔面罩上并且可连接第二个孔,其固定到鼻腔面罩上;其中当它们连接在一起时,它包括麻醉全面罩,在口和鼻子周围覆盖和密封;然而无论是口腔面罩还是鼻腔面罩都可分离,使得该面罩可单独用于鼻腔无创正压通气(CPAP/BiPAP)或单独用于口腔无创正压通气(CPAP/BiPAP)。

[0171] 上述鼻腔和口腔面罩优选的特征在于以下一个或多个特征:

[0172] (a)其中所述第二模制凸缘和所述第一模制凸缘具有协同定位的缺口,以容纳佩戴者的鼻梁;

- [0173] (b)其中所述第一鼻膜模制凸缘和所述第二鼻膜模制凸缘大致为鞍形；
- [0174] (c)其中所述第二鼻膜成形为使得所述密封部在使用中至少接触佩戴者的鼻子；
- [0175] (d)其中所述密封部在使用中接触围绕鼻梁的侧面和在鼻梁上以及在鼻子的底部和上唇之间的面部组织；
- [0176] (e)其中所述第二凸缘和密封部成形为大体上匹配围绕鼻梁的侧面和在鼻梁上以及在鼻子的底部和上唇之间的面部组织的区域中的面部轮廓；
- [0177] (f)其中第一和第二鼻膜包括一个模制件，不通过粘合剂粘附在一起；
- [0178] (g)其中所述第一鼻膜的第一模制向内弯曲凸缘与所述第二鼻膜一样厚、更薄或更厚；
- [0179] (h)其中所述第二鼻膜的第二模制向内弯曲凸缘与所述第一鼻膜一样厚、更薄或更厚；
- [0180] (i)其中所述第二模制凸缘和所述第一模制凸缘具有协同定位的缺口，以容纳佩戴者的嘴唇；
- [0181] (j)其中所述第一口膜模制凸缘和所述第二口膜模制凸缘大致为椭圆形；
- [0182] (k)其中所述第二口膜成形为使得所述密封部在使用中至少接触佩戴者的上下嘴唇；
- [0183] (l)其中所述密封部在使用中接触围绕上下嘴唇的侧面以及在其上的面部组织；
- [0184] (m)其中所述第二凸缘和密封部成形为大体上匹配围绕上下嘴唇的侧面以及在其上的面部组织的区域中的面部轮廓；
- [0185] (n)其中第一和第二口膜包括一个模制件，不通过粘合剂粘附在一起；
- [0186] (o)其中所述第一口膜的第一模制向内弯曲凸缘与所述第二口膜一样厚、更薄或更厚；以及
- [0187] (p)其中所述第二口膜的第二模制向内弯曲凸缘与所述第一口膜一样厚、更薄或更厚。
- [0188] 二十八、还提供了鼻腔面罩、口腔面罩或全面罩，用于连接到佩戴者的面部，包括：用于连接吸入气体供应的面罩主体，无论是氧气、空气、麻醉气体或任何其它气体；以及固定到所述面罩主体上的充气或不可充气的鼻腔衬垫，主体和衬垫形成鼻接收腔，所述衬垫包括：鼻梁区域、脸颊区域和上唇区域；弹性材料的大致三角形形状的第一鼻膜具有第一模制向内弯曲凸缘以围绕佩戴者的鼻子；第二鼻膜也是弹性材料，所述第二膜比所述第一鼻膜相对更有弹性，所述第二鼻膜具有第二模制向内弯曲凸缘，所述第二模制凸缘具有与所述第一模制凸缘相同的一般形状，并固定到和远离所述第一鼻膜延伸，以便使第二鼻膜内表面与所述第一模制凸缘的外表面在所述脸颊区域内间隔开第一距离，并且所述第二膜内表面与所述第一模制凸缘的所述第一鼻膜外表面在所述鼻梁区域内间隔开第二距离，所述第二距离大于所述第一距离，在不使用面罩时测量所述距离，所述第二模制凸缘的一部分形成面部接触密封；并且其中所述密封部基本上相对于所述第二模制凸缘毗连，并且在使用所述面罩时朝向所述第一鼻膜弹性变形。
- [0189] 上述鼻腔面罩、口腔面罩或全面罩，覆盖并密封口和鼻子，优选的特征在于一个或多个下列特征：
- [0190] (a)其中所述鼻腔面罩、口腔面罩或全面罩主体包括使用前路手术或后路手术的

集成头带附接点,或者它可具有使用前路手术或后路手术的分离头带附接点,其放置在所述鼻腔面罩、口腔面罩或全面罩主体上,其附接到可将鼻腔面罩、口腔面罩或全面罩固定到佩戴者面部的表面上,以确保紧密密封并保持佩戴者的头部和颈部在期望的位置上,以保持呼吸道通畅;

[0191] (b)还包括固定到所述附接点上的固定带,可将佩戴者的头部固定到表面上并保持佩戴者的头部和颈部在期望的位置上;

[0192] (c)其中所述第二膜模制凸缘和所述第一鼻膜模制凸缘各具有协同定位的缺口,以容纳鼻梁;

[0193] (d)其中所述第一和第二模制凸缘大致为鞍形;

[0194] (e)其中所述第二鼻膜成形为使得所述密封部在使用中至少接触佩戴者的鼻子;

[0195] (f)其中所述密封部在使用中接触围绕鼻梁的侧面和在鼻梁上以及在鼻子的底部和上唇之间的面部组织,以及

[0196] (g)其中所述凸缘和密封部成形为大体上匹配围绕鼻梁的侧面和在鼻梁上以及在鼻子的底部和上唇之间的面部组织的区域中的面部轮廓。

[0197] 二十九、还提供了鼻腔无创正压通气(CPAP/BiPAP)、口腔无创正压通气(CPAP/BiPAP)或全面罩无创正压通气(CPAP/BiPAP)的治疗装置,包括:用于在低于、等于或高于大气压的压力时供应气体的发生器;接合到所述发生器的气体运送导管;以及依次接合到所述导管的鼻腔面罩、口腔面罩、全面罩,所述鼻腔面罩、口腔面罩、全面罩包括:用于连接吸入气体供应的面罩主体;以及固定到所述面罩主体上的充气或不可充气的鼻腔衬垫,主体和衬垫形成鼻接收腔,所述衬垫包括:鼻梁区域、脸颊区域和嘴唇区域;弹性材料的大致三角形形状的第一鼻膜具有模制向内弯曲凸缘;第二鼻膜也具有弹性材料的第二模制向内弯曲凸缘,所述第二鼻膜比所述第一膜相对更有弹性,并具有与所述第一模制向内弯曲凸缘相同的一般形状,并固定到和远离所述第一鼻膜延伸,以便使内表面与所述第一模制凸缘在所述脸颊区域内间隔开第一距离,并且所述第二鼻膜内表面与所述第一模制凸缘间隔开第二距离,所述第二距离大于所述第一距离,在不使用面罩时测量所述距离,所述第二模制凸缘的一部分形成面部接触密封;并且其中所述密封部基本上相对于所述第二模制凸缘毗连,并且在使用所述面罩时朝向所述第一膜弹性变形。

[0198] 上述无创正压通气(BiPAP/CPAP)的治疗装置优选的特征在于一个或多个下列特征:

[0199] (a)其中所述面罩主体包括附接点,其可将佩戴者的头部固定到表面上并保持佩戴者的头部和颈部在适当的位置;

[0200] (b)还包括固定到所述附接点上的固定带,其可将佩戴者的头部固定到表面上并保持佩戴者的头部和颈部在适当的位置;

[0201] (c)其中所述第一和第二模制凸缘各具有协同定位的缺口,以容纳鼻梁;

[0202] (d)其中所述第一和第二模制凸缘大致为鞍形;

[0203] (e)其中所述第二鼻膜成形为使得所述密封部在使用中至少接触佩戴者的鼻子;

[0204] (f)其中所述密封部在使用中接触围绕鼻梁的侧面和在鼻梁上的面部组织,以及接触围绕鼻梁的侧面和在鼻梁上、在鼻子的底部和上唇之间的面部组织,以及接触在鼻子的底部和上唇之间的面部组织,以及

[0205] (g)其中所述第二模制凸缘和所述密封部成形为大体上匹配围绕鼻梁的侧面和在鼻梁上以及在鼻子的底部和上唇之间的面部组织以及在鼻子的底部和上唇之间的面部组织的区域中的面部轮廓。

[0206] 三十、还提供了口腔面罩,用于连接到佩戴者的面部,包括:用于连接吸入气体供应的面罩主体;以及固定到所述面罩主体上的充气或不可充气的口腔衬垫,主体和衬垫形成口接收腔,所述衬垫包括:嘴部区域、脸颊区域和上下嘴唇区域;弹性材料的大致椭圆形状的第一口膜具有第一模制向内弯曲凸缘以围绕佩戴者的鼻子;第二口膜也是弹性材料的,所述第二口膜比所述第一口膜相对更有弹性,所述第二口膜具有第二模制向内弯曲凸缘,所述第二模制凸缘具有与所述第一模制凸缘相同的一般形状,并固定到和远离所述第一口膜延伸,以便使第二口膜内表面与所述第一模制凸缘的外表面在所述脸颊区域内间隔开第一距离,并且所述第二口膜内表面与所述第一模制凸缘的所述第一口膜外表面在所述嘴部区域内间隔开第二距离,所述第二距离大于所述第一距离,在不使用面罩时测量所述距离,所述第二模制凸缘的一部分形成面部接触密封;并且其中所述密封部基本上相对于所述第二模制凸缘毗连,并且在使用所述面罩时朝向所述第一口膜弹性变形。

[0207] 上述面罩优选的特征在于以下一个或多个特征:

[0208] (a)其中所述面罩主体包括附接点,其可将佩戴者的头部固定到表面上并保持佩戴者的头部和颈部在适当的位置;

[0209] (b)还包括固定到所述附接点上的固定带,其可将佩戴者的头部固定到表面上并保持佩戴者的头部和颈部在适当的位置;

[0210] (c)其中所述第二膜模制凸缘和所述第一口膜模制凸缘各具有协同定位的缺口,以容纳嘴部;

[0211] (d)其中所述第一和第二模制凸缘大致为椭圆形;

[0212] (e)其中所述第二口膜成形为使得所述密封部在使用中至少接触佩戴者的嘴部;

[0213] (f)其中所述密封部在使用中接触围绕嘴部的侧面和在其上以及上下嘴唇之间的面部组织;

[0214] (g)其中所述凸缘和所述密封部成形为大体上匹配围绕嘴部的侧面以及上下嘴唇之间的面部组织的区域中的面部轮廓。

[0215] 上述鼻腔面罩、口腔面罩或全面罩进一步优选的包括配管,其具有两端,用作输送患者的气体源,其中该配管的远端连接到单独的或便携式发生器,用于在低于、等于或高于大气压的压力时供应气体;气体输送导管接合到所述便携式气体供应的发生器,且近端连接到适配器,其包含呼气末CO₂端口、喷雾器端口、PEEP阀口、呼气端口和/或阀、泄压阀,其具有一个孔连接到或者鼻腔面罩、口腔面罩或者全面罩。

[0216] 上述鼻腔面罩、口腔面罩或全面罩还优选地可连接到发生器,用于气体的供应,其中运送的气体量和浓度通过供给源以及呼气端口来控制,和/或通过同时连接鼻腔面罩和口腔面罩用作换气系统,其中鼻腔面罩可用于提供正压,并且口腔面罩可连接到抽吸装置以正确地储存和/或处理气体。

[0217] 上述鼻腔面罩、口腔面罩或全面罩还优选地是围绕患者的鼻梁、鼻子和上唇的轮廓,使得它和气体供给发生器连接,而不干涉操作者接触嘴/口腔、嘴唇、脸颊、下巴,下颌、颈部,和/或连接到复苏气囊,具有或不具有附接到该复苏气囊的气体供给。

[0218] 三十一、还提供了具有如上所述的定位装置的手术台,以及一个或多个与定位装置的厚度接近的垫,其在手术台上。

[0219] 在上述手术台中,优选地,至少一个垫是板条做的或起褶的,以便于弯曲。另外,上述手术台优选地还包括一个基垫片,具有多个位于主垫之下的辊。

附图说明

[0220] 本发明的进一步特征和优点将通过下面的结合附图的详细描述看出,其中:

[0221] 图1是示出了根据本发明的实施方式的横向定位装置的侧立面视图,并示出了患者侧躺(侧卧位)以取代减轻他或她的胸部重量来协助通气;以及

[0222] 图2是在侧卧位从x、y和z方向观察的横向装置。

[0223] 图3A和3B概略地示出了根据本发明用于定位患者仰卧的装置和方法。

[0224] 图3A-3C是根据本发明的仰卧定位装置的又一实施方式的前后透视图和侧立面视图;

[0225] 图4A和4B是在降低的位置中所示的当前实施方式的顶部透视和侧立面视图;

[0226] 图5和6是改装到分别在上升和降低位置的现有手术台上的图4A-4B的定位装置的侧立面视图;

[0227] 图7A和7B是类似于图6的本发明可选择实施方式的视图,示出了安装在提升支撑件上的头部和颈部的独立支撑件;

[0228] 图8示出了根据现有技术的传统患者面罩条带;

[0229] 图9A和9B示出了根据本发明的实施方式的面罩条带;

[0230] 图10-12示出了根据本发明的面罩条带的另一实施方式;

[0231] 图13示出了根据本发明的头部保护装置;

[0232] 图14A-14C示出了根据本发明的面罩锚环;

[0233] 图14D示出了面罩的环形部分以及如何从后面附接条带;

[0234] 图14D示出了面罩的环形部分以及如何将从后面附接条带;

[0235] 图15A-15C示出了根据本发明的面罩锚环的使用,以及图15D示出了面罩,其中面罩锚环或面罩锚带内置于面罩中;

[0236] 图15E和44F是根据本发明的面罩的另一个方面的顶部和底部平面图;

[0237] 图16A-16C示出了根据本发明的充气头枕或颈枕;

[0238] 图16D示出了患者,其头部由前带限制。

[0239] 图17A-17D和18A-18D示出了根据本发明的充气头枕或颈枕的细节;

[0240] 图19是根据本发明的实施方式的流程图;

[0241] 图20A、20B、20C、20D、22和23示出了根据本发明的颞爪和斜面组件的实施方式;

[0242] 图21A和21B以及24A-24D示出了根据本发明的颞爪的使用;

[0243] 图25是结合图24和图26示出了根据本发明的颞爪的使用步骤;

[0244] 图27和28A以及28B示出了下颌骨结构模型,并且图28C示出了在根据本发明的装置上的颅骨和下颌骨坐标系;

[0245] 图29A-29C概略地示出了根据本发明的压力传感阵列;

[0246] 图30A-30B以及31A-31C提供了根据本发明的托下颌的附加细节;

- [0247] 图32A-32D、33A和33B示出了本发明装置的颈部和头部定位调节能力；
- [0248] 图34示意性地示出了本发明的升降机构的四连杆机构的几何形状；
- [0249] 图35A-35C和36A-36F概略地示出了根据本发明的升降机构；
- [0250] 图37标绘了根据本发明的联动长度、斜面角度和头部支撑角度；
- [0251] 图38示出了患者在嗅探位置上利用根据本发明的托下颌装置；
- [0252] 图39是使用该装置的流程图，以保持根据本发明的联动轴4上一致的颈部和颈部支撑位置；
- [0253] 图40A-40D、41和41A示出了根据本发明的又一实施方式的组合鼻腔和口腔通气面罩；以及
- [0254] 图42-45和46A-46C示出了根据本发明的优选实施方式，其安装在传统的手术台上。

具体实施方式

- [0255] 参照图1和2,对于侧卧位,用于实现嗅位和托下颌的装置和步骤描述如下。
- [0256] 步骤1:托架分组合件10沿Z轴并沿基部分组合件轨道12转换直到支撑表面14,是对于患者侧躺时的舒适高度。
- [0257] 步骤2:嗅探分组合件,表面16,沿Y轴调节直到舒适地对准患者并锁定在合适的位置。
- [0258] 步骤3:嗅探分组合件,表面16,沿X轴调节直到舒适地对准患者并锁定在合适的位置。
- [0259] 步骤4:头夹18沿z轴并沿托架分组合件转换直到患者的头部被舒适地约束。
- [0260] 步骤5:弹性带20放置在患者的前额上并附接到约束患者的头部绕Z轴旋转的嗅探分组合件的后侧。
- [0261] 步骤6:左右颞爪分组合件22、24的垂直调整臂沿Z轴移动,直到与患者的下颌骨对齐。
- [0262] 步骤7:垂直调整臂24、26围绕Z轴径向地调整,直到一致接合患者的下颌骨。
- [0263] 步骤8:左右颞爪分组合件22、24绕Z轴旋转,直到下颌骨接合并延伸到所需的量。
- [0264] 步骤9:沿Z轴调节背板分组合件28的高度,直到与背部的中心对齐。
- [0265] 步骤10:沿X轴调节背板分组合件28相对于背部的位置,以支持维护患者的头部在35°的嗅位角度。
- [0266] 步骤11:弹性带30围绕患者的腹部和背板分组合件28的后表面放置,以在X-Y平面上约束患者。
- [0267] 如上所述,本发明提供了若干不同的优点。这些包括:
- [0268] (1)无需使用下颌支撑构件实现了所期望的位置,也称为嗅探位置或下巴升降(35°的颈部弯曲和15°的头部伸展),这在患者处于侧卧位时可引起刺激以及对于患者是舒适的;
- [0269] (2)对准三条轴线(口咽、喉、气管),以提供在侧卧位时用于插管的最优视野;
- [0270] (3)限制患者的头部移动以及从所期望的位置脱落;
- [0271] (4)提供简单、用户友好的机构,以在患者侧躺时用免持方式进行托下颌操作;

[0272] (5)具有廉价的一次性部件的耐用装置,其可接触患者;

[0273] (6)装置是易于消毒的;

[0274] (7)装置是MRI或X光兼容的;以及

[0275] (8)提供了露出外科区的最大量。

[0276] 图3-7示出了用于仰卧位的本发明的另外其它实施方式。接下来参照图3A-3C,提供了患者定位装置,包括:

[0277] 1.可调整斜面50,其适合于患者的身体。斜面50包括一个基部52,其附接到手术台54上。枢转轴56允许该斜面在基部相对于手术台54旋转。

[0278] 2.升降顶部58容纳患者的头部和颈部,并且包括枢转轴60,其允许升降顶部相对于斜面旋转。

[0279] 3.线性致动器沿着指示轴伸出或缩回。该线性致动器包括第一线性致动器62,其在附接到手术台54的基部51和斜面50的后面之间连接。斜面50铰接地附接到基部51上。一个或多个致动器可用来提供所需的力。致动导致致动器长度 L_{A1} 的变化。第二线性致动器64通过斜面50的顶部和升降顶部58之间的铰链55在斜面50的后面和升降顶部58的后面之间进行连接。一个或多个致动器可用来提供所需的力。致动导致致动器长度 L_{A2} 的变化。附接到斜面50的第三线性致动器66用于伸出和缩回斜面长度,以满足所需患者的身体长度。一个或多个致动器可用来提供所需的力。致动导致致动器长度的变化。

[0280] 图4A-4B示出了在降低位置的图3A-3C的装置。

[0281] 在又一个实施方式中,该定位装置可结合到手术台上,或改装到现有的手术台上。在后者的实施方式中:

[0282] 1.该装置可改装到现有的手术台68上或结合到图5所示的新手术台的设计中。

[0283] 2.斜面通过线性致动器62的分别伸出或收缩相对于手术台上升和下降。该斜面围绕 X_R 轴线枢转导致如图5和6所示的 θ_R 变化。

[0284] 3.当所述线性致动器64伸出或缩回时,升降顶部(LT)相对于斜面围绕如图5和图6所示的 X_{LT} 轴旋转。

[0285] 4.线性驱动器64的伸出可独立于升降致动器62操作,以产生升降顶部围绕 X_{LT} 轴的倾斜位置。线性致动器64的伸出或缩回也可与线性致动器62的伸出或缩回协调,以保持升降顶部的角度随着角度 θ_R 变化相对于手术台是不变的,这是由于如图6和图7所示的线性致动器62的长度变化,其中升降顶部保持与手术台的顶部平行。

[0286] 5.斜面长度 L_R 可通过线性致动器62的伸出或缩回来控制。

[0287] 6.如果需要,将在下文详细描述的颞爪可结合到该系统的升降顶部中。

[0288] 如图7A-7B所示的另一个实施方式,该装置包括升降顶部70,其与患者的头部和颈部交界。升降顶部70包括两个元件72,74,其在Z方向上调整以最佳地与颈部和头部交界,如图7A-7B所示。颈部和头部调整在Z方向上是独立于标称位置可调整的,并包括气动驱动枕头或机械驱动垫。另一种选择是仅具有颈部或头部调整,并且相应的头部或颈部区域是静止垫。示出了每一个的标称和扩展范围。

[0289] 本发明还解决了使用面罩所遇到的问题,包括在过程期间保持面罩在患者的面部上,特别是在长期呼吸事件期间。此外,作为非故意接触,患者的移动可导致面罩脱落。

[0290] 参照图8,示出了传统的患者面罩条带102。面罩条带102包括一条或两条条带104,

106,其设计为可捆绑到患者头部的后面。参照图9A-9B,本发明提供了面罩107,,其中条带108,110(图9A)或连体带111(图9B)放置在面罩上方并固定到患者头部下面的基板112上。在通气软管已附接到面罩的情况下,面罩107可在一侧113分离以容纳通气软管115,并且仍然允许面罩附接到基部上,如图10和11所示。

[0291] 在氧气管还没有附接到面罩上的情况下,未经分离的面罩条带可附接到面罩上,然后附接到软管上,然后附接到患者上,如图12所示。

[0292] 除了将患者和面罩绑定到基部上,如果头部需要约束,则患者头部的其它部分可附接到基部上,如图13所示。

[0293] 图14A-14D示出了我们发明的又一实施方式,其中所述通气面罩120通过条带122从前方附接到基部上,例如患者支撑件,其中所述条带包括弹性带,其直径可从例如0.125'变化至0.25'。面罩锚环124运动地在面罩锚环上的多个交界点处与面罩交界,优选为三个,产生更均匀地施加到面罩上的力,如图15A-15C所示,或者该面罩可具有内置于面罩中的面罩锚环条带(在面罩的每一侧上有一条或多条),其中将不需要面罩锚环(参见图15D)。优选的,一条或多条弹性带125,127固定到面罩锚环124上或内置于面罩中(图15D,条带125A,127A),在虚圆上间隔开任意角度,例如如果是使用4条条带时,则它们将间隔开90°,其中每条条带将固定面罩的四个侧面的一个(右侧、左侧、额头侧、下巴侧)。面罩通过力 $F_{\text{条带}}$ 仅附接在患者的鼻子上或鼻子和嘴上,所述力 $F_{\text{条带}}$ 由连接头部支撑件的细长条带施加。

[0294] 图15A-15C示出了每侧配置上的单独的面罩锚环条带125,127。每条面罩锚环条带向后在头部后面附接到各自的面罩锚夹129,131上,其利用摩擦力连接而附接到头部支撑件上。可选择地,该条带可包括多个孔,用于连接到头部支撑件的尖头上。这种连接产生了在通气面罩和患者面部之间的基本气密密封。

[0295] 本发明的面罩条带超过常规面罩的优点是它允许医生从患者面部的正面接近患者,放置鼻腔面罩、全面罩或组合的鼻口面罩,然后将任一面罩附接到表面上,使得患者头部搁置在表面上,它防止了患者的头部移出所期望的位置。因此,如果患者的头部已经在表面上,服务人员不用必须抬起患者的头部以将面罩系在患者的面部上。此外,这种方法将患者放置在所期望的位置上并将它们的头部和颈部固定在该位置上以保持呼吸道通畅。本发明的面罩条带比常规面罩更小,并且仅包括两个表面,其中有孔在中心并放置在面罩上,以及具有多个孔的连接到表面的两臂伸出部分。它不包含宽的矩形头枕,其在传统面罩的情况下缠绕患者的头部。它也不需要面罩上的尖头,从而消除了服务人员和患者受伤的风险。

[0296] 本发明的另一个优点是它既通过将患者的头部固定到台子上来维持嗅探位置,又能在患者面部的正面放置。因此,如果患者躺下则可施加条带,无需抬起患者的头部离开台子。

[0297] 在本发明的另一个方面,提供了一次性的或重新使用的鼻腔面罩,具有用于通气和/或用于氧气的偏离中心的孔,或提供了组合的且可拆卸以及一次性的或可重复使用的鼻腔面罩和口腔面罩,它可一致地用作全面罩以在气管插管之前或全身麻醉(GA)过程中给患者通气,或提供了可与鼻腔面罩分离的口腔面罩以及可用于施加鼻腔无创正压通气(BiPAP-双相气道正压通气/CPAP-连续气道正压通气)的鼻罩,以帮助维持呼吸道通畅,并在麻醉师试图插管时为患者通气,这将显著延长时间,直到患者开始减小饱和度。更具体

地,本发明还提供了面罩,其比现有技术的面罩更能够充当改进的麻醉面罩,因为它唯一地结合了以下优点:

[0298] (1)能够在密封患者面部时提供和疏散气体(多种气体),

[0299] (2)提供具有单独鼻腔面罩的全面罩或者单独提供鼻腔面罩,以在呼吸暂停期间(当患者没有自主呼吸时)、镇静的情况下、全身麻醉(GA)的情况下施加鼻腔无创正压通气(BiPAP/CPAP)和/或氧合,以用于呼吸机治疗,它有独立的口腔面罩,当附接到鼻腔面罩上时,其基本是传统的全面罩,用于在面罩通气、GA以及呼吸机治疗的过程中氧合和通气,或者所述口腔面罩是可拆卸的,以提供麻醉师进入呼吸道气管插管和光纤插管,

[0300] (3)不仅将鼻腔面罩和鼻口腔面罩固定到患者的面部,而且将患者的头部和颈部固定在合适的位置,以保持呼吸道通畅,并将面罩稳定在患者的面部而不会影响其密封能力,以及

[0301] (4)分离口腔面罩或使用独立支架的鼻腔面罩,以及附接鼻腔面罩和使用具有面罩条带的头枕和/或颈枕盖,以从正面夹在鼻腔面罩上并将该鼻腔面罩固定道患者的面部,以及将鼻腔面罩附接到便携式供氧源,且使用鼻腔面罩以在运送患者的过程中供氧。

[0302] (5)另一个优点是偏离中心的端口或多个端口将在插管过程中使对麻醉师的声门视野的阻挡最小化。中心端口将部分地或完全阻挡声门视野。

[0303] 参照图40A-40B,左上图示出了鼻腔面罩的侧视图,以及左下图示出了主视图,它由三个表面组成;其中第一表面是底面,开放的,具有柔软、有弹性的气动边框,与鼻梁、鼻翼、脸颊和上嘴唇轮廓相符,以在接触患者面部时产生密封。底面还具有在每一侧上的多个孔,其允许条带附接或可拆卸的,用于将面罩固定到患者面部以及将患者的头部和/或颈部固定在所期望的位置上。夹子内置于这些多个孔中,当面罩条带从患者的头部后面过来并在前面附接到这些夹子上时,其允许面罩条带附接。第二表面是鼻腔面罩的顶面,并包含一个或多个开口,其第一个可以是在左侧或右侧偏离中心的,并连接到麻醉环路、BiPAP/CPAP机或复苏气囊,以防止阻挡声门视野,或者它可以是居中的并连接到呼吸环路,以使气体交换。第二开口可连接到呼气末CO₂监测器或便携式氧气供应。第三开口可用于允许使用来自氧气供应装置的补充氧气并用于监视呼气末CO₂。第三表面是基部表面,其可包括或不包括开口以及门,其中当门由嘴部面罩的接合而打开时,它将允许气体的双侧转移,并且当其由口腔面罩的脱离而关闭时,它将防止气体从鼻腔面罩逸出。

[0304] 参照图40C-40D,右上图示出了口腔面罩的侧视图,以及右下图示出了口腔面罩的主视图,其也包括三个表面;其中第一表面是底面,开放的,具有柔软、有弹性的气动边框,与下嘴唇、脸颊和上嘴唇轮廓相符,以在接触患者面部时产生密封。第二表面是顶面。第三表面是基部,其包括连接器,当与鼻腔面罩的门接合时,推开门并允许气体的的双侧流动,以及当连接器脱开时,它使鼻腔面罩的门关闭以防止气体渗漏。

[0305] 图41示出了在接合鼻腔面罩的嘴部面罩内的口腔面罩连接器,这将导致鼻腔面罩的门摆动打开,并允许气体双边流入嘴和鼻子中。当嘴部面罩与鼻腔面罩接合时,所述组合产生了传统的面罩,其可用于面罩通气、全身麻醉、呼吸机治疗等。当口腔面罩连接器从鼻腔面罩脱离时,鼻腔面罩的门关闭,它防止气体逸出,并且现在将传统面罩变成鼻腔面罩,其可以在气管插管、全身麻醉,呼吸机治疗的过程中用于镇静情况下的鼻腔BiPAP/CPAP、通气,并可附接到便携式氧气供给源以及用于运送患者时输送氧气等等。图41还示出了面罩

锚,其可围绕鼻腔面罩的开口或内置于鼻腔面罩内(图41A)并附接到表面上,这将鼻腔面罩和/或鼻口腔面罩固定到患者的面部,以保持紧密的密封,防止麻醉气体的泄漏,并且还维持患者的头部和颈部在所期望的位置上,以确保呼吸道通畅。

[0306] 虽然本发明已经描述了结合手术使用,但本发明也可在镇静的情况下使用,尤其是深度镇静或患者有障碍性睡眠呼吸暂停(OSA)或肥胖,其中许多这类患者的上呼吸道被阻塞并阻碍了他们呼吸。本发明的口腔面罩可与鼻腔面罩以及是鼻腔面罩或仅是单独支架的鼻腔面罩分离,可用于施加BiPAP和/或连续气道正压通气(CPAP),以帮助缓解上呼吸道阻塞,保持呼吸道通畅,并在某些情况下协助通气。本发明相对于现有的鼻腔面罩的另一个优点是鼻腔面罩不足以给患者通气的情况。本发明能够重新附接口腔面罩,现在所述面罩可用于传统的面罩通气。本发明的另一个优点是在半清醒光纤插管的过程中施加鼻腔BiPAP/CPAP,其中能够保持患者的氧饱和度也是很关键的。当前鼻腔面罩和/或鼻口腔面罩的另一个优点是能够将其连接到需要的便携式氧气供给并用于为患者输送氧气。它也可同时连接到补充氧气供给源以及复苏气囊上,以同时提供氧合和通气。最后的优点是,本发明优于现有麻醉面罩的技术是能够不仅将组合的鼻腔面罩和口腔面罩固定到患者的面部允许维持通气,而且还通过附接到表面上且维持患者在确保呼吸道通畅的位置上来固定患者的头部和颈部到位,这对于氧合和通气是至关重要的。

[0307] 在另一个方面,本发明提供了对我们上述申请中描述的系统的改进,通过提供简单而优雅的头枕/颈枕,其包括兼容可调的头和颈枕(即:机械的风箱),可独立控制以支撑患者的头部/颈部,通过独立于托架抬起患者的颈部和头部来获得最佳的嗅位。

[0308] 参照图16-18,本发明的另一个特征和优点是提供了头部/颈部支撑件302,其可独立地控制以通过独立于斜面抬起患者的头部和颈部来支撑最佳的嗅位,由此实时的改进了声门视野。更具体地说,根据本发明,提供了允许在Z轴上调节的可调节头部/颈部支撑机构。在一个实施方式中,可调节头部/颈部支撑机构包括气动千斤顶,例如兼容风箱304,其固定或定位在升降顶部70的顶表面上。可选择地,如下所述,可调节的头部/颈部支撑件包括机械千斤顶。

[0309] 再次参照图16-18,根据本发明的气动头部/颈部支撑件302包括可充气气囊或风箱304,包括多个刚性的同心环320,322,324,326,由柔性膜330,332,334在刚性基部336上连接。该风箱包括双向阀338,通过它可增加或减少空气,以为所述风箱充气并增加内部压力和风箱的高度。患者头部或颈部的相对(高度)位置以及最佳嗅位的实现可通过调节风箱内的压力来控制。因此,当空气流入风箱内时,头部/颈部风箱304升高,而当空气流出风箱时,头部/颈部风箱304降低。本发明的特征和优点是可充气的风箱提供了相对低价高可调节性装置,其是易于消毒的。然而,该装置还是足够低成本的,它可使用一次然后丢弃。此外,相比于如果头枕/颈枕是由纯兼容风箱制成用于升降头部/颈部,则头枕/颈枕的横向移动是更受约束的。

[0310] 参照图19,本发明还提供了用于定位患者的方法。该方法包括以下步骤:提供根据本发明的如本文所述的装置,将患者的头部基本放置在可调节机构(风箱)的顶部,升降斜面然后调整机构,以使患者处于嗅位。

[0311] 特别参照图20A和图20B,在另一方面,本发明提供了装置,包括:

[0312] 基部400,包括支撑患者头部和颈部的第一侧面,作为基础的第二侧面,在第一和

第二侧面之间的内垂直可调节支撑结构406,以及可拆卸的第三倾斜侧面或斜面408,其支撑患者的上背部、中间背部和肩部,并在x轴上是旋转的和可调节的;

[0313] 定位在基部的第二侧面上的第一支撑件410,其相对于基部的第二侧面在x轴和y轴上可锁定的调节;

[0314] 定位在基部的第二侧面上的第二支撑件412,其相对于基部的第二侧面在x轴和y轴上可锁定的调节;

[0315] 第一下颌骨臂414从第一支撑件410的第一垂直调整部延伸,其中第一垂直调整部在z轴上是可锁定的,以相对于z轴可锁定地调节第一下颌骨臂,并且其中所述第一下颌骨臂414可定位成接触患者的下颌;以及

[0316] 第二下颌骨臂416从第二支撑件412的第二垂直调整部延伸,其中第二垂直调整部在z轴上是可锁定的,以相对于z轴可锁定地调节第二下颌骨臂416,并且其中所述第二下颌骨臂416可定位成接触患者的下颌;

[0317] 其中,第一下颌骨臂414和第二臂颌骨416是可移动的,使得每个可定位成与患者的下颌接触,并维持患者在所期望的位置上。在这种情况下,优选的是嗅探位置、对齐所有三条轴线(口咽、喉、气管)和/或托下颌手法,以及保持服务人员免持。

[0318] 在优选的实施方式中,基部400是矩形的。

[0319] 在一个实施方式中,下颌骨臂414、416可定位成在三个点上接触患者的下颌。下颌骨臂的最远端可枢转三种角度,以便符合下颌的角度。

[0320] 第一下颌骨臂414和第二下臂颌骨416的每一个包括下颌骨垫420、422,其优选地由可弹性变形的材料例如泡沫形成。在另一个实施方式中,第一下颌骨臂414和第二下颌骨臂416可分别拆卸地连接到第一支撑件410和第二支撑件412上;并且第一和第二下颌骨臂414、416的最远端可拆卸地连接到第一和第二支撑件410、412的远端上。

[0321] 在另一个实施方式中,第一下颌骨臂414可相对于第一支撑件410移动,并且第二下颌骨臂416可相对于第一支撑件412移动。

[0322] 在进一步的实施方式中,下颌骨臂414、416可定位成使得下颌骨垫420、422在一个或多个点上接触患者的下颌。

[0323] 在一些实施方式中,下颌骨臂414、416可定位成使得下颌骨垫420、422在三个点上与患者的下颌接触,并且在其它的实施方式中,第一支撑件410可相对于基部400移动,并且第二支撑件412可相对于基部400移动。

[0324] 在各种实施方式中,第一支撑件410可相对于基部400在X和Y轴上移动,并且第二支撑件412可相对于基部400在X和Y轴上移动。

[0325] 特别参照图21A和21B,在本发明的一个实施方式中,下颌骨臂各包括弯曲部430,它由可调节的且可锁定的机械装置432组成,其附接到相应的下颌骨垫420、422上,其中所述下颌骨垫420、422是柔性的,并且其中所述下颌骨垫具有配置为附接到所述弯曲部的远端侧以及配置为在多个点处接触患者下颌的近端侧,其可在远端侧处以所有角度枢转;以及连接器部分,其配置为附接到支撑件上。

[0326] 参照附图22-24,在又一实施方式中,连接器部分450配置为附接到支撑件452上,其附接到包括左侧和右侧的基部454,其中基部454配置为基本容纳患者的颈部和头部,其中所述支撑件452可在三条轴线上移动,使得下颌骨垫420、422定位成与在一个或多个点处

接触所述患者的下颌,并保持所期望的位置。

[0327] 本发明进一步的实施方式包括可拆卸的倾斜表面500,其可附接到基部454上,并且该倾斜表面500在此定位的角度可以改变,同时也能够延伸更远的距离以维持同样的角度,这有助于支撑较大的患者。该倾斜表面具有背部和肩部杆502,搁置在其上将支撑患者的上背部、中间背部和肩部。该支撑件将使得重力取代减轻患者的胸部重量,实现呼吸道更通畅。

[0328] 在本发明的另一实施方式中,任选地包括测量装置530例如水平仪,以确认35°的最佳颈部弯曲角度。一个实施方式包括两个侧面,其第一侧面532是半圆柱形的和并由四个臂554、556、558、560组成,其每一个位于四个角的每一个内,其每一个接触患者的颈部;第二侧面562包括35°的水平校准角。

[0329] 在又一个实施方式中,本发明任选地包括调平装置564,用于确认15°的最佳头部伸展角度。后一种实施方式包括两个侧面,其第一侧面566或三角形侧面由三个臂568、570、572组成,其每一个位于三个角的每一个内,其中每一个在z轴上是可调节的,其每一个接触患者的面部;以及第二侧面574包括15°的水平校准角。

[0330] 现在参照图25,在又一个实施方式中,本发明包括用于定位患者的方法,包括以下步骤:沿着基本上在该装置的基部上的患者颈部和头部将患者的上背部、中间背部和肩部放置在倾斜表面上;将患者的头部和颈部放置在所期望的位置上,利用测量装置确认该位置;限制患者的头部以防止患者从所期望的位置脱落;移动第一下颌骨臂接触患者的下颌;移动第二下颌骨臂接触患者的下颌;其中第一下颌骨臂和第二下颌骨臂的接触提供了足够的力以充分维持患者的头部、颈部和/或下颌在所期望的位置上。

[0331] 将参照图22-26对本发明作进一步的说明,其示出了使用上述装置实现嗅探位置和托下颌的如下步骤:

[0332] 步骤1:在z轴上利用千斤顶分组合件调整头部高度,通过转动手柄600和接合梯形螺纹实现35°的角度。

[0333] 步骤2:调整斜面长度。

[0334] 步骤3:校正半径头枕在适当的位置,利用弹性带将前额约束至千斤顶分组合件以实现15°的角度。

[0335] 步骤4:利用头部平面之下的分离(通过沿Z轴相对于彼此转动)和倾斜(绕Y轴转动)的卡爪将以颞爪为基础的分组合件附接到千斤顶分组合件的顶部,如图4所示。标称地定位它们各自的下颌骨位置之下的卡爪的左右填充元件(通过绕z轴朝向彼此转动它们),并沿X轴滑动卡爪组件以及锁定卡爪组件就位至千斤顶分组合件的顶部。通过沿y轴以及沿托下颌滑动件朝向患者的头部滑动它们以及挤压托下颌握把来调整左右托下颌分组合件,导致它绕x轴旋转,导致在正z方向上的转换,直至托下颌搁架在下颌骨之下轻轻地接合并锁定到适当的位置。

[0336] 步骤5:利用在千斤顶分组合件上锁定在适当位置的卡爪分组合件绕Z轴旋转卡爪分组合件的左右臂,直到填充部分与下颌的它们各自的左右下颌骨接合。在所述垫牢固地与下颌骨接合后绕Y轴的Y方向旋转卡爪的左右臂,直到下颌在Z方向上伸展所需的量。通过同时挤压左右颞爪握把来伸展下颌骨至所需要的量,导致颞爪旋转并与下颌骨的伸出部分接合。

[0337] 通过绕x轴旋转托下颌锁定件将左右托下颌组件锁定到托下颌滑动件上。这在x-y平面上固定了托下颌组件的位置。通过挤压托下颌握把至所需要的量继续接合左右托下颌搁架来伸展下颌骨,导致它绕x轴转动,并导致在正z方向上转换,直到正确地伸展下颌并使呼吸道开放。

[0338] 前述步骤:

[0339] (1)无需使用下颌支撑构件实现了也称为嗅探位置的所期望的位置或下巴升降(35° 的颈部弯曲和 15° 的头部伸展),可引起刺激并对于患者是舒适的;

[0340] (2)限制了患者的头部的移动以及患者从所期望的位置脱离;

[0341] (3)实现了肥胖患者的定位,其中耳朵与胸骨水平地对齐以达到大量的空气交换;

[0342] (4)提供了简单、用户友好的机构,以免持方式进行托下颌操作;

[0343] (5)借助于重力通过使用倾斜表面取代减轻患者的胸部重量;

[0344] (6)提供升降肥胖患者的机械装置而无需使用医护人员,以限制工伤;

[0345] (7)提供测量装置以确认所期望位置的最佳角度;

[0346] (8)对齐三条轴线(口咽、喉、气管)以提供气管插管的最优视野;以及

[0347] 本发明被认为是首开先河的以免持方式使通气最大化,其能够进行托下颌手法,伴随着能够通过利用升降装置以取代减轻体患者的胸部重量。本发明还被认为是首次利用在主体上的测量装置(即水平仪),以使服务人员再次确保患者的头部和颈部在嗅探位置上正确地对准。本发明还给出了服务人员能首次尝试以较小的侵入性方式,通过将患者放置在适当的嗅探位置而不会引起任何疼痛刺激来维持呼吸道通畅。然后,服务人员可限制患者的头部,以防止患者从所期望的位置移动。如果患者的呼吸道尚未打开,服务人员可以使用2个夹子向前取代下颌,该夹子具有棘轮能力,每一个应用于下颌骨的每一个侧面上。如果患者仍无法保持呼吸道通畅,则本发明通过将患者放置在所期望的位置上,对齐所有三条轴线以实现对患者插管的最佳视野。参见图27-31。

[0348] 图32A-32D示出了本发明的另一实施方式,并且图33A和33B示出了本发明的定位装置,患者最初水平地在手术室台上,然后升高到倾斜的位置。当该装置升高和降低时,其绕X轴的点1枢转 θ_{X1} 。随着装置升高或降低,含有独立可调的头部和颈部致动器的头部支撑件来定位头部和颈部用于最佳的插管视野,该头部支撑件通过绕沿X轴的点4旋转 θ_{Z4} 而标称地保持平行于Y轴,其中 $\theta_{Z4} = -\theta_{X1}$ 。患者在倾斜的位置时被插管,然后重新定位到斜倚的位置以用于手术。该装置和患者形成了在下面的表1中所定义的四连杆机构(图34)。

[0349] 表1

[0350]

联动	联动描述	注释
a	连接斜面枢转点 1 和患者臀部枢转点 2 (转节点)	定长, a
b	连接患者臀部枢转点 2 和颈部致动器顶部点 3 (头部/颈部枢转位置)	定长, b
c	连接头部/颈部枢转位置点 3 和头部支撑枢转点 4	定长, c
d	连接头部支撑枢转点 4 和斜面枢转点 1	可调节长度, d

[0351] 图35A-37示出了用于升降联动的广义几何结构,并且相关的已知变量以及关于作为斜面角度 θ_{x1} 的函数 θ_2 的方程式、关于作为头部支撑角度 θ_{x4} 的函数 θ_4 的方程式以及未知变量 θ_3 以及d的定义如下:

[0352] ●a、b、c、 θ'_2 和 θ'_4 是已知的

[0353] 1. $\theta_2 = \theta'_2 - \theta_{x1}$, 其中 θ'_2 是用于斜倚的位置,并且 θ_{x1} 是绕点1的斜面枢转角度

[0354] 2. $\theta_4 = \theta'_4 + \theta_{x4}$, 其中 θ'_4 是用于斜倚的位置,并且 θ_{x4} 是绕点2的头部支撑枢转角度

[0355] 3. $\theta_3 = a \sin[(c \sin \theta_4 - a \sin \theta_2)]/b$

[0356] 4. $d = a \cos \theta_2 + b \cos \theta_3 - c \cos \theta_4$

[0357] 问题是,随着斜面上升和或头部支撑件绕其枢转轴旋转,一个或多个联动长度必须改变或患者将被迫沿装置表面和手术台滑动。该滑动有效地改变了联动长度a和c,给出的长度b和d都是固定的。所期望的是,保持联动的长度和位置a, θ_a 和c, θ_c 相对于它们的支撑表面是固定的,因为斜面角度 θ_{x1} 和头部支撑角度 θ_{x4} 是可调整的。本发明根据初期的患者外形,通过改变斜面长度、联动d斜面角度 θ_{x1} 和头枕角度 θ_{x4} 来完成该要求。

[0358] 再次参照图36A-36F和37,随着斜面倾斜度 θ_{x1} 改变,在大多数情况下,通过改变头枕角度 θ_{x4} 相反的量,头枕方向保持横向地平行于手术台。这可以下列方式实现:

[0359] a. 基于已知或估计的所有参数的几何形状的开环处理;或

[0360] b. 闭环处理,其中是当前角度

[0361] θ_{x4} 是相对于初始角度 θ'_{x4} 测量的,并返回到所述初始角度。这可利用多个反馈传感器来完成,包括但不限于:

[0362] 1). 利用倾角仪相对于重力测量角度

[0363] 2). 编码器

[0364] 特别参照图37,随着斜面倾斜度 θ_{z1} 改变,和/或头枕角度 θ_{z4} 改变为定位患者,斜面(联动d)的长度是变化的,以满足联动的位置a, θ_a 和c, θ_c 相对于它们的支撑表面是固定的情况。这可以防止患者沿手术台表面滑动,因为斜面和头枕角度是可调整的。这可以下列方式实现:

[0365] a. 基于已知或估计的所有参数的几何形状的开环处理

[0366] 1). 方程式1-4提供了计算的分析解决方案以及控制长度d;或

[0367] b.闭环处理,其中在闭环控制下测量一个或多个以下联动端点的相对位置以及调节长度d是通过传感器反馈来驱动的,以将所测量的参数返回到原来的位置。

[0368] 1).联动a的点2是点1的相对位置

[0369] 2).联动c的点3是点4的相对位置

[0370] 3).替换轴点3,其中患者的头部满足头枕

[0371] a.反馈传感器监测点的相对位置限定了联动位置,可包括:

[0372] 1).位置测量传感器,包括但不限于:

[0373] 1.霍尔效应传感器

[0374] 2.磁阻性传感器

[0375] 3.光学传感器

[0376] a.编码器

[0377] b.干涉计

[0378] c.位置传感探测器

[0379] 2).位于点接口处的应力/应变/受力/扭矩监测传感器通过在闭环控制下调节联动长度d使这些参数最小化。

[0380] 再次参照图36A-36F,在优选的示范性实施方式中,该装置包括线性致动器联动d,其调节斜面长度以容纳患者,联动g绕Z轴、枢轴1提升斜面,以及联动j通过绕Z轴沿枢转轴4反向旋转来维持头部支撑件平行于X轴。该装置和患者形成了在表1中所定义的四连杆机构。相关的初始斜倚位置和用于作为致动器的函数的角度和致动器d和j、联动长度g和驱动斜面角度 θ_{z1} 的关系方程式也限定在下面的表2中。

[0381] 表2.患者4连杆机构及致动器联动

[0382]

斜倚时的初始条件									
X轴联动枢转点定义									
斜倚 (初始) 位置	相关致动器	最小值	最大值	调整	从颈部到髋关节的距离 cm	函数	定义方程		
X轴点	Y(cm)	Z(cm)	d		59.9	斜面枢转轴 髋关节 颈部枢转和 Y颈部调节 头部支撑枢 转轴 头部Y调节	$\theta_{u1}=\theta_u-\theta_{d0}$	$\theta_{d0}=\theta_u-\theta_{d0}$	
1	0.00	0.00	d						
2	-11.95	6.90							
3	45.44	6.90		6.90	0				
4	42.90	0.00	d	38.4	21		$\theta_{u4}=\theta_{u4}$		
5									
6	9.58	-3.52	g						
7	26.14	0.00	g						
8	44.00	-3.40	j						
9	65.68	-1.28	j						
联动定义									
第一轴	第二轴	长度 cm	联动 / 相反角 度	联动 / 相反角 度 Rad	联动 / 相反角 度值度	致动器?	函数	方程	
a	1	2	13.80	θ_a	2.6180	150.00		$\theta_u=\theta_u-\theta_{u1}$	$\theta_{u1}=\theta_u-\theta_{u1}$
b	2	3	59.99	θ_b	0.0000	0.00		$\theta_u=a\sin[(\sin\theta_c-\sin\theta_a)/b]$	θ_{u0} 用于大小值
c	3	4	7.35	θ_c	1.2180	69.79		$\theta_u=\theta_u-\theta_{u4}$	$\theta_{u4}=\theta_u\cos(2.54\text{cm}/c)$
d	1	4	45.50	θ_d	0.0000	0.00	23010021002256 6线性制动器	确定斜 面长度	
e	1	6	10.21	θ_e	0.2094	12.00		$\theta_u=a\cos[(\theta^3+\theta^2-\theta^3)/2f]$	
f	1	7	26.14	θ_f	2.5800	147.82		$\theta_u=a\cos[(\theta^3+\theta^2-\theta^3)/2g]$	
g	6	7	16.83	θ_g	0.3521	20.17	23310021020506 6线性制动器	确定斜 面长度	
h	4	8	3.57	θ_h	0.1512	8.66		$\theta_u=a\cos[(\theta^3+\theta^2-\theta^3)/2j]$	
i	4	9	22.82	θ_i	1.8485	105.91		$\theta_u=a\cos[(\theta^3+\theta^2-\theta^3)/2h]$	$\theta_u=\theta_u-\theta_{u4}$
j	8	9	21.58	θ_j	1.1419	65.43	23310021020506 6线性制动器	确定斜 面长度	$\theta_u=\theta_u-\theta_{u4}$
								$j=(\theta^3+\theta^2-\theta^3)\cos(\theta)^{1/2}$	

[0383] 图32A-32D中的说明是用于中型的男性患者,颈部枢转到臀部枢转的距离为

59.9cm, 提供了臀部枢转轴2至斜面枢转轴2。相关联的表3提供了作为驱动联动的长度16.75cm-22cm的函数的角度和联动长度。图36A-36F提供了作为联动长度g的函数的一小块联动长度d和j以及斜面角度 θ_{x1} 和头部支撑角度 θ_{x4} 。

[0384] 表3, 作为联动g的函数的联动长度命令d和j

[0385]

联动 g(cm)	θ_{x1} (度数)	θ_{x1} (弧 度)	θ_{x4} (度数)	θ_{x4} (弧 度)	联动 d(cm)	θ_a (弧 度)	θ_b (弧 度)	θ_c (弧 度)	θ_d (弧 度)	联动 j(cm)	θ_j (弧 度)
16.75	-1.98079995	-0.0346	1.98079995	0.0346	45.27	2.6526	0.0070	1.2180	0.3175	21.70	1.1765
17.00	0.727219333	0.0127	-0.727219333	-0.0127	45.50	2.6053	-0.0031	1.2053	0.3648	21.53	1.1292
17.25	3.168850885	0.0553	-3.168850885	-0.0553	45.52	2.5627	-0.0134	1.1627	0.4074	21.39	1.0866
17.50	5.421111271	0.0946	-5.421111271	-0.0946	45.55	2.5234	-0.0228	1.1234	0.4467	21.26	1.0473
17.75	7.530863273	0.1314	-7.530863273	-0.1314	45.59	2.4866	-0.0317	1.0866	0.4836	21.13	1.0105
18.00	9.529107906	0.1663	-9.529107906	-0.1663	45.65	2.4517	-0.0400	1.0517	0.5184	21.02	0.9756
18.25	11.43760228	0.1996	-11.43760228	-0.1996	45.72	2.4184	-0.0479	1.0184	0.5517	20.92	0.9423
18.50	13.27230674	0.2316	-13.27230674	-0.2316	45.79	2.3863	-0.0555	0.9864	0.5838	20.82	0.9103
18.75	15.04534012	0.2626	-15.04534012	-0.2626	45.88	2.3554	-0.0627	0.9554	0.6147	20.72	0.8793
19.00	16.76616329	0.2926	-16.76616329	-0.2926	45.97	2.3254	-0.0697	0.9254	0.6447	20.63	0.8493
19.25	18.44233307	0.3219	-18.44233307	-0.3219	46.07	2.2961	-0.0765	0.8961	0.6740	20.54	0.8201
19.50	20.08000305	0.3505	-20.08000305	-0.3505	46.17	2.2675	-0.0830	0.8676	0.7026	20.46	0.7915
19.75	21.68426774	0.3785	-21.68426774	-0.3785	46.29	2.2395	-0.0894	0.8396	0.7306	20.38	0.7635
20.00	23.25940615	0.4060	-23.25940615	-0.4060	46.40	2.2120	-0.0955	0.8121	0.7581	20.31	0.7360
20.25	24.80905851	0.4330	-24.80905851	-0.4330	46.53	2.1850	-0.1015	0.7850	0.7851	20.24	0.7089
20.50	26.33635727	0.4597	-26.33635727	-0.4597	46.66	2.1583	-0.1074	0.7584	0.8118	20.17	0.6823
20.75	27.66406041	0.4828	-27.66406041	-0.4828	46.78	2.1352	-0.1124	0.7352	0.8349	20.11	0.6591

[0386]

21.00	29.33445565	0.5120	-29.33445565	-0.5120	46.94	2.1060	-0.1186	0.7060	0.8641	20.04	0.6300
21.25	30.80976336	0.5377	-30.80976336	-0.5377	47.08	2.0803	-0.1240	0.6803	0.8899	19.98	0.6042
21.50	32.27183984	0.5632	-32.27183984	-0.5632	47.24	2.0547	-0.1293	0.6548	0.9154	19.92	0.5787
21.75	33.7223866	0.5886	-33.7223866	-0.5886	47.40	2.0294	-0.1345	0.6294	0.9407	19.86	0.5534
22.00	35.16294644	0.6137	-35.16294644	-0.6137	47.56	2.0043	-0.1395	0.6043	0.9658	19.81	0.5282

[0387] 用于装置初始化和操作的控制步骤在图39中有概述。任选地,如果需要,可提供传感器用于测量轴3的Y位置,这是颈部高度的调节。如果提供了传感器,调整d的致动器控制律将被适当修改。

[0388] 图27-29中提供了托下颌参数和相关联的直角坐标系的图示。在托下颌操作中,由于所施加的力 $F_{推}$,下颌骨移动 $\Delta L_{推}$ 。为了避免肌肉和表皮组织坏死,可在推力中施加最大允许的压力 $P_{推}$ 。鉴于托下颌对称地施加在下颌骨的左侧和右侧,在每一侧上的负荷是 $F_{推}/2$ 。对于托下颌操作的初始要求列于表4中。

[0389] 表4,托下颌操作的顶级要求

[0390]

	参数	数值	注释
1	托下颌移位 $\Delta L_{推}$	7mm-10mm, 绕 Y _{颅骨} 轴@+22°	下颌骨的最佳突伸为 7mm-10mm, >10mm 不能增加 通畅 ²⁴
2	总的托下颌的力 $F_{推}$	34.07±9.33N	完成托下颌操作 ²⁶ 的最高力的 平均值
3	由托下颌产生的最大允许压力 $P_{推}$	4 小时<66kPa	高压短时间 ²⁶ 产生的肌肉损伤

[0391] 图28A-28C中提供了简化的下颌骨结构模型。对于本说明的目的,假定下颌骨为无限刚性,其相关坐标系为 X_M 、 Y_M 和 Z_M 。具有其相关坐标系的颅骨的背面连接至地面,并假设它无论在扭转和平移时都是固定的,下颌骨被约束在其中,除了推力轴。下颌骨的合规性由左右翼外肌弹性刚度 $K_M/2$ 和推力 $F_{推}/2$ 下的肌肉和表皮组织的有效弹性刚度表示。要注意的是,当患者位于该装置上时,推力矢量以绕 Y_{AS} 轴的标称7°角施加,如图45A的右上部所示。托下颌力 $F_{推}$ 在区域 $A_{推}$ 上通过下颌骨每一侧上的肌肉/表皮组织弹性 $K_{E\&M}$ 传递。 $A_{推}$ 是由坏死压力极限 $P_{推}$ 和推力施加的时间周期来确定的。参见下面的表5。

[0392] 表5,生物力学精确的下颌骨模型要求

[0393]

	参数	数值	注释
1	下颌骨肌肉弹性刚度 K_M	4.86N/mm	基于 34N 的平均推力和 7mm ^{24,26} 的伸展
2	最小推力区域 $A_{推}$	$>6.6\text{cm}^2$	需要 43.4N 的推力以及 4 小时 ²⁷ $<66\text{kPa}$ 的允许最大压力等级 P 推的区域
3	下颌骨每一侧上的肌肉/表皮组织弹性 $K_{E\&M}$	11N/mm	基于 101.20kPa 的杨氏模量, 3mm 的厚度和 $A_{推}/2$ 的区域 ²⁸

[0394] 患者定位在该装置上,颈部弯曲角度为 35° ,并且面部的平面与水平面成 -15° 。其结果是颅骨的坐标系 $Y_{颅骨}$ 轴和为 -15° 的装置 Y 轴 Y_{AS} 旋转,如图28C所示。其结果是,以相对于所述 Y_{AS} 轴成 7° 施加标称托下颌力矢量。要注意的是推力角相对于 $Y_{颅骨}$ 轴为 22° 。

[0395] 再次参照图29A-29C,下颌骨基部通过测量反应力和力矩的六自由度(DOF)测压元件连接到结构性地面上。下颌骨沿基部滑动,在所有轴内受约束,除了所示的 $\Delta L_{推}$ 轴(围绕 Y_{AS} 轴为 7°)。提供了推力阻力的左右侧翼外肌的刚性由弹性刚度 K_M 表示。模拟的下颌骨由通过绿色显示的弹性体材料覆盖的“无限”硬的下颌骨组成(硅橡胶是初始选择,因为它的机械性能相似于皮肤³⁰)。对于100kPa的弹性模量,当压力施加在厚度为3mm的区域 $A_{推}/2$ 上时,有效弹性刚度为 $K_{E\&M}$ (表皮和肌肉)。托下颌力施加到下颌骨的左侧和右侧上,如图所示,或沿着下颌骨的侧面剪切。压力传感栅格将应用到下颌骨的外表面上,以在托下颌应用到下颌骨的模型上时测量所述压力区域。沿下颌骨基部的下颌骨位移将利用千分表或其它距离测量装置来测量。下面提供了测压元件和压力测量阵列的细节。

[0396] 可使用多个托下颌的方法。两种方法包括图28A-28C所示托下颌方法,其中绕 Y_{AS} 轴施加的推力力矩 $M_{推}$ 产生了在下颌骨的左侧和右侧上的推力 $F_{推}/2$ 。在这种方法中,免持托下颌装置从所述装置的基部脱离,图29A-29C中示出了与下颌骨交界的颞杯。第二种方法通过吸杯配合下颌骨的侧面,该吸杯提供了剪切推力。吸杯方法的好处是在侧面上有更大区域的接口,与下颌骨的背面相对,导致了需要较低的压力来施加推力,并减少了皮肤或肌肉损伤的可能性。优先使用真空以减少瘀伤或其它损伤,例如在怀孕期间真空辅助输送的情况。在所有的情况下,由于所施加的力或力矩,将测量推力和下颌骨的位移,并在托下颌装置的闭环控制下提供推力。

[0397] 由该装置提供的托下颌的力将在直接或间接测量 $P_{推}$ 的闭环反馈下提供,例如由位于颞杯/吸杯-下颌骨交界面中的压力阵列传感器测量,类似于这样在下颌骨模型中使用的,或者在测量所施加的力 $F_{推}$ 或力矩 $M_{推}$ 的测压元件中测量。该反馈将确定托下颌操作所需施加的推力。

[0398] 利用本发明的免持托下颌装置来测试下颌骨模型涉及以绕 Y_{AS} 成 $5^\circ-10^\circ$ (以 1° 的步幅)的角度推动下颌骨的增量距离为5mm-15mm(以1mm的步幅)。在测试期间可同时测量和记

录四个参数作为时间的函数,如图29A-29C所示。这些包括:

[0399] 1.在下颌骨参考系中测量的在下颌骨交界面处的推力压力场 $P_{推}(X_M, Y_M, Z_M)$ 。

[0400] 2.通过下颌骨转移到颅骨以及装置机械接地平面的反应力 $F(X_{AS}, Y_{AS}, Z_{AS})$ 和力矩 $M(X_{AS}, Y_{AS}, Z_{AS})$ 。

[0401] 3.下颌骨相对于装置参考系的位移 ΔL 。

[0402] 4.由免持托下颌装置施加到下颌骨上的托下颌操作的力 $F_{推}$,如在免持托下颌装置测量的 $F(X_{JC}, Y_{JC}, Z_{JC})$ 和力矩 $M(X_{JC}, Y_{JC}, Z_{JC})$ 。要注意的是,这些被认为是类似于第2条。

[0403] 表6提供了用于测试的测量参数、要求和测量方法。最后一列确认了传感器的解决方案,并提供了要求的基础。

[0404] 表6,测试测量参数、要求和方法

[0405]

	参数	要求	要求的候选传感器/基础
1	压力场传感器 $P_{推}(X_M, Y_M, Z_M)$ @下颌骨交界面		参考表 TekScan4205 是候选传感器 http://tekscan.com/4205-pressure-sensor
1.1	范围	0-100kPa	4 小时<66kPa 是初步要求 ²⁷
1.2	压力测量准确性	0.7kPa	占位符, 1/100 的初步要求
1.3	压力测量精密度	0.5kPa	占位符, 1/100 的范围
1.4	压力测量传感器区域	$1.5 \times 10^{-3} \text{m}^2 / 6.0 \times 10^{-3} \text{m}^2$	左右下颌骨的后部和侧面的大致区域
1.5	压力栅格空间分辨率	在 X 和 Y 上 <2mm	占位符
1.6	压力阵列表面最小半径	“IBD”	
1.7	压力测量带宽	>10Hz	占位符
2 和 4	反应力/力矩传感器 $F(X_{AS}, Y_{AS}, Z_{AS})$ 和 $M(X_{AS}, Y_{AS}, Z_{AS})$		参考表候选 SRI3702A 是候选传感器, http://srisensor.com/pdf/m3202.pdf
2.1	力范围	-50-+50N	34.07±9.33N 是预期的托下颌力 ²⁶
2.2	力矩范围	-0.75N-m 至 +0.75N-m	占位符
2.3	力准确性	<1N, 1%	占位符
2.4	力精密度	0.05N, 1%	占位符
2.5	测量带宽	>10Hz	占位符
3	下颌骨位移传感器		参考表候选传感器是“IBD”
3.1	托下颌位移的长度 $\theta L_{推}$	0.7mm-10.0mm	实现呼吸道开放和可接受的声门视野 ²⁴ 的所需距离
3.2	测量准确性	0.01mm, 1%	
3.3	测量精密度	0.005mm, 1%	占位符
3.4	测量带宽	>10Hz	占位符

[0406] 本发明被认为是首开先河的结合几种不同的机构以免持方式使通气最大化。该装置也是新颖的,因为它是唯一的患者定位装置可在插管过程中实时调整头部和/或颈部的

位置。这是必要的,因为嗅探位置对于每一个患者来说不都是最佳的插管位置,尽管对于大多数来说是。所描述的发明能够适应那些在嗅探位置看不见声门的患者,通过调整头部和/或颈部直到看见声门。

[0407] 该设备也是新颖的,因为它是唯一的患者定位装置能将患者的头部和颈部固定在最佳的通气和插管位置,并可在同时试图插管时提供鼻腔持续正压通气。这有助于显著延长患者最后一口气和固定气管导管之间的短暂而关键的时间段。

[0408] 本发明还能够在横向位置进行托下颌操作,连同通过利用卧位取代减轻患者的胸部重量,连同将患者放置在嗅探位置上,其对准三条轴线(口咽、喉、气管)。本发明还给出了服务人员能首次尝试以较小的侵入性方式,通过将患者放置在适当的嗅探位置而不会引起任何疼痛刺激来维持呼吸道通畅。然后,服务人员可限制患者的头部,以防止患者从所期望的位置移动。如果患者的呼吸道尚未打开,服务人员可利用棘轮能力调节下颌骨臂来向前移动下颌,每一个应用于下颌骨的每一个侧面上。如果患者仍无法保持呼吸道通畅,则本发明通过将患者放置在所期望的位置上,对齐所有三条轴线以实现对患者插管的最可能的视野。

[0409] 图42-46C示出了本发明的定位装置1002的另一个和优选的实施方式,其安装在传统的手术台1004上。更具体地,示出了维持患者的头部和头的支撑的可选择方法,联动轴3在并列位置上,随着该装置升高或降低,或随着升降支撑件升高或降低,允许将被容许的髋轴2(X_2)沿Y轴和Z轴平移,如图46A-46C所示。可选择的方法包括连接患者躺在上面滑动后背支撑的顶垫,并且如果长度是可调的,允许顶垫相对于固定的后背支撑件滑动,并在沿Y轴的滚轮总成上滑动。另外,随着升降支撑件绕X轴转动,头部在头部支撑件上沿Y轴滑动,以补偿轴3和4之间的角度和联动长度的变化。

[0410] 图46A示出了患者躺在仰卧位,头部和头部支撑件并置在联动轴3上。随着该斜面通过绕 X_1 轴旋转而升高到倾斜位置,在顶垫上的患者在装置上且沿Y轴既滑动,参见图46B。头部和头部支撑件保持同位,并且和髋关节轴2可以移动。

[0411] 首先参照图42,足垫片1006和基部垫片1008放置在手术台上以便提供水平表面,每一个具有的厚度等于定位装置1002的厚度。脚垫片1006例如由高密度的泡沫形成。基部垫片1008优选地包括多个辊1010,以允许主垫1012(图44)随着定位斜面如前所述的上升和下降或伸展而前后滚动。还提供了脚垫1014,并且主垫1012和脚垫1014厚度相同以便接近定位装置的头部和颈部支撑件1016的高度。也参照图43,主垫1012包括用板条做的或打褶的基垫1018,其允许支撑结构弯曲以支持斜面抬高超过其延伸的范围。图45示出了组装单元。此外,如果需要的话,当定位装置1002伸展以支持更高的患者时,附加的间隔垫1020可插入在脚垫1014和主垫1012之间。也可参见图46A-46C。

[0412] 虽然参照示例性实施方式已对本发明作了详细描述,但可做出各种改变并采用等同物,而不脱离本发明的范围。以举例的方式,鼻腔面罩、口腔面罩和/或全面罩可用于喷雾器的治疗。此外,鼻腔面罩、口腔面罩和全面罩可用于测量呼气末 CO_2 ($EtCO_2$)或二氧化碳图。此外,鼻腔面罩、口腔面罩和全面罩还包括明显(patent)配管,其包括两个端部,用作输送患者的气体源,其中所述配管的远端连接到单独的或便携式发生器上,用于在低于、等于或高于大气压的压力时供应气体;气体输送导管接合到所述便携式气体(氧气、麻醉气体、空气或任何其它其它)供应的发生器,且近端连接到适配器,其包含呼气末 CO_2 端口、喷雾器端

口、PEEP阀口、呼气端口和/或阀、泄压阀,其具有一个孔连接到或者鼻腔面罩、口腔面罩或者全面罩。

[0413] 在其它的实施方式中,鼻腔面罩、口腔面罩和/或全面罩可连接到发生器,用于气体的供应,其中运送的气体量和浓度通过供给源以及呼气端口来控制。

[0414] 在其它的实施方式中,鼻腔面罩、口腔面罩和/或全面罩通过同时连接鼻腔面罩和口腔面罩可用作换气系统,其中鼻腔面罩可用于提供正压,并且口腔面罩可连接到抽吸装置以正确地储存和/或处理气体。

[0415] 本发明的特征和优点是鼻腔面罩将围绕患者的鼻梁、鼻子和上唇的轮廓,以这样的方式使得它和气体供给发生器连接,而不干涉操作者接触嘴/口腔、嘴唇、脸颊、下巴,下颌和颈部。

[0416] 此外,鼻腔面罩和全面罩可连接到复苏气囊,其具有或不具有附接到该复苏气囊的气体供给。还有其它的修改是可能的。本发明的另外其它的特征和优点包括:

[0417] ●可利用以下一个或一些组合来完成用于优化视野以及实现嗅探位置的颈部和头部弯曲:

[0418] a. 颈部支撑件沿Z轴提升平移

[0419] b. 头部支撑件沿Z轴提升平移

[0420] c. 提升支撑件绕联动轴4(X轴)旋转(头部支撑件和颈部支撑件连接到该提升支撑件上)

[0421] d. 注意,一个实施方式可能不具有颈部支撑件

[0422] ●面罩锚前带可具有2条或多条条带,一条条带固定下巴。

[0423] ●面罩锚带附接到头部支撑件的顶面上,还包含软凝胶状环状物以支撑头部,具有摩擦楔。

[0424] ●具有软凝胶状环状物的头部支撑件顶部支撑头部,其可从升降底部拆卸。如果需要将患者移动到手术室台的不同部分而不用患者定位装置时,这允许具有凝胶状物的头部支撑件顶部和面罩锚固定到患者上。

[0425] ●头部支撑件的升降机顶部覆盖有一次性屏障。此屏障的顶部具有贴在它上的弹性条带,其可被除去并从后方附接到还具有氧气端口的面罩上。当氧气管线附接到氧气端口上时,通气端口用作CO₂的排气口,该氧气管线向患者供给O₂。这允许面罩也可用作术后的供氧面罩。

[0426] ●保持前面罩条带以及后弹性条带楔的面罩锚连接可以是面罩的一体部分,而不是在其它实施方式中示出的单独组件。

[0427] 为了说明和描述的目的,已经提出了本发明的优选实施方式的前面描述。它并非意在穷举或限制本发明到公开的精确形式,鉴于上述教导修改和变型是可能的,或者可从本发明的实践中获得。选择和描述实施方式是为了解释本发明及其实际应用的原理,以使本领域的技术人员能够利用本发明的各种实施方式,其适合于预期的特定用途。其意图在于本发明的范围由所附的权利要求以及其等同物来限定。上述各文件的全部内容通过引用的方式并入本文。

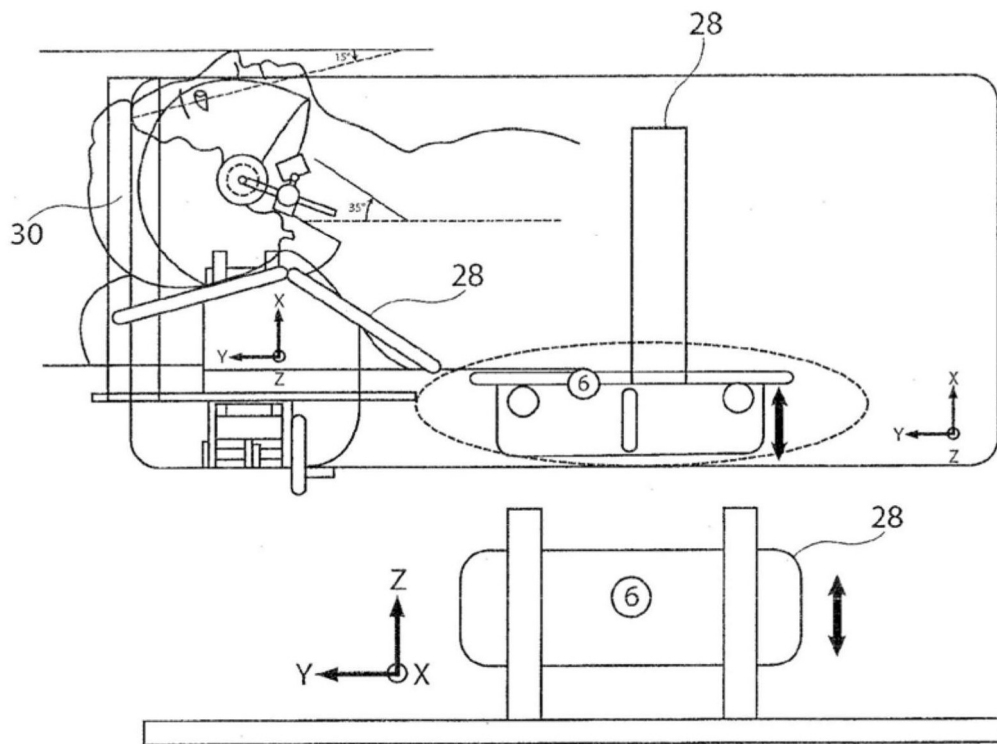


图1

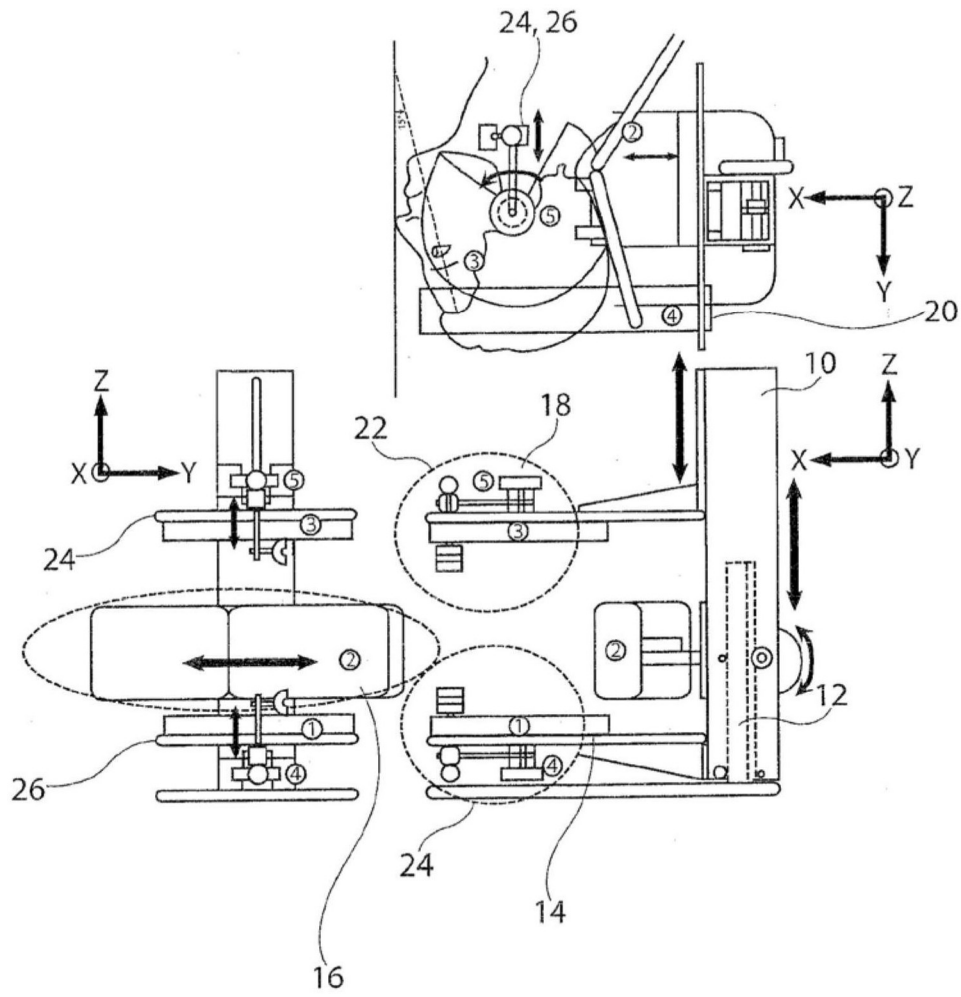


图2

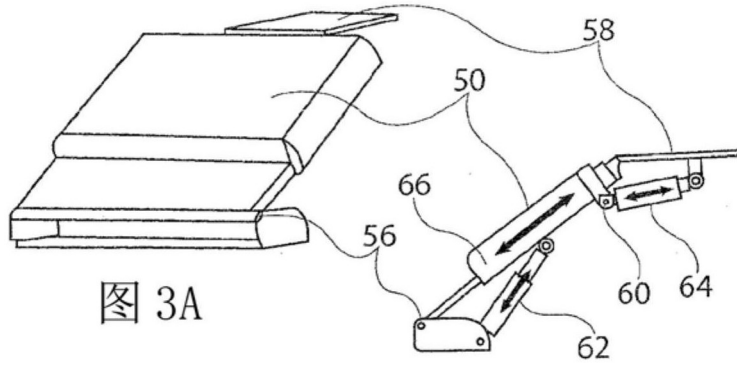


图 3A

图 3C

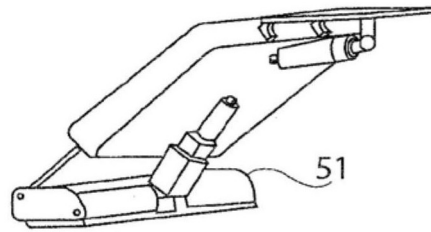


图 3B

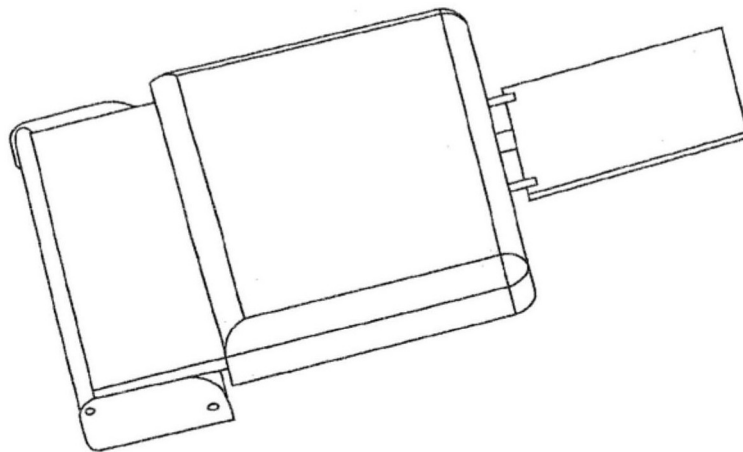


图4A

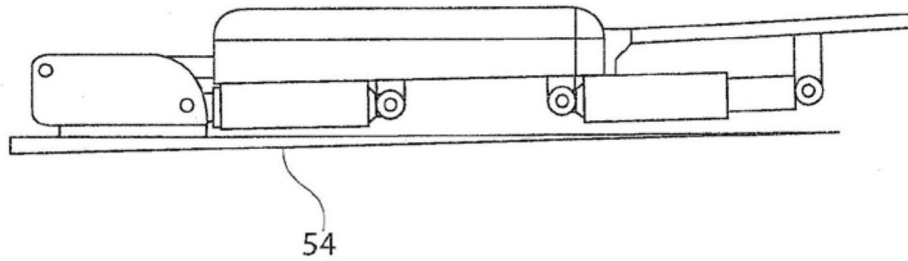


图4B

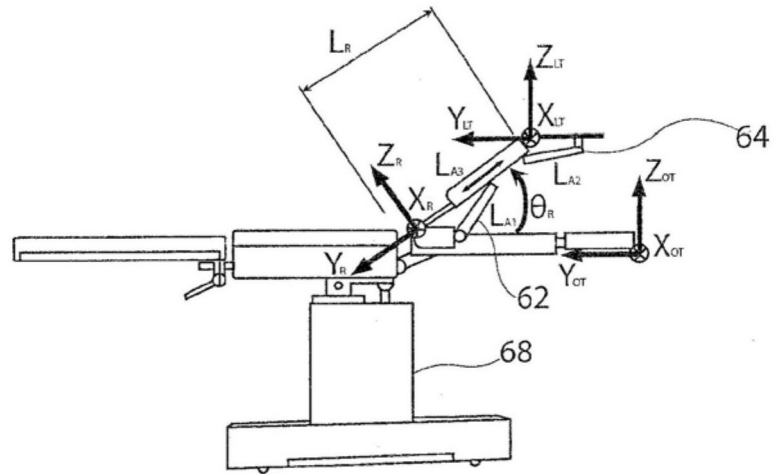


图5

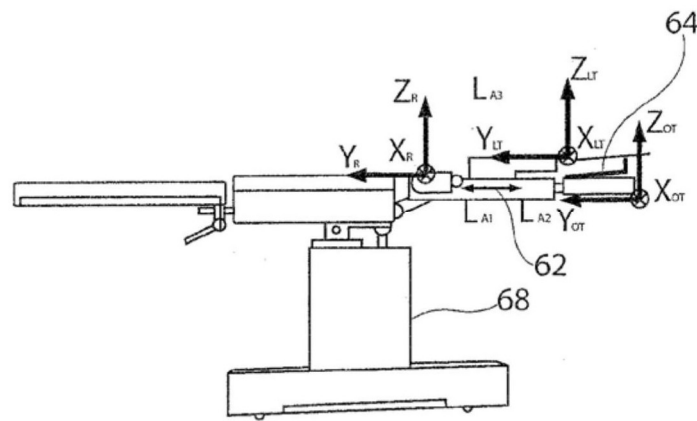
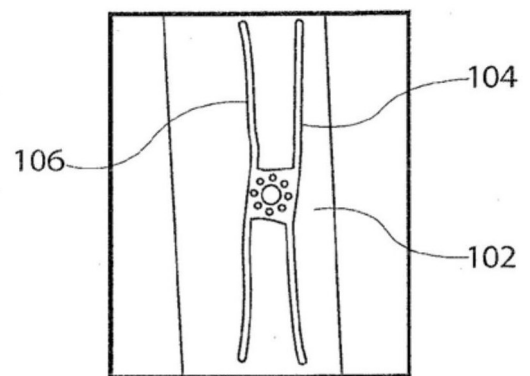
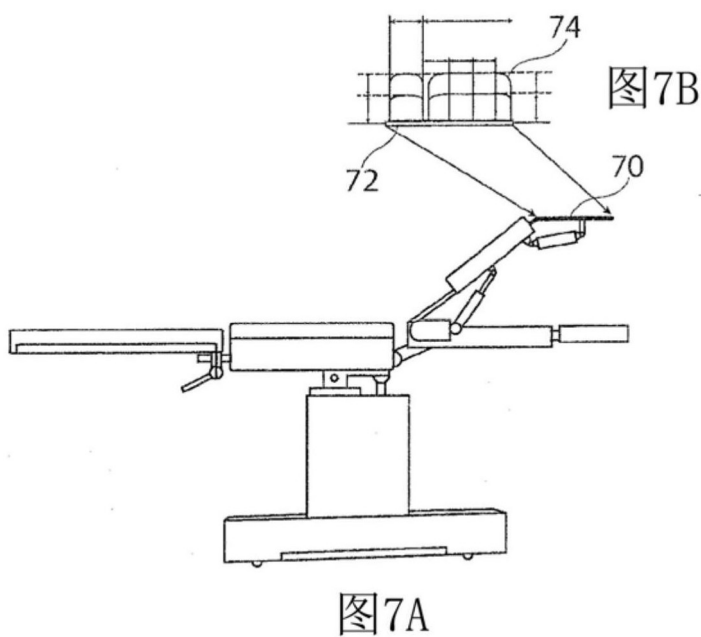


图6



现有技术

图8

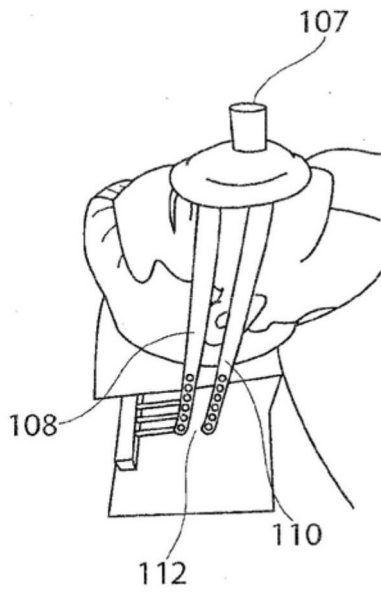


图9B

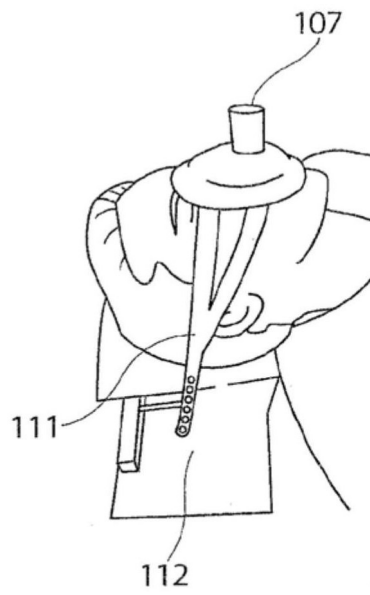


图9A

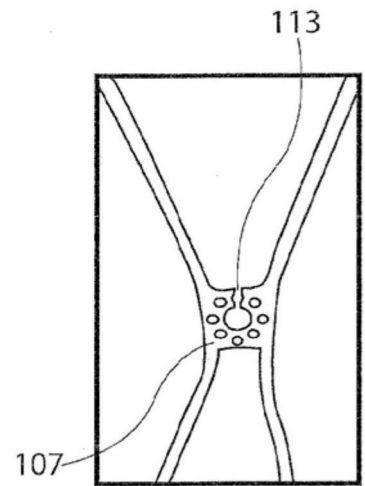


图10

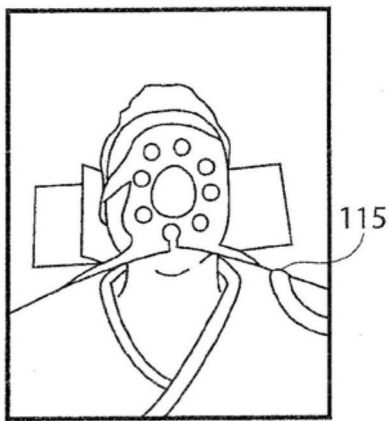


图11



图12



图13



图14A

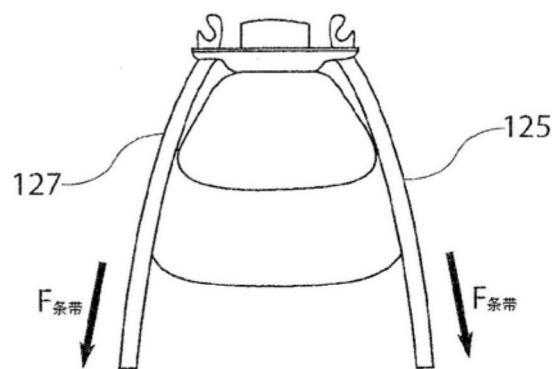


图14B

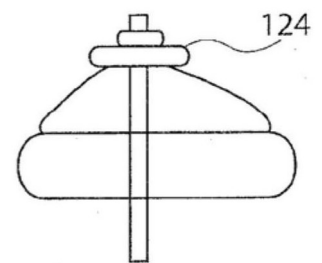


图14C

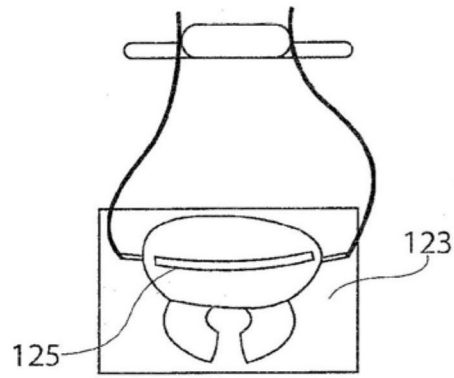


图14D

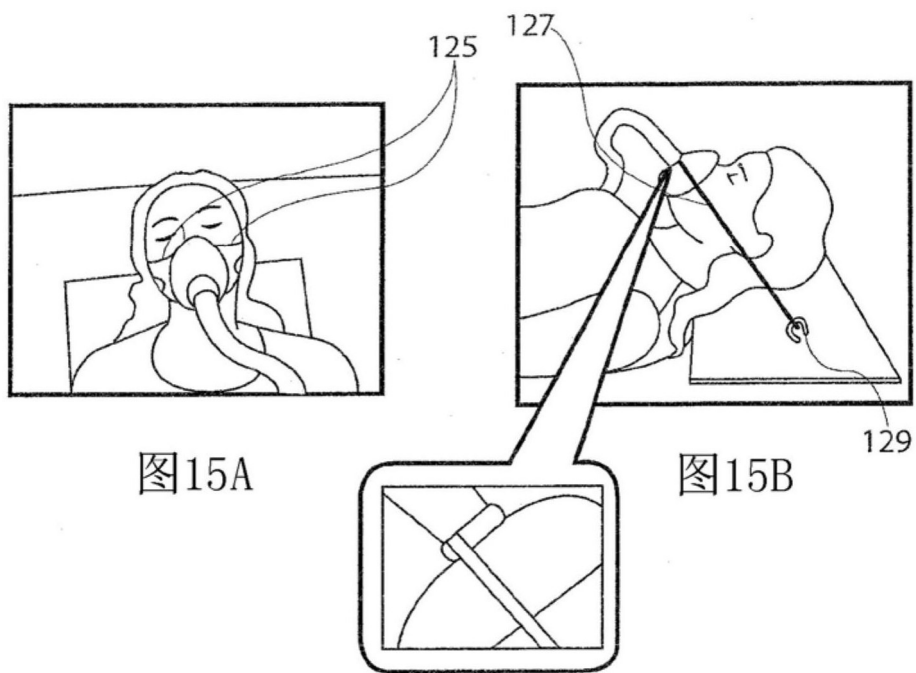


图15A

图15B

图15C

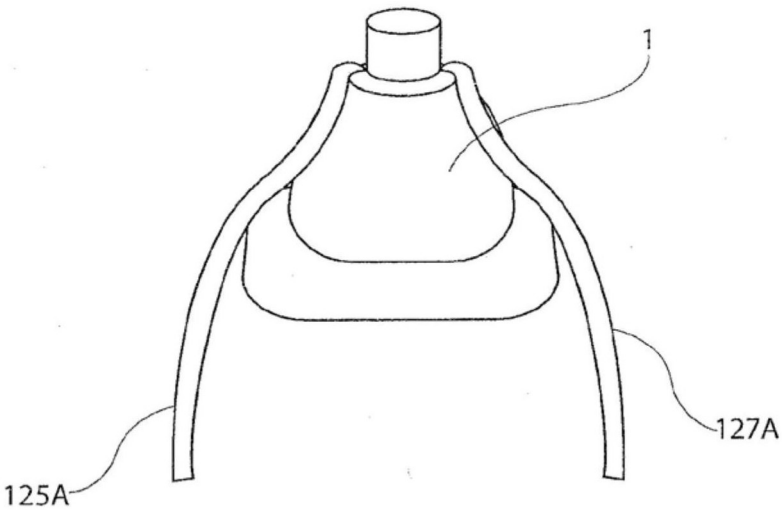


图15D

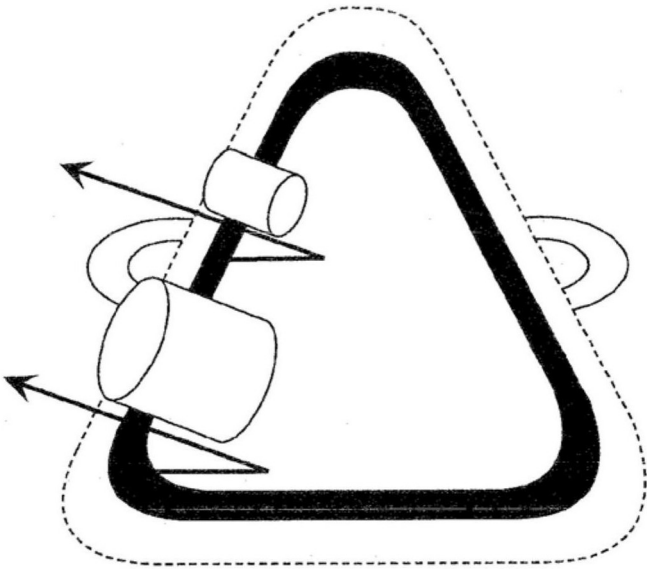


图15E

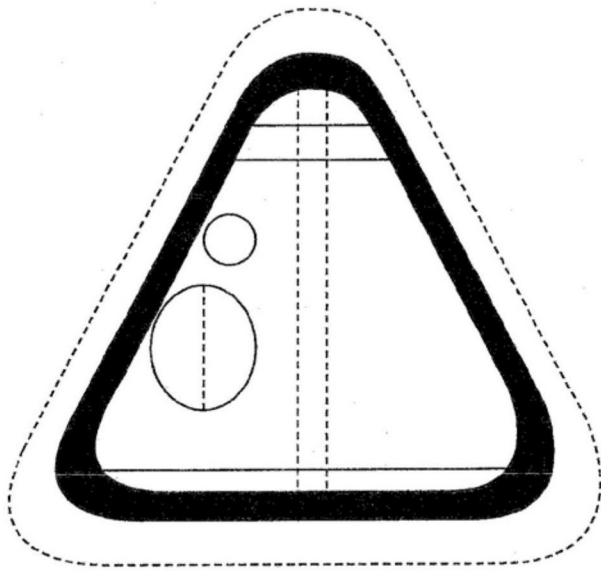


图15F

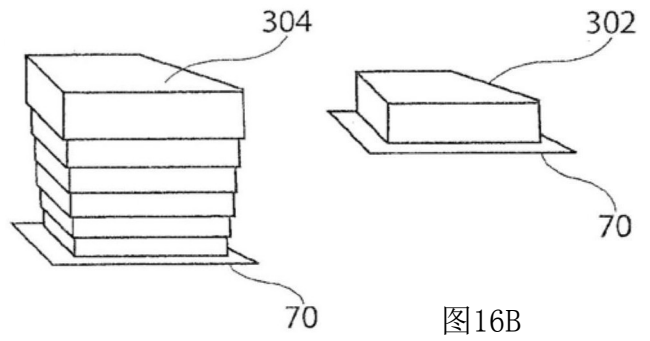


图16A

图16B

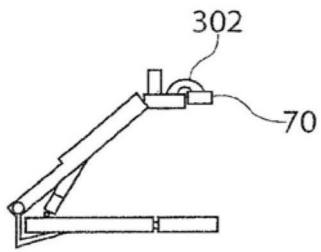


图16C

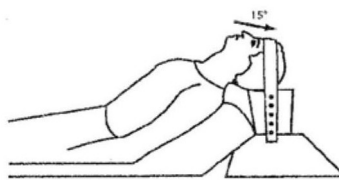


图16D

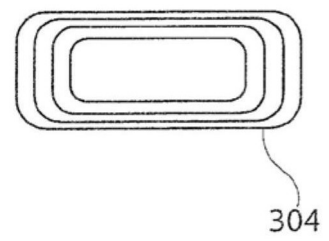


图17A

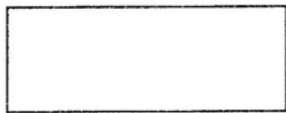


图17B

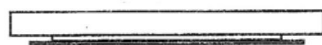


图17C

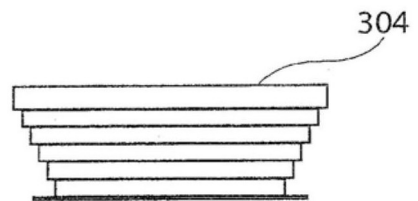


图17D

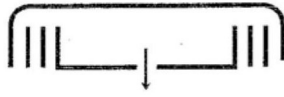


图18A

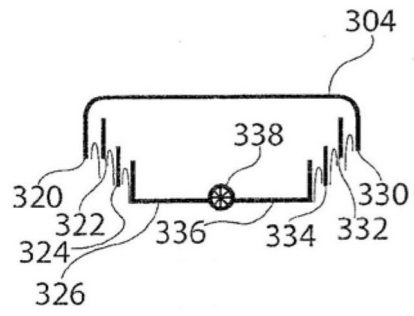


图18B

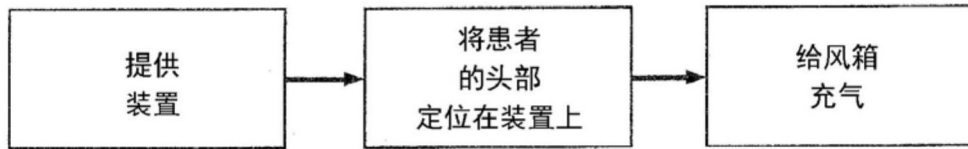


图19

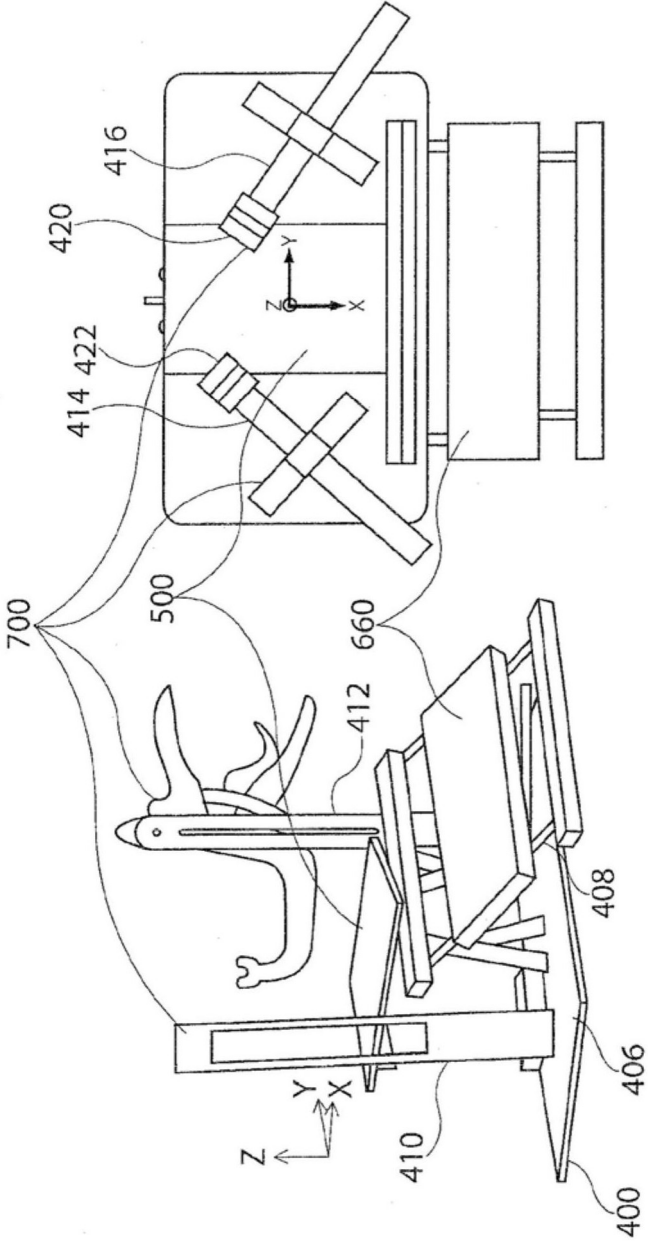


图20B

图20A

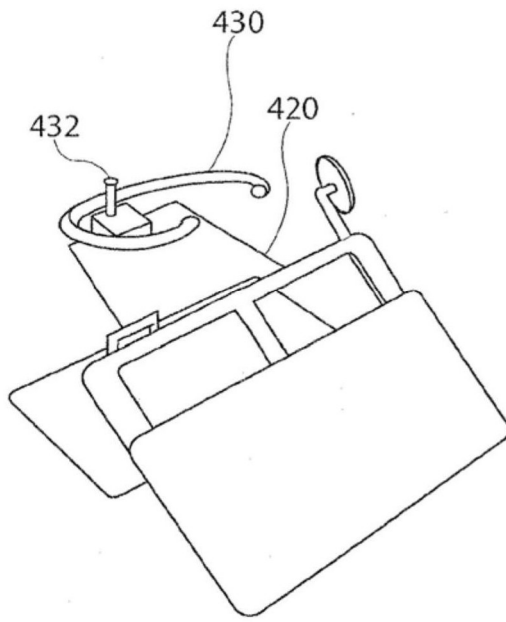


图21A

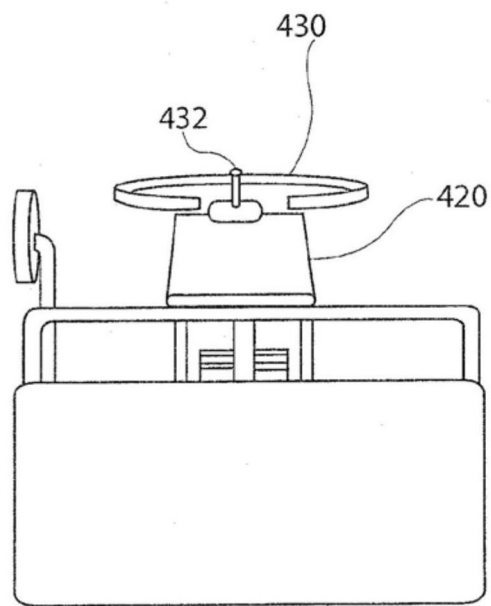


图21B

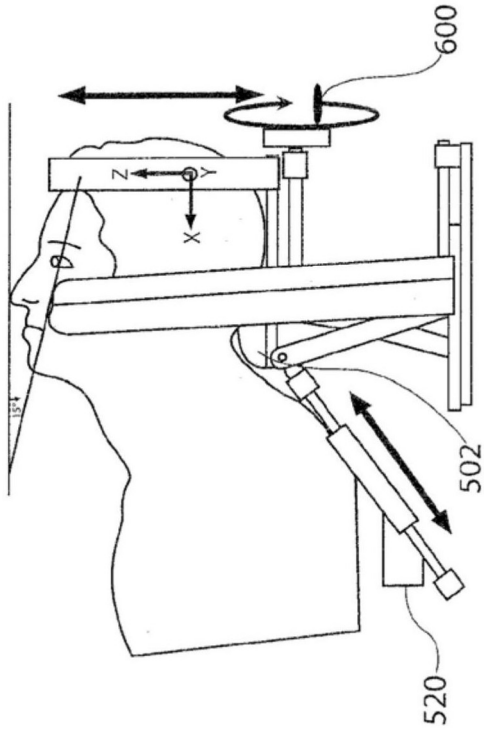


图22

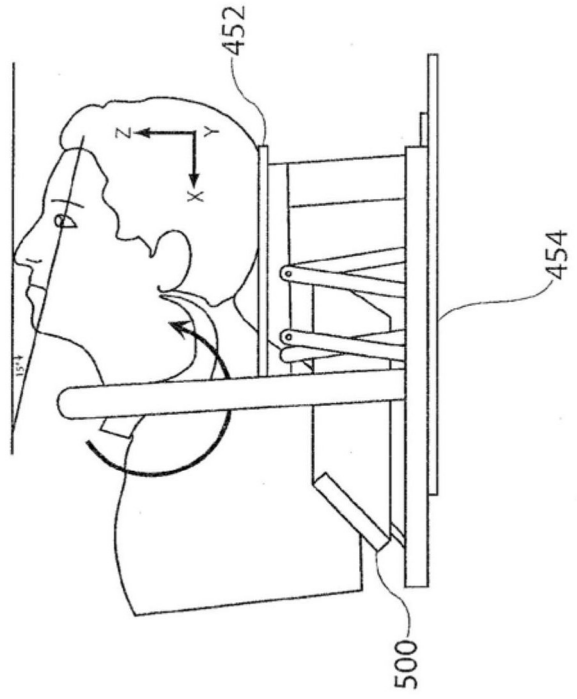


图23

图24A-24D, 步骤4和5

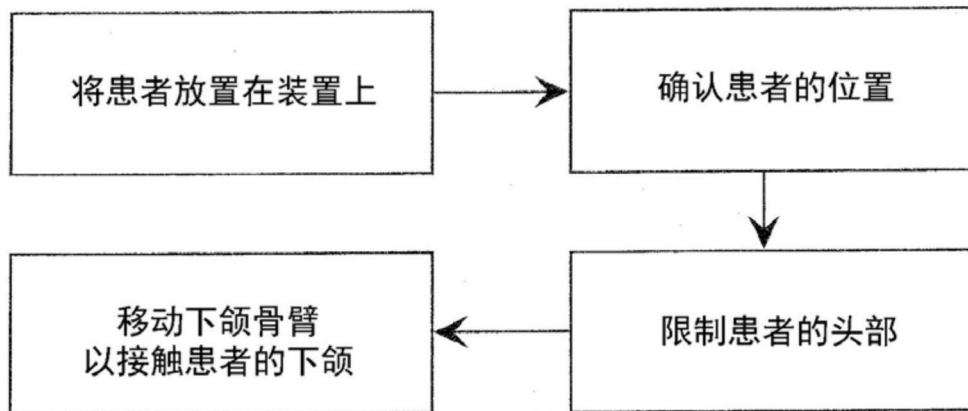
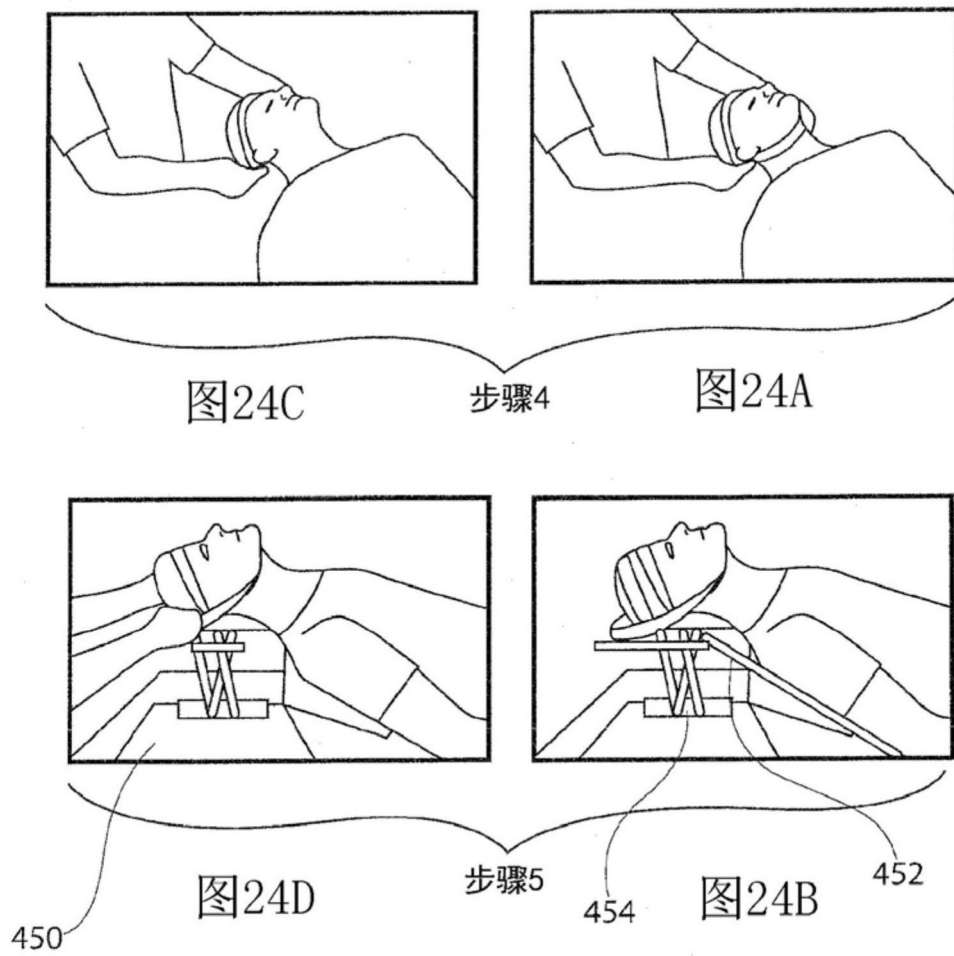


图25

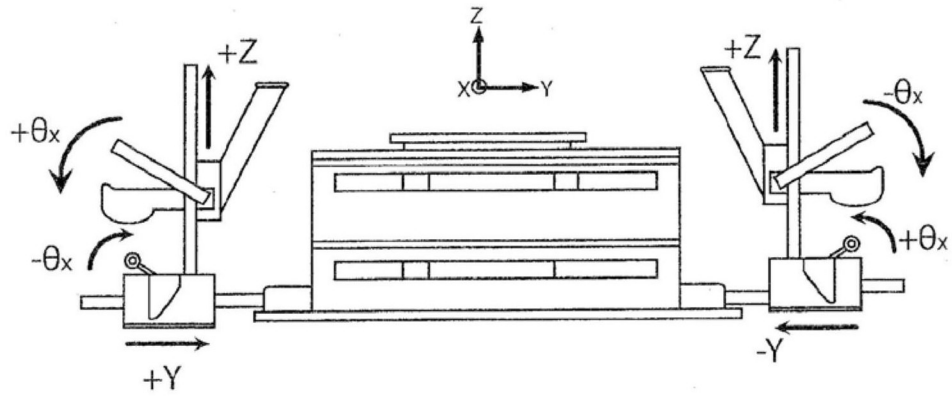
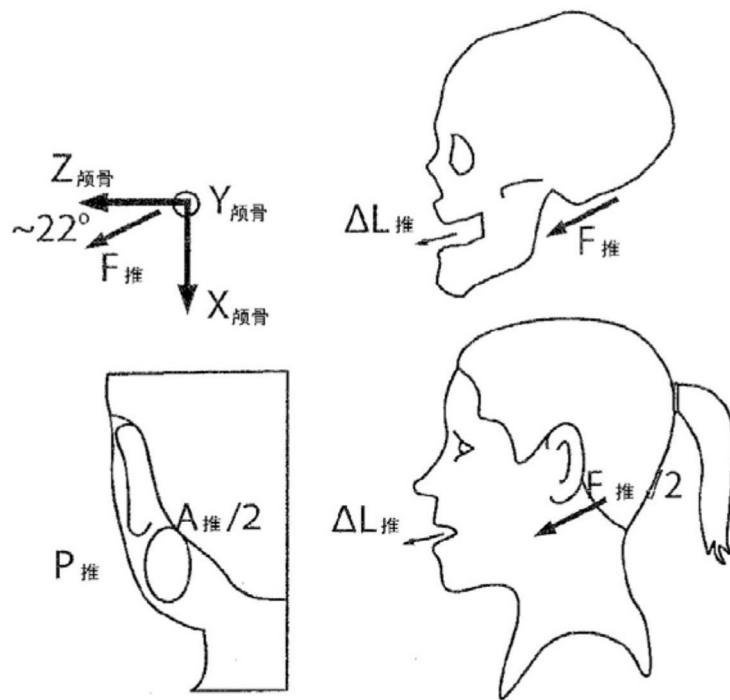


图26



下颌骨托下
颌操作矢量定义
现有技术

图27

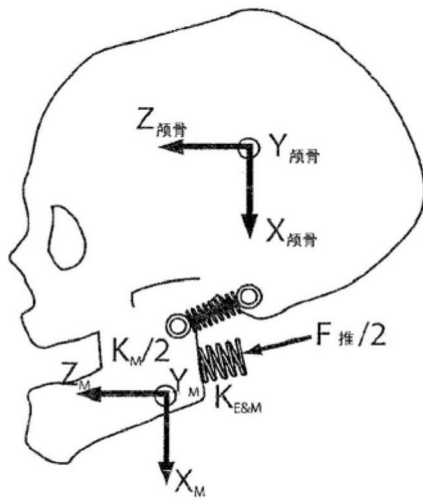


图28A

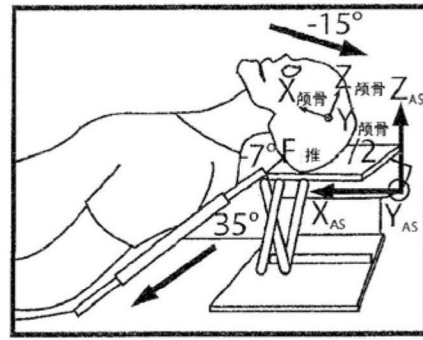


图28C

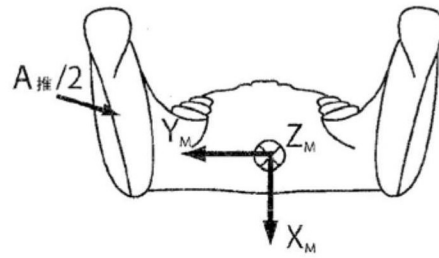
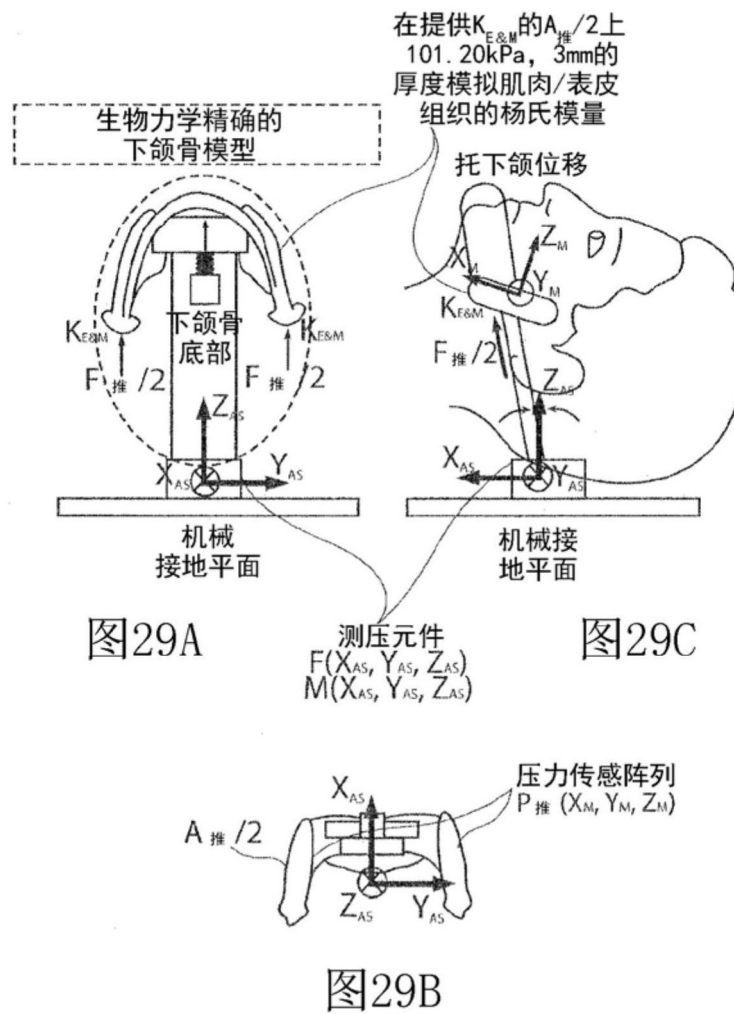


图28B

图28A-28C, 下颌骨结构模型

图29A-29C, 生物力学
精确的下颌骨模型



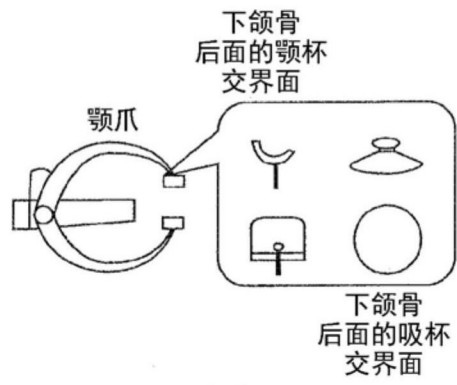


图30A

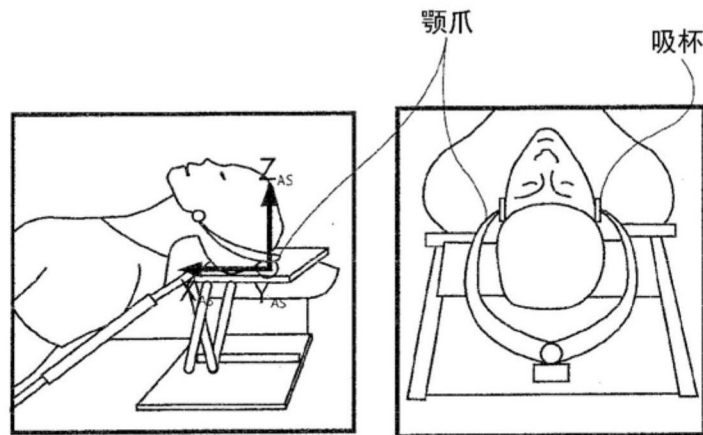


图30B

图30A-30B, 具有颞杯
或吸杯的颞爪

患者在仰卧组件上



通过挤压托下颌握把
至所需要的量进行接合
左右托下颌搁架来伸展下颌骨，
导致它绕x轴转动，
并导致在正Z方向上转换，
直到正确地伸展下颌并
使呼吸道开放

图31A



图31B



沿Z轴转换托下颌
分组合件导致
适当地伸展
下颌

图31C

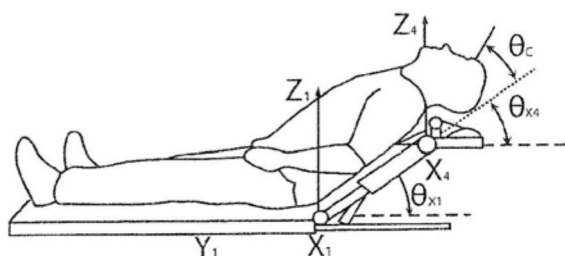
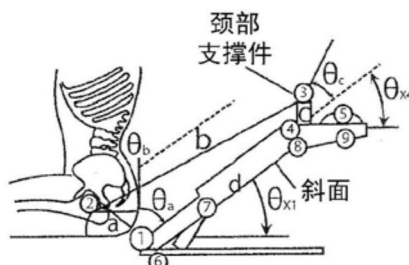
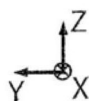


图32C



四连杆机构 (a、b、c、d)
倾斜位置, 角度 θ_{x1}
头枕转动 $\theta_{x4} = -\theta_{x1}$
以维持头部支撑件平行于Y轴

图32D

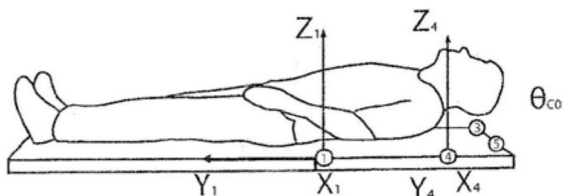
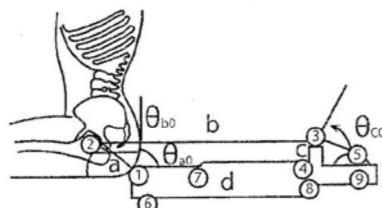


图32A



斜倚位置的四连杆机构
(a、b、c、d)

图32B

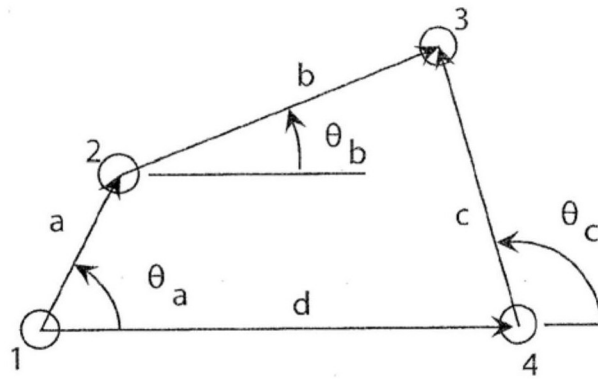
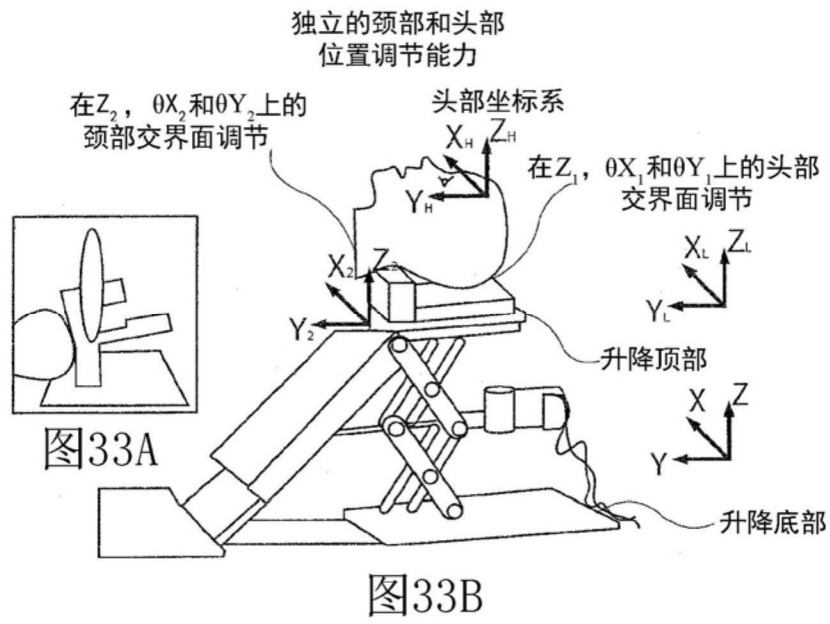
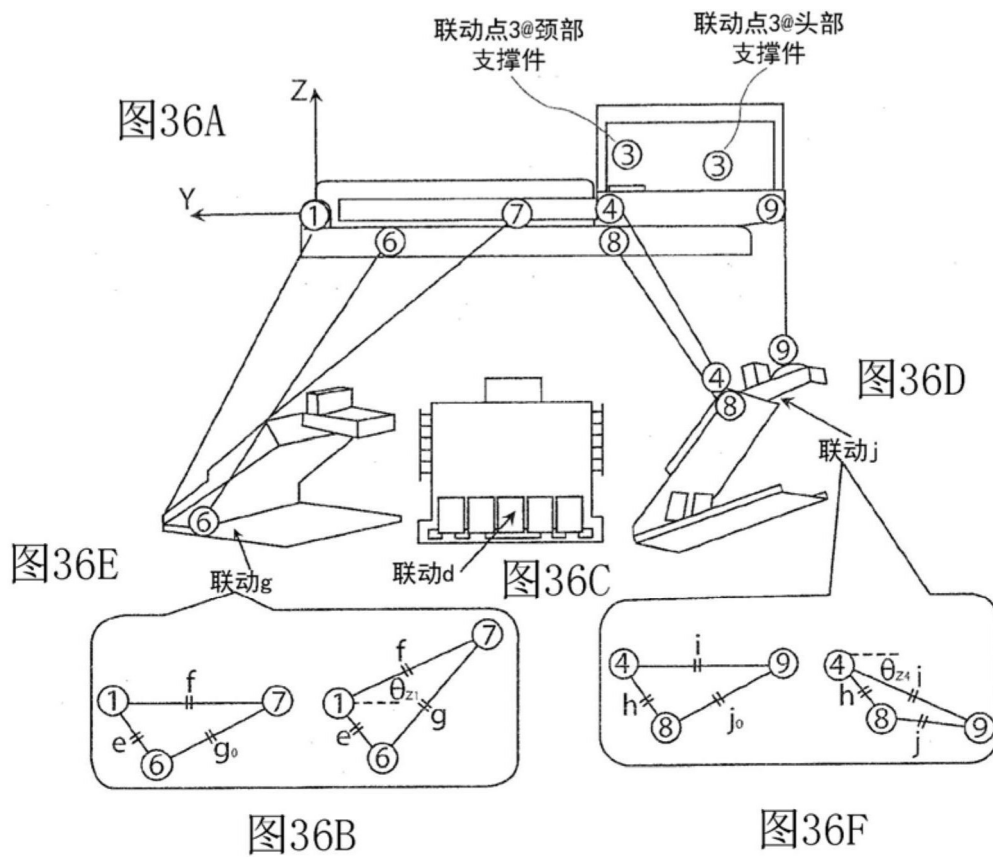
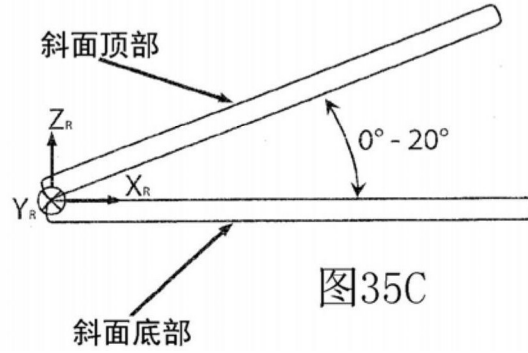
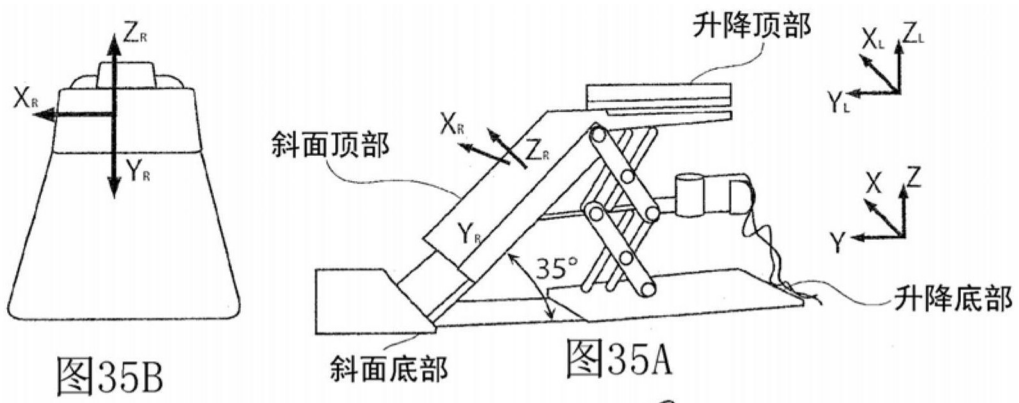
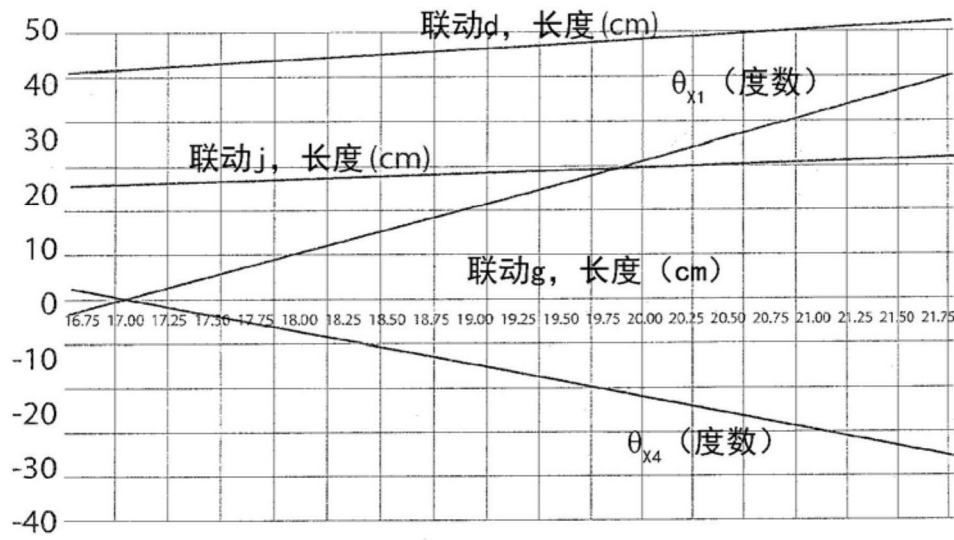


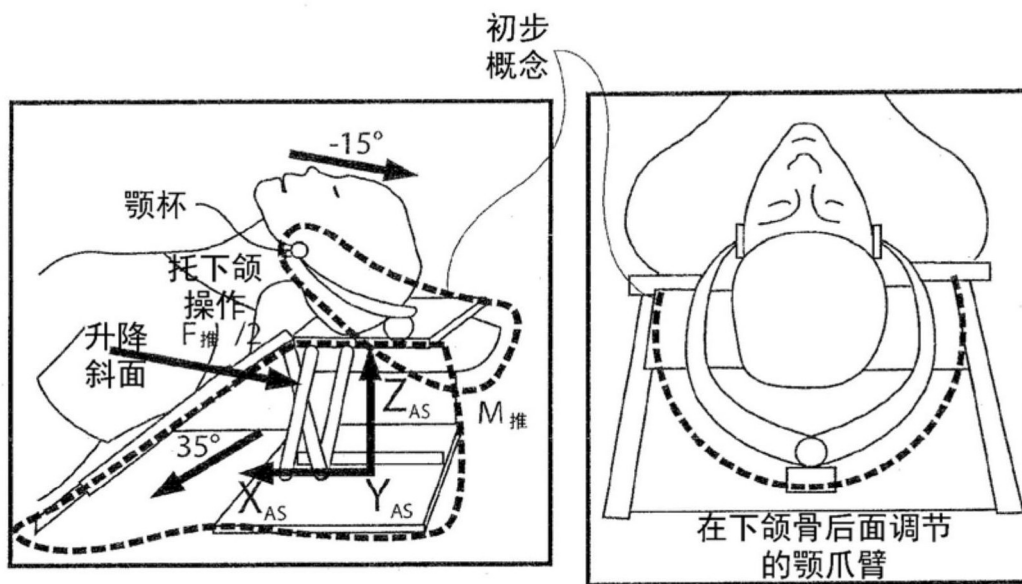
图34





联动长度d和j、斜面角度 θ_{x1}
和头部支撑件角度 θ_{x4}

图37



空气嗅探位置和下巴高度

图38

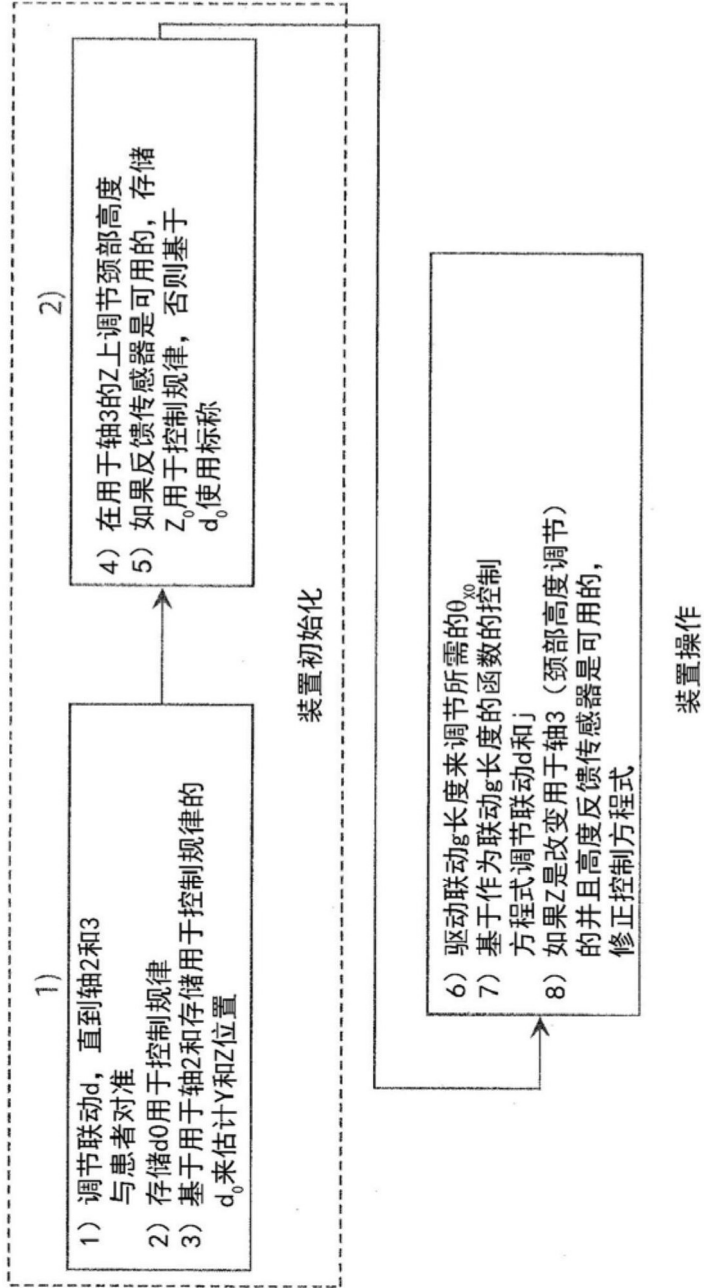
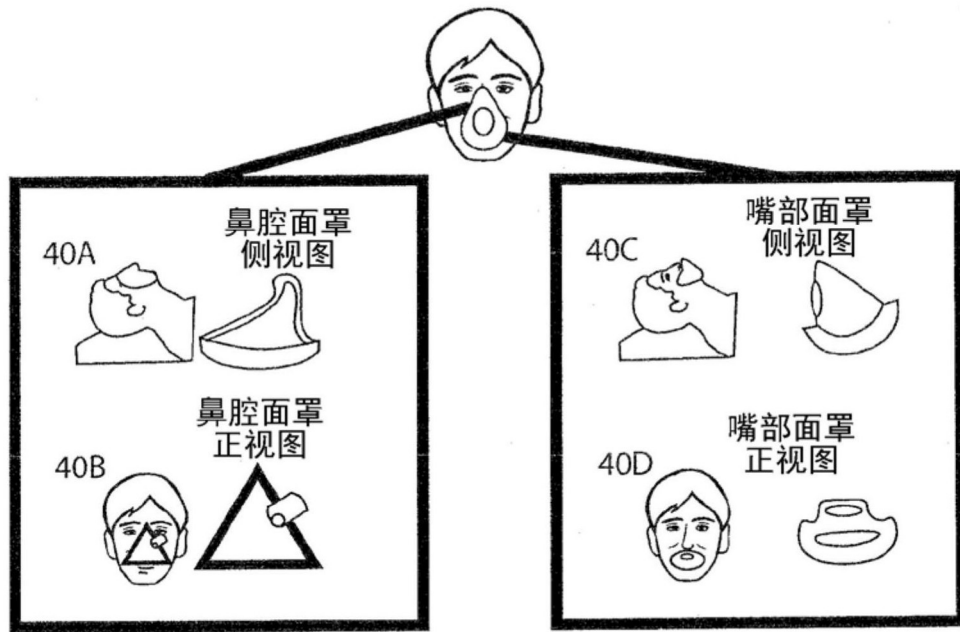


图39



组合的鼻腔和嘴部通气面罩

图40

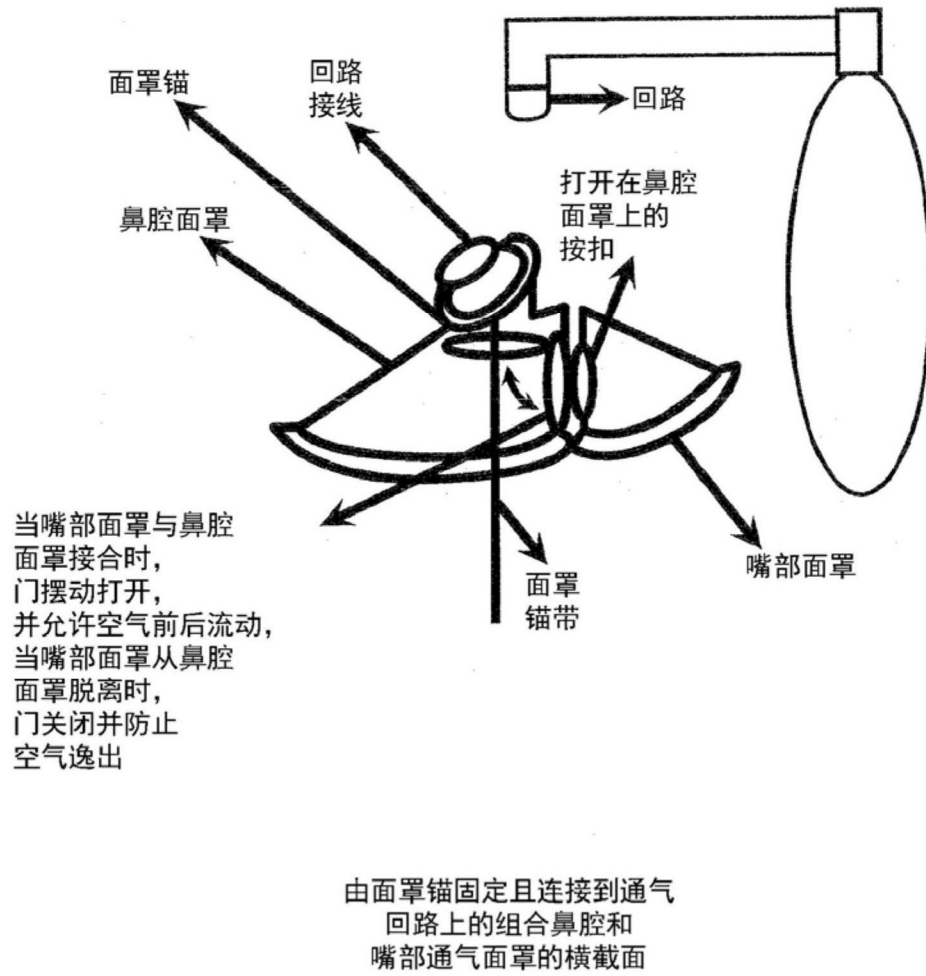


图41

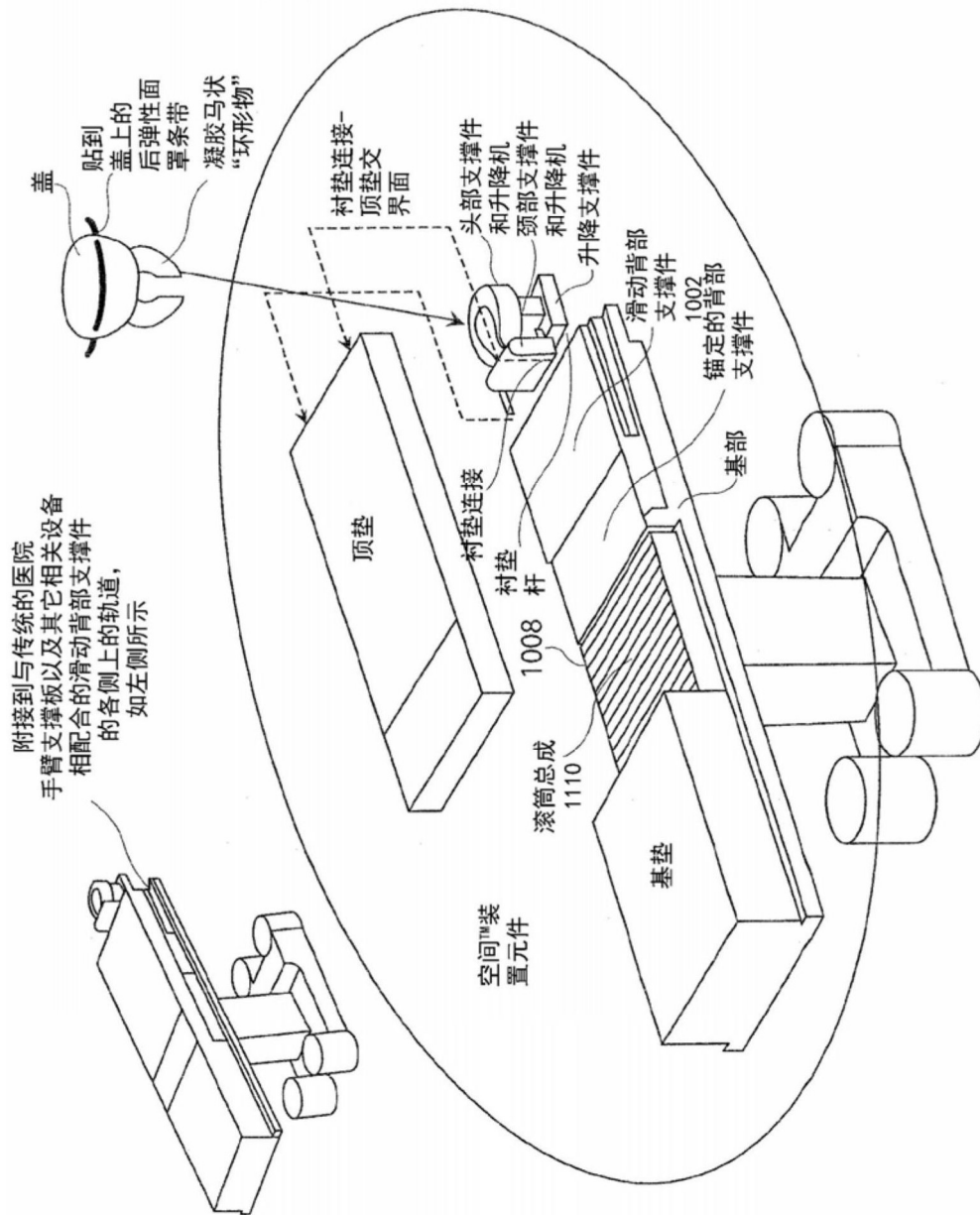


图42

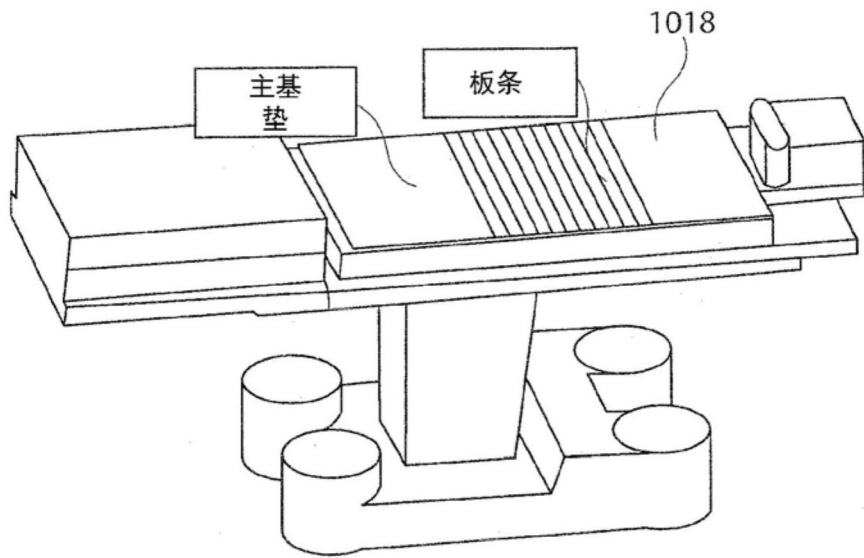


图43

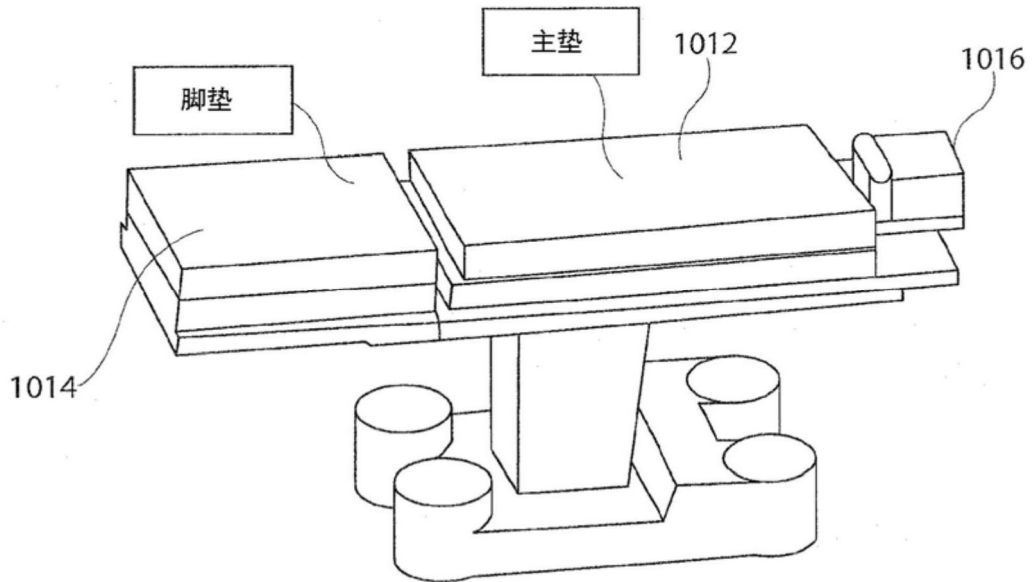


图44

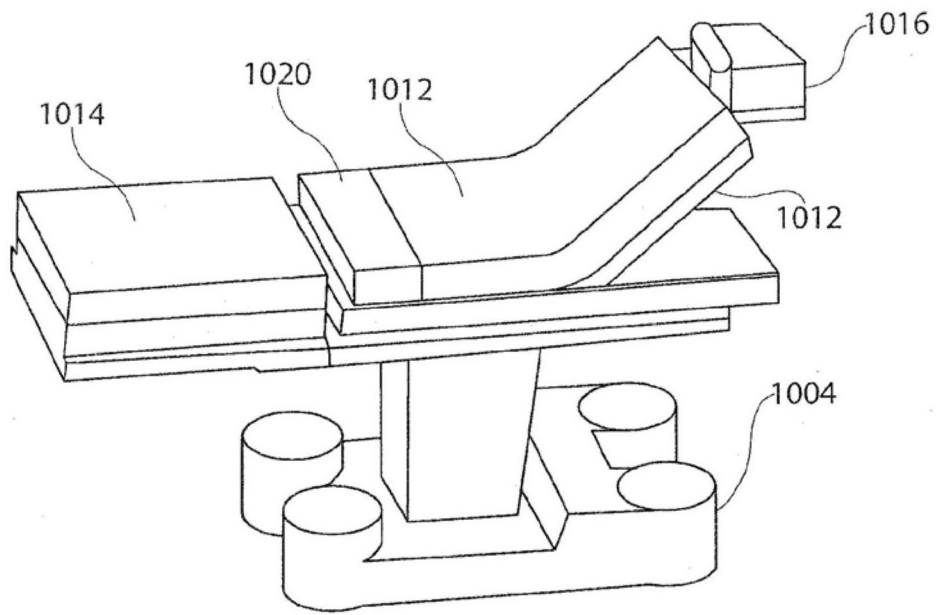


图45

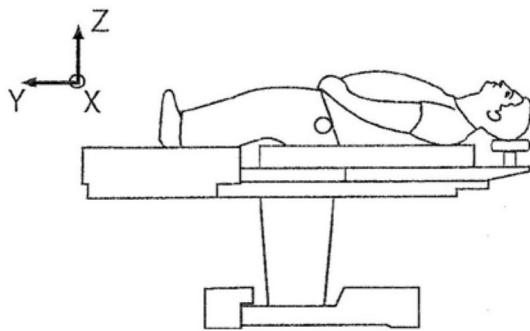


图46A

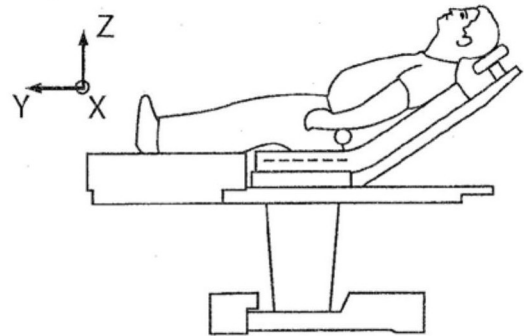


图46B

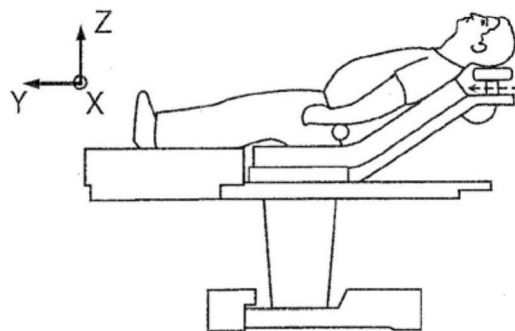


图46C