(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
07 September 2023 (07.09.2023)

WIPO | PCT

(10) International Publication Number
WO 2023/164747 A1

(51) International Patent Classification:
A61M 16/06 (2006.01) *A61M 16/20* (2006.01)
A61M 16/08 (2006.01)

(21) International Application Number:
PCT/AU2023/050141

(22) International Filing Date:
02 March 2023 (02.03.2023)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
2022900507 03 March 2022 (03.03.2022) AU

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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, CV, CZ, DE, DJ, DK, DM, DO, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN, HR, HU, ID, IL, IN, IQ, IR, IS, IT, JM, JO, JP, KE, KG, KH, KN, KP, KR, KW, KZ, LA, LC, LK, LR, LS, LU, LY, MA, MD, 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, ST, SV, SY, TH,

(54) Title: POSITIONING AND STABILISING STRUCTURE WITH PATIENT CONTACTING PORTIONS

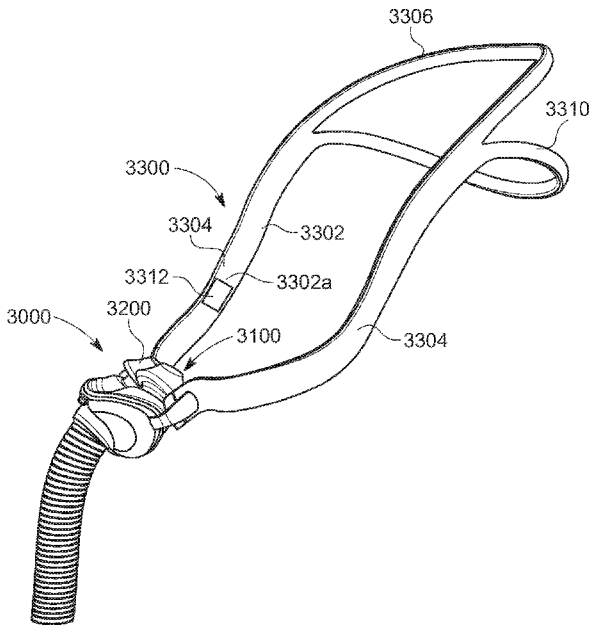


FIG. 5

(57) Abstract: A positioning and stabilising structure is configured to hold a seal- forming structure of a patient interface in a therapeutically effective position on the patient's head. The positioning and stabilising structure comprises a tie which is constructed and arranged so that at least a portion overlies a region of the patient's head superior to an otobasion superior, wherein a portion of the positioning and stabilising structure extends around a back of the patient's head. A flexible portion of the positioning and stabilising structure comprises at least one patient contacting portion which is configured to contact the patient's cheek. The coefficient of friction between at least a portion of the patient contacting portion and the patient's skin is higher than the coefficient of friction between an adjacent portion of the positioning and stabilising structure and the patient's skin.

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[Continued on next page]

TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, WS, ZA, ZM, ZW.

(84) **Designated States** *(unless otherwise indicated, for every kind of regional protection available)*: ARIPO (BW, CV, GH, GM, KE, LR, LS, MW, MZ, NA, RW, SC, SD, SL, ST, 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, ME, 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))*

— *in black and white; the international application as filed contained color or greyscale and is available for download from PATENTSCOPE*

POSITIONING AND STABILISING STRUCTURE WITH PATIENT CONTACTING PORTIONS

1 BACKGROUND OF THE TECHNOLOGY

1.1 FIELD OF THE TECHNOLOGY

[0001] The present technology relates to one or more of the screening, diagnosis, monitoring, treatment, prevention and amelioration of respiratory-related disorders. The present technology also relates to medical devices or apparatus, and their use.

1.2 DESCRIPTION OF THE RELATED ART

1.2.1 Human Respiratory System and its Disorders

[0002] The respiratory system of the body facilitates gas exchange. The nose and mouth form the entrance to the airways of a patient.

[0003] The airways include a series of branching tubes, which become narrower, shorter and more numerous as they penetrate deeper into the lung. The prime function of the lung is gas exchange, allowing oxygen to move from the inhaled air into the venous blood and carbon dioxide to move in the opposite direction. The trachea divides into right and left main bronchi, which further divide eventually into terminal bronchioles. The bronchi make up the conducting airways, and do not take part in gas exchange. Further divisions of the airways lead to the respiratory bronchioles, and eventually to the alveoli. The alveolated region of the lung is where the gas exchange takes place, and is referred to as the respiratory zone. See "*Respiratory Physiology*", by John B. West, Lippincott Williams & Wilkins, 9th edition published 2012.

[0004] A range of respiratory disorders exist. Certain disorders may be characterised by particular events, e.g. apneas, hypopneas, and hyperpneas.

[0005] Examples of respiratory disorders include Obstructive Sleep Apnea (OSA), Cheyne-Stokes Respiration (CSR), respiratory insufficiency, Obesity Hyperventilation Syndrome (OHS), Chronic Obstructive Pulmonary Disease (COPD), Neuromuscular Disease (NMD) and Chest wall disorders.

[0006] Obstructive Sleep Apnea (OSA), a form of Sleep Disordered Breathing (SDB), is characterised by events including occlusion or obstruction of the upper air

passage during sleep. It results from a combination of an abnormally small upper airway and the normal loss of muscle tone in the region of the tongue, soft palate and posterior oropharyngeal wall during sleep. The condition causes the affected patient to stop breathing for periods typically of 30 to 120 seconds in duration, sometimes 200 to 300 times per night. It often causes excessive daytime somnolence, and it may cause cardiovascular disease and brain damage. The syndrome is a common disorder, particularly in middle aged overweight males, although a person affected may have no awareness of the problem. See US Patent No. 4,944,310 (Sullivan).

[0007] Cheyne-Stokes Respiration (CSR) is another form of sleep disordered breathing. CSR is a disorder of a patient's respiratory controller in which there are rhythmic alternating periods of waxing and waning ventilation known as CSR cycles. CSR is characterised by repetitive de-oxygenation and re-oxygenation of the arterial blood. It is possible that CSR is harmful because of the repetitive hypoxia. In some patients CSR is associated with repetitive arousal from sleep, which causes severe sleep disruption, increased sympathetic activity, and increased afterload. See US Patent No. 6,532,959 (Berthon-Jones).

[0008] Respiratory failure is an umbrella term for respiratory disorders in which the lungs are unable to inspire sufficient oxygen or exhale sufficient CO2 to meet the patient's needs. Respiratory failure may encompass some or all of the following disorders.

[0009] A patient with respiratory insufficiency (a form of respiratory failure) may experience abnormal shortness of breath on exercise.

[0010] Obesity Hyperventilation Syndrome (OHS) is defined as the combination of severe obesity and awake chronic hypercapnia, in the absence of other known causes for hypoventilation. Symptoms include dyspnea, morning headache and excessive daytime sleepiness.

[0011] Chronic Obstructive Pulmonary Disease (COPD) encompasses any of a group of lower airway diseases that have certain characteristics in common. These include increased resistance to air movement, extended expiratory phase of respiration, and loss of the normal elasticity of the lung. Examples of COPD are emphysema and chronic bronchitis. COPD is caused by chronic tobacco smoking

(primary risk factor), occupational exposures, air pollution and genetic factors. Symptoms include: dyspnea on exertion, chronic cough and sputum production.

[0012] Neuromuscular Disease (NMD) is a broad term that encompasses many diseases and ailments that impair the functioning of the muscles either directly via intrinsic muscle pathology, or indirectly via nerve pathology. Some NMD patients are characterised by progressive muscular impairment leading to loss of ambulation, being wheelchair-bound, swallowing difficulties, respiratory muscle weakness and, eventually, death from respiratory failure. Neuromuscular disorders can be divided into rapidly progressive and slowly progressive: (i) Rapidly progressive disorders: Characterised by muscle impairment that worsens over months and results in death within a few years (e.g. Amyotrophic lateral sclerosis (ALS) and Duchenne muscular dystrophy (DMD) in teenagers); (ii) Variable or slowly progressive disorders: Characterised by muscle impairment that worsens over years and only mildly reduces life expectancy (e.g. Limb girdle, Facioscapulohumeral and Myotonic muscular dystrophy). Symptoms of respiratory failure in NMD include: increasing generalised weakness, dysphagia, dyspnea on exertion and at rest, fatigue, sleepiness, morning headache, and difficulties with concentration and mood changes.

[0013] Chest wall disorders are a group of thoracic deformities that result in inefficient coupling between the respiratory muscles and the thoracic cage. The disorders are usually characterised by a restrictive defect and share the potential of long term hypercapnic respiratory failure. Scoliosis and/or kyphoscoliosis may cause severe respiratory failure. Symptoms of respiratory failure include: dyspnea on exertion, peripheral oedema, orthopnea, repeated chest infections, morning headaches, fatigue, poor sleep quality and loss of appetite.

[0014] A range of therapies have been used to treat or ameliorate such conditions. Furthermore, otherwise healthy individuals may take advantage of such therapies to prevent respiratory disorders from arising. However, these have a number of shortcomings.

1.2.2 Therapies

[0015] Various respiratory therapies, such as Continuous Positive Airway Pressure (CPAP) therapy, Non-invasive ventilation (NIV), Invasive ventilation (IV),

and High Flow Therapy (HFT) have been used to treat one or more of the above respiratory disorders.

1.2.2.1 Respiratory pressure therapies

[0016] Respiratory pressure therapy is the application of a supply of air to an entrance to the airways at a controlled target pressure that is nominally positive with respect to atmosphere throughout the patient's breathing cycle (in contrast to negative pressure therapies such as the tank ventilator or cuirass).

[0017] Continuous Positive Airway Pressure (CPAP) therapy has been used to treat Obstructive Sleep Apnea (OSA). The mechanism of action is that continuous positive airway pressure acts as a pneumatic splint and may prevent upper airway occlusion, such as by pushing the soft palate and tongue forward and away from the posterior oropharyngeal wall. Treatment of OSA by CPAP therapy may be voluntary, and hence patients may elect not to comply with therapy if they find devices used to provide such therapy one or more of: uncomfortable, difficult to use, expensive and aesthetically unappealing.

[0018] Non-invasive ventilation (NIV) provides ventilatory support to a patient through the upper airways to assist the patient breathing and/or maintain adequate oxygen levels in the body by doing some or all of the work of breathing. The ventilatory support is provided via a non-invasive patient interface. NIV has been used to treat CSR and respiratory failure, in forms such as OHS, COPD, NMD and Chest Wall disorders. In some forms, the comfort and effectiveness of these therapies may be improved.

[0019] Invasive ventilation (IV) provides ventilatory support to patients that are no longer able to effectively breathe themselves and may be provided using a tracheostomy tube or endotracheal tube. In some forms, the comfort and effectiveness of these therapies may be improved.

1.2.2.2 Flow therapies

[0020] Not all respiratory therapies aim to deliver a prescribed therapeutic pressure. Some respiratory therapies aim to deliver a prescribed respiratory volume, by delivering an inspiratory flow rate profile over a targeted duration, possibly

superimposed on a positive baseline pressure. In other cases, the interface to the patient's airways is 'open' (unsealed) and the respiratory therapy may only supplement the patient's own spontaneous breathing with a flow of conditioned or enriched gas. In one example, High Flow therapy (HFT) is the provision of a continuous, heated, humidified flow of air to an entrance to the airway through an unsealed or open patient interface at a "treatment flow rate" that may be held approximately constant throughout the respiratory cycle. The treatment flow rate is nominally set to exceed the patient's peak inspiratory flow rate. HFT has been used to treat OSA, CSR, respiratory failure, COPD, and other respiratory disorders. One mechanism of action is that the high flow rate of air at the airway entrance improves ventilation efficiency by flushing, or washing out, expired CO2 from the patient's anatomical deadspace. Hence, HFT is thus sometimes referred to as a deadspace therapy (DST). Other benefits may include the elevated warmth and humidification (possibly of benefit in secretion management) and the potential for modest elevation of airway pressures. As an alternative to constant flow rate, the treatment flow rate may follow a profile that varies over the respiratory cycle.

[0021] Another form of flow therapy is long-term oxygen therapy (LTOT) or supplemental oxygen therapy. Doctors may prescribe a continuous flow of oxygen enriched air at a specified oxygen concentration (from 21%, the oxygen fraction in ambient air, to 100%) at a specified flow rate (e.g., 1 litre per minute (LPM), 2 LPM, 3 LPM, etc.) to be delivered to the patient's airway.

1.2.3 Respiratory Therapy Systems

[0022] These respiratory therapies may be provided by a respiratory therapy system or device. Such systems and devices may also be used to screen, diagnose, or monitor a condition without treating it.

[0023] A respiratory therapy system may comprise a Respiratory Pressure Therapy Device (RPT device), an air circuit, a humidifier, a patient interface, an oxygen source, and data management.

1.2.3.1 Patient Interface

[0024] A patient interface may be used to interface respiratory equipment to its wearer, for example by providing a flow of air to an entrance to the airways. The flow

of air may be provided via a mask to the nose and/or mouth, a tube to the mouth or a tracheostomy tube to the trachea of a patient. Depending upon the therapy to be applied, the patient interface may form a seal, e.g., with a region of the patient's face, to facilitate the delivery of gas at a pressure at sufficient variance with ambient pressure to effect therapy, e.g., at a positive pressure of about 10 cmH_2O relative to ambient pressure. For other forms of therapy, such as the delivery of oxygen, the patient interface may not include a seal sufficient to facilitate delivery to the airways of a supply of gas at a positive pressure of about 10 cmH_2O. For flow therapies such as nasal HFT, the patient interface is configured to insufflate the nares but specifically to avoid a complete seal. One example of such a patient interface is a nasal cannula.

[0025] Certain other mask systems may be functionally unsuitable for the present field. For example, purely ornamental masks may be unable to maintain a suitable pressure. Mask systems used for underwater swimming or diving may be configured to guard against ingress of water from an external higher pressure, but not to maintain air internally at a higher pressure than ambient.

[0026] Certain masks may be clinically unfavourable for the present technology e.g. if they block airflow via the nose and only allow it via the mouth.

[0027] Certain masks may be uncomfortable or impractical for the present technology if they require a patient to insert a portion of a mask structure in their mouth to create and maintain a seal via their lips.

[0028] Certain masks may be impractical for use while sleeping, e.g. for sleeping while lying on one's side in bed with a head on a pillow.

[0029] The design of a patient interface presents a number of challenges. The face has a complex three-dimensional shape. The size and shape of noses and heads varies considerably between individuals. Since the head includes bone, cartilage and soft tissue, different regions of the face respond differently to mechanical forces. The jaw or mandible may move relative to other bones of the skull. The whole head may move during the course of a period of respiratory therapy.

[0030] As a consequence of these challenges, some masks suffer from being one or more of obtrusive, aesthetically undesirable, costly, poorly fitting, difficult to use,

and uncomfortable especially when worn for long periods of time or when a patient is unfamiliar with a system. Wrongly sized masks can give rise to reduced compliance, reduced comfort and poorer patient outcomes. Masks designed solely for aviators, masks designed as part of personal protection equipment (e.g. filter masks), SCUBA masks, or for the administration of anaesthetics may be tolerable for their original application, but nevertheless such masks may be undesirably uncomfortable to be worn for extended periods of time, e.g., several hours. This discomfort may lead to a reduction in patient compliance with therapy. This is even more so if the mask is to be worn during sleep.

[0031] CPAP therapy is highly effective to treat certain respiratory disorders, provided patients comply with therapy. If a mask is uncomfortable, or difficult to use a patient may not comply with therapy. Since it is often recommended that a patient regularly wash their mask, if a mask is difficult to clean (e.g., difficult to assemble or disassemble), patients may not clean their mask and this may impact on patient compliance.

[0032] While a mask for other applications (e.g. aviators) may not be suitable for use in treating sleep disordered breathing, a mask designed for use in treating sleep disordered breathing may be suitable for other applications.

[0033] For these reasons, patient interfaces for delivery of CPAP during sleep form a distinct field.

1.2.3.1.1 Seal-forming structure

[0034] Patient interfaces may include a seal-forming structure. Since it is in direct contact with the patient's face, the shape and configuration of the seal-forming structure can have a direct impact the effectiveness and comfort of the patient interface.

[0035] A patient interface may be partly characterised according to the design intent of where the seal-forming structure is to engage with the face in use. In one form of patient interface, a seal-forming structure may comprise a first sub-portion to form a seal around the left naris and a second sub-portion to form a seal around the right naris. In one form of patient interface, a seal-forming structure may comprise a single element that surrounds both nares in use. Such single element may be designed

to for example overlay an upper lip region and a nasal bridge region of a face. In one form of patient interface a seal-forming structure may comprise an element that surrounds a mouth region in use, e.g. by forming a seal on a lower lip region of a face. In one form of patient interface, a seal-forming structure may comprise a single element that surrounds both nares and a mouth region in use. These different types of patient interfaces may be known by a variety of names by their manufacturer including nasal masks, full-face masks, nasal pillows, nasal puffs and oro-nasal masks.

[0036] A seal-forming structure that may be effective in one region of a patient's face may be inappropriate in another region, e.g. because of the different shape, structure, variability and sensitivity regions of the patient's face. For example, a seal on swimming goggles that overlays a patient's forehead may not be appropriate to use on a patient's nose.

[0037] Certain seal-forming structures may be designed for mass manufacture such that one design is able to fit and be comfortable and effective for a wide range of different face shapes and sizes. To the extent to which there is a mismatch between the shape of the patient's face, and the seal-forming structure of the mass-manufactured patient interface, one or both must adapt in order for a seal to form.

[0038] One type of seal-forming structure extends around the periphery of the patient interface, and is intended to seal against the patient's face when force is applied to the patient interface with the seal-forming structure in confronting engagement with the patient's face. The seal-forming structure may include an air or fluid filled cushion, or a moulded or formed surface of a resilient seal element made of an elastomer such as a rubber. With this type of seal-forming structure, if the fit is not adequate, there will be gaps between the seal-forming structure and the face, and additional force will be required to force the patient interface against the face in order to achieve a seal.

[0039] Another type of seal-forming structure incorporates a flap seal of thin material positioned about the periphery of the mask so as to provide a self-sealing action against the face of the patient when positive pressure is applied within the mask. Like the previous style of seal forming portion, if the match between the face

and the mask is not good, additional force may be required to achieve a seal, or the mask may leak. Furthermore, if the shape of the seal-forming structure does not match that of the patient, it may crease or buckle in use, giving rise to leaks.

[0040] Another type of seal-forming structure may comprise a friction-fit element, e.g. for insertion into a naris, however some patients find these uncomfortable.

[0041] Another form of seal-forming structure may use adhesive to achieve a seal.

[0042] A range of patient interface seal-forming structure technologies are disclosed in the following patent applications, assigned to ResMed Limited: WO 1998/004,310; WO 2006/074,513; WO 2010/135,785.

[0043] One form of nasal pillow is found in the Adam Circuit manufactured by Puritan Bennett. Another nasal pillow, or nasal puff is the subject of US Patent 4,782,832 (Trimble et al.), assigned to Puritan-Bennett Corporation.

[0044] ResMed Limited has manufactured the following products that incorporate nasal pillows: SWIFTTM nasal pillows mask, SWIFTTM II nasal pillows mask, SWIFTTM LT nasal pillows mask, SWIFTTM FX nasal pillows mask and MIRAGE LIBERTYTM full-face mask. The following patent applications, assigned to ResMed Limited, describe examples of nasal pillows masks: International Patent Application WO2004/073,778 (describing amongst other things aspects of the ResMed Limited SWIFTTM nasal pillows), US Patent Application 2009/0044808 (describing amongst other things aspects of the ResMed Limited SWIFTTM LT nasal pillows); International Patent Applications WO 2005/063,328 and WO 2006/130,903 (describing amongst other things aspects of the ResMed Limited MIRAGE LIBERTYTM full-face mask); International Patent Application WO 2009/052,560 (describing amongst other things aspects of the ResMed Limited SWIFTTM FX nasal pillows).

1.2.3.1.2 Positioning and stabilising

[0045] A seal-forming structure of a patient interface used for positive air pressure therapy is subject to the corresponding force of the air pressure to disrupt a

seal. Thus a variety of techniques have been used to position the seal-forming structure, and to maintain it in sealing relation with the appropriate portion of the face.

[0046] Several factors may be considered when comparing different positioning and stabilising techniques. These include: how effective the technique is at maintaining the seal-forming structure in the desired position and in sealed engagement with the face during use of the patient interface; how comfortable the interface is for the patient; whether the patient feels intrusiveness and/or claustrophobia when wearing the patient interface; and aesthetic appeal.

[0047] One technique is the use of adhesives to adhere the seal-forming structure to the patient's face. See for example US Patent Application Publication No. US 2010/0000534.

[0048] Another technique is the use of one or more straps and/or stabilising harnesses.

[0049] In examples, the positioning and stabilising may be structured and arranged to pull the seal-forming structure towards the patient's face with a sealing force vector.

[0050] In some cases patients may find that the seal created by the seal forming structure is disturbed while they sleep, inducing a leak. Such leaks may disturb the patient's sleep, and may also reduce the effectiveness of the therapy.

[0051] Often, these disturbances are caused by the patient changing position as they sleep, thereby inducing tube drag and/or other forces on the patient interface, for example from contact between the interface and the patient's pillow.

[0052] Many users will attempt to reduce such leaks by increasing the tension on the positioning and stabilising structure. This is often ineffective at reducing leaks, but may result in significant discomfort and/or skin damage to the patient.

1.2.3.1.3 Pressurised Air Conduit

[0053] In one type of treatment system, a flow of pressurised air is provided to a patient interface through a conduit in an air circuit that fluidly connects to the patient interface at a location that is in front of the patient's face when the patient interface is

positioned on the patient's face during use. The conduit may extend from the patient interface forwards away from the patient's face.

1.2.3.1.4 Pressurised Air Conduit used for Positioning / Stabilising the Seal-Forming Structure

[0054] Another type of treatment system comprises a patient interface in which a tube that delivers pressurised air to the patient's airways also functions as part of the headgear to position and stabilise the seal-forming portion of the patient interface at the appropriate part of the patient's face. This type of patient interface may be referred to as having "conduit headgear" or "headgear tubing". Such patient interfaces allow the conduit in the air circuit providing the flow of pressurised air from a respiratory pressure therapy device to connect to the patient interface in a position other than in front of the patient's face. One example of such a treatment system is disclosed in US Patent Publication No. US 2007/0246043, the contents of which are incorporated herein by reference, in which the conduit connects to a tube in the patient interface through a port positioned in use on top of the patient's head.

1.2.3.2 Respiratory Pressure Therapy (RPT) Device

[0055] A respiratory pressure therapy (RPT) device may be used individually or as part of a system to deliver one or more of a number of therapies described above, such as by operating the device to generate a flow of air for delivery to an interface to the airways. The flow of air may be pressure-controlled (for respiratory pressure therapies) or flow-controlled (for flow therapies such as HFT). Thus RPT devices may also act as flow therapy devices. Examples of RPT devices include a CPAP device and a ventilator.

1.2.3.3 Air circuit

[0056] An air circuit is a conduit or a tube constructed and arranged to allow, in use, a flow of air to travel between two components of a respiratory therapy system such as the RPT device and the patient interface. In some cases, there may be separate limbs of the air circuit for inhalation and exhalation. In other cases, a single limb air circuit is used for both inhalation and exhalation.

1.2.3.4 Humidifier

[0057] Delivery of a flow of air without humidification may cause drying of airways. The use of a humidifier with an RPT device and the patient interface produces humidified gas that minimizes drying of the nasal mucosa and increases patient airway comfort. In addition, in cooler climates, warm air applied generally to the face area in and about the patient interface is more comfortable than cold air.

1.2.3.5 Vent technologies

[0058] Some forms of treatment systems may include a vent to allow the washout of exhaled carbon dioxide. The vent may allow a flow of gas from an interior space of a patient interface, e.g., the plenum chamber, to an exterior of the patient interface, e.g., to ambient.

[0059] The vent may comprise an orifice and gas may flow through the orifice in use of the mask. Many such vents are noisy. Others may become blocked in use and thus provide insufficient washout. Some vents may be disruptive of the sleep of a bed partner 1100 of the patient 1000, e.g. through noise or focussed airflow.

[0060] ResMed Limited has developed a number of improved mask vent technologies. See International Patent Application Publication No. WO 1998/034,665; International Patent Application Publication No. WO 2000/078,381; US Patent No. 6,581,594; US Patent Application Publication No. US 2009/0050156; US Patent Application Publication No. 2009/0044808.

2 BRIEF SUMMARY OF THE TECHNOLOGY

[0061] The present technology is directed towards providing medical devices used in the screening, diagnosis, monitoring, amelioration, treatment, or prevention of respiratory disorders having one or more of improved comfort, cost, efficacy, ease of use and manufacturability.

[0062] A first aspect of the present technology relates to apparatus used in the screening, diagnosis, monitoring, amelioration, treatment or prevention of a respiratory disorder.

[0063] Another aspect of the present technology relates to methods used in the screening, diagnosis, monitoring, amelioration, treatment or prevention of a respiratory disorder.

[0064] An aspect of certain forms of the present technology is to provide methods and/or apparatus that improve the compliance of patients with respiratory therapy.

[0065] One form of the present technology comprises a patient interface comprising:

a plenum chamber pressurisable to a therapeutic pressure of at least 6 cmH2O above ambient air pressure, said plenum chamber including a plenum chamber inlet port sized and structured to receive a flow of air at the therapeutic pressure for breathing by a patient,

a seal-forming structure constructed and arranged to form a seal with a region of the patient's face surrounding an entrance to the patient's airways, said seal-forming structure having a hole therein such that the flow of air at said therapeutic pressure is delivered to at least an entrance to the patient's nares, the seal-forming structure constructed and arranged to maintain said therapeutic pressure in the plenum chamber throughout the patient's respiratory cycle in use; and

a positioning and stabilising structure to provide a force to hold the seal-forming structure in a therapeutically effective position on the patient's head, the positioning and stabilising structure comprising a tie, the tie being constructed and arranged so that at least a portion overlies a region of the patient's head superior to an otobasion superior of the patient's head in use, wherein a portion of the positioning and stabilising structure extends around a back of the patient's head, in use;

wherein a flexible portion of the positioning and stabilising structure comprises at least one patient contacting portion which is configured to contact the patient's cheek, in use, wherein the coefficient of friction between the patient contacting portion and the patient's skin is higher than the coefficient of friction between an adjacent portion of the positioning and stabilising structure and the patient's skin.

[0066] In examples:

a) the patient contacting portion has a higher coefficient of friction than any other portion of the positioning and stabilising structure which is in contact with the patient's skin;

b) a portion of the positioning and stabilising structure, between the patient contacting portion and the back of the patient's head, is held in tension, in use;

c) the positioning and stabilising structure is configured such that the patient contacting portion does not transfer sealing forces to the patient's face;

d) the patient contacting portion is integrally formed with the flexible portion of the positioning and stabilising structure;

e) the patient contacting portion comprises a layer of material attached to the flexible portion of the positioning and stabilising structure, wherein the coefficient of friction between the layer of material and the patient's skin is higher than the coefficient of friction between the patient's skin and an adjacent portion of the positioning and stabilising structure;

f) the layer of material comprises silicone, a gel, polyurethane and/or a coating of medical adhesive;

g) an intermediate layer is provided between the flexible portion of the positioning and stabilising structure, and the layer of material;

h) the intermediate layer is resilient;

i) the intermediate layer comprises foam;

j) the patient contacting portion comprises a surface texture or pattern configured to increase the coefficient of friction of the patient contacting portion;

k) the flexible portion of the positioning and stabilising structure extends between the patient's eye and ear, in use;

l) the flexible portion of the positioning and stabilising structure comprises a strap; and/or

m) the flexible portion of the positioning and stabilising structure comprises a tube.

[0067] Another form of the present technology comprises a patient interface comprising:

a plenum chamber pressurisable to a therapeutic pressure of at least 6 cmH2O above ambient air pressure, said plenum chamber including a plenum chamber inlet port sized and structured to receive a flow of air at the therapeutic pressure for breathing by a patient,

a seal-forming structure constructed and arranged to form a seal with a region of the patient's face surrounding an entrance to the patient's airways, said seal-forming structure having a hole therein such that the flow of air at said therapeutic pressure is delivered to at least an entrance to the patient's nares, the seal-forming structure constructed and arranged to maintain said therapeutic pressure in the plenum chamber throughout the patient's respiratory cycle in use; and

a positioning and stabilising structure to provide a force to hold the seal-forming structure in a therapeutically effective position on the patient's head, the positioning and stabilising structure comprising a tie, the tie being constructed and arranged so that at least a portion overlies a region of the patient's head superior to an otobasion superior of the patient's head in use, wherein a portion of the positioning and stabilising structure extends around a back of the patient's head, in use;

wherein the positioning and stabilising structure comprises at least two side straps, each of the side straps extending along a respective one of the patient's cheeks in use, between the patient's eye and ear, each strap provided with at least one patient contacting portion which is configured to contact the patient's cheek, in use, wherein the coefficient of friction between the patient contacting portion and the patient's skin is higher coefficient than the coefficient of friction between the patient's skin and an adjacent portion of the strap.

[0068] In examples:

a) the patient contacting portion is formed integrally with the strap; and/or

b) the patient contacting portion comprises a layer of material attached to the strap, wherein the layer of material has higher coefficient of friction than an adjacent portion of the strap.

[0069] Another form of the present technology comprises a patient interface comprising:

a plenum chamber pressurisable to a therapeutic pressure of at least 6 cmH2O above ambient air pressure, said plenum chamber including a plenum chamber inlet port sized and structured to receive a flow of air at the therapeutic pressure for breathing by a patient,

a seal-forming structure constructed and arranged to form a seal with a region of the patient's face surrounding an entrance to the patient's airways, said seal-forming structure having a hole therein such that the flow of air at said therapeutic pressure is delivered to at least an entrance to the patient's nares, the seal-forming structure constructed and arranged to maintain said therapeutic pressure in the plenum chamber throughout the patient's respiratory cycle in use; and

a positioning and stabilising structure to provide a force to hold the seal-forming structure in a therapeutically effective position on the patient's head, the positioning and stabilising structure comprising at least one gas delivery tube to deliver the flow of air to the entrance of a patient's airways via the seal-forming structure, the at least one gas delivery tube arranged to contact, in use, a region of the patient's head superior to an otobasion superior of the patient's head, wherein a portion of the positioning and stabilising structure extends around a back of the patient's head, in use;

wherein the gas delivery tube is provided with at least one patient contacting portion which is configured to contact the patient's cheek, in use, wherein the coefficient of friction between the patient contacting portion and the patient's skin is higher than the coefficient of friction between an adjacent portion of the gas delivery tube and the patient's skin.

[0070] In examples:

a) the patient contacting portion is formed integrally with the gas delivery tube; and/or

b) the patient contacting portion comprises a layer of material attached to the gas delivery tube, wherein the layer of material has higher coefficient of friction than an adjacent portion of the gas delivery tube.

[0071] Another form of the present technology comprises a patient interface comprising:

a plenum chamber pressurisable to a therapeutic pressure of at least 6 cmH2O above ambient air pressure, said plenum chamber including a plenum chamber inlet port sized and structured to receive a flow of air at the therapeutic pressure for breathing by a patient,

a seal-forming structure constructed and arranged to form a seal with a region of the patient's face surrounding an entrance to the patient's airways, said seal-forming structure having a hole therein such that the flow of air at said therapeutic pressure is delivered to at least an entrance to the patient's nares, the seal-forming structure constructed and arranged to maintain said therapeutic pressure in the plenum chamber throughout the patient's respiratory cycle in use; and

a positioning and stabilising structure to provide a force to hold the seal-forming structure in a therapeutically effective position on the patient's head, the positioning and stabilising structure comprising a tie, the tie being constructed and arranged so that at least a portion overlies a region of the patient's head superior to an otobasion superior of the patient's head in use, wherein a portion of the positioning and stabilising structure extends around a back of the patient's head, in use;

wherein the positioning and stabilising structure comprises at least one patient contacting portion which is configured to contact the patient's cheek, in use, wherein the coefficient of friction between the patient contacting portion and the patient's skin is higher coefficient than the coefficient of friction between an adjacent portion of the positioning and stabilising structure and the patient's skin, and

wherein the positioning and stabilising structure is configured such that the patient contacting portion does not transfer sealing forces to the patient's face.

[0072] Another form of the present technology comprises a positioning and stabilising structure configured to provide a force, in use, to hold a seal-forming structure of a patient interface in a therapeutically effective position on the patient's head, to provide a therapeutic pressure of at least 6 cmH2O to the patient's airways,

the positioning and stabilising structure comprising a tie, the tie being constructed and arranged so that at least a portion overlies a region of the patient's head superior to an otobasion superior of the patient's head in use, wherein a portion of the positioning and stabilising structure extends around a back of the patient's head, in use;

wherein a flexible portion of the positioning and stabilising structure comprises at least one patient contacting portion which is configured to contact the patient's cheek, in use, wherein the coefficient of friction between the patient contacting portion and the patient's skin is higher than the coefficient of friction between an adjacent portion of the positioning and stabilising structure and the patient's skin.

[0073] Another aspect of one form of the present technology is a patient interface that is moulded or otherwise constructed with a perimeter shape which is complementary to that of an intended wearer.

[0074] An aspect of one form of the present technology is a method of manufacturing apparatus.

[0075] An aspect of certain forms of the present technology is a medical device that is easy to use, e.g. by a person who does not have medical training, by a person who has limited dexterity, vision or by a person with limited experience in using this type of medical device.

[0076] An aspect of one form of the present technology is a portable RPT device that may be carried by a person, e.g., around the home of the person.

[0077] An aspect of one form of the present technology is a patient interface that may be washed in a home of a patient, e.g., in soapy water, without requiring specialised cleaning equipment. An aspect of one form of the present technology is a humidifier tank that may be washed in a home of a patient, e.g., in soapy water, without requiring specialised cleaning equipment.

[0078] The methods, systems, devices and apparatus described may be implemented so as to improve the functionality of a processor, such as a processor of a specific purpose computer, respiratory monitor and/or a respiratory therapy apparatus. Moreover, the described methods, systems, devices and apparatus can provide improvements in the technological field of automated management, monitoring and/or treatment of respiratory conditions, including, for example, sleep disordered breathing.

[0079] Of course, portions of the aspects may form sub-aspects of the present technology. Also, various ones of the sub-aspects and/or aspects may be combined in various manners and also constitute additional aspects or sub-aspects of the present technology.

[0080] Other features of the technology will be apparent from consideration of the information contained in the following detailed description, abstract, drawings and claims.

3 BRIEF DESCRIPTION OF THE DRAWINGS

[0081] The present technology is illustrated by way of example, and not by way of limitation, in the figures of the accompanying drawings, in which like reference numerals refer to similar elements including:

3.1 RESPIRATORY THERAPY SYSTEMS

[0082] Fig. 1A shows a system including a patient 1000 wearing a patient interface 3000, in the form of nasal pillows, receiving a supply of air at positive pressure from an RPT device 4000. Air from the RPT device 4000 is humidified in a humidifier 5000, and passes along an air circuit 4170 to the patient 1000. A bed partner 1100 is also shown. The patient is sleeping in a supine sleeping position.

[0083] Fig. 1B shows a system including a patient 1000 wearing a patient interface 3000, in the form of a nasal mask, receiving a supply of air at positive pressure from an RPT device 4000. Air from the RPT device is humidified in a humidifier 5000, and passes along an air circuit 4170 to the patient 1000.

[0084] Fig. 1C shows a system including a patient 1000 wearing a patient interface 3000, in the form of a full-face mask, receiving a supply of air at positive pressure from an RPT device 4000. Air from the RPT device is humidified in a humidifier 5000, and passes along an air circuit 4170 to the patient 1000. The patient is sleeping in a side sleeping position.

3.2 RESPIRATORY SYSTEM AND FACIAL ANATOMY

[0085] Fig. 2A shows an overview of a human respiratory system including the nasal and oral cavities, the larynx, vocal folds, oesophagus, trachea, bronchus, lung, alveolar sacs, heart and diaphragm.

[0086] Fig. 2B shows a view of a human upper airway including the nasal cavity, nasal bone, lateral nasal cartilage, greater alar cartilage, nostril, lip superior, lip inferior, larynx, hard palate, soft palate, oropharynx, tongue, epiglottis, vocal folds, oesophagus and trachea.

[0087] Fig. 2C is a front view of a face with several features of surface anatomy identified including the lip superior, upper vermilion, lower vermilion, lip inferior, mouth width, endocanthion, a nasal ala, nasolabial sulcus and cheilion. Also indicated are the directions superior, inferior, radially inward and radially outward.

[0088] Fig. 2D is a side view of a head with several features of surface anatomy identified including glabella, sellion, pronasale, subnasale, lip superior, lip inferior, supramenton, nasal ridge, alar crest point, otobasion superior and otobasion inferior. Also indicated are the directions superior & inferior, and anterior & posterior.

[0089] Fig. 2E is a further side view of a head. The approximate locations of the Frankfort horizontal and nasolabial angle are indicated. The coronal plane is also indicated.

[0090] Fig. 2F shows a base view of a nose with several features identified including naso-labial sulcus, lip inferior, upper Vermilion, naris, subnasale, columella, pronasale, the major axis of a naris and the midsagittal plane.

[0091] Fig. 2G shows a side view of the superficial features of a nose.

[0092] Fig. 2H shows subcutaneal structures of the nose, including lateral cartilage, septum cartilage, greater alar cartilage, lesser alar cartilage, sesamoid cartilage, nasal bone, epidermis, adipose tissue, frontal process of the maxilla and fibrofatty tissue.

[0093] Fig. 2I shows a medial dissection of a nose, approximately several millimeters from the midsagittal plane, amongst other things showing the septum cartilage and medial crus of greater alar cartilage.

[0094] Fig. 2J shows a front view of the bones of a skull including the frontal, nasal and zygomatic bones. Nasal concha are indicated, as are the maxilla, and mandible.

[0095] Fig. 2K shows a lateral view of a skull with the outline of the surface of a head, as well as several muscles. The following bones are shown: frontal, sphenoid, nasal, zygomatic, maxilla, mandible, parietal, temporal and occipital. The mental protuberance is indicated. The following muscles are shown: digastricus, masseter, sternocleidomastoid and trapezius.

[0096] Fig. 2L shows an anterolateral view of a nose.

3.3 PATIENT INTERFACE

[0097] Fig. 3A shows a patient interface in the form of a nasal mask in accordance with one form of the present technology.

[0098] Fig. 3B shows a schematic of a cross-section through a structure at a point. An outward normal at the point is indicated. The curvature at the point has a positive sign, and a relatively large magnitude when compared to the magnitude of the curvature shown in Fig. 3C.

[0099] Fig. 3C shows a schematic of a cross-section through a structure at a point. An outward normal at the point is indicated. The curvature at the point has a positive sign, and a relatively small magnitude when compared to the magnitude of the curvature shown in Fig. 3B.

[0100] Fig. 3D shows a schematic of a cross-section through a structure at a point. An outward normal at the point is indicated. The curvature at the point has a value of zero.

[0101] Fig. 3E shows a schematic of a cross-section through a structure at a point. An outward normal at the point is indicated. The curvature at the point has a negative sign, and a relatively small magnitude when compared to the magnitude of the curvature shown in Fig. 3F.

[0102] Fig. 3F shows a schematic of a cross-section through a structure at a point. An outward normal at the point is indicated. The curvature at the point has a negative sign, and a relatively large magnitude when compared to the magnitude of the curvature shown in Fig. 3E.

[0103] Fig. 3G shows a cushion for a mask that includes two pillows. An exterior surface of the cushion is indicated. An edge of the surface is indicated. Dome and saddle regions are indicated.

[0104] Fig. 3H shows a cushion for a mask. An exterior surface of the cushion is indicated. An edge of the surface is indicated. A path on the surface between points A and B is indicated. A straight line distance between A and B is indicated. Two saddle regions and a dome region are indicated.

[0105] Fig. 3I shows the surface of a structure, with a one dimensional hole in the surface. The illustrated plane curve forms the boundary of a one dimensional hole.

[0106] Fig. 3J shows a cross-section through the structure of Fig.3I. The illustrated surface bounds a two dimensional hole in the structure of Fig. 3I.

[0107] Fig. 3K shows a perspective view of the structure of Fig. 3I, including the two dimensional hole and the one dimensional hole. Also shown is the surface that bounds a two dimensional hole in the structure of Fig. 3I.

[0108] Fig. 3L shows a mask having an inflatable bladder as a cushion.

[0109] Fig. 3M shows a cross-section through the mask of Fig. 3L, and shows the interior surface of the bladder. The interior surface bounds the two dimensional hole in the mask.

[0110] Fig. 3N shows a further cross-section through the mask of Fig. 3L. The interior surface is also indicated.

[0111] Fig. 3O illustrates a left-hand rule.

[0112] Fig. 3P illustrates a right-hand rule.

[0113] Fig. 3Q shows a left ear, including the left ear helix.

[0114] Fig. 3R shows a right ear, including the right ear helix.

[0115] Fig. 3S shows a right-hand helix.

[0116] Fig. 3T shows a view of a mask, including the sign of the torsion of the space curve defined by the edge of the sealing membrane in different regions of the mask.

[0117] Fig. 3U shows a view of a plenum chamber 3200 showing a sagittal plane and a mid-contact plane.

[0118] Fig. 3V shows a view of a posterior of the plenum chamber of Fig. 3U. The direction of the view is normal to the mid-contact plane. The sagittal plane in Fig. 3V bisects the plenum chamber into left-hand and right-hand sides.

[0119] Fig. 3W shows a cross-section through the plenum chamber of Fig. 3V, the cross-section being taken at the sagittal plane shown in Fig. 3V. A 'mid-contact' plane is shown. The mid-contact plane is perpendicular to the sagittal plane. The orientation of the mid-contact plane corresponds to the orientation of a chord 3210 which lies on the sagittal plane and just touches the cushion of the plenum chamber at two points on the sagittal plane: a superior point 3220 and an inferior point 3230. Depending on the geometry of the cushion in this region, the mid-contact plane may be a tangent at both the superior and inferior points.

[0120] Fig. 3X shows the plenum chamber 3200 of Fig. 3U in position for use on a face. The sagittal plane of the plenum chamber 3200 generally coincides with the midsagittal plane of the face when the plenum chamber is in position for use. The mid-contact plane corresponds generally to the 'plane of the face' when the plenum chamber is in position for use. In Fig. 3X the plenum chamber 3200 is that of a nasal mask, and the superior point 3220 sits approximately on the sellion, while the inferior point 3230 sits on the lip superior.

[0121] Fig. 3Y shows a patient interface in the form of a nasal cannula in accordance with one form of the present technology.

[0122] Fig. 3Z shows a patient interface in the form of a mask having conduit headgear in accordance with one form of the present technology.

3.4 POSITIONING AND STABILISING STRUCTURES OF THE PRESENT TECHNOLOGY

[0123] Fig. 4 is a diagrammatic drawing showing forces exerted on a patient by a headgear of a patient interface according to one form of the technology.

[0124] Fig. 5 shows a patient interface comprising a positioning and stabilising structure according to one form of the technology.

[0125] Figs. 6A to 6E show layers of material with various surface textures.

[0126] Fig. 7 shows a diagrammatic cross-section view of a patient contacting portion of a positioning and stabilising structure according to one form of the technology.

[0127] Fig. 8 shows part of a positioning and stabilising structure according to another form of the technology.

[0128] Fig. 9 shows a perspective view of a patient contacting portion provided to a sleeve.

4 DETAILED DESCRIPTION OF EXAMPLES OF THE TECHNOLOGY

[0129] Before the present technology is described in further detail, it is to be understood that the technology is not limited to the particular examples described herein, which may vary. It is also to be understood that the terminology used in this disclosure is for the purpose of describing only the particular examples discussed herein, and is not intended to be limiting.

[0130] The following description is provided in relation to various examples which may share one or more common characteristics and/or features. It is to be understood that one or more features of any one example may be combinable with one or more features of another example or other examples. In addition, any single feature or combination of features in any of the examples may constitute a further example.

4.1 THERAPY

[0131] In one form, the present technology comprises a method for treating a respiratory disorder comprising applying positive pressure to the entrance of the airways of a patient 1000.

[0132] In certain examples of the present technology, a supply of air at positive pressure is provided to the nasal passages of the patient via one or both nares.

[0133] In certain examples of the present technology, mouth breathing is limited, restricted or prevented.

4.2 RESPIRATORY THERAPY SYSTEMS

[0134] In one form, the present technology comprises a respiratory therapy system for treating a respiratory disorder. The respiratory therapy system may comprise an RPT device 4000 for supplying a flow of air to the patient 1000 via an air circuit 4170 and a patient interface 3000 or 3800.

4.3 PATIENT INTERFACE

[0135] A non-invasive patient interface 3000, such as that shown in Fig. 3A, in accordance with one aspect of the present technology comprises the following

functional aspects: a seal-forming structure 3100, a plenum chamber 3200, a positioning and stabilising structure 3300, a vent 3400, one form of connection port 3600 for connection to air circuit 4170, and a forehead support 3700. In some forms a functional aspect may be provided by one or more physical components. In some forms, one physical component may provide one or more functional aspects. In use the seal-forming structure 3100 is arranged to surround an entrance to the airways of the patient so as to maintain positive pressure at the entrance(s) to the airways of the patient 1000. The sealed patient interface 3000 is therefore suitable for delivery of positive pressure therapy.

[0136] As shown in Fig. 3Z, a non-invasive patient interface 3000 in accordance with another aspect of the present technology comprises the following functional aspects: a seal-forming structure 3000, a plenum chamber 3200, a positioning and stabilising structure 3300, a vent 3400 and one form of connection port 3600 for connection to an air circuit (such as the air circuit 4170 shown in Figs. 1A-1C). The plenum chamber 3200 may be formed of one or more modular components in the sense that it or they can be replaced with different components, for example components of a different size.

[0137] An unsealed patient interface 3800, in the form of a nasal cannula, includes nasal prongs 3810a, 3810b which can deliver air to respective nares of the patient 1000 via respective orifices in their tips. Such nasal prongs do not generally form a seal with the inner or outer skin surface of the nares. This type of interface results in one or more gaps that are present in use by design (intentional) but they are typically not fixed in size such that they may vary unpredictably by movement during use. This can present a complex pneumatic variable for a respiratory therapy system when pneumatic control and/or assessment is implemented, unlike other types of mask-based respiratory therapy systems. The air to the nasal prongs may be delivered by one or more air supply lumens 3820a, 3820b that are coupled with the nasal cannula-type unsealed patient interface 3800. The lumens 3820a, 3820b lead from the nasal cannula-type unsealed patient interface 3800 to a respiratory therapy device via an air circuit. The unsealed patient interface 3800 is particularly suitable for delivery of flow therapies, in which the RPT device generates the flow of air at controlled flow rates rather than controlled pressures. The “vent” or gap at the unsealed patient

interface 3800, through which excess airflow escapes to ambient, is the passage between the end of the prongs 3810a and 3810b of the nasal cannula-type unsealed patient interface 3800 via the patient's nares to atmosphere.

[0138] If a patient interface is unable to comfortably deliver a minimum level of positive pressure to the airways, the patient interface may be unsuitable for respiratory pressure therapy.

[0139] The patient interface 3000 in accordance with one form of the present technology is constructed and arranged to be able to provide a supply of air at a positive pressure of at least 4 cmH2O with respect to ambient, e.g. at least 6 cmH2O.

[0140] The patient interface 3000 in accordance with one form of the present technology is constructed and arranged to be able to provide a supply of air at a positive pressure of at least 10 cmH2O with respect to ambient.

[0141] The patient interface 3000 in accordance with one form of the present technology is constructed and arranged to be able to provide a supply of air at a positive pressure of at least 20 cmH2O with respect to ambient, e.g. up to 30 cmH2O.

4.3.1 Seal-forming structure

[0142] In one form of the present technology, a seal-forming structure 3100 provides a target seal-forming region, and may additionally provide a cushioning function. The target seal-forming region is a region on the seal-forming structure 3100 where sealing may occur. The region where sealing actually occurs- the actual sealing surface- may change within a given treatment session, from day to day, and from patient to patient, depending on a range of factors including for example, where the patient interface was placed on the face, tension in the positioning and stabilising structure and the shape of a patient's face.

[0143] In one form the target seal-forming region is located on an outside surface of the seal-forming structure 3100.

[0144] In certain forms of the present technology, the seal-forming structure 3100 is constructed from a biocompatible material, e.g. silicone rubber.

[0145] A seal-forming structure 3100 in accordance with the present technology may be constructed from a soft, flexible, resilient material such as silicone.

[0146] In certain forms of the present technology, a system is provided comprising more than one a seal-forming structure 3100, each being configured to correspond to a different size and/or shape range. For example the system may comprise one form of a seal-forming structure 3100 suitable for a large sized head, but not a small sized head and another suitable for a small sized head, but not a large sized head.

4.3.1.1 Sealing mechanisms

[0147] In one form, the seal-forming structure includes a sealing flange utilizing a pressure assisted sealing mechanism. In use, the sealing flange can readily respond to a system positive pressure in the interior of the plenum chamber 3200 acting on its underside to urge it into tight sealing engagement with the face. The pressure assisted mechanism may act in conjunction with elastic tension in the positioning and stabilising structure.

[0148] In one form, the seal-forming structure 3100 comprises a sealing flange and a support flange. The sealing flange comprises a relatively thin member with a thickness of less than about 1mm, for example about 0.25mm to about 0.45mm, which extends around the perimeter of the plenum chamber 3200. Support flange may be relatively thicker than the sealing flange. The support flange is disposed between the sealing flange and the marginal edge of the plenum chamber 3200, and extends at least part of the way around the perimeter. The support flange is or includes a spring-like element and functions to support the sealing flange from buckling in use.

[0149] In one form, the seal-forming structure may comprise a compression sealing portion or a gasket sealing portion. In use the compression sealing portion, or the gasket sealing portion is constructed and arranged to be in compression, e.g. as a result of elastic tension in the positioning and stabilising structure.

[0150] In one form, the seal-forming structure comprises a tension portion. In use, the tension portion is held in tension, e.g. by adjacent regions of the sealing flange.

[0151] In one form, the seal-forming structure comprises a region having a tacky or adhesive surface.

[0152] In certain forms of the present technology, a seal-forming structure may comprise one or more of a pressure-assisted sealing flange, a compression sealing portion, a gasket sealing portion, a tension portion, and a portion having a tacky or adhesive surface.

4.3.1.2 Nose bridge or nose ridge region

[0153] In one form, the non-invasive patient interface 3000 comprises a seal-forming structure that forms a seal in use on a nose bridge region or on a nose-ridge region of the patient's face.

[0154] In one form, the seal-forming structure includes a saddle-shaped region constructed to form a seal in use on a nose bridge region or on a nose-ridge region of the patient's face.

4.3.1.3 Upper lip region

[0155] In one form, the non-invasive patient interface 3000 comprises a seal-forming structure that forms a seal in use on an upper lip region (that is, the lip superior) of the patient's face.

[0156] In one form, the seal-forming structure includes a saddle-shaped region constructed to form a seal in use on an upper lip region of the patient's face.

4.3.1.4 Chin-region

[0157] In one form the non-invasive patient interface 3000 comprises a seal-forming structure that forms a seal in use on a chin-region of the patient's face.

[0158] In one form, the seal-forming structure includes a saddle-shaped region constructed to form a seal in use on a chin-region of the patient's face.

4.3.1.5 Forehead region

[0159] In one form, the seal-forming structure that forms a seal in use on a forehead region of the patient's face. In such a form, the plenum chamber may cover the eyes in use.

4.3.1.6 Nose-only Masks

[0160] In one form, the patient interface 3000 comprises a seal-forming structure 3100 configured to seal around an entrance to the patient's nasal airways but not around the patient's mouth. The seal-forming structure 3100 may be configured to seal to the patient's lip superior. The patient interface 3000 may leave the patient's mouth uncovered. This patient interface 3000 may deliver a supply of air or breathable gas to both nares of patient 1000 and not to the mouth. This type of patient interface may be identified as a nose-only mask.

[0161] One form of nose-only mask according to the present technology is what has traditionally been identified as a "nasal mask", having a seal-forming structure 3100 configured to seal on the patient's face around the nose and over the bridge of the nose. A nasal mask may be generally triangular in shape. In one form, the non-invasive patient interface 3000 comprises a seal-forming structure 3100 that forms a seal in use to an upper lip region (e.g. the lip superior), to the patient's nose bridge or at least a portion of the nose ridge above the pronasale, and to the patient's face on each lateral side of the patient's nose, for example proximate the patient's nasolabial sulci. The patient interface 3000 shown in Fig. 1B has this type of seal-forming structure 3100. This patient interface 3000 may deliver a supply of air or breathable gas to both nares of patient 1000 through a single orifice.

[0162] Another form of nose-only mask may seal around an inferior periphery of the patient's nose without engaging the user's nasal ridge. This type of patient interface 3000 may be identified as a "nasal cradle" mask and the seal-forming structure 3100 may be identified as a "nasal cradle cushion", for example. In one form, for example as shown in Fig. 3Z, the seal-forming structure 3100 is configured to form a seal in use with inferior surfaces of the nose around the nares. The seal-forming structure 3100 may be configured to seal around the patient's nares at an inferior periphery of the patient's nose including to an inferior and/or anterior surface of a pronasale region of the patient's nose and to the patient's nasal alae. The seal-forming structure 3100 may seal to the patient's lip superior. The shape of the seal-forming structure 3100 may be configured to match or closely follow the underside of the patient's nose and may not contact a nasal bridge region of the patient's nose or any portion of the patient's nose superior to the pronasale. In one form of nasal cradle

cushion, the seal-forming structure 3100 comprises a bridge portion dividing the opening into two orifices, each of which, in use, supplies air or breathable gas to a respective one of the patient's nares. The bridge portion may be configured to contact or seal against the patient's columella in use. Alternatively, the seal-forming structure 3100 may comprise a single opening to provide a flow or air or breathable gas to both of the patient's nares.

[0163] In some forms, a nose-only mask may comprise nasal pillows, described above.

4.3.1.7 Nose and Mouth Masks

[0164] In one form, the patient interface 3000 comprises a seal-forming structure 3100 configured to seal around an entrance to the patient's nasal airways and also around the patient's mouth. The seal-forming structure 3100 may be configured to seal to the patient's face proximate a chin region. This patient interface 3000 may deliver a supply of air or breathable gas to both nares and to the mouth of patient 1000. This type of patient interface may be identified as a nose and mouth mask.

[0165] One form of nose and mouth mask according to the present technology is what has traditionally been identified as a "full-face mask", having a seal-forming structure 3100 configured to seal on the patient's face around the nose, below the mouth and over the bridge of the nose. A full-face mask may be generally triangular in shape. In one form the patient interface 3000 comprises a seal-forming structure 3100 that forms a seal in use to a patient's chin-region (which may include the patient's lip inferior and/or a region directly inferior to the lip inferior), to the patient's nose bridge or at least a portion of the nose ridge superior to the pronasale, and to cheek regions of the patient's face. The patient interface 3000 shown in Fig. 1C is of this type. This patient interface 3000 may deliver a supply of air or breathable gas to both nares and mouth of patient 1000 through a single orifice. This type of seal-forming structure 3100 may be referred to as a "full face cushion".

[0166] In another form the patient interface 3000 comprises a seal-forming structure 3100 that forms a seal in use on a patient's chin region (which may include the patient's lip inferior and/or a region directly inferior to the lip inferior), to an inferior and/or an anterior surface of a pronasale portion of the patient's nose, to the

alae of the patient's nose and to the patient's face on each lateral side of the patient's nose, for example proximate the nasolabial sulci. The seal-forming structure 3100 may also form a seal against a patient's lip superior. A patient interface 3000 having this type of seal-forming structure may have a single opening configured to deliver a flow of air or breathable gas to both nares and mouth of a patient, may have an oral hole configured to provide air or breathable gas to the mouth and a nasal hole configured to provide air or breathable gas to the nares, or may have an oral hole for delivering air to the patient's mouth and two nasal holes for delivering air to respective nares. This type of patient interface 3000 may have a nasal portion and an oral portion, the nasal portion sealing to the patient's face at similar locations to a nasal cradle mask.

[0167] In a further form of nose and mouth mask, the patient interface 3000 may comprise a seal-forming structure 3100 having a nasal portion comprising nasal pillows and an oral portion configured to form a seal to the patient's face around the patient's mouth.

[0168] In some forms, the seal-forming structure 3100 may have a nasal portion that is separate and distinct from an oral portion. In other forms, a seal-forming structure 3100 may form a contiguous seal around the patient's nose and mouth.

[0169] It is to be understood that the above examples of different forms of patient interface 3000 do not constitute an exhaustive list of possible configurations. In some forms a patient interface 3000 may comprise a combination of different features of the above described examples of nose-only and nose and mouth masks.

4.3.2 Plenum chamber

[0170] The plenum chamber 3200 has a perimeter that is shaped to be complementary to the surface contour of the face of an average person in the region where a seal will form in use. In use, a marginal edge of the plenum chamber 3200 is positioned in close proximity to an adjacent surface of the face. Actual contact with the face is provided by the seal-forming structure 3100. The seal-forming structure 3100 may extend in use about the entire perimeter of the plenum chamber 3200. In some forms, the plenum chamber 3200 and the seal-forming structure 3100 are formed from a single homogeneous piece of material.

[0171] In certain forms of the present technology, the plenum chamber 3200 does not cover the eyes of the patient in use. In other words, the eyes are outside the pressurised volume defined by the plenum chamber. Such forms tend to be less obtrusive and / or more comfortable for the wearer, which can improve compliance with therapy.

[0172] In certain forms of the present technology, the plenum chamber 3200 is constructed from a transparent material, e.g. a transparent polycarbonate. The use of a transparent material can reduce the obtrusiveness of the patient interface, and help improve compliance with therapy. The use of a transparent material can aid a clinician to observe how the patient interface is located and functioning.

[0173] In certain forms of the present technology, the plenum chamber 3200 is constructed from a translucent material. The use of a translucent material can reduce the obtrusiveness of the patient interface, and help improve compliance with therapy.

4.3.3 Positioning and stabilising structure

[0174] The seal-forming structure 3100 of the patient interface 3000 of the present technology may be held in sealing position in use by the positioning and stabilising structure 3300. The positioning and stabilising structure 3300 may comprise and function as “headgear” since it engages the patient’s head in order to hold the patient interface 3000 in a sealing position.

[0175] In one form the positioning and stabilising structure 3300 provides a retention force at least sufficient to overcome the effect of the positive pressure in the plenum chamber 3200 to lift off the face.

[0176] In one form the positioning and stabilising structure 3300 provides a retention force to overcome the effect of the gravitational force on the patient interface 3000.

[0177] Fig. 4 shows the main forces applied to the patient by one form of patient interface having one example of a positioning and stabilising structure 3300.

[0178] Vector F1 represents the force exerted on the mask (e.g. on the frame) around the patient’s airways by the positioning and stabilising structure 3300. This

force opposes the weight force of the patent interface and the lifting force created by the positive pressure within the plenum chamber.

[0179] The positioning and stabilising structure exerts opposing forces on the patient's head via the two back straps, as represented by vectors F2 and F3. Vector F1 is equal and opposite to the sum of vectors F2 and F3.

[0180] In one form of the present technology, a positioning and stabilising structure 3300 is provided that is configured in a manner consistent with being worn by a patient while sleeping. In one example the positioning and stabilising structure 3300 has a low profile, or cross-sectional thickness, to reduce the perceived or actual bulk of the apparatus. In one example, the positioning and stabilising structure 3300 comprises at least one strap having a rectangular cross-section. In one example the positioning and stabilising structure 3300 comprises at least one flat strap.

[0181] In one form of the present technology, a positioning and stabilising structure 3300 is provided that is configured so as not to be too large and bulky to prevent the patient from lying in a supine sleeping position with a back region of the patient's head on a pillow.

[0182] In one form of the present technology, a positioning and stabilising structure 3300 is provided that is configured so as not to be too large and bulky to prevent the patient from lying in a side sleeping position with a side region of the patient's head on a pillow.

[0183] In one form of the present technology, a positioning and stabilising structure 3300 is provided with a decoupling portion located between an anterior portion of the positioning and stabilising structure 3300, and a posterior portion of the positioning and stabilising structure 3300. The decoupling portion does not resist compression and may be, e.g. a flexible or floppy strap. The decoupling portion is constructed and arranged so that when the patient lies with their head on a pillow, the presence of the decoupling portion prevents a force on the posterior portion from being transmitted along the positioning and stabilising structure 3300 and disrupting the seal.

[0184] In one form of the present technology, a positioning and stabilising structure 3300 comprises a strap constructed from a laminate of a fabric patient-contacting layer, a foam inner layer and a fabric outer layer. In one form, the foam is porous to allow moisture, (e.g., sweat), to pass through the strap. In one form, the fabric outer layer comprises loop material to engage with a hook material portion.

[0185] In certain forms of the present technology, a positioning and stabilising structure 3300 comprises a strap that is extensible, e.g. resiliently extensible. For example the strap may be configured in use to be in tension, and to direct a force to draw a seal-forming structure into sealing contact with a portion of a patient's face. In an example the strap may be configured as a tie.

[0186] In one form of the present technology, the positioning and stabilising structure comprises a first tie, the first tie being constructed and arranged so that in use at least a portion of an inferior edge thereof passes superior to an otobasion superior of the patient's head and overlays a portion of a parietal bone without overlaying the occipital bone.

[0187] In one form of the present technology suitable for a nasal-only mask or for a full-face mask, the positioning and stabilising structure includes a second tie, the second tie being constructed and arranged so that in use at least a portion of a superior edge thereof passes inferior to an otobasion inferior of the patient's head and overlays or lies inferior to the occipital bone of the patient's head.

[0188] In one form of the present technology suitable for a nasal-only mask or for a full-face mask, the positioning and stabilising structure includes a third tie that is constructed and arranged to interconnect the first tie and the second tie to reduce a tendency of the first tie and the second tie to move apart from one another.

[0189] In certain forms of the present technology, a positioning and stabilising structure 3300 comprises a strap that is bendable and e.g. non-rigid. An advantage of this aspect is that the strap is more comfortable for a patient to lie upon while the patient is sleeping.

[0190] In certain forms of the present technology, a positioning and stabilising structure 3300 comprises a strap constructed to be breathable to allow moisture vapour to be transmitted through the strap.

[0191] In certain forms of the present technology, a system is provided comprising more than one positioning and stabilizing structure 3300, each being configured to provide a retaining force to correspond to a different size and/or shape range. For example the system may comprise one form of positioning and stabilizing structure 3300 suitable for a large sized head, but not a small sized head, and another. suitable for a small sized head, but not a large sized head.

4.3.3.1 Conduit headgear

4.3.3.1.1 Conduit headgear tubes

[0192] In some forms of the present technology, the positioning and stabilising structure 3300 comprises one or more headgear tubes 3350 that deliver pressurised air received from a conduit forming part of the air circuit 4170 from the RPT device to the patient's airways, for example through the plenum chamber 3200 and seal-forming structure 3100. In the form of the present technology illustrated in Fig. 3Z, the positioning and stabilising structure 3300 comprises two tubes 3350 that deliver air to the plenum chamber 3200 from the air circuit 4170. The tubes 3350 are configured to position and stabilise the seal-forming structure 3100 of the patient interface 3000 at the appropriate part of the patient's face (for example, the nose and/or mouth) in use. This allows the conduit of air circuit 4170 providing the flow of pressurised air to connect to a connection port 3600 of the patient interface in a position other than in front of the patient's face, for example on top of the patient's head.

[0193] In the form of the present technology illustrated in Fig. 3Z, the positioning and stabilising structure 3300 comprises two tubes 3350, each tube 3350 being positioned in use on a different side of the patient's head and extending across the respective cheek region, above the respective ear (superior to the otobasion superior on the patient's head) to the elbow 3610 on top of the head of the patient 1000. This form of technology may be advantageous because, if a patient sleeps with their head on its side and one of the tubes is compressed to block or partially block the flow of

gas along the tube, the other tube remains open to supply pressurised gas to the patient. In other examples of the technology, the patient interface 3000 may comprise a different number of tubes, for example one tube, or three or more tubes. In one example in which the patient interface has one tube 3350, the single tube 3350 is positioned on one side of the patient's head in use (e.g. across one cheek region) and a strap forms part of the positioning and stabilising structure 3300 and is positioned on the other side of the patient's head in use (e.g. across the other region) to assist in securing the patient interface 3000 on the patient's head.

[0194] In the form of the technology shown in Fig. 3Z the two tubes 3350 are fluidly connected at superior ends to each other and to the connection port 3600. In some examples, the two tubes 3350 are integrally formed while in other examples the tubes 3350 are formed separately but are connected in use and may be disconnected, for example for cleaning or storage. Where separate tubes are used they may be indirectly connected together, for example each may be connected to a T-shaped connector having two arms/branches each fluidly connectable to a respective one of the tubes 3350 and a third arm or opening in the T-shaped connector providing the connection port 3600 for fluid connection to the air circuit 4170 in use.

[0195] The tubes 3350 may be formed from a flexible material, such as an elastomer, e.g. silicone or TPE, and/or from one or more textile and/or foam materials. The tubes 3350 may have a preformed shape and may be able to be bent or moved into another shape upon application of a force but may return to the original preformed shape in the absence of said force. The tubes 3350 may be generally arcuate or curved in a shape approximating the contours of a patient's head between the top of the head and the nasal or oral region.

[0196] In some examples, the one or more tubes 3350 are crush resistant to resist being blocked if crushed during use, for example if squashed between a patient's head and pillow, especially if there is only one tube 3350. The tubes 3350 may be formed with a sufficient structural stiffness to resist crushing or may be as described in US Patent no. 6,044,844, the contents of which are incorporated herein by reference.

[0197] Each tube 3350 may be configured to receive a flow of air from the connection port 3600 on top of the patient's head and to deliver the flow of air to the

seal-forming structure 3100 at the entrance of the patient's airways. In the example shown in Fig. 3Z, each tube 3350 lies in use on a path extending from the plenum chamber 3200 across the patient's cheek region and superior to the patient's ear to the elbow 3610. For example, a portion of each tube 3350 proximate the plenum chamber 3200 may overlie a maxilla region of the patient's head in use. Another portion of each tube 3350 may overlie a region of the patient's head superior to an otobasion superior of the patient's head. Each of the tubes 3350 may also lie over the patient's sphenoid bone and/or temporal bone and either or both of the patient's frontal bone and parietal bone. The elbow 3610 may be located in use over the patient's parietal bone, over the frontal bone and/or over the junction therebetween (e.g. the coronal suture).

[0198] In certain forms of the present technology the patient interface 3000 is configured such that the connection port 3600 can be positioned in a range of positions across the top of the patient's head so that the patient interface 3000 can be positioned as appropriate for the comfort or fit of an individual patient. In some examples, the headgear tubes 3350 are configured to allow movement of an upper portion of the patient interface 3000 (e.g. a connection port 3600) with respect to a lower portion of the patient interface 3000 (e.g. a plenum chamber 3200). That is, the connection port 3600 may be at least partially decoupled from the plenum chamber 3200. In this way, the seal-forming structure 3100 may form an effective seal with the patient's face irrespective of the position of the connection port 3600 (at least within a predetermined range of positions) on the patient's head.

[0199] As described above, in some examples of the present technology the patient interface 3000 comprises a seal-forming structure 3100 in the form of a cradle cushion which lies generally under the nose and seals to an inferior periphery of the nose (e.g. an under-the-nose cushion). The positioning and stabilising structure 3300, including the tubes 3350 may be structured and arranged to pull the seal-forming structure 3100 into the patient's face under the nose with a sealing force vector in a posterior and superior direction (e.g. a posterosuperior direction). A sealing force vector with a posterosuperior direction may cause the seal-forming structure 3100 to form a good seal to both the inferior periphery of the patient's nose and anterior-

facing surfaces of the patient's face, for example on either side of the patient's nose and the patient's lip superior.

4.3.3.1.2 Extendable and non-extendable tube portions

[0200] In some examples of the present technology, one or both of the tubes 3350 are not extendable in length. However, in some forms, the tubes 3350 may comprise one or more extendable tube sections, for example formed by an extendable concertina structure. In some forms, the patient interface 3000 may comprise a positioning and stabilising structure 3300 including at least one gas delivery tube comprising a tube wall having an extendable concertina structure. The patient interface 3000 shown in Fig. 3Z comprises tubes 3350, the superior portions of which comprise extendable tube sections each in the form of an extendable concertina structure 3362.

[0201] The cross-sectional shape of the non-extendable tube sections 3363 of the tubes 3350 may be circular, elliptical, oval, D-shaped or a rounded rectangle, for example as described in US Patent No. 6,044,844. A cross-sectional shape that presents a flattened surface of tube on the side that faces and contacts the patient's face or other part of the head may be more comfortable to wear than, for example a tube with a circular cross-section.

[0202] In some examples of the present technology, the non-extendable tube sections 3363 connect to the plenum chamber 3200 from a low angle. The headgear tubes 3350 may extend and inferiorly down the sides of the patient's head and then curve anteriorly and medially to connect to the plenum chamber 3200 in front of the patient's face. The tubes 3350, before connecting to the plenum chamber 3200, may extend to a location at the same vertical position as (or, in some examples, inferior to) the connection with the plenum chamber 3200. That is, the tubes 3350 may project in an at least partially superior direction before connecting with the plenum chamber 3200. A portion of the tubes 3350 may be located inferior to the cushion module 3150 and/or the seal forming structure 3100. The tubes 3350 may contact the patient's face below the patient's cheekbones, which may be more comfortable than contact on the patient's cheekbones and may avoid excessively obscuring the patient's peripheral vision.

4.3.3.1.3 Conduit headgear connection port

[0203] In certain forms of the present technology, the patient interface 3000 may comprise a connection port 3600 located proximal to a superior, lateral or posterior portion of a patient's head. For example, in the form of the present technology illustrated in Fig 3Z, the connection port 3600 is located on top of the patient's head (e.g. at a superior location with respect to the patient's head). In this example the patient interface 3000 comprises an elbow 3610 forming the connection port 3600. The elbow 3610 may be configured to fluidly connect with a conduit of an air circuit 4170. The elbow 3610 may be configured to swivel with respect to the positioning and stabilising structure 3300 to at least partially decouple the conduit from the positioning and stabilising structure 3300. In some examples the elbow 3610 may be configured to swivel by rotation about a substantially vertical axis and, in some particular examples, by rotation about two or more axes. In some examples the elbow may comprise or be connected to the tubes 3350 by a ball-and-socket joint. The connection portion 3600 may be located in the sagittal plane of the patient's head in use.

[0204] Patient interfaces having a connection port that is not positioned anterior to the patient's face may be advantageous as some patients may find a conduit that connects to a patient interface anterior to their face to be unsightly and/or obtrusive. For example, a conduit connecting to a patient interface anterior to the patient's face may be prone to interference with bedclothes or bed linen, particularly if the conduit extends inferiorly from the patient interface in use. Forms of the present technology comprising a patient interface having a connection port positioned superiorly to the patient's head in use may make it easier or more comfortable for a patient to lie or sleep in one or more of the following positions: a side-sleeping position, a supine position (e.g. on their back, facing generally upwards) or in a prone position (e.g. on their front, facing generally downwards). Moreover, connecting a conduit to an anterior portion of a patient interface may exacerbate a problem known as tube drag in which the conduit exerts an undesired force upon the patient interface during movement of the patient's head or the conduit, thereby causing dislodgement away from the face. Tube drag may be less of a problem when force is received at a superior location of the patient's head than anterior to the patient's face proximate to

the seal-forming structure (where tube drag forces may be more likely to disrupt the seal).

4.3.3.1.4 Headgear Tube Fluid Connections

[0205] The two tubes 3350 are fluidly connected at their inferior ends to the plenum chamber 3200. In certain forms of the technology, the connection between the tubes 3350 and the plenum chamber 3200 is achieved by connection of two rigid connectors. The tubes 3350 and plenum chamber 3200 may be configured to enable the patient to easily connect the two components together in a reliable manner. The tubes 3350 and plenum chamber 3200 may be configured to provide tactile and/or audible feedback in the form of a 're-assuring click' or a similar sound, so that the patient may easily know that each tube 3350 has been correctly connected to the plenum chamber 3200. In one form, the tubes 3350 are formed from a silicone or textile material and the inferior end of each of the silicone tubes 3350 is overmolded to a rigid connector made, for example, from polypropylene, polycarbonate, nylon or the like. The rigid connector on each tube 3350 may comprise a female mating feature configured to connect with a male mating feature on the plenum chamber 3200. Alternatively, the rigid connector on each tube 3350 may comprise a male mating feature configured to connect to a female mating feature on the plenum chamber 3200. In other examples the tubes 3350 may each comprise a male or female connector formed from a flexible material, such as silicone or TPE, for example the same material from which the tubes 3350 are formed.

[0206] In other examples a compression seal is used to connect each tube 3350 to the plenum chamber 3200. For example, a resiliently flexible (e.g. silicone) tube 3350 without a rigid connector may be configured to be squeezed to reduce its diameter so that it can be compressed into a port in the plenum chamber 3200 and the inherent resilience of the silicone pushes the tube 3350 outwards to seal the tube 3350 in the port in an air-tight manner. Alternatively, in a hard-to-hard type engagement between the tube 3350 and the plenum chamber 3200, each tube 3350 and/or plenum chamber 3200 may comprise a pressure activated seal, for example a peripheral sealing flange. When pressurised gas is supplied through the tubes 3350 the sealing flange may be urged against the join between the tubes and a circumferential surface around a port or

connector of the plenum chamber 3200 to form or enhance a seal between the tube 3350 and plenum chamber 3200.

4.3.3.1.5 Conduit headgear straps

[0207] In certain forms of the present technology, the positioning and stabilising structure 3300 comprises at least one headgear strap acting in addition to the tubes 3350 to position and stabilise the seal-forming structure 3100 at the entrance to the patient's airways. As shown in Fig. 3Z, the patient interface 3000 comprises a strap 3310 forming part of the positioning and stabilising structure 3300. The strap 3310 may be known as a back strap or a rear headgear strap, for example. In other examples of the present technology, one or more further straps may be provided. For example, patient interfaces 3000 according to examples of the present technology having a full face cushion may have a second, lower, strap configured to lie against the patient's head proximate the patient's neck and/or against posterior surfaces of the patient's neck.

[0208] In the example shown in Fig. 3Z, strap 3310 of the positioning and stabilising structure 3300 is connected between the two tubes 3350 positioned on each side of the patient's head and passing around the back of the patient's head, for example overlying or lying inferior to the occipital bone of the patient's head in use. The strap 3310 connects to each tube above the patient's ears. With reference to Fig. 3Z, the positioning and stabilising structure 3300 comprises a pair of tabs 3320. In use a strap 3310 may be connected between the tabs 3320. The strap 3310 may be sufficiently flexible to pass around the back of the patient's head and lie comfortably against the patient's head, even when under tension in use.

4.3.4 Patient contacting portion

[0209] Referring next to Fig. 5, a patient interface 3000 according to one form of the technology is shown.

[0210] In the example shown in Fig. 5, the positioning and stabilising structure 3300 comprises a pair of flexible straps 3302 which form side straps 3304 and bifurcate to form upper and lower back straps 3306, 3310. Both back straps 3306, 3310 may extend around the back of the patient's head, in use, although the patient may choose to position the upper back strap 3306 over the top of their head. In the

example shown the pair of straps 3302 are formed integrally with each other, but in other examples separate straps 3302 may be joined with a suitable connector. In examples the straps 3302 may be elastic.

[0211] In examples the straps 3302 may be primarily made from Breathoprene™ or a similar material.

[0212] The straps 3302 are configured to hold to hold the seal forming structure 3100 in position on the patient's face. The positioning and stabilising structure 3300 provides a retention force (e.g. a sealing force) at least sufficient to overcome the effect of the positive pressure in the plenum chamber 3200 lifting away from the patient's face, and the weight of the patient interface. The straps 3302 pass these forces to the back (and optionally the top) of the patient's head, as described above with reference to Fig. 4.

[0213] In one form of the technology, a patient contacting portion 3312 of the straps 3302 may comprise a material which has a higher coefficient of friction (e.g. resistance to sliding across the user's skin) than an adjacent portion of the strap 3302a. The patient contacting portion 3312 may be located so as to be in contact with the patient when the patent interface 3000 is in use. In examples, the patient contacting portion 3312 is located such as to be in contact with the patient's cheek, in use. In examples the entire patient contacting portion 3312 may have the higher coefficient of friction, but in other examples only a portion of the patient contacting portion 3312 has the higher friction coefficient.

[0214] In examples of the technology the patent contacting portion 3312 has a higher coefficient of friction than every adjacent (e.g. abutting) portion of the strap 3302, e.g. a higher coefficient of friction than the portions of the strap 3302 which surround the patient contacting portion 3312.

[0215] In use, the patient contacting portion 3312 is configured to resist lateral movement of the straps across the surface of the patient's face caused by external forces acting on the patient interface 3000 (for example as a result of tube drag or interference with the patient's pillow).

[0216] However, it will be appreciated that in the absence of such external forces, there is substantially no force on the patient contacting portions 3312 in a direction parallel to the plane of the patient's face (e.g. shear force), since the normal patient interface forces (e.g. those related to the sealing force) are transferred through the straps 3302 to the back of the patient's head, as described above. In this way the sensation of the patient contacting portions "pulling" on the patient's skin is minimised or substantially eliminated.

[0217] The patient contacting portion 3312 may comprise any bio-compatible material which has a higher friction coefficient than the surrounding portion 3302a of the positioning and stabilising structure 3300. Suitable materials for the patent contacting portion 3312 may include silicone (for example under-cured silicone), gel or polyurethane. Surfaces coated with medical adhesive, such as that made by 3M ™ may be used in some examples.

[0218] In examples the patient contacting portion 3312 may be configured with a surface texture or pattern which is configured to increase the friction or engagement between the patient contacting portion and the patient's skin, for example dimples (Fig. 6A), zig-zag ribs (Fig. 6B), parallel ribs (Fig. 6C), sucker cups (Fig. 6D) and/or perforations (Fig. 6E). Such textures or patterns may be formed in a layer of material which is attached to a strap 3302, or may be integrally formed in a surface of an outer layer of the strap 3302. In examples, the surface of the patient contacting portion may be sticky or tacky in addition to, or as an alternative to, having a surface texture or pattern which increases the friction.

[0219] In examples, the patient contacting portion 3312 may comprise a higher friction layer 3314 comprising a coating or layer of material applied directly to the surface of a headgear strap 3302. However, as shown in Fig. 7, in other forms of the technology an intermediate layer 3316 may be provided between the material of the headgear strap 3302 and the higher friction layer 3314. In examples the intermediate layer 3316 may be a resilient layer such as a foam, which is configured to conform to the contours of the patient's face.

[0220] Referring next to Fig. 8, in examples a patient contacting portion 3312 may be provided to an air delivery tube 3350 that forms part of a positioning and

stabilising structure 3300 (e.g. a conduit headgear tube). The patient contacting portion 3312 may take any of the forms described above, or it may comprise a portion of the tube which has a different chemical composition or structure to the remainder of the tube 3350, and which therefore has a higher coefficient of friction than an adjacent portion.

[0221] In examples the patient contacting portion 3312 may be replaceable. For example, in one form a layer 3314 of high friction material may be attached to a headgear strap 3302 or tube 3350 by means of a hook and loop fastener such as Velcro™. In another example a layer 3314 of high friction material may be attached to a surface of a headgear strap 3302 or tube 3350 (and/or to an intermediate layer 3316) by means of an adhesive. In examples, the patient contacting portion 3312 may be provided to a sleeve, as described further below.

[0222] In alternative examples the patient contacting portion 3312 may be permanently attached to, or may permanently form a part of, a headgear strap 3302 or tube 3350. For example, a patient contacting portion 3312 made from silicone may be overmoulded to a strap 3302 of a headgear.

[0223] Referring next to Fig. 9, in another form of the technology the patient contacting portion may comprise a high friction layer of material 3314, for example any of the high friction materials and/or surface textures/patterns described above, provided to a sleeve 3318. The sleeve 3318 may be configured to engage a headgear strap 3302 or a conduit headgear tube 3350. The sleeve 3318 may be configured to sufficiently resist slipping relative to the headgear strap 3302 or a conduit headgear tube 3350 in use, while still allowing the sleeve 3318 to be slid over the strap or conduit for installation and removal.

[0224] In one example, the sleeve 3318 may be made from silicone. The high friction layer 3314 may also be made from a suitable silicone. In another example the sleeve 3318 may be made from a textile.

[0225] In examples (not shown), an intermediate layer 3316 may be provided between the sleeve 3318 and the high friction layer 3314.

[0226] Advantages of this form of the technology include the ability to replace the patient contacting portion without replacing the entire positioning and stabilising structure 3300. In addition, the patient may be able to position the patient contacting portion 3312 in a preferred position, and may be able to select a preferred size and/or colour.

[0227] Patient contacting portions 3312 of the present technology are preferably positioned on a strap 3302 or conduit headgear tube 3350 such that they contact the patient's cheek, in use. Such a strap 3302 or conduit headgear tube 3350 may extend along the patient's face between the patient's eye and the patient's ear, when in use.

[0228] In examples the patient contacting portion 3312 does not extend to a non-patient contacting side of the strap 3302 or headgear tube 3350. In this way the strap or tube can move over the patient's bedclothes or pillow without additional drag being created.

[0229] In examples, the friction between the patient contacting portion and the patient's skin may be sufficient that the patient contacting portion substantially decouples the portion of the positioning and stabilising structure which is on the opposite side of the patient contacting portion to the plenum chamber (e.g. the portion which extends around the back of the patient's head) from forces caused by typical disturbances the patient interface may experience while the patient is asleep (e.g. as a result of tube drag).

[0230] While the technology has been described above in relation to its use with nasal pillows mask, the technology may be used with any form of mask, including (without limitation) nasal masks, full-face masks, nasal pillows, nasal puffs and oro-nasal masks.

4.3.5 Vent

[0231] In one form, the patient interface 3000 includes a vent 3400 constructed and arranged to allow for the washout of exhaled gases, e.g. carbon dioxide.

[0232] In certain forms the vent 3400 is configured to allow a continuous vent flow from an interior of the plenum chamber 3200 to ambient whilst the pressure within the plenum chamber is positive with respect to ambient. The vent 3400 is

configured such that the vent flow rate has a magnitude sufficient to reduce rebreathing of exhaled CO2 by the patient while maintaining the therapeutic pressure in the plenum chamber in use.

[0233] One form of vent 3400 in accordance with the present technology comprises a plurality of holes, for example, about 20 to about 80 holes, or about 40 to about 60 holes, or about 45 to about 55 holes.

[0234] The vent 3400 may be located in the plenum chamber 3200. Alternatively, the vent 3400 is located in a decoupling structure, e.g., a swivel.

4.3.6 Decoupling structure(s)

[0235] In one form the patient interface 3000 includes at least one decoupling structure, for example, a swivel or a ball and socket.

4.3.7 Connection port

[0236] Connection port 3600 allows for connection to the air circuit 4170.

4.3.8 Forehead support

[0237] In one form, the patient interface 3000 includes a forehead support 3700.

4.3.9 Anti-asphyxia valve

[0238] In one form, the patient interface 3000 includes an anti-asphyxia valve.

4.3.10 Ports

[0239] In one form of the present technology, a patient interface 3000 includes one or more ports that allow access to the volume within the plenum chamber 3200. In one form this allows a clinician to supply supplementary oxygen. In one form, this allows for the direct measurement of a property of gases within the plenum chamber 3200, such as the pressure.

4.4 RPT DEVICE

[0240] An RPT device 4000 in accordance with one aspect of the present technology comprises mechanical, pneumatic, and/or electrical components and is configured to execute one or more algorithms such as any of the methods, in whole or in part, described herein. The RPT device 4000 may be configured to generate a flow

of air for delivery to a patient's airways, such as to treat one or more of the respiratory conditions described elsewhere in the present document.

4.5 HUMIDIFIER

[0241] In one form of the present technology there is provided a humidifier 5000 (e.g. as shown in Fig. 1A) to change the absolute humidity of air or gas for delivery to a patient relative to ambient air. Typically, the humidifier 5000 is used to increase the absolute humidity and increase the temperature of the flow of air (relative to ambient air) before delivery to the patient's airways.

4.6 GLOSSARY

[0242] For the purposes of the present technology disclosure, in certain forms of the present technology, one or more of the following definitions may apply. In other forms of the present technology, alternative definitions may apply.

4.6.1 General

[0243] *Air*: In certain forms of the present technology, air may be taken to mean atmospheric air, and in other forms of the present technology air may be taken to mean some other combination of breathable gases, e.g. oxygen enriched air.

[0244] *Ambient:* In certain forms of the present technology, the term ambient will be taken to mean (i) external of the treatment system or patient, and (ii) immediately surrounding the treatment system or patient.

[0245] For example, ambient humidity with respect to a humidifier may be the humidity of air immediately surrounding the humidifier, e.g. the humidity in the room where a patient is sleeping. Such ambient humidity may be different to the humidity outside the room where a patient is sleeping.

[0246] In another example, ambient pressure may be the pressure immediately surrounding or external to the body.

[0247] In certain forms, ambient (e.g., acoustic) noise may be considered to be the background noise level in the room where a patient is located, other than for example, noise generated by an RPT device or emanating from a mask or patient interface. Ambient noise may be generated by sources outside the room.

[0248] *Automatic Positive Airway Pressure (APAP) therapy*: CPAP therapy in which the treatment pressure is automatically adjustable, e.g. from breath to breath, between minimum and maximum limits, depending on the presence or absence of indications of SDB events.

[0249] *Continuous Positive Airway Pressure (CPAP) therapy*: Respiratory pressure therapy in which the treatment pressure is approximately constant through a respiratory cycle of a patient. In some forms, the pressure at the entrance to the airways will be slightly higher during exhalation, and slightly lower during inhalation. In some forms, the pressure will vary between different respiratory cycles of the patient, for example, being increased in response to detection of indications of partial upper airway obstruction, and decreased in the absence of indications of partial upper airway obstruction.

[0250] *Flow rate*: The volume (or mass) of air delivered per unit time. Flow rate may refer to an instantaneous quantity. In some cases, a reference to flow rate will be a reference to a scalar quantity, namely a quantity having magnitude only. In other cases, a reference to flow rate will be a reference to a vector quantity, namely a quantity having both magnitude and direction. Flow rate may be given the symbol *Q*. 'Flow rate' is sometimes shortened to simply 'flow' or 'airflow'.

[0251] In the example of patient respiration, a flow rate may be nominally positive for the inspiratory portion of a breathing cycle of a patient, and hence negative for the expiratory portion of the breathing cycle of a patient. Device flow rate, *Qd*, is the flow rate of air leaving the RPT device. Total flow rate, *Qt*, is the flow rate of air and any supplementary gas reaching the patient interface via the air circuit. Vent flow rate, *Qv*, is the flow rate of air leaving a vent to allow washout of exhaled gases. Leak flow rate, *Ql*, is the flow rate of leak from a patient interface system or elsewhere. Respiratory flow rate, *Qr*, is the flow rate of air that is received into the patient's respiratory system.

[0252] *Flow therapy*: Respiratory therapy comprising the delivery of a flow of air to an entrance to the airways at a controlled flow rate referred to as the treatment flow rate that is typically positive throughout the patient's breathing cycle.

[0253] *Humidifier*: The word humidifier will be taken to mean a humidifying apparatus constructed and arranged, or configured with a physical structure to be capable of providing a therapeutically beneficial amount of water (H_2O) vapour to a flow of air to ameliorate a medical respiratory condition of a patient.

[0254] *Leak*: The word leak will be taken to be an unintended flow of air. In one example, leak may occur as the result of an incomplete seal between a mask and a patient's face. In another example leak may occur in a swivel elbow to the ambient.

[0255] *Noise, conducted (acoustic)*: Conducted noise in the present document refers to noise which is carried to the patient by the pneumatic path, such as the air circuit and the patient interface as well as the air therein. In one form, conducted noise may be quantified by measuring sound pressure levels at the end of an air circuit.

[0256] *Noise, radiated (acoustic)*: Radiated noise in the present document refers to noise which is carried to the patient by the ambient air. In one form, radiated noise may be quantified by measuring sound power/pressure levels of the object in question according to ISO 3744.

[0257] *Noise, vent (acoustic)*: Vent noise in the present document refers to noise which is generated by the flow of air through any vents such as vent holes of the patient interface.

[0258] *Oxygen enriched air*: Air with a concentration of oxygen greater than that of atmospheric air (21%), for example at least about 50% oxygen, at least about 60% oxygen, at least about 70% oxygen, at least about 80% oxygen, at least about 90% oxygen, at least about 95% oxygen, at least about 98% oxygen, or at least about 99% oxygen. "Oxygen enriched air" is sometimes shortened to "oxygen".

[0259] *Medical Oxygen*: Medical oxygen is defined as oxygen enriched air with an oxygen concentration of 80% or greater.

[0260] *Patient*: A person, whether or not they are suffering from a respiratory condition.

[0261] *Pressure*: Force per unit area. Pressure may be expressed in a range of units, including cmH_2O, g-f/cm^2 and hectopascal. 1 cmH_2O is equal to 1 g-f/cm^2 and

is approximately 0.98 hectopascal (1 hectopascal = 100 Pa = 100 N/m^2 = 1 millibar ~ 0.001 atm). In this specification, unless otherwise stated, pressure is given in units of cmH_2O.

[0262] The pressure in the patient interface is given the symbol *Pm*, while the treatment pressure, which represents a target value to be achieved by the interface pressure *Pm* at the current instant of time, is given the symbol *Pt*.

[0263] *Respiratory Pressure Therapy*: The application of a supply of air to an entrance to the airways at a treatment pressure that is typically positive with respect to atmosphere.

[0264] *Ventilator*: A mechanical device that provides pressure support to a patient to perform some or all of the work of breathing.

4.6.1.1 Materials

[0265] *Silicone or Silicone Elastomer*: A synthetic rubber. In this specification, a reference to silicone is a reference to liquid silicone rubber (LSR) or a compression moulded silicone rubber (CMSR). One form of commercially available LSR is SILASTIC (included in the range of products sold under this trademark), manufactured by Dow Corning. Another manufacturer of LSR is Wacker. Unless otherwise specified to the contrary, an exemplary form of LSR has a Shore A (or Type A) indentation hardness in the range of about 35 to about 45 as measured using ASTM D2240.

[0266] *Polycarbonate*: a thermoplastic polymer of Bisphenol-A Carbonate.

4.6.1.2 Mechanical properties

[0267] *Resilience*: Ability of a material to absorb energy when deformed elastically and to release the energy upon unloading.

[0268] *Resilient*: Will release substantially all of the energy when unloaded. Includes e.g. certain silicones, and thermoplastic elastomers.

[0269] *Hardness*: The ability of a material per se to resist deformation (e.g. described by a Young's Modulus, or an indentation hardness scale measured on a standardised sample size).

- 'Soft' materials may include silicone or thermo-plastic elastomer (TPE), and may, e.g. readily deform under finger pressure.
- 'Hard' materials may include polycarbonate, polypropylene, steel or aluminium, and may not e.g. readily deform under finger pressure.

[0270] *Stiffness* (or *rigidity*) of a structure or component: The ability of the structure or component to resist deformation in response to an applied load. The load may be a force or a moment, e.g. compression, tension, bending or torsion. The structure or component may offer different resistances in different directions. The inverse of stiffness is flexibility.

[0271] *Floppy* structure or component: A structure or component that will change shape, e.g. bend, when caused to support its own weight, within a relatively short period of time such as 1 second.

[0272] *Rigid* structure or component: A structure or component that will not substantially change shape when subject to the loads typically encountered in use. An example of such a use may be setting up and maintaining a patient interface in sealing relationship with an entrance to a patient's airways, e.g. at a load of approximately 20 to 30 cmH2O pressure.

[0273] As an example, an I-beam may comprise a different bending stiffness (resistance to a bending load) in a first direction in comparison to a second, orthogonal direction. In another example, a structure or component may be floppy in a first direction and rigid in a second direction.

4.6.2 Respiratory cycle

[0274] *Apnea*: According to some definitions, an apnea is said to have occurred when flow falls below a predetermined threshold for a duration, e.g. 10 seconds. An obstructive apnea will be said to have occurred when, despite patient effort, some obstruction of the airway does not allow air to flow. A central apnea will be said to have occurred when an apnea is detected that is due to a reduction in breathing effort, or the absence of breathing effort, despite the airway being patent. A mixed apnea occurs when a reduction or absence of breathing effort coincides with an obstructed airway.

[0275] *Breathing rate*: The rate of spontaneous respiration of a patient, usually measured in breaths per minute.

[0276] *Duty cycle*: The ratio of inhalation time, Ti to total breath time, Ttot.

[0277] *Effort* (breathing): The work done by a spontaneously breathing person attempting to breathe.

[0278] *Expiratory portion* of a breathing cycle: The period from the start of expiratory flow to the start of inspiratory flow.

[0279] *Flow limitation*: Flow limitation will be taken to be the state of affairs in a patient's respiration where an increase in effort by the patient does not give rise to a corresponding increase in flow. Where flow limitation occurs during an inspiratory portion of the breathing cycle it may be described as inspiratory flow limitation. Where flow limitation occurs during an expiratory portion of the breathing cycle it may be described as expiratory flow limitation.

[0280] Types of flow limited inspiratory waveforms:

(i) Flattened: Having a rise followed by a relatively flat portion, followed by a fall.

(ii) M-shaped: Having two local peaks, one at the leading edge, and one at the trailing edge, and a relatively flat portion between the two peaks.

(iii) Chair-shaped: Having a single local peak, the peak being at the leading edge, followed by a relatively flat portion.

(iv) Reverse-chair shaped: Having a relatively flat portion followed by single local peak, the peak being at the trailing edge.

[0281] *Hypopnea*: According to some definitions, a hypopnea is taken to be a reduction in flow, but not a cessation of flow. In one form, a hypopnea may be said to have occurred when there is a reduction in flow below a threshold rate for a duration. A central hypopnea will be said to have occurred when a hypopnea is detected that is due to a reduction in breathing effort. In one form in adults, either of the following may be regarded as being hypopneas:

(i) a 30% reduction in patient breathing for at least 10 seconds plus an associated 4% desaturation; or

(ii) a reduction in patient breathing (but less than 50%) for at least 10 seconds, with an associated desaturation of at least 3% or an arousal.

[0282] *Hyperpnea*: An increase in flow to a level higher than normal.

[0283] *Inspiratory portion* of a breathing cycle: The period from the start of inspiratory flow to the start of expiratory flow will be taken to be the inspiratory portion of a breathing cycle.

[0284] *Patency* (airway): The degree of the airway being open, or the extent to which the airway is open. A patent airway is open. Airway patency may be quantified, for example with a value of one (1) being patent, and a value of zero (0), being closed (obstructed).

[0285] *Positive End-Expiratory Pressure (PEEP)*: The pressure above atmosphere in the lungs that exists at the end of expiration.

[0286] *Peak flow rate* (*Qpeak*): The maximum value of flow rate during the inspiratory portion of the respiratory flow waveform.

[0287] *Respiratory flow rate, patient airflow rate, respiratory airflow rate* (*Qr*): These terms may be understood to refer to the RPT device's estimate of respiratory flow rate, as opposed to "true respiratory flow rate" or "true respiratory flow rate", which is the actual respiratory flow rate experienced by the patient, usually expressed in litres per minute.

[0288] *Tidal volume* (*Vt*): The volume of air inhaled or exhaled during normal breathing, when extra effort is not applied. In principle the inspiratory volume *Vi* (the volume of air inhaled) is equal to the expiratory volume *Ve* (the volume of air exhaled), and therefore a single tidal volume *Vt* may be defined as equal to either quantity. In practice the tidal volume *Vt* is estimated as some combination, e.g. the mean, of the inspiratory volume Vi and the expiratory volume *Ve*.

[0289] *Inhalation Time* (*Ti*): The duration of the inspiratory portion of the respiratory flow rate waveform.

[0290] *Exhalation Time* (*Te*): The duration of the expiratory portion of the respiratory flow rate waveform.

[0291] *Total Time* (*Ttot*): The total duration between the start of one inspiratory portion of a respiratory flow rate waveform and the start of the following inspiratory portion of the respiratory flow rate waveform.

[0292] *Typical recent ventilation*: The value of ventilation around which recent values of ventilation Vent over some predetermined timescale tend to cluster, that is, a measure of the central tendency of the recent values of ventilation.

[0293] *Upper airway obstruction (UAO)*: includes both partial and total upper airway obstruction. This may be associated with a state of flow limitation, in which the flow rate increases only slightly or may even decrease as the pressure difference across the upper airway increases (Starling resistor behaviour).

[0294] *Ventilation* (*Vent*): A measure of a rate of gas being exchanged by the patient's respiratory system. Measures of ventilation may include one or both of inspiratory and expiratory flow, per unit time. When expressed as a volume per minute, this quantity is often referred to as "minute ventilation". Minute ventilation is sometimes given simply as a volume, understood to be the volume per minute.

4.6.3 Ventilation

[0295] Adaptive Servo-Ventilator (ASV): A servo-ventilator that has a changeable, rather than fixed target ventilation. The changeable target ventilation may be learned from some characteristic of the patient, for example, a respiratory characteristic of the patient.

[0296] Backup rate: A parameter of a ventilator that establishes the minimum breathing rate (typically in number of breaths per minute) that the ventilator will deliver to the patient, if not triggered by spontaneous respiratory effort.

[0297] Cycled: The termination of a ventilator's inspiratory phase. When a ventilator delivers a breath to a spontaneously breathing patient, at the end of the

inspiratory portion of the breathing cycle, the ventilator is said to be cycled to stop delivering the breath.

[0298] Expiratory positive airway pressure (EPAP): a base pressure, to which a pressure varying within the breath is added to produce the desired interface pressure which the ventilator will attempt to achieve at a given time.

[0299] End expiratory pressure (EEP): Desired interface pressure which the ventilator will attempt to achieve at the end of the expiratory portion of the breath. If the pressure waveform template $\Pi(\Phi)$ is zero-valued at the end of expiration, i.e. $\Pi(\Phi) = 0$ when $\Phi = 1$, the EEP is equal to the EPAP.

[0300] Inspiratory positive airway pressure (IPAP): Maximum desired interface pressure which the ventilator will attempt to achieve during the inspiratory portion of the breath.

[0301] Pressure support: A number that is indicative of the increase in pressure during ventilator inspiration over that during ventilator expiration, and generally means the difference in pressure between the maximum value during inspiration and the base pressure (e.g., PS = IPAP – EPAP). In some contexts, pressure support means the difference which the ventilator aims to achieve, rather than what it actually achieves.

[0302] Servo-ventilator: A ventilator that measures patient ventilation, has a target ventilation, and which adjusts the level of pressure support to bring the patient ventilation towards the target ventilation.

[0303] Spontaneous/Timed (S/T): A mode of a ventilator or other device that attempts to detect the initiation of a breath of a spontaneously breathing patient. If however, the device is unable to detect a breath within a predetermined period of time, the device will automatically initiate delivery of the breath.

[0304] Swing: Equivalent term to pressure support.

[0305] Triggered: When a ventilator, or other respiratory therapy device such as an RPT device or portable oxygen concentrator, delivers a volume of breathable gas to a spontaneously breathing patient, it is said to be triggered to do so. Triggering

usually takes place at or near the initiation of the respiratory portion of the breathing cycle by the patient's efforts.

4.6.4 Anatomy

4.6.4.1 Anatomy of the face

[0306] Ala: the external outer wall or "wing" of each nostril (plural: alar)

[0307] Alare: The most lateral point on the nasal ala.

[0308] Alar curvature (or alar crest) point: The most posterior point in the curved base line of each ala, found in the crease formed by the union of the ala with the cheek.

[0309] Auricle: The whole external visible part of the ear.

[0310] (nose) Bony framework: The bony framework of the nose comprises the nasal bones, the frontal process of the maxillae and the nasal part of the frontal bone.

[0311] (nose) Cartilaginous framework: The cartilaginous framework of the nose comprises the septal, lateral, major and minor cartilages.

[0312] Columella: the strip of skin that separates the nares and which runs from the pronasale to the upper lip.

[0313] Columella angle: The angle between the line drawn through the midpoint of the nostril aperture and a line drawn perpendicular to the Frankfort horizontal while intersecting subnasale.

[0314] Frankfort horizontal plane: A line extending from the most inferior point of the orbital margin to the left tragion. The tragion is the deepest point in the notch superior to the tragus of the auricle.

[0315] Glabella: Located on the soft tissue, the most prominent point in the midsagittal plane of the forehead.

[0316] Lateral nasal cartilage: A generally triangular plate of cartilage. Its superior margin is attached to the nasal bone and frontal process of the maxilla, and its inferior margin is connected to the greater alar cartilage.

[0317] Lip, lower (labrale inferius):

[0318] Lip, upper (labrale superius):

[0319] Greater alar cartilage: A plate of cartilage lying below the lateral nasal cartilage. It is curved around the anterior part of the naris. Its posterior end is connected to the frontal process of the maxilla by a tough fibrous membrane containing three or four minor cartilages of the ala.

[0320] Nares (Nostrils): Approximately ellipsoidal apertures forming the entrance to the nasal cavity. The singular form of nares is naris (nostril). The nares are separated by the nasal septum.

[0321] Naso-labial sulcus or Naso-labial fold: The skin fold or groove that runs from each side of the nose to the corners of the mouth, separating the cheeks from the upper lip.

[0322] Naso-labial angle: The angle between the columella and the upper lip, while intersecting subnasale.

[0323] Otobasion inferior: The lowest point of attachment of the auricle to the skin of the face.

[0324] Otobasion superior: The highest point of attachment of the auricle to the skin of the face.

[0325] Pronasale: the most protruded point or tip of the nose, which can be identified in lateral view of the rest of the portion of the head.

[0326] Philtrum: the midline groove that runs from lower border of the nasal septum to the top of the lip in the upper lip region.

[0327] Pogonion: Located on the soft tissue, the most anterior midpoint of the chin.

[0328] Ridge (nasal): The nasal ridge is the midline prominence of the nose, extending from the Sellion to the Pronasale.

[0329] Sagittal plane: A vertical plane that passes from anterior (front) to posterior (rear). The midsagittal plane is a sagittal plane that divides the body into right and left halves.

[0330] Sellion: Located on the soft tissue, the most concave point overlying the area of the frontonasal suture.

[0331] Septal cartilage (nasal): The nasal septal cartilage forms part of the septum and divides the front part of the nasal cavity.

[0332] Subalare: The point at the lower margin of the alar base, where the alar base joins with the skin of the superior (upper) lip.

[0333] Subnasal point: Located on the soft tissue, the point at which the columella merges with the upper lip in the midsagittal plane.

[0334] Supramenton: The point of greatest concavity in the midline of the lower lip between labrale inferius and soft tissue pogonion

4.6.4.2 Anatomy of the skull

[0335] Frontal bone: The frontal bone includes a large vertical portion, the squama frontalis, corresponding to the region known as the forehead.

[0336] Mandible: The mandible forms the lower jaw. The mental protuberance is the bony protuberance of the jaw that forms the chin.

[0337] Maxilla: The maxilla forms the upper jaw and is located above the mandible and below the orbits. The frontal process of the maxilla projects upwards by the side of the nose, and forms part of its lateral boundary.

[0338] Nasal bones: The nasal bones are two small oblong bones, varying in size and form in different individuals; they are placed side by side at the middle and upper part of the face, and form, by their junction, the “bridge” of the nose.

[0339] Nasion: The intersection of the frontal bone and the two nasal bones, a depressed area directly between the eyes and superior to the bridge of the nose.

[0340] Occipital bone: The occipital bone is situated at the back and lower part of the cranium. It includes an oval aperture, the foramen magnum, through which the cranial cavity communicates with the vertebral canal. The curved plate behind the foramen magnum is the squama occipitalis.

[0341] Orbit: The bony cavity in the skull to contain the eyeball.

[0342] Parietal bones: The parietal bones are the bones that, when joined together, form the roof and sides of the cranium.

[0343] Temporal bones: The temporal bones are situated on the bases and sides of the skull, and support that part of the face known as the temple.

[0344] Zygomatic bones: The face includes two zygomatic bones, located in the upper and lateral parts of the face and forming the prominence of the cheek.

4.6.4.3 Anatomy of the respiratory system

[0345] Diaphragm: A sheet of muscle that extends across the bottom of the rib cage. The diaphragm separates the thoracic cavity, containing the heart, lungs and ribs, from the abdominal cavity. As the diaphragm contracts the volume of the thoracic cavity increases and air is drawn into the lungs.

[0346] Larynx: The larynx, or voice box houses the vocal folds and connects the inferior part of the pharynx (hypopharynx) with the trachea.

[0347] Lungs: The organs of respiration in humans. The conducting zone of the lungs contains the trachea, the bronchi, the bronchioles, and the terminal bronchioles. The respiratory zone contains the respiratory bronchioles, the alveolar ducts, and the alveoli.

[0348] Nasal cavity: The nasal cavity (or nasal fossa) is a large air filled space above and behind the nose in the middle of the face. The nasal cavity is divided in two by a vertical fin called the nasal septum. On the sides of the nasal cavity are three horizontal outgrowths called nasal conchae (singular “concha”) or turbinates. To the

front of the nasal cavity is the nose, while the back blends, via the choanae, into the nasopharynx.

[0349] Pharynx: The part of the throat situated immediately inferior to (below) the nasal cavity, and superior to the oesophagus and larynx. The pharynx is conventionally divided into three sections: the nasopharynx (epipharynx) (the nasal part of the pharynx), the oropharynx (mesopharynx) (the oral part of the pharynx), and the laryngopharynx (hypopharynx).

4.6.5 Patient interface

[0350] Anti-asphyxia valve (AAV): The component or sub-assembly of a mask system that, by opening to atmosphere in a failsafe manner, reduces the risk of excessive CO2 rebreathing by a patient.

[0351] Elbow: An elbow is an example of a structure that directs an axis of flow of air travelling therethrough to change direction through an angle. In one form, the angle may be approximately 90 degrees. In another form, the angle may be more, or less than 90 degrees. The elbow may have an approximately circular cross-section. In another form the elbow may have an oval or a rectangular cross-section. In certain forms an elbow may be rotatable with respect to a mating component, e.g. about 360 degrees. In certain forms an elbow may be removable from a mating component, e.g. via a snap connection. In certain forms, an elbow may be assembled to a mating component via a one-time snap during manufacture, but not removable by a patient.

[0352] Frame: Frame will be taken to mean a mask structure that bears the load of tension between two or more points of connection with a headgear. A mask frame may be a non-airtight load bearing structure in the mask. However, some forms of mask frame may also be air-tight.

[0353] Headgear: Headgear will be taken to mean a form of positioning and stabilizing structure designed for use on a head. For example the headgear may comprise a collection of one or more struts, ties and stiffeners configured to locate and retain a patient interface in position on a patient's face for delivery of respiratory therapy. Some ties are formed of a soft, flexible, elastic material such as a laminated composite of foam and fabric.

[0354] Membrane: Membrane will be taken to mean a typically thin element that has, preferably, substantially no resistance to bending, but has resistance to being stretched.

[0355] Plenum chamber: a mask plenum chamber will be taken to mean a portion of a patient interface having walls at least partially enclosing a volume of space, the volume having air therein pressurised above atmospheric pressure in use. A shell may form part of the walls of a mask plenum chamber.

[0356] Seal: May be a noun form ("a seal") which refers to a structure, or a verb form ("to seal") which refers to the effect. Two elements may be constructed and/or arranged to 'seal' or to effect 'sealing' therebetween without requiring a separate 'seal' element per se.

[0357] Shell: A shell will be taken to mean a curved, relatively thin structure having bending, tensile and compressive stiffness. For example, a curved structural wall of a mask may be a shell. In some forms, a shell may be faceted. In some forms a shell may be airtight. In some forms a shell may not be airtight.

[0358] Stiffener: A stiffener will be taken to mean a structural component designed to increase the bending resistance of another component in at least one direction.

[0359] Strut: A strut will be taken to be a structural component designed to increase the compression resistance of another component in at least one direction.

[0360] Swivel (noun): A subassembly of components configured to rotate about a common axis, preferably independently, preferably under low torque. In one form, the swivel may be constructed to rotate through an angle of at least 360 degrees. In another form, the swivel may be constructed to rotate through an angle less than 360 degrees. When used in the context of an air delivery conduit, the sub-assembly of components preferably comprises a matched pair of cylindrical conduits. There may be little or no leak flow of air from the swivel in use.

[0361] Tie (noun): A structure designed to resist tension.

[0362] Vent: (noun): A structure that allows a flow of air from an interior of the mask, or conduit, to ambient air for clinically effective washout of exhaled gases. For example, a clinically effective washout may involve a flow rate of about 10 litres per minute to about 100 litres per minute, depending on the mask design and treatment pressure.

4.6.6 Shape of structures

[0363] Products in accordance with the present technology may comprise one or more three-dimensional mechanical structures, for example a mask cushion or an impeller. The three-dimensional structures may be bounded by two-dimensional surfaces. These surfaces may be distinguished using a label to describe an associated surface orientation, location, function, or some other characteristic. For example a structure may comprise one or more of an anterior surface, a posterior surface, an interior surface and an exterior surface. In another example, a seal-forming structure may comprise a face-contacting (e.g. outer) surface, and a separate non-face-contacting (e.g. underside or inner) surface. In another example, a structure may comprise a first surface and a second surface.

[0364] To facilitate describing the shape of the three-dimensional structures and the surfaces, we first consider a cross-section through a surface of the structure at a point, *p*. See Fig. 3B to Fig. 3F, which illustrate examples of cross-sections at point *p* on a surface, and the resulting plane curves. Figs. 3B to 3F also illustrate an outward normal vector at *p*. The outward normal vector at *p* points away from the surface. In some examples we describe the surface from the point of view of an imaginary small person standing upright on the surface.

4.6.6.1 Curvature in one dimension

[0365] The curvature of a plane curve at p may be described as having a sign (e.g. positive, negative) and a magnitude (e.g. 1/radius of a circle that just touches the curve at p).

[0366] Positive curvature: If the curve at p turns towards the outward normal, the curvature at that point will be taken to be positive (if the imaginary small person leaves the point p they must walk uphill). See Fig. 3B (relatively large positive

curvature compared to Fig. 3C) and Fig. 3C (relatively small positive curvature compared to Fig. 3B). Such curves are often referred to as concave.

[0367] Zero curvature: If the curve at p is a straight line, the curvature will be taken to be zero (if the imaginary small person leaves the point p, they can walk on a level, neither up nor down). See Fig. 3D.

[0368] Negative curvature: If the curve at p turns away from the outward normal, the curvature in that direction at that point will be taken to be negative (if the imaginary small person leaves the point p they must walk downhill). See Fig. 3E (relatively small negative curvature compared to Fig. 3F) and Fig. 3F (relatively large negative curvature compared to Fig. 3E). Such curves are often referred to as convex.

4.6.6.2 Curvature of two dimensional surfaces

[0369] A description of the shape at a given point on a two-dimensional surface in accordance with the present technology may include multiple normal cross-sections. The multiple cross-sections may cut the surface in a plane that includes the outward normal (a "normal plane"), and each cross-section may be taken in a different direction. Each cross-section results in a plane curve with a corresponding curvature. The different curvatures at that point may have the same sign, or a different sign. Each of the curvatures at that point has a magnitude, e.g. relatively small. The plane curves in Figs. 3B to 3F could be examples of such multiple cross-sections at a particular point.

[0370] Principal curvatures and directions: The directions of the normal planes where the curvature of the curve takes its maximum and minimum values are called the principal directions. In the examples of Fig. 3B to Fig. 3F, the maximum curvature occurs in Fig. 3B, and the minimum occurs in Fig. 3F, hence Fig. 3B and Fig. 3F are cross sections in the principal directions. The principal curvatures at p are the curvatures in the principal directions.

[0371] Region of a surface: A connected set of points on a surface. The set of points in a region may have similar characteristics, e.g. curvatures or signs.

[0372] Saddle region: A region where at each point, the principal curvatures have opposite signs, that is, one is positive, and the other is negative (depending on the direction to which the imaginary person turns, they may walk uphill or downhill).

[0373] Dome region: A region where at each point the principal curvatures have the same sign, e.g. both positive (a "concave dome") or both negative (a "convex dome").

[0374] Cylindrical region: A region where one principal curvature is zero (or, for example, zero within manufacturing tolerances) and the other principal curvature is non-zero.

[0375] Planar region: A region of a surface where both of the principal curvatures are zero (or, for example, zero within manufacturing tolerances).

[0376] Edge of a surface: A boundary or limit of a surface or region.

[0377] Path: In certain forms of the present technology, 'path' will be taken to mean a path in the mathematical – topological sense, e.g. a continuous space curve from f(0) to f(1) on a surface. In certain forms of the present technology, a 'path' may be described as a route or course, including e.g. a set of points on a surface. (The path for the imaginary person is where they walk on the surface, and is analogous to a garden path).

[0378] Path length: In certain forms of the present technology, 'path length' will be taken to mean the distance along the surface from f(0) to f(1), that is, the distance along the path on the surface. There may be more than one path between two points on a surface and such paths may have different path lengths. (The path length for the imaginary person would be the distance they have to walk on the surface along the path).

[0379] Straight-line distance: The straight-line distance is the distance between two points on a surface, but without regard to the surface. On planar regions, there would be a path on the surface having the same path length as the straight-line distance between two points on the surface. On non-planar surfaces, there may be no paths having the same path length as the straight-line distance between two points.

(For the imaginary person, the straight-line distance would correspond to the distance 'as the crow flies'.)

4.6.6.3 Space curves

[0380] Space curves: Unlike a plane curve, a space curve does not necessarily lie in any particular plane. A space curve may be closed, that is, having no endpoints. A space curve may be considered to be a one-dimensional piece of three-dimensional space. An imaginary person walking on a strand of the DNA helix walks along a space curve. A typical human left ear comprises a helix, which is a left-hand helix, see Fig. 3Q. A typical human right ear comprises a helix, which is a right-hand helix, see Fig. 3R. Fig. 3S shows a right-hand helix. The edge of a structure, e.g. the edge of a membrane or impeller, may follow a space curve. In general, a space curve may be described by a curvature and a torsion at each point on the space curve. Torsion is a measure of how the curve turns out of a plane. Torsion has a sign and a magnitude. The torsion at a point on a space curve may be characterised with reference to the Tangent, normal and binormal vectors at that point.

[0381] Tangent unit vector (or unit tangent vector): For each point on a curve, a vector at the point specifies a direction from that point, as well as a magnitude. A tangent unit vector is a unit vector pointing in the same direction as the curve at that point. If an imaginary person were flying along the curve and fell off her vehicle at a particular point, the direction of the tangent vector is the direction she would be travelling.

[0382] Unit normal vector: As the imaginary person moves along the curve, this tangent vector itself changes. The unit vector pointing in the same direction that the tangent vector is changing is called the unit principal normal vector. It is perpendicular to the tangent vector.

[0383] Binormal unit vector: The binormal unit vector is perpendicular to both the tangent vector and the principal normal vector. Its direction may be determined by a right-hand rule (see e.g. Fig. 3P), or alternatively by a left-hand rule (Fig. 3O).

[0384] Osculating plane: The plane containing the unit tangent vector and the unit principal normal vector. See Figures 3O and 3P.

[0385] Torsion of a space curve: The torsion at a point of a space curve is the magnitude of the rate of change of the binormal unit vector at that point. It measures how much the curve deviates from the osculating plane. A space curve which lies in a plane has zero torsion. A space curve which deviates a relatively small amount from the osculating plane will have a relatively small magnitude of torsion (e.g. a gently sloping helical path). A space curve which deviates a relatively large amount from the osculating plane will have a relatively large magnitude of torsion (e.g. a steeply sloping helical path). With reference to Fig. 3S, since T2>T1, the magnitude of the torsion near the top coils of the helix of Fig. 3S is greater than the magnitude of the torsion of the bottom coils of the helix of Fig. 3S

[0386] With reference to the right-hand rule of Fig. 3P, a space curve turning towards the direction of the right-hand binormal may be considered as having a right-hand positive torsion (e.g. a right-hand helix as shown in Fig. 3S). A space curve turning away from the direction of the right-hand binormal may be considered as having a right-hand negative torsion (e.g. a left-hand helix).

[0387] Equivalently, and with reference to a left-hand rule (see Fig. 3O), a space curve turning towards the direction of the left-hand binormal may be considered as having a left-hand positive torsion (e.g. a left-hand helix). Hence left-hand positive is equivalent to right-hand negative. See Fig. 3T.

4.6.6.4 Holes

[0388] A surface may have a one-dimensional hole, e.g. a hole bounded by a plane curve or by a space curve. Thin structures (e.g. a membrane) with a hole, may be described as having a one-dimensional hole. See for example the one dimensional hole in the surface of structure shown in Fig. 3I, bounded by a plane curve.

[0389] A structure may have a two-dimensional hole, e.g. a hole bounded by a surface. For example, an inflatable tyre has a two dimensional hole bounded by the interior surface of the tyre. In another example, a bladder with a cavity for air or gel could have a two-dimensional hole. See for example the cushion of Fig. 3L and the example cross-sections therethrough in Fig. 3M and Fig. 3N, with the interior surface bounding a two dimensional hole indicated. In a yet another example, a conduit may comprise a one-dimension hole (e.g. at its entrance or at its exit), and a two-dimension

hole bounded by the inside surface of the conduit. See also the two dimensional hole through the structure shown in Fig. 3K, bounded by a surface as shown.

4.7 OTHER REMARKS

[0390] A portion of the disclosure of this patent document contains material which is subject to copyright protection. The copyright owner has no objection to the facsimile reproduction by anyone of the patent document or the patent disclosure, as it appears in Patent Office patent files or records, but otherwise reserves all copyright rights whatsoever.

[0391] Unless the context clearly dictates otherwise and where a range of values is provided, it is understood that each intervening value, to the tenth of the unit of the lower limit, between the upper and lower limit of that range, and any other stated or intervening value in that stated range is encompassed within the technology. The upper and lower limits of these intervening ranges, which may be independently included in the intervening ranges, are also encompassed within the technology, subject to any specifically excluded limit in the stated range. Where the stated range includes one or both of the limits, ranges excluding either or both of those included limits are also included in the technology.

[0392] Furthermore, where a value or values are stated herein as being implemented as part of the technology, it is understood that such values may be approximated, unless otherwise stated, and such values may be utilized to any suitable significant digit to the extent that a practical technical implementation may permit or require it.

[0393] Unless defined otherwise, all technical and scientific terms used herein have the same meaning as commonly understood by one of ordinary skill in the art to which this technology belongs. Although any methods and materials similar or equivalent to those described herein can also be used in the practice or testing of the present technology, a limited number of the exemplary methods and materials are described herein.

[0394] When a particular material is identified as being used to construct a component, obvious alternative materials with similar properties may be used as a substitute. Furthermore, unless specified to the contrary, any and all components

herein described are understood to be capable of being manufactured and, as such, may be manufactured together or separately.

[0395] It must be noted that as used herein and in the appended claims, the singular forms “a”, “an”, and “the” include their plural equivalents, unless the context clearly dictates otherwise.

[0396] All publications mentioned herein are incorporated herein by reference in their entirety to disclose and describe the methods and/or materials which are the subject of those publications. The publications discussed herein are provided solely for their disclosure prior to the filing date of the present application. Nothing herein is to be construed as an admission that the present technology is not entitled to antedate such publication by virtue of prior invention. Further, the dates of publication provided may be different from the actual publication dates, which may need to be independently confirmed.

[0397] The terms “comprises” and “comprising” should be interpreted as referring to elements, components, or steps in a non-exclusive manner, indicating that the referenced elements, components, or steps may be present, or utilized, or combined with other elements, components, or steps that are not expressly referenced.

[0398] The subject headings used in the detailed description are included only for the ease of reference of the reader and should not be used to limit the subject matter found throughout the disclosure or the claims. The subject headings should not be used in construing the scope of the claims or the claim limitations.

[0399] Although the technology herein has been described with reference to particular examples, it is to be understood that these examples are merely illustrative of the principles and applications of the technology. In some instances, the terminology and symbols may imply specific details that are not required to practice the technology. For example, although the terms “first” and “second” may be used, unless otherwise specified, they are not intended to indicate any order but may be utilised to distinguish between distinct elements. Furthermore, although process steps in the methodologies may be described or illustrated in an order, such an ordering is not required. Those skilled in the art will recognize that such ordering may be

modified and/or aspects thereof may be conducted concurrently or even synchronously.

[0400] It is therefore to be understood that numerous modifications may be made to the illustrative examples and that other arrangements may be devised without departing from the spirit and scope of the technology.

4.8 REFERENCE SIGNS LIST

patient	1000
bed partner	1100
patient interface	3000
seal forming structure	3100
cushion module	3150
plenum chamber	3200
chord	3210
superior point	3220
inferior point	3230
positioning and stabilising structure	3300
straps	3302
adjacent portion	3302a
side strap	3304
upper back strap	3306
lower back strap	3310
patient contacting portion	3312
high friction layer	3314
intermediate layer	3316
sleeve	3318
tabs	3320

tubes	3350
concertina structure	3362
non-extendible tube section	3363
vent	3400
connection port	3600
elbow	3610
forehead support	3700
patient interface	3800
RPT device	4000
air circuit	4170
humidifier	5000

5 CLAIMS

1. A patient interface comprising:

a plenum chamber pressurisable to a therapeutic pressure of at least 6 cmH2O above ambient air pressure, said plenum chamber including a plenum chamber inlet port sized and structured to receive a flow of air at the therapeutic pressure for breathing by a patient,

a seal-forming structure constructed and arranged to form a seal with a region of the patient's face surrounding an entrance to the patient's airways, said seal-forming structure having a hole therein such that the flow of air at said therapeutic pressure is delivered to at least an entrance to the patient's nares, the seal-forming structure constructed and arranged to maintain said therapeutic pressure in the plenum chamber throughout the patient's respiratory cycle in use; and

a positioning and stabilising structure to provide a force to hold the seal-forming structure in a therapeutically effective position on the patient's head, the positioning and stabilising structure comprising a tie, the tie being constructed and arranged so that at least a portion overlies a region of the patient's head superior to an otobasion superior of the patient's head in use, wherein a portion of the positioning and stabilising structure extends around a back of the patient's head, in use;

wherein a flexible portion of the positioning and stabilising structure comprises at least one patient contacting portion which is configured to contact the patient's cheek, in use, wherein the coefficient of friction between at least a portion of the patient contacting portion and the patient's skin is higher than the coefficient of friction between an adjacent portion of the positioning and stabilising structure and the patient's skin.

2. The patient interface of claim 1, wherein the patient contacting portion has a higher coefficient of friction than any other portion of the positioning and stabilising structure which is in contact with the patient's skin.

3. The patient interface of claim 1 or 2, wherein a portion of the positioning and stabilising structure, between the patient contacting portion and the back of the patient's head, is held in tension, in use.

4. The patient interface of any one of claims 1, 2 or 3, wherein the positioning and stabilising structure is configured such that the patient contacting portion does not transfer sealing forces to the patient's face.

5. The patient interface of any one of claims 1, 2, 3 or 4, wherein the patient contacting portion is integrally formed with the flexible portion of the positioning and stabilising structure.

6. The patient interface of any one of claims 1, 2, 3 or 4, wherein the patient contacting portion comprises a layer of material attached to the flexible portion of the positioning and stabilising structure, wherein the coefficient of friction between the layer of material and the patient's skin is higher than the coefficient of friction between the patient's skin and an adjacent portion of the positioning and stabilising structure.

7. The patient interface of claim 6, wherein the layer of material comprises silicone, a gel, polyurethane and/or a coating of medical adhesive.

8. The patient interface of claim 6 or 7, wherein an intermediate layer is provided between the flexible portion of the positioning and stabilising structure, and the layer of material.

9. The patient interface of claim 8, wherein the intermediate layer is resilient.

10. The patient interface of claim 9, wherein the intermediate layer comprises foam.

11. The patient interface of any one of claims 1 to 10, wherein the patient contacting portion comprises a surface texture or pattern configured to increase the coefficient of friction of the patient contacting portion.

12. The patient interface of any one of claims 1 to 11, wherein the flexible portion of the positioning and stabilising structure extends between the patient's eye and ear, in use.

13. The patient interface of any one of claims 1 to 12, wherein the flexible portion of the positioning and stabilising structure comprises a strap.

13. The patient interface of any one of claims 1 to 12, wherein the flexible portion of the positioning and stabilising structure comprises a tube.

14. A patient interface comprising:

a plenum chamber pressurisable to a therapeutic pressure of at least 6 cmH2O above ambient air pressure, said plenum chamber including a plenum chamber inlet port sized and structured to receive a flow of air at the therapeutic pressure for breathing by a patient,

a seal-forming structure constructed and arranged to form a seal with a region of the patient's face surrounding an entrance to the patient's airways, said seal-forming structure having a hole therein such that the flow of air at said therapeutic pressure is delivered to at least an entrance to the patient's nares, the seal-forming structure constructed and arranged to maintain said therapeutic pressure in the plenum chamber throughout the patient's respiratory cycle in use; and

a positioning and stabilising structure to provide a force to hold the seal-forming structure in a therapeutically effective position on the patient's head, the positioning and stabilising structure comprising a tie, the tie being constructed and arranged so that at least a portion overlies a region of the patient's head superior to an otobasion superior of the patient's head in use, wherein a portion of the positioning and stabilising structure extends around a back of the patient's head, in use;

wherein the positioning and stabilising structure comprises at least two side straps, each of the side straps extending along a respective one of the patient's cheeks in use, between the patient's eye and ear, each side strap provided with at least one patient contacting portion which is configured to contact the patient's cheek, in use, wherein the coefficient of friction between at least a portion of each patient contacting portion and the patient's skin is higher coefficient than the coefficient of friction between the patient's skin and an adjacent portion of the respective strap.

15. The patient interface of claim 14, wherein each patient contacting portion is formed integrally with the respective strap.

16. The patient interface of claim 14, wherein each patient contacting portion comprises a layer of material attached to the respective strap, wherein the layer of material has higher coefficient of friction than an adjacent portion of the strap.

17. A patient interface comprising:

a plenum chamber pressurisable to a therapeutic pressure of at least 6 cmH2O above ambient air pressure, said plenum chamber including a plenum chamber inlet port sized and structured to receive a flow of air at the therapeutic pressure for breathing by a patient,

a seal-forming structure constructed and arranged to form a seal with a region of the patient's face surrounding an entrance to the patient's airways, said seal-forming structure having a hole therein such that the flow of air at said therapeutic pressure is delivered to at least an entrance to the patient's nares, the seal-forming structure constructed and arranged to maintain said therapeutic pressure in the plenum chamber throughout the patient's respiratory cycle in use; and

a positioning and stabilising structure to provide a force to hold the seal-forming structure in a therapeutically effective position on the patient's head, the positioning and stabilising structure comprising at least one gas delivery tube to deliver the flow of air to the entrance of a patient's airways via the seal-forming structure, the at least one gas delivery tube arranged to contact, in use, a region of the patient's head superior to an otobasion superior of the patient's head, wherein a portion of the positioning and stabilising structure extends around a back of the patient's head, in use;

wherein the or each gas delivery tube is provided with at least one patient contacting portion which is configured to contact the patient's cheek, in use, wherein the coefficient of friction between at least a portion of the patient contacting portion and the patient's skin is higher than the coefficient of friction between an adjacent portion of the gas delivery tube and the patient's skin.

18. The patient interface of claim 17, wherein the patient contacting portion is formed integrally with the gas delivery tube.

19. The patient interface of claim 17, wherein the patient contacting portion comprises a layer of material attached to the gas delivery tube, wherein the layer of material has higher coefficient of friction than an adjacent portion of the gas delivery tube.

20. A patient interface comprising:

a plenum chamber pressurisable to a therapeutic pressure of at least 6 cmH2O above ambient air pressure, said plenum chamber including a plenum chamber inlet port sized and structured to receive a flow of air at the therapeutic pressure for breathing by a patient,

a seal-forming structure constructed and arranged to form a seal with a region of the patient's face surrounding an entrance to the patient's airways, said seal-forming structure having a hole therein such that the flow of air at said therapeutic pressure is delivered to at least an entrance to the patient's nares, the seal-forming structure constructed and arranged to maintain said therapeutic pressure in the plenum chamber throughout the patient's respiratory cycle in use; and

a positioning and stabilising structure to provide a force to hold the seal-forming structure in a therapeutically effective position on the patient's head, the positioning and stabilising structure comprising a tie, the tie being constructed and arranged so that at least a portion overlies a region of the patient's head superior to an otobasion superior of the patient's head in use, wherein a portion of the positioning and stabilising structure extends around a back of the patient's head, in use;

wherein the positioning and stabilising structure comprises at least one patient contacting portion which is configured to contact the patient's cheek, in use, wherein the coefficient of friction between at least a portion of the patient contacting portion and the patient's skin is higher than the coefficient of friction between an adjacent portion of the positioning and stabilising structure and the patient's skin, and

wherein the positioning and stabilising structure is configured such that the patient contacting portion does not transfer sealing forces to the patient's face.

21. A positioning and stabilising structure configured to provide a force, in use, to hold a seal-forming structure of a patient interface in a therapeutically effective position on the patient's head, to provide a therapeutic pressure of at least 6 cmH2O to the patient's airways,

the positioning and stabilising structure comprising a tie, the tie being constructed and arranged so that at least a portion overlies a region of the patient's head superior to an otobasion superior of the patient's head in use, wherein a portion of the positioning and stabilising structure extends around a back of the patient's head, in use;

wherein a flexible portion of the positioning and stabilising structure comprises at least one patient contacting portion which is configured to contact the patient's cheek, in use, wherein the coefficient of friction between at least a portion of the patient contacting portion and the patient's skin is higher than the coefficient of friction between an adjacent portion of the positioning and stabilising structure and the patient's skin.

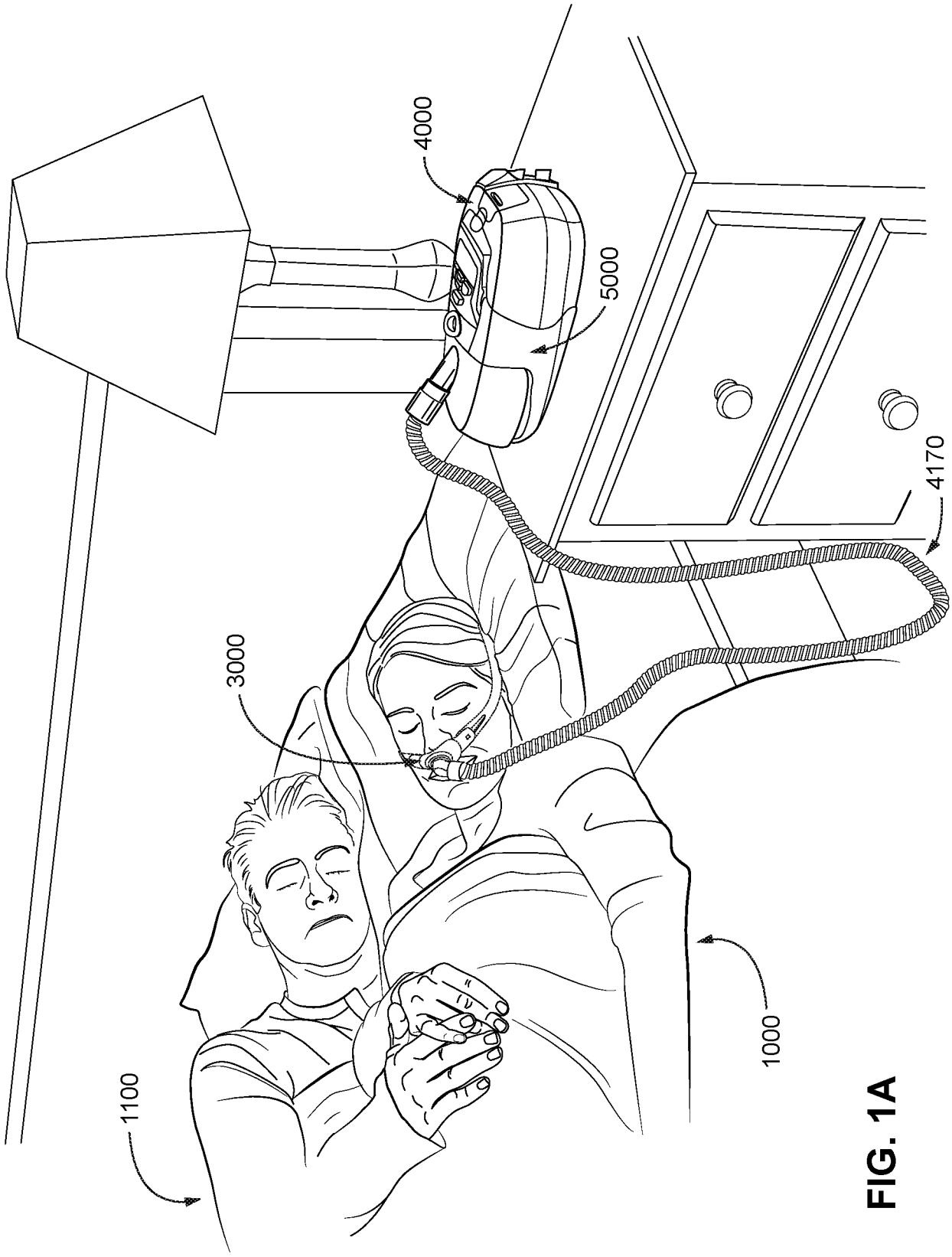


FIG. 1A

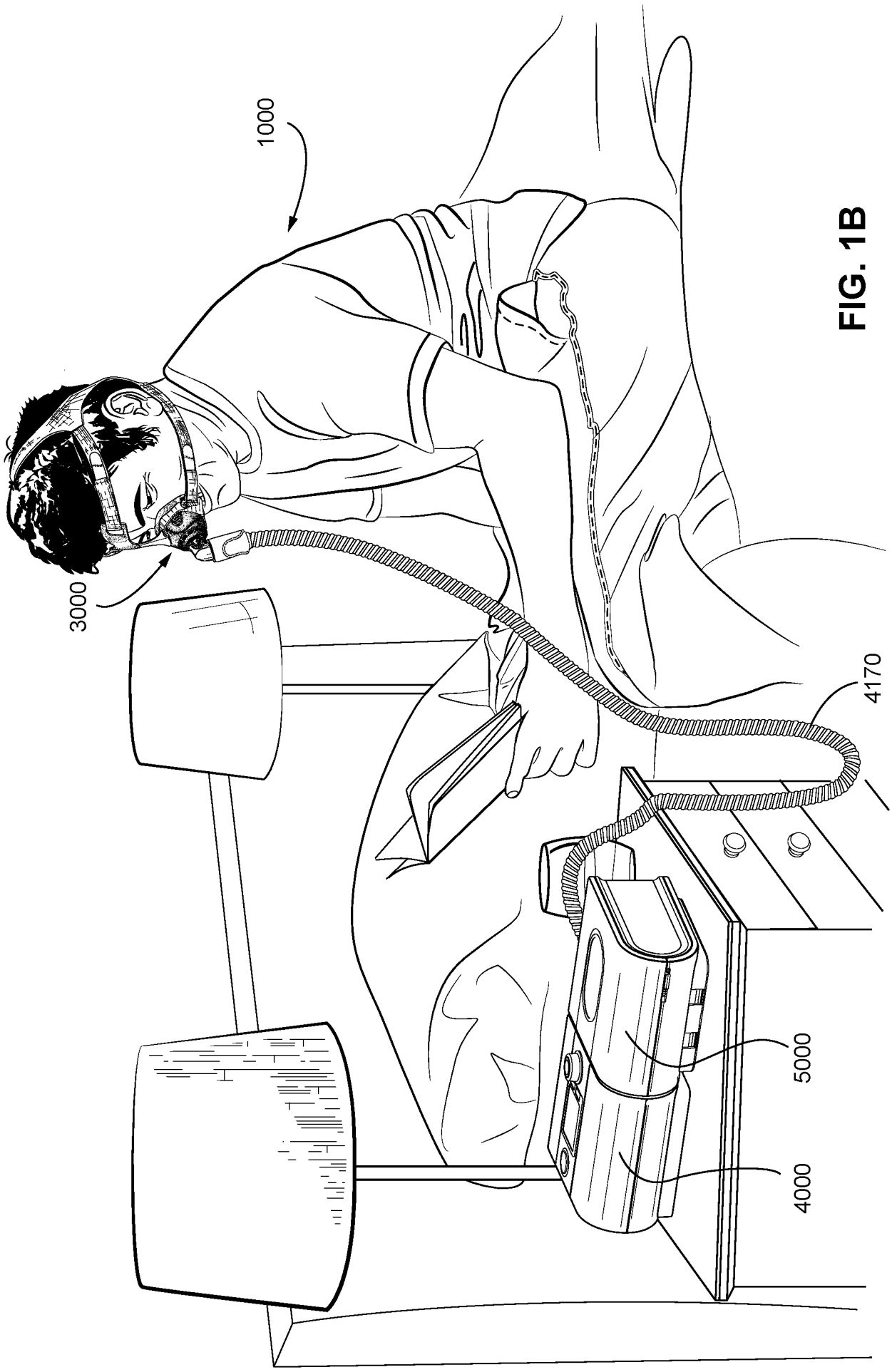


FIG. 1B



FIG. 1C

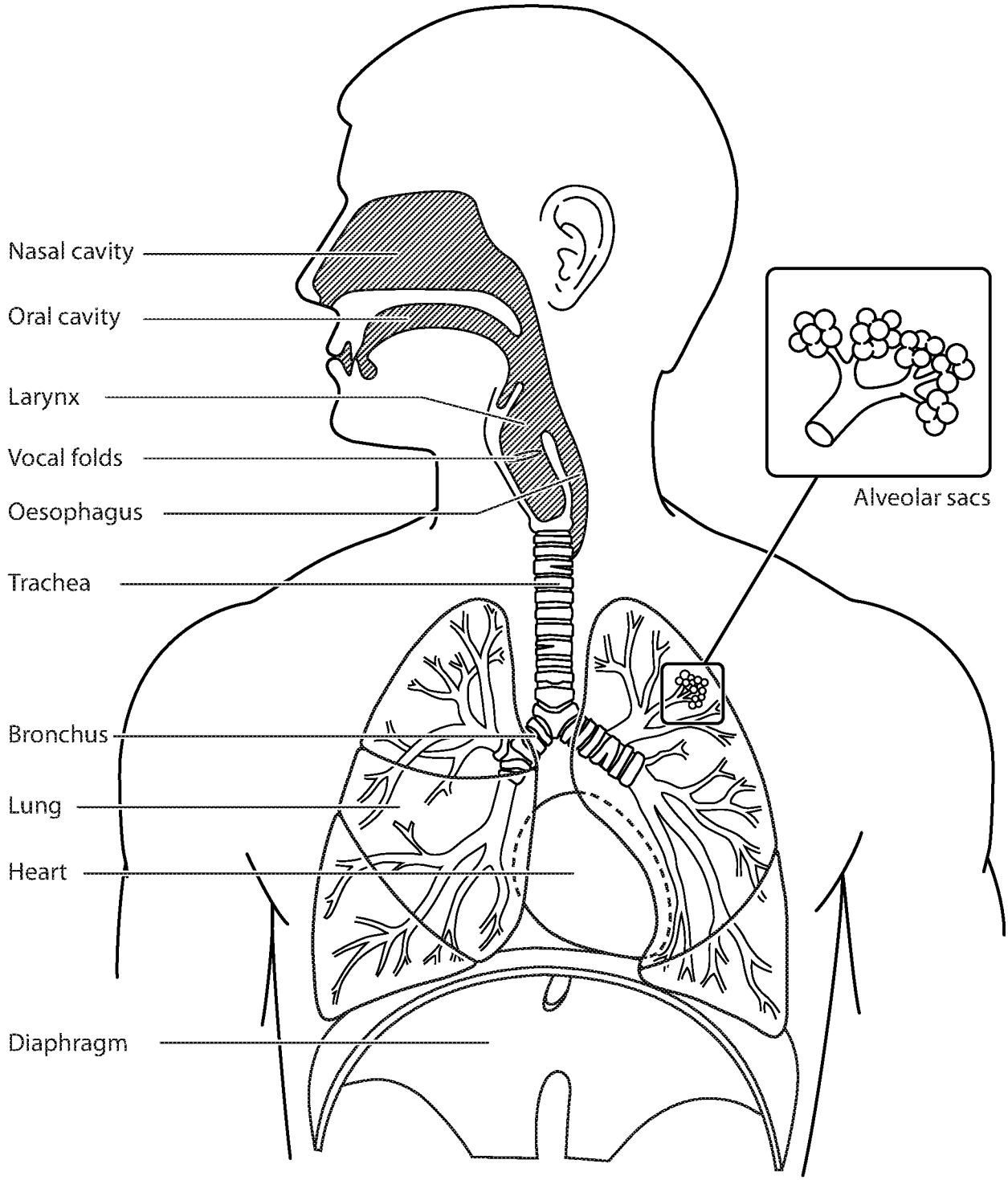

Nasal cavity
Oral cavity
Larynx
Vocal folds
Oesophagus
Trachea
Bronchus
Lung
Heart
Diaphragm
Alveolar sacs

FIG. 2A

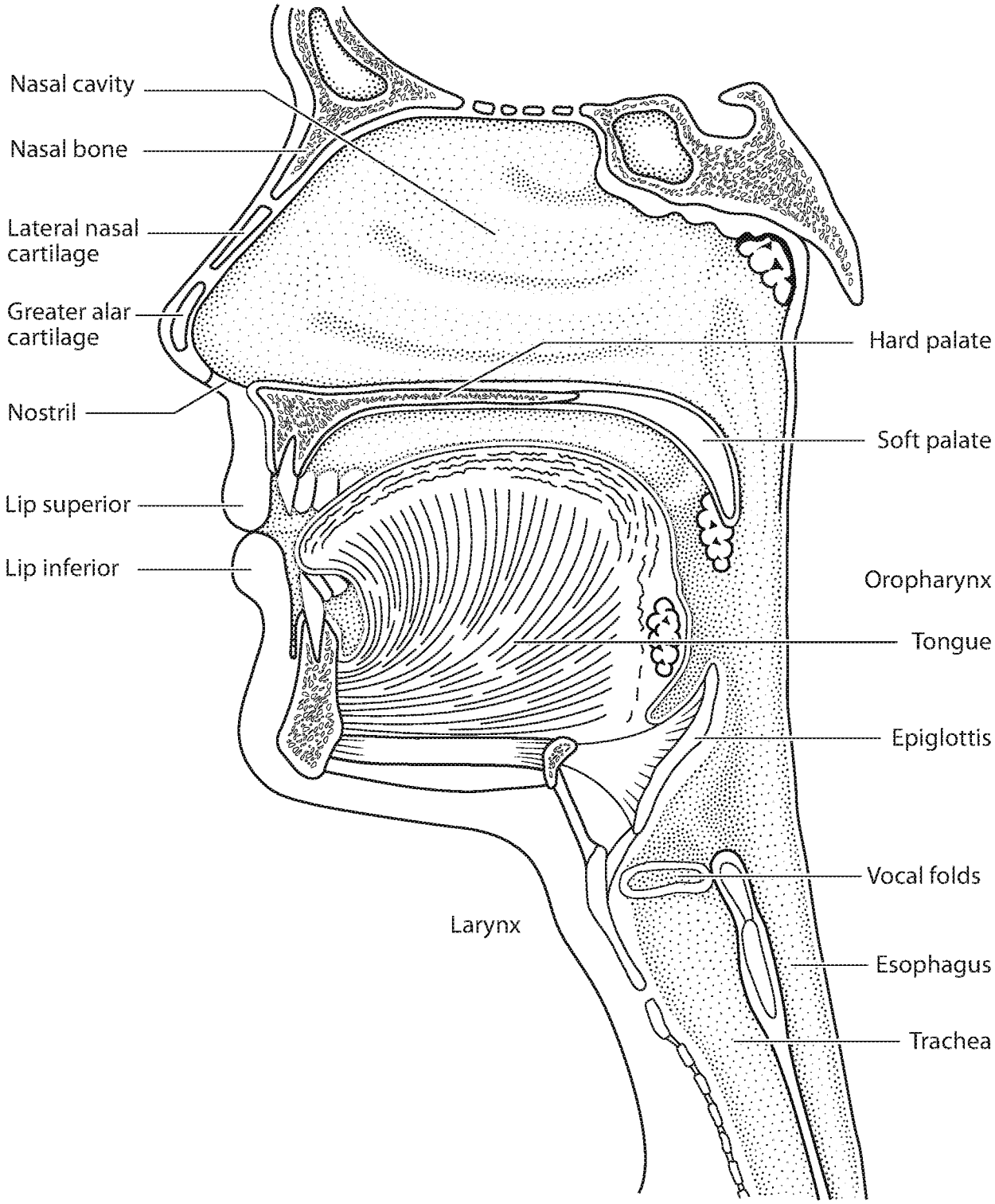

Nasal cavity
Nasal bone
Lateral nasal cartilage
Greater alar cartilage
Nostril
Lip superior
Lip inferior
Hard palate
Soft palate
Oropharynx
Tongue
Epiglottis
Vocal folds
Larynx
Esophagus
Trachea

FIG. 2B

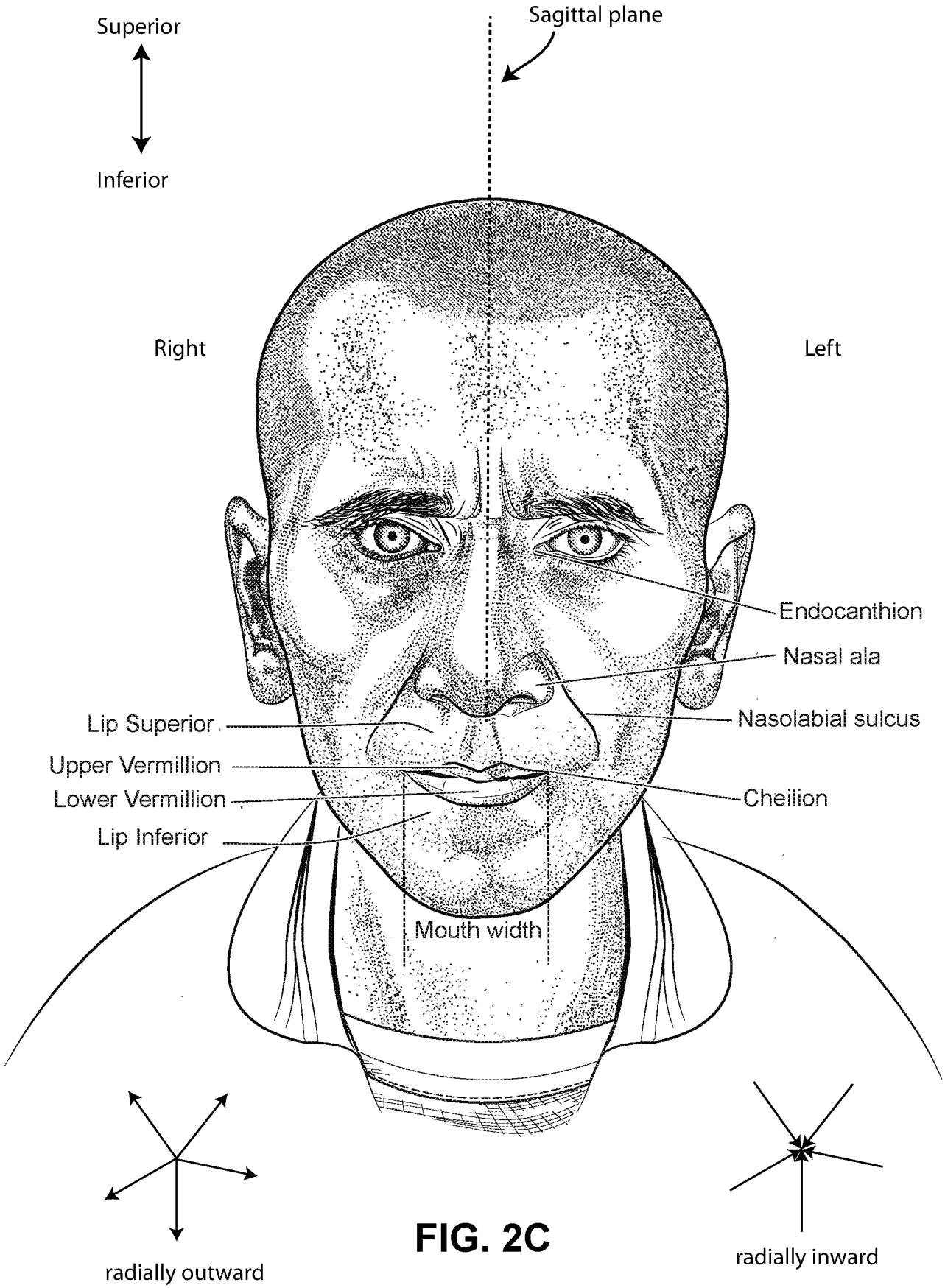

Superior
Inferior
Sagittal plane
Right
Left
Endocanthion
Nasal ala
Nasolabial sulcus
Cheilion
Lip Superior
Upper Vermillion
Lower Vermillion
Lip Inferior
Mouth width
radially outward
radially inward

FIG. 2C

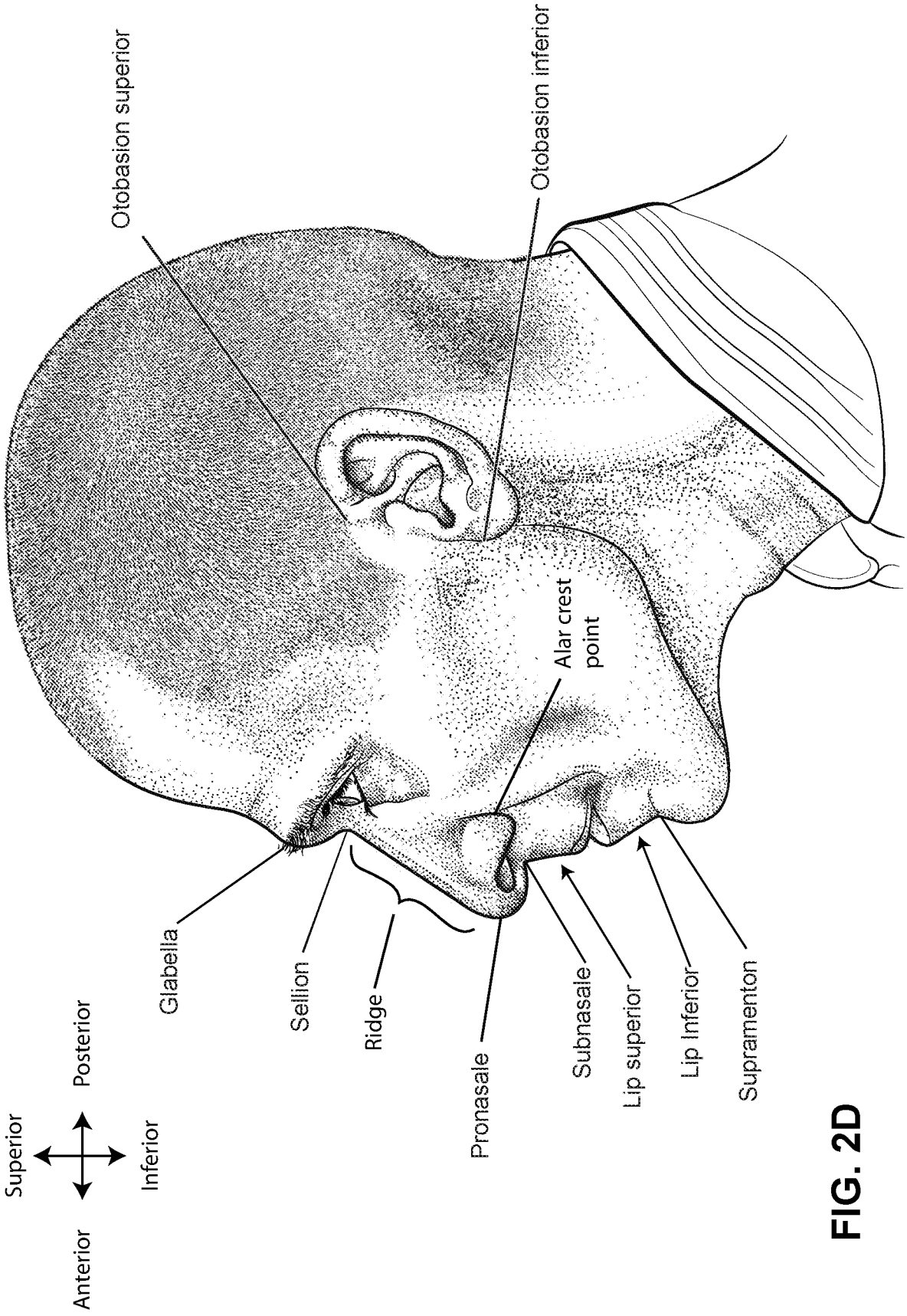

Otobasion superior
Otobasion inferior
Alar crest point
Glabella
Sellion
Ridge
Pronasale
Subnasale
Lip superior
Lip Inferior
Supramenton
Superior
Inferior
Posterior
Anterior

FIG. 2D

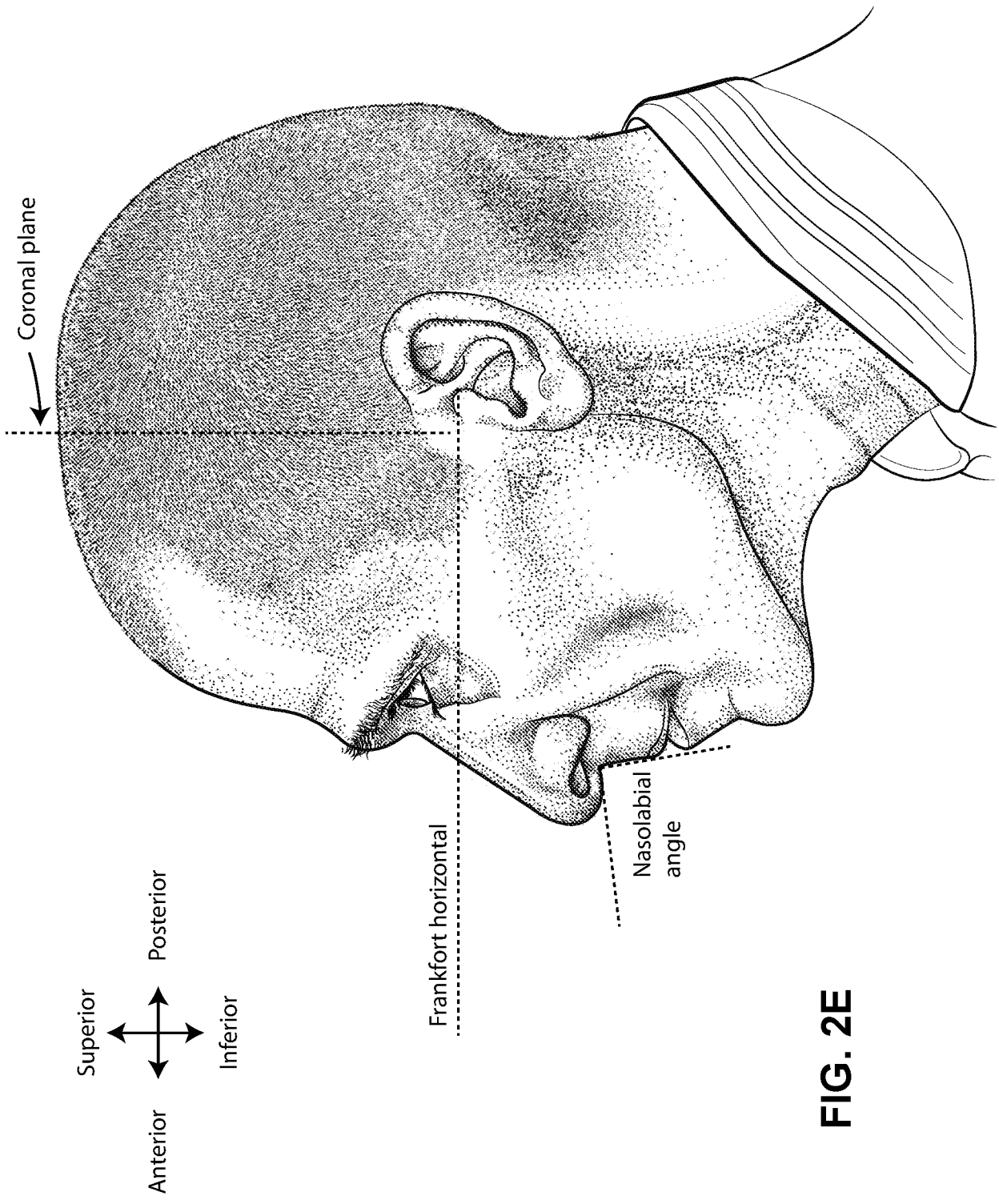

Coronal plane
Frankfort horizontal
Nasolabial angle
Superior
Inferior
Posterior
Anterior

FIG. 2E

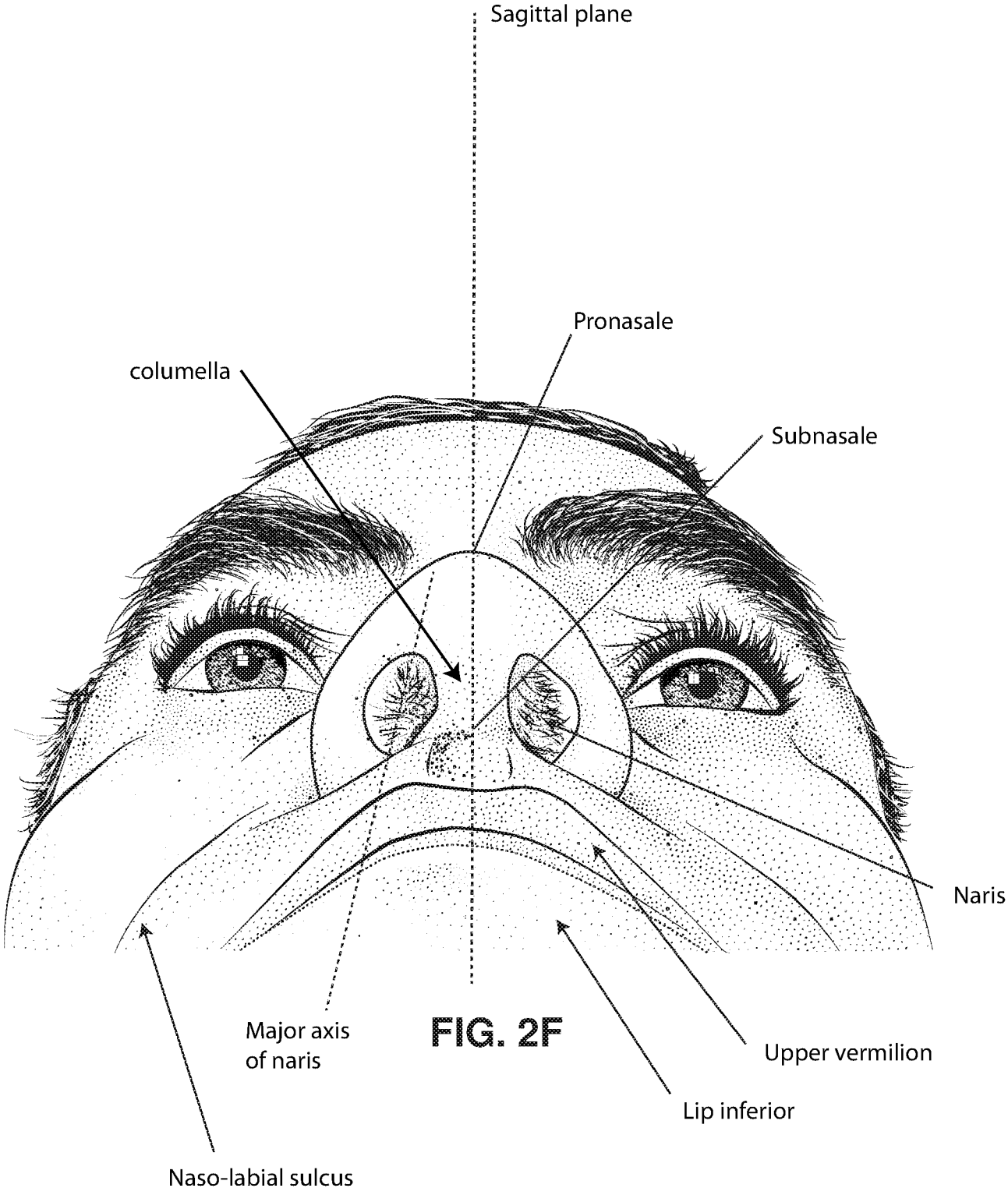

Sagittal plane
Pronasale
columella
Subnasale
Naris
Major axis
of naris
Upper vermilion
Lip inferior
Naso-labial sulcus

FIG. 2F

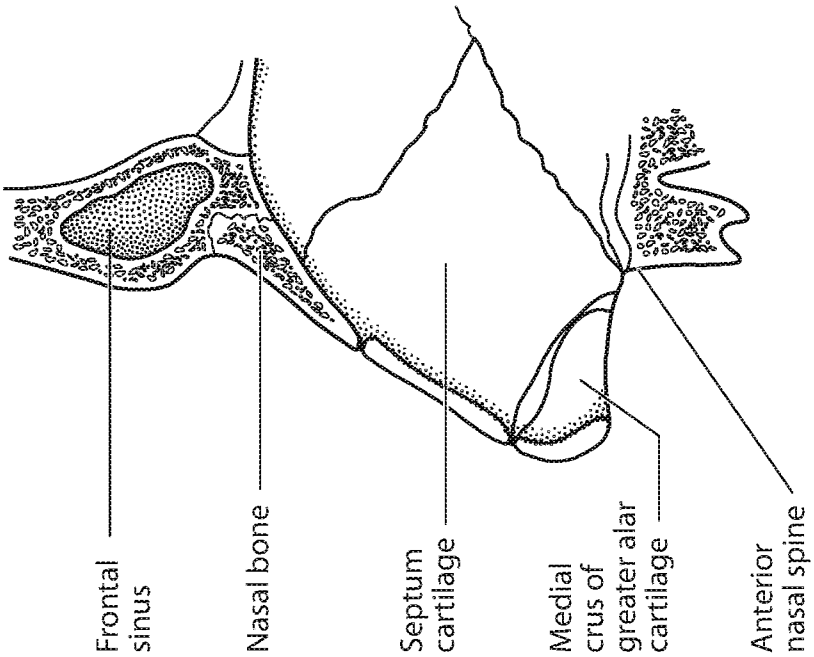


FIG. 2I

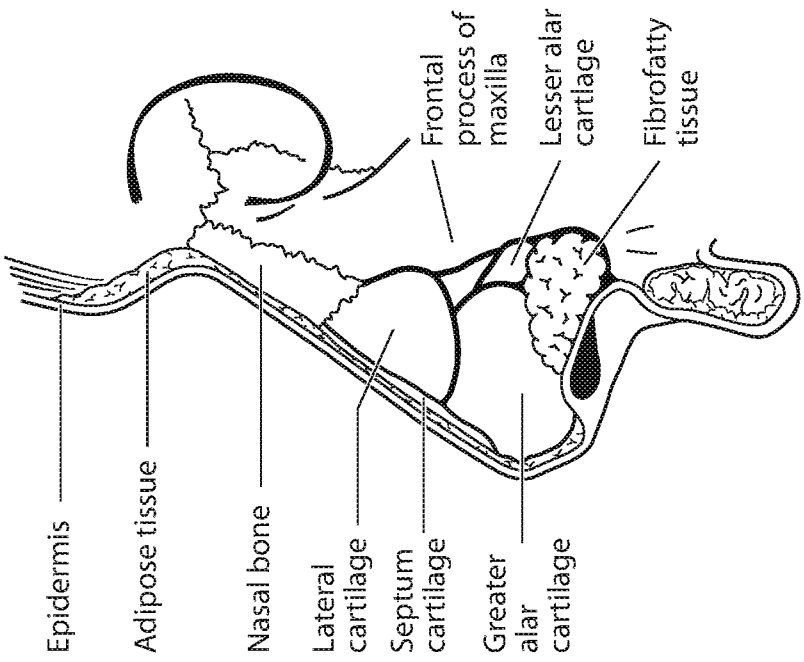


FIG. 2H



FIG. 2G

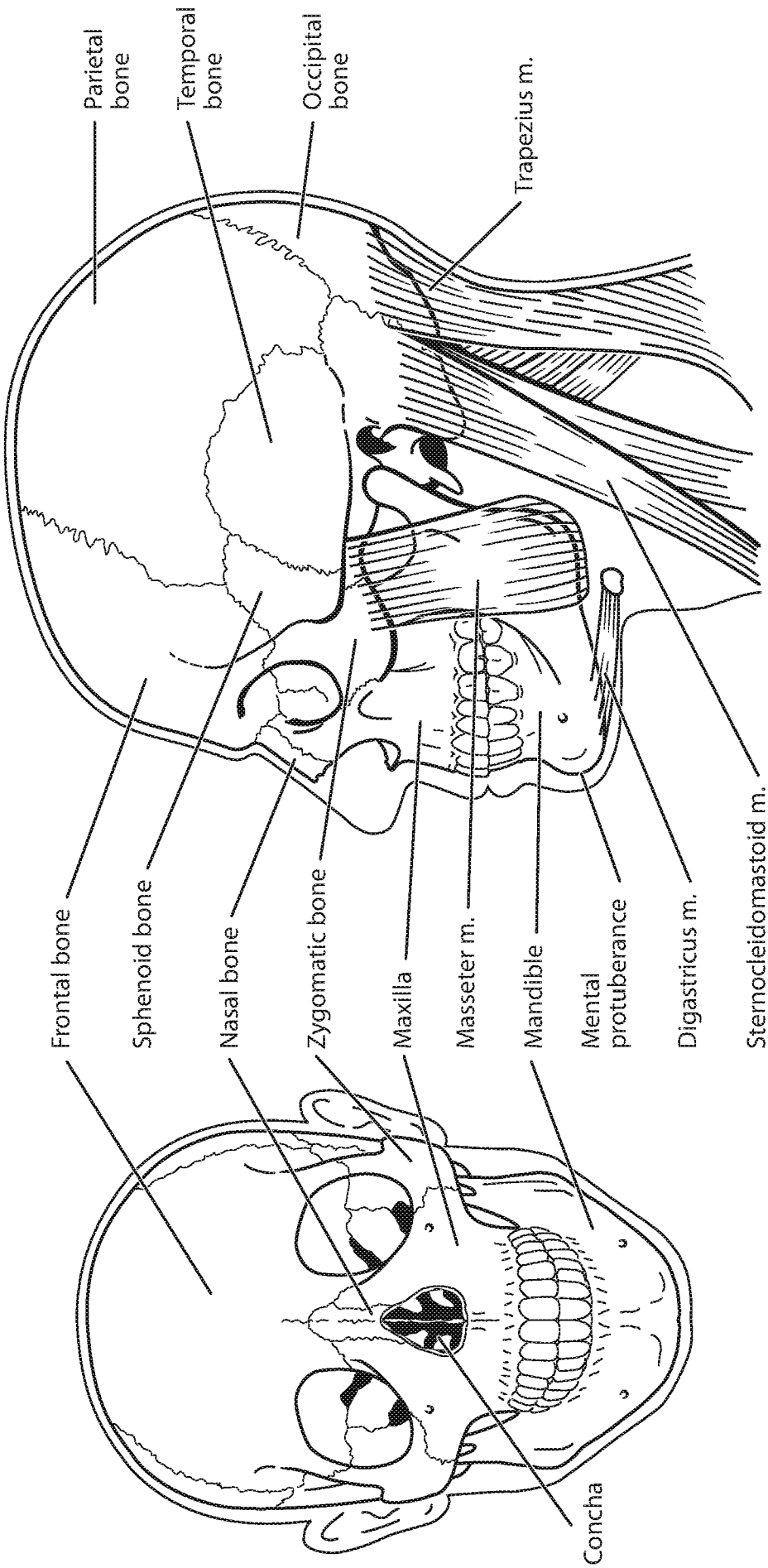

Parietal bone
Temporal bone
Occipital bone
Trapezius m.
Frontal bone
Sphenoid bone
Nasal bone
Zygomatic bone
Maxilla
Masseter m.
Mandible
Mental protuberance
Digastricus m.
Sternocleidomastoid m.
Concha

FIG. 2J

FIG. 2K

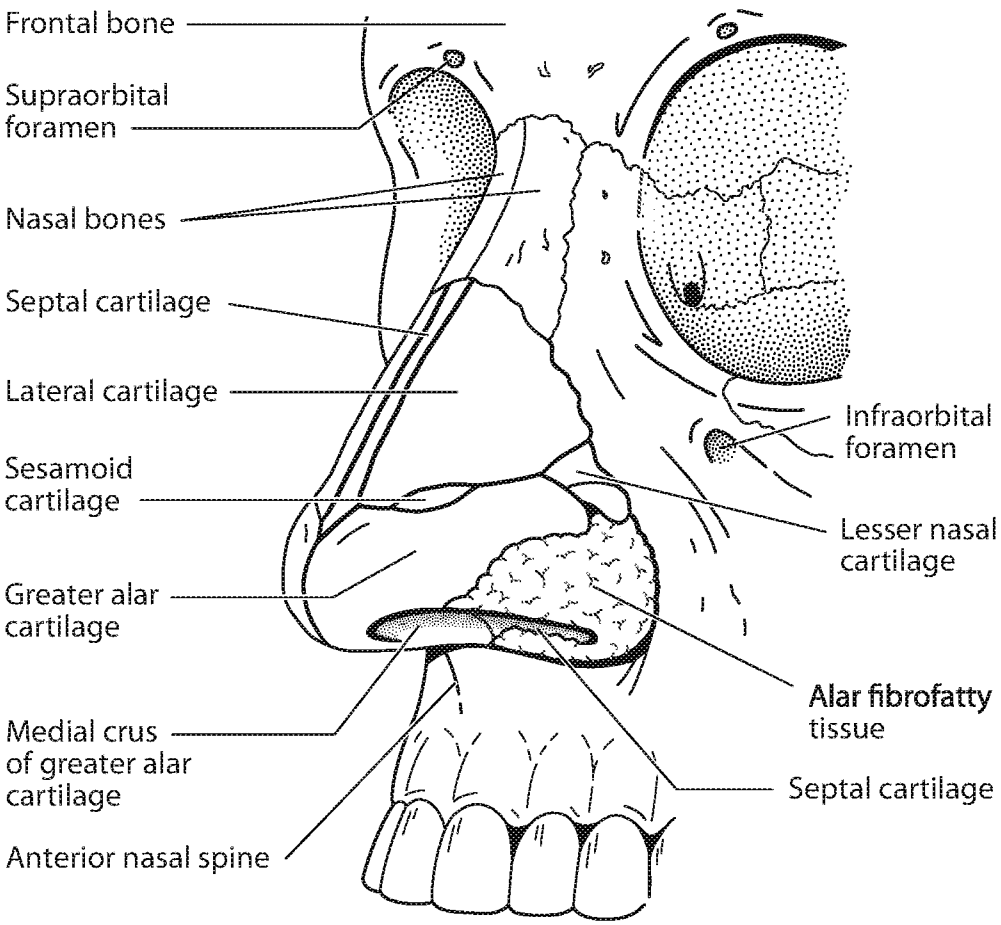

Frontal bone
Supraorbital foramen
Nasal bones
Septal cartilage
Lateral cartilage
Sesamoid cartilage
Greater alar cartilage
Medial crus of greater alar cartilage
Anterior nasal spine
Infraorbital foramen
Lesser nasal cartilage
Alar fibrofatty tissue
Septal cartilage

FIG. 2L

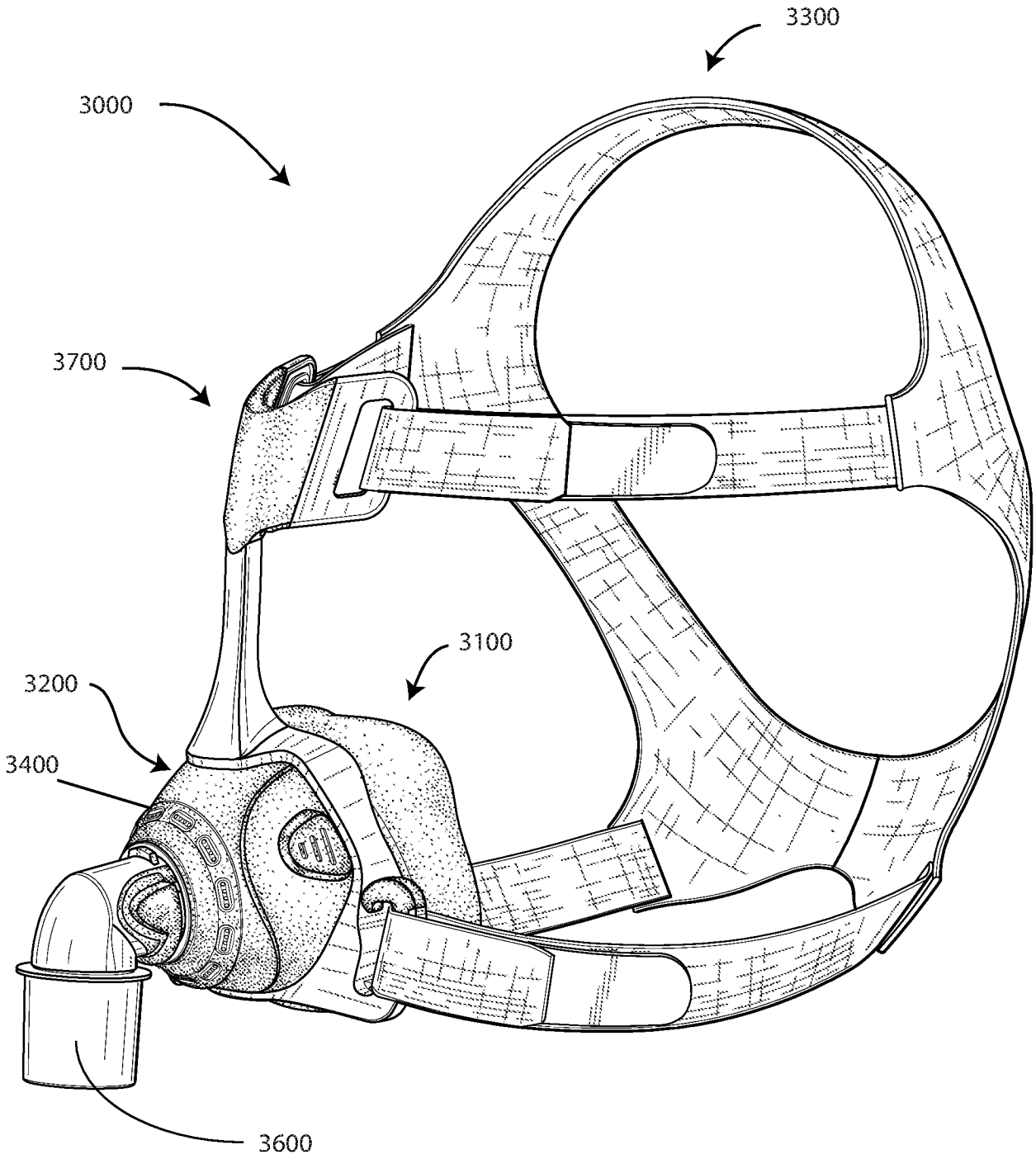


FIG. 3A

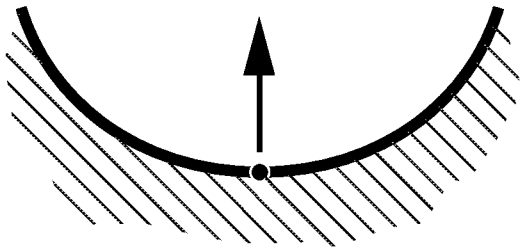


FIG. 3B

Relatively Large
Positive Curvature

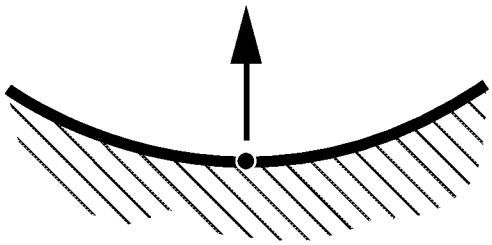


FIG. 3C

Relatively Small
Positive Curvature

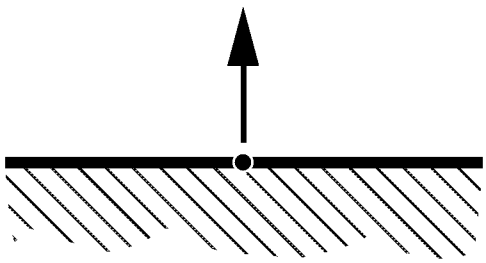


FIG. 3D

Zero Curvature

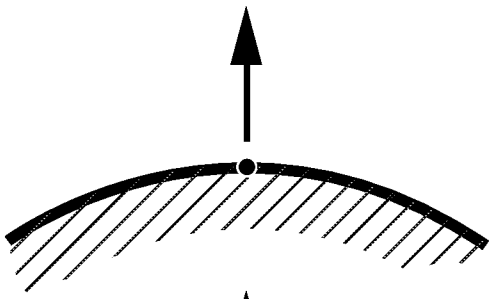


FIG. 3E

Relatively Small
Negative Curvature

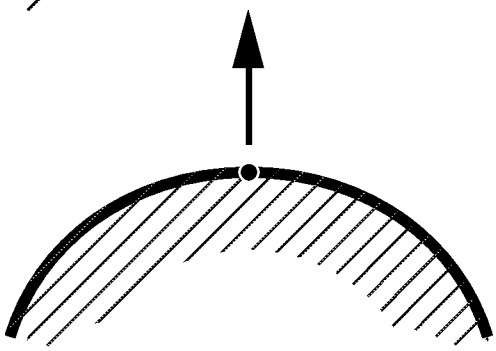


FIG. 3F

Relatively Large
Negative Curvature

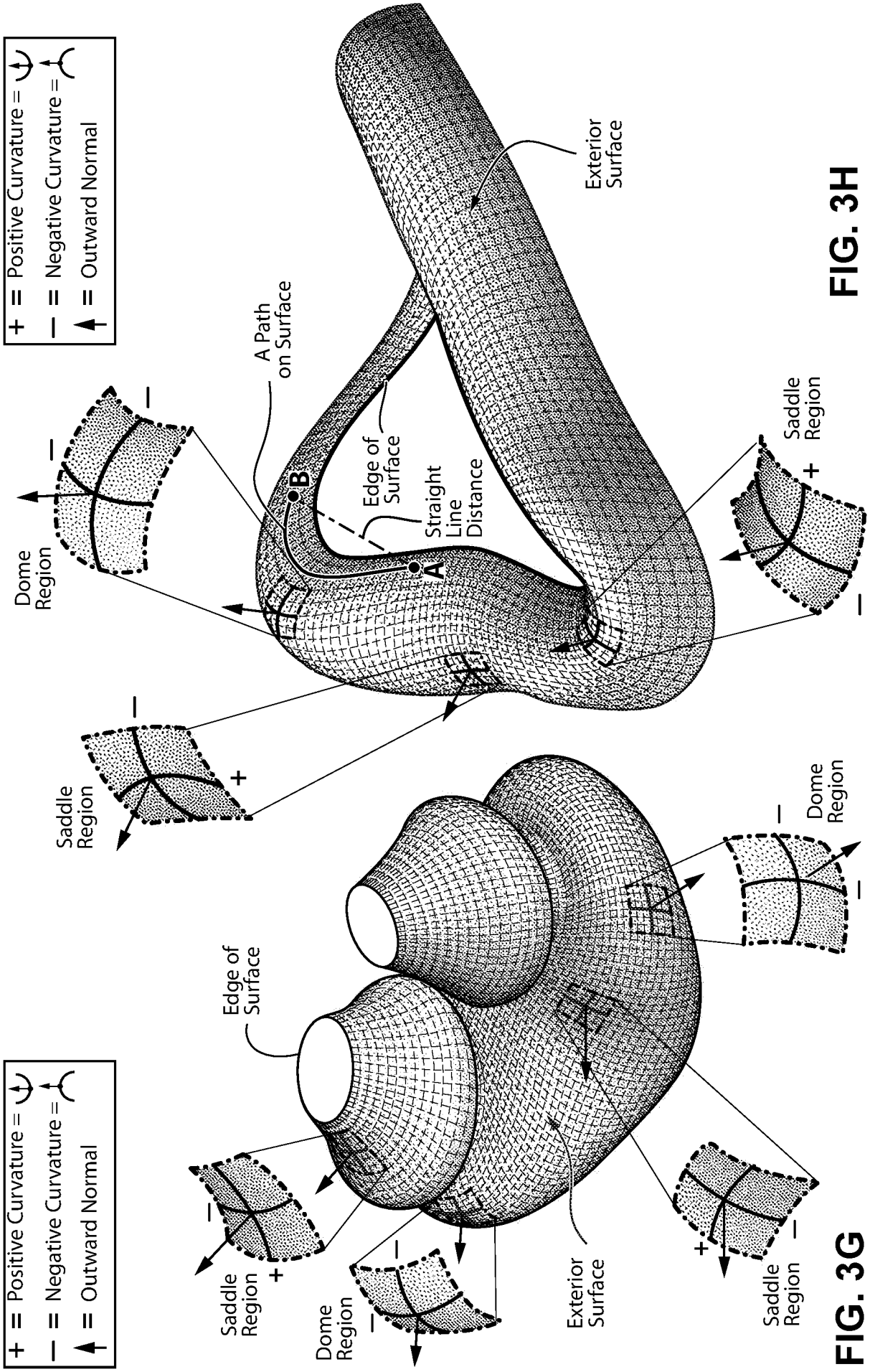

+ = Positive Curvature =
– = Negative Curvature =
= Outward Normal
Saddle Region
Dome Region
Edge of Surface
Exterior Surface
A Path on Surface
Straight Line Distance
A
B

FIG. 3G

FIG. 3H

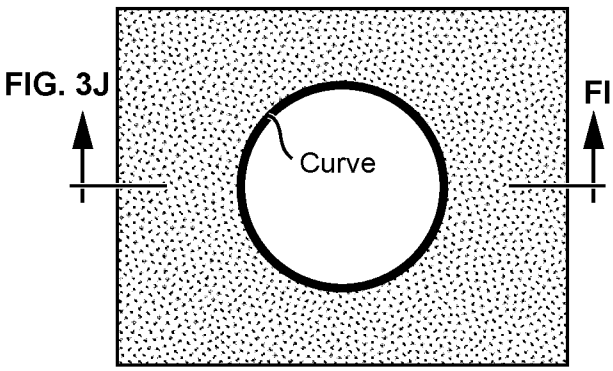


FIG. 3I

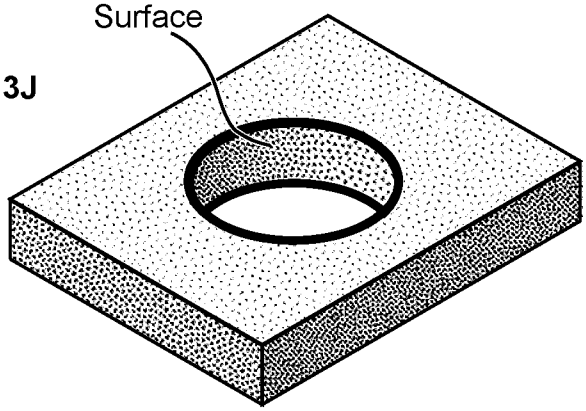


FIG. 3K

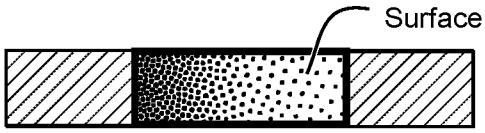


FIG. 3J

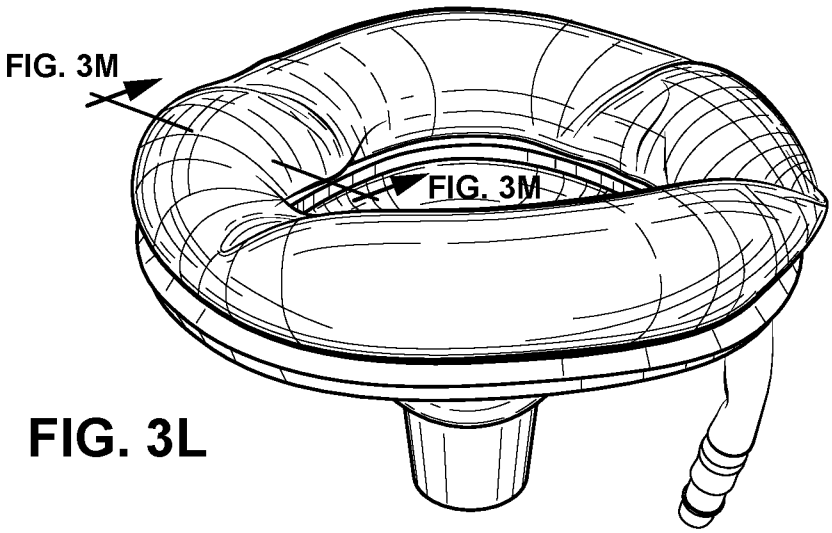


FIG. 3L

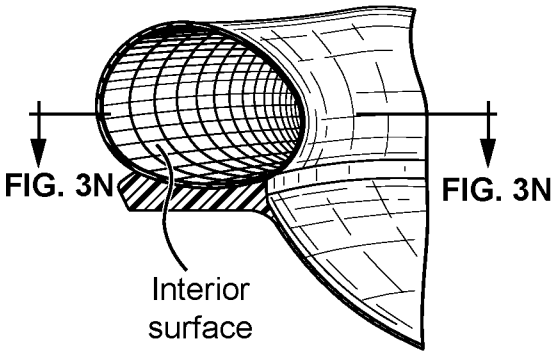


FIG. 3M

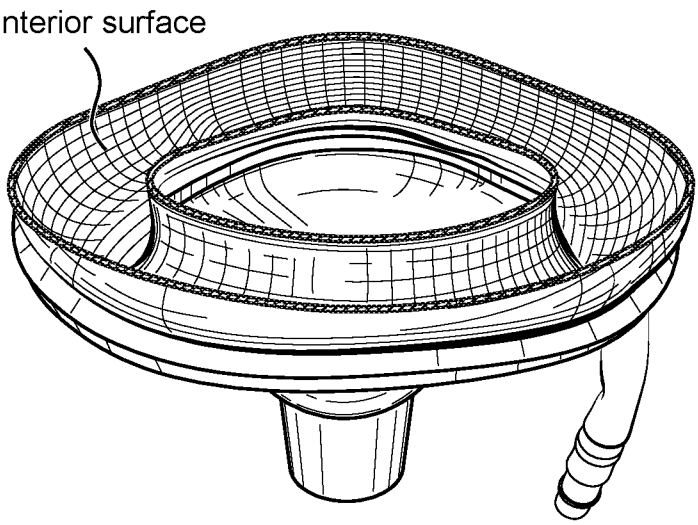


FIG. 3N

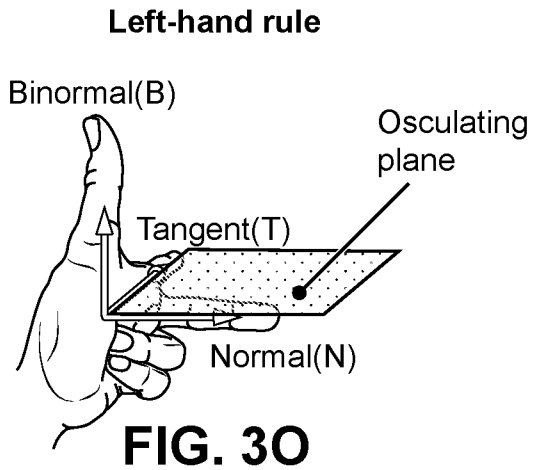


FIG. 3O

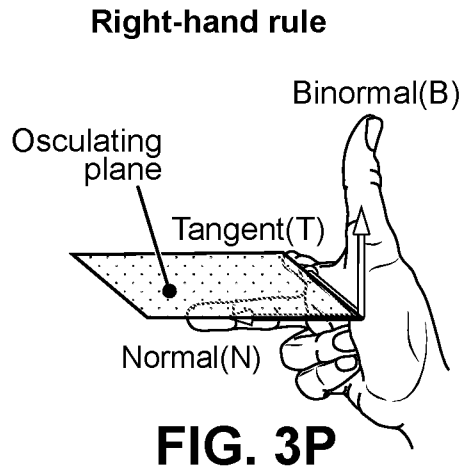


FIG. 3P

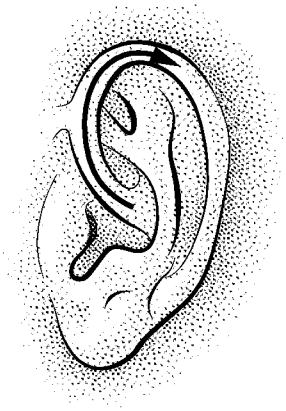
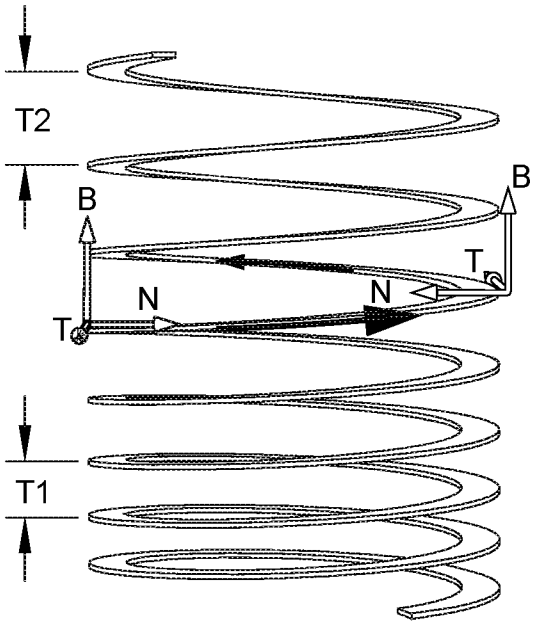


FIG. 3Q



Right-hand helix
Right-hand positive

FIG. 3S



FIG. 3R

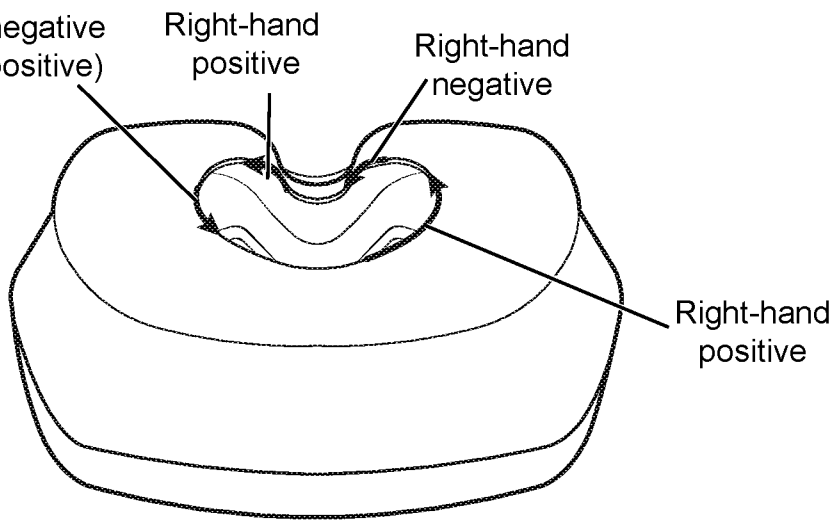


FIG. 3T

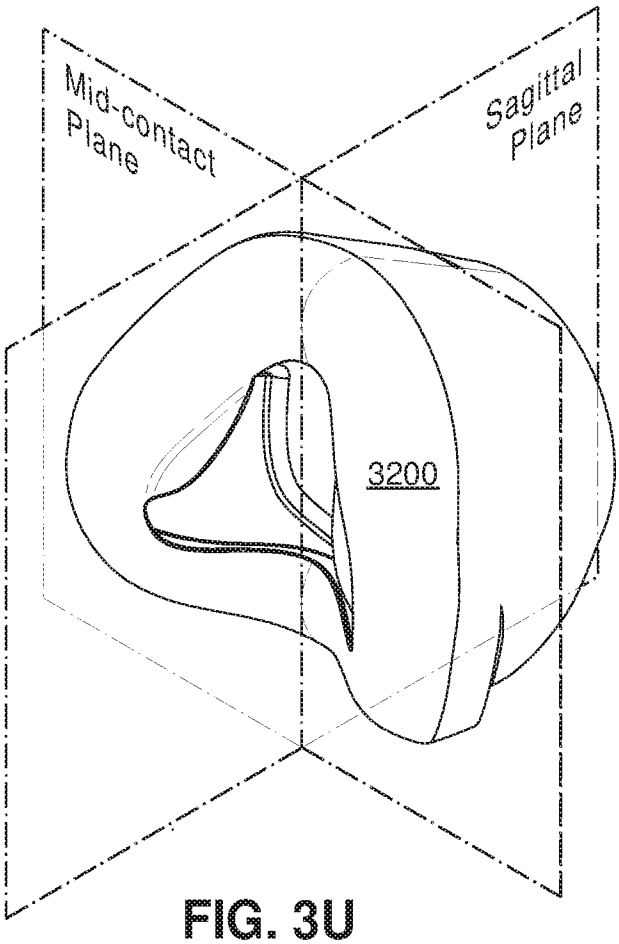


FIG. 3U

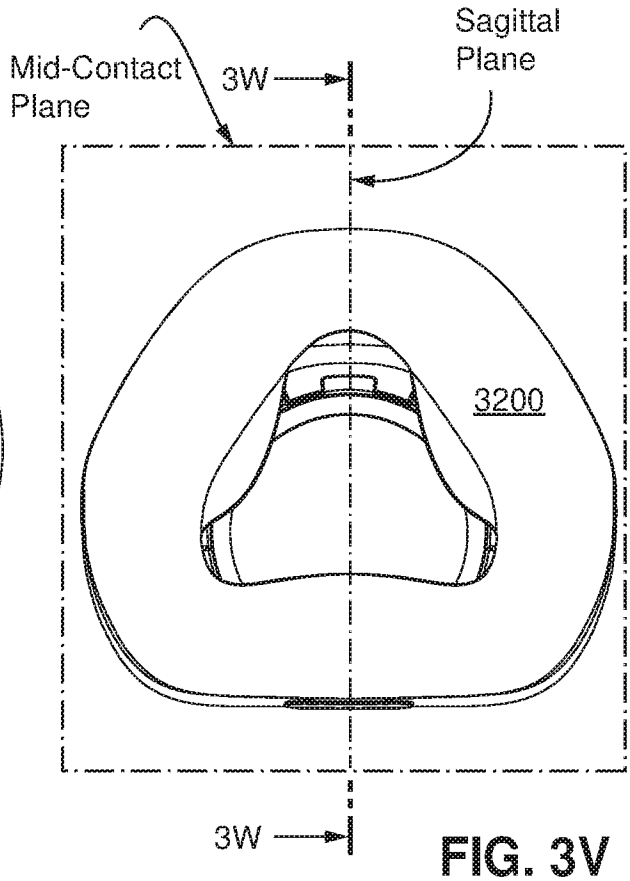


FIG. 3V

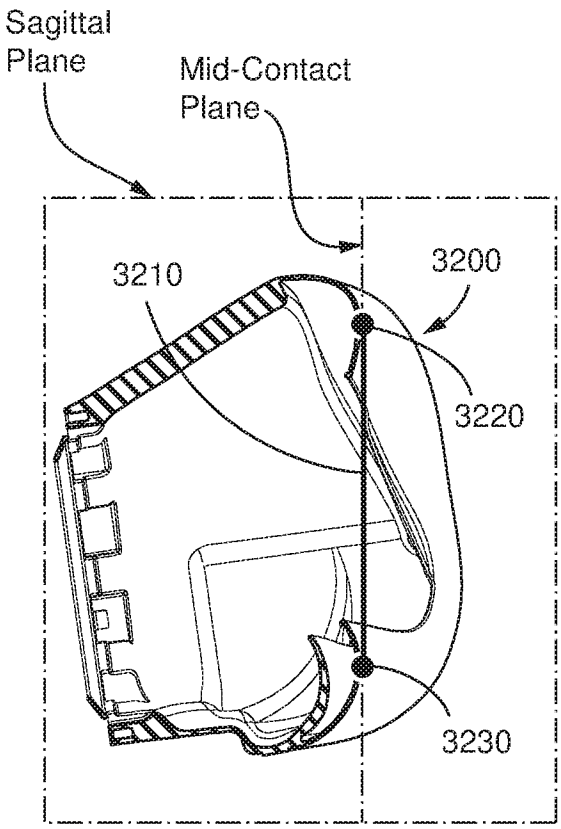


FIG. 3W

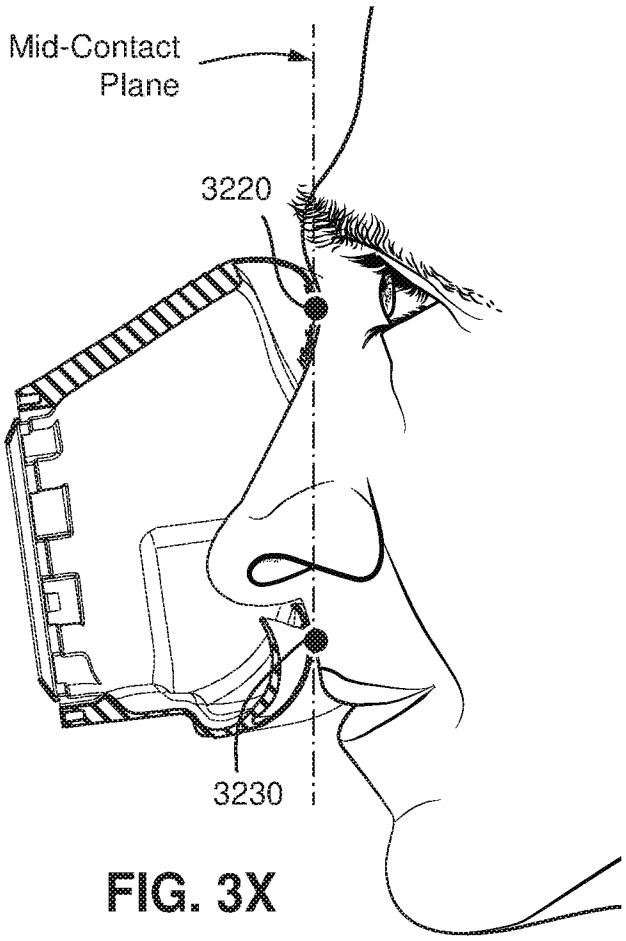


FIG. 3X

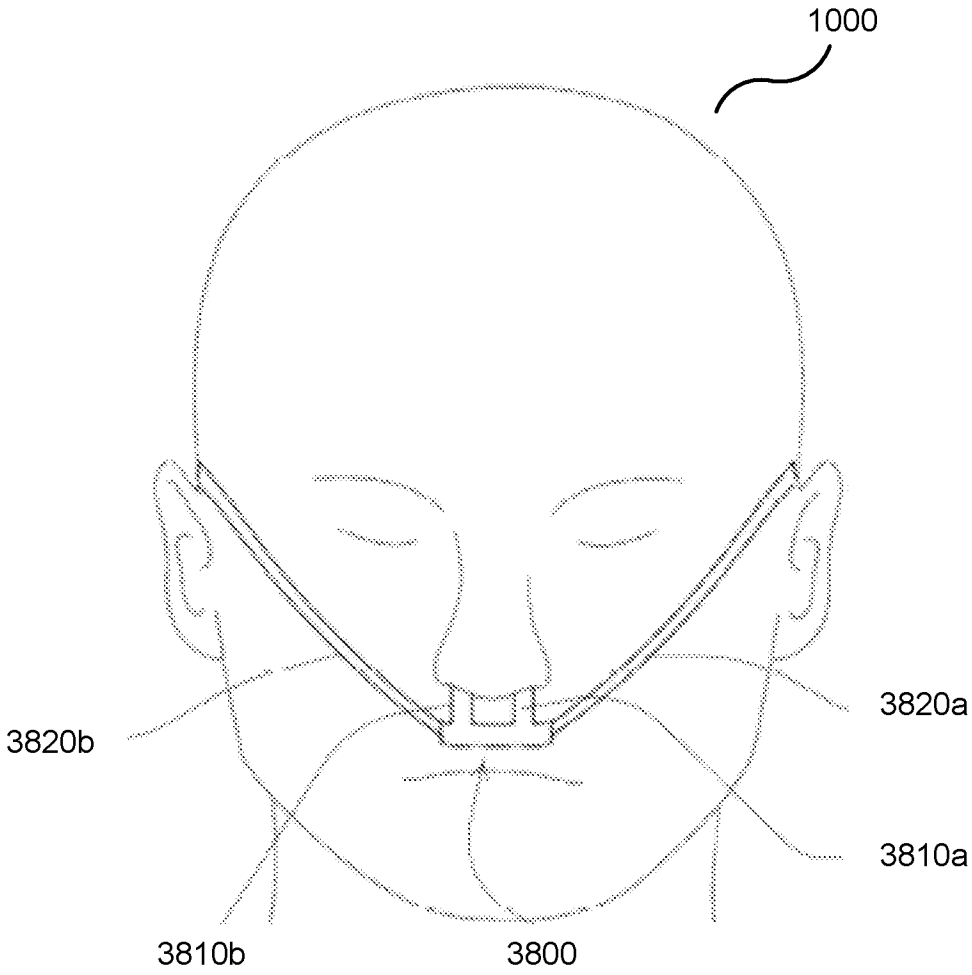


FIG. 3Y

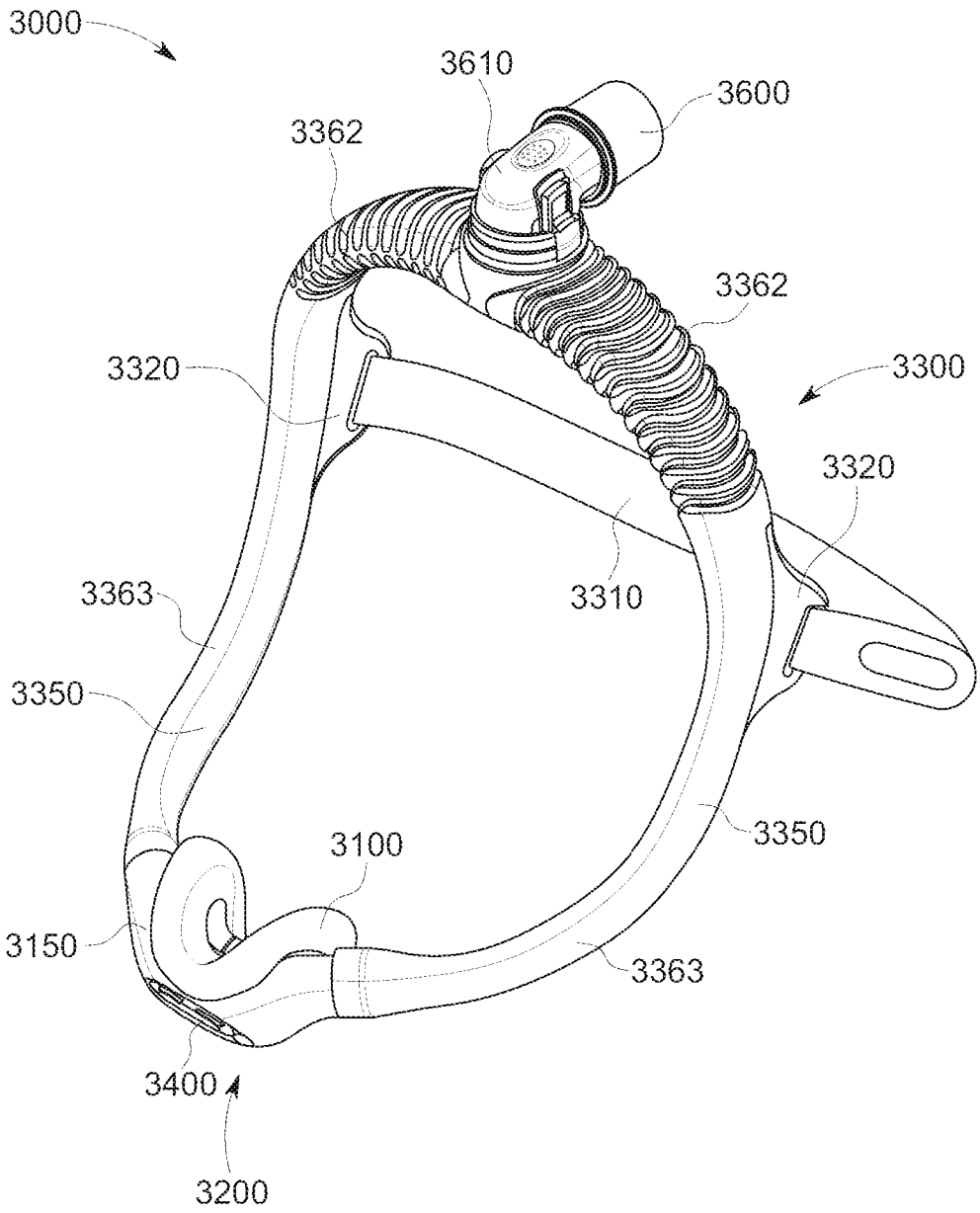

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FIG. 3Z

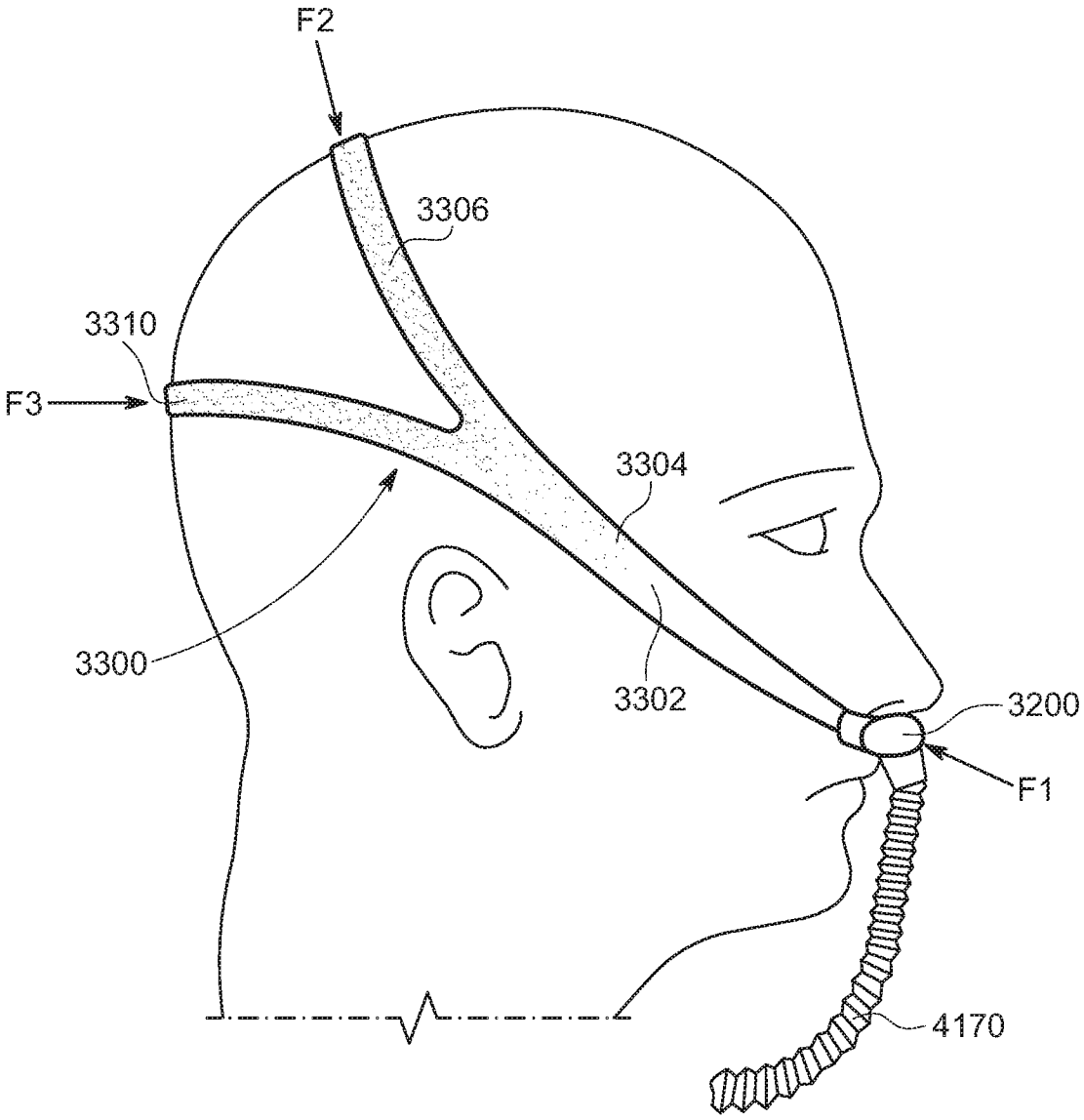


FIG. 4

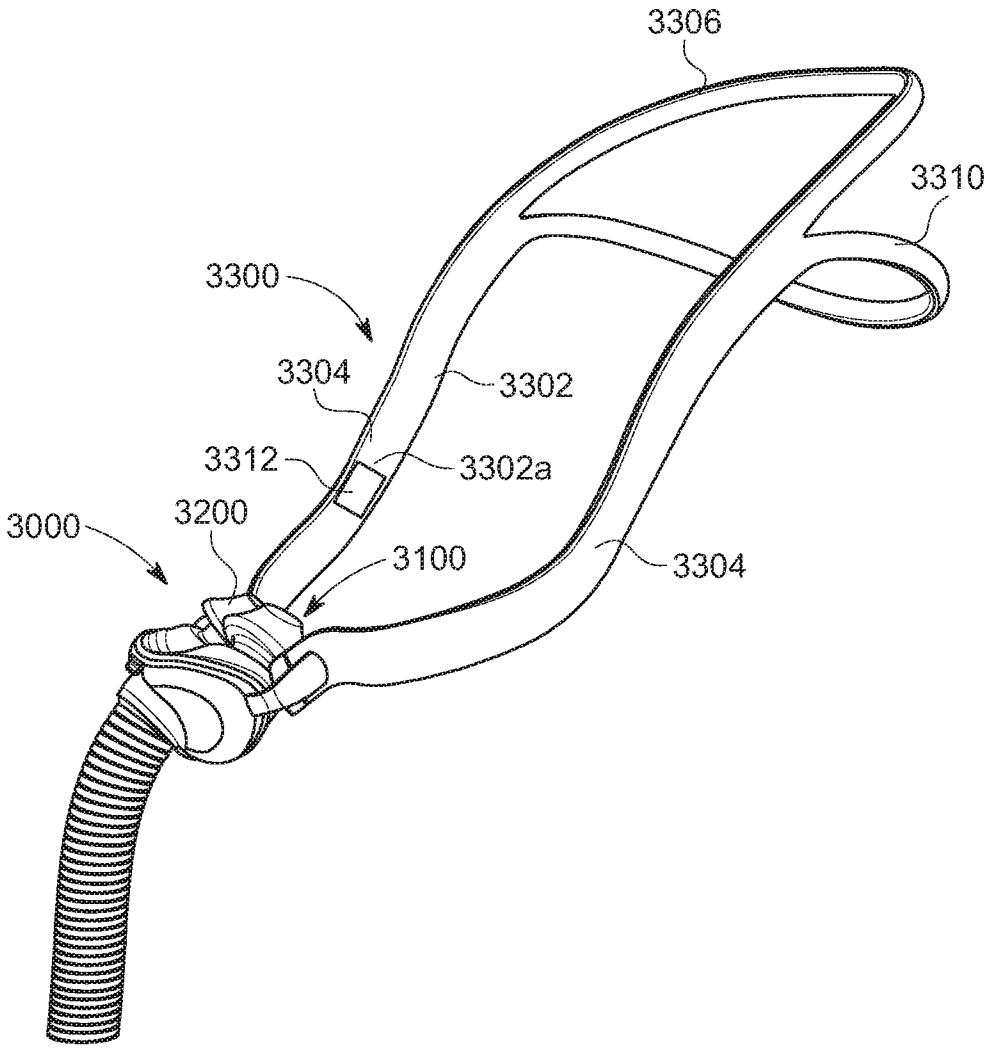


FIG. 5

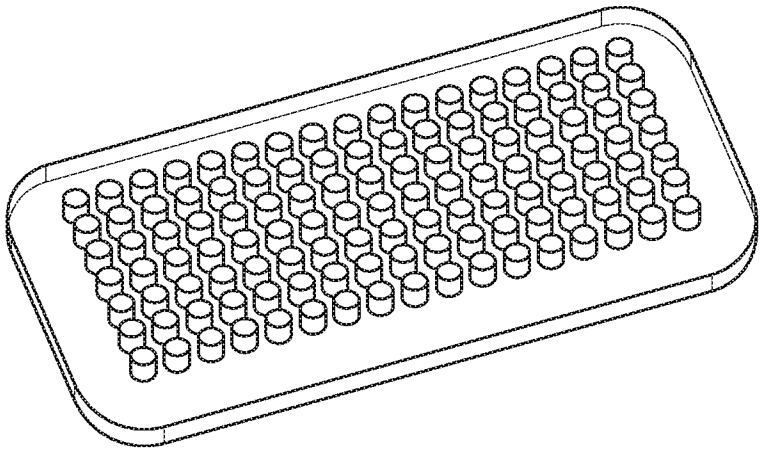


FIG. 6A

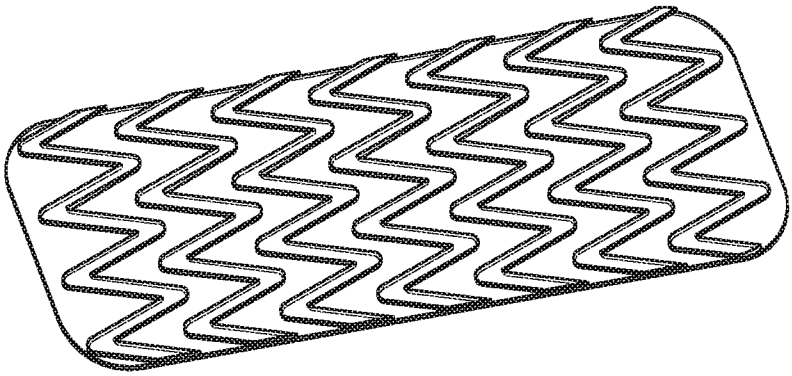


FIG. 6B

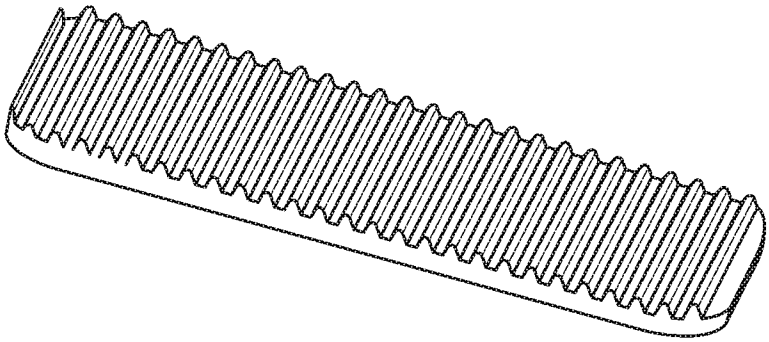


FIG. 6C

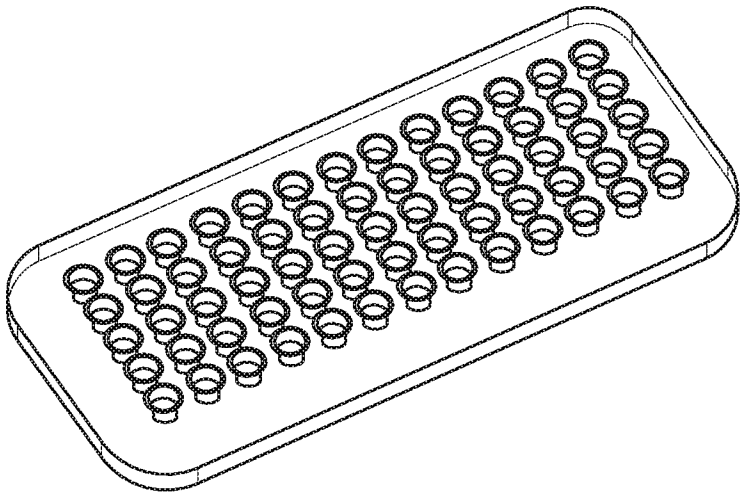


FIG. 6D

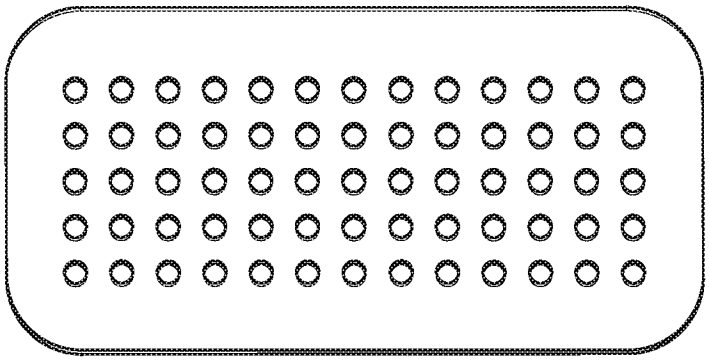


FIG. 6E

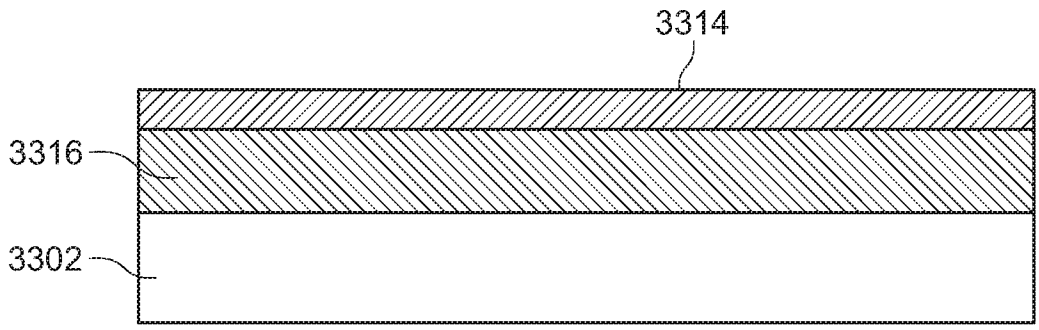


FIG. 7

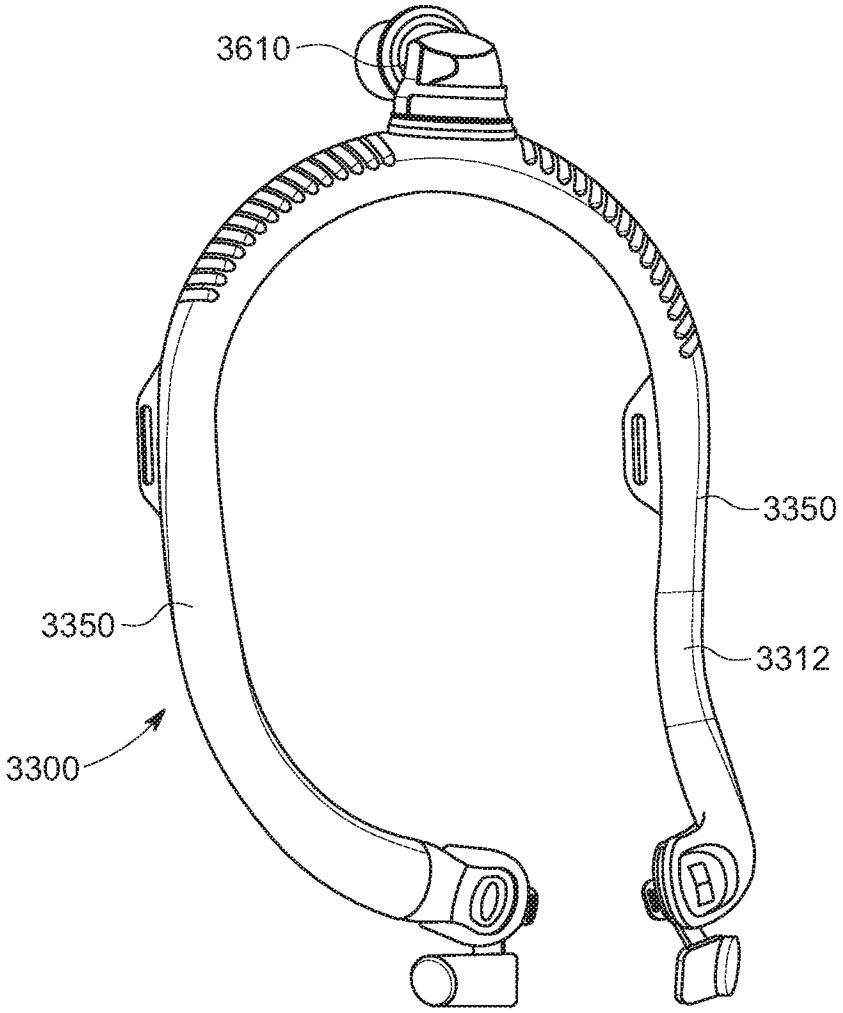


FIG. 8

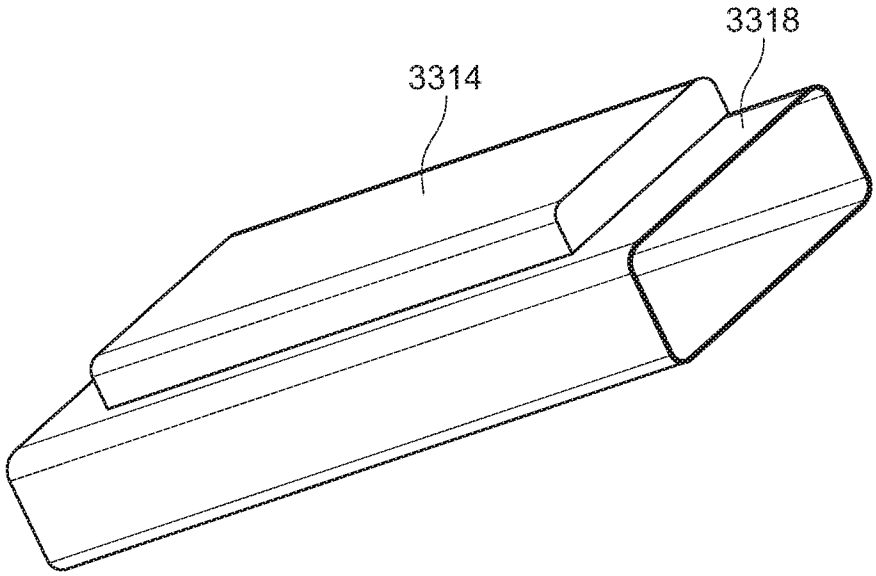


FIG. 9

INTERNATIONAL SEARCH REPORT

International application No.
PCT/AU2023/050141

A. CLASSIFICATION OF SUBJECT MATTER

A61M 16/06 (2006.01) A61M 16/08 (2006.01) A61M 16/20 (2006.01)

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)

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

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

PATENW: IPC/CPC: A61M16/06/LOW, A61M16/0683, A61M16/0688, A61M16/0633, A61M16/0683/LOW; Keywords: friction, coefficient of friction, textile, grip, silicone, adhesive, cheek, face, positioning and stabilising structure, strap, tie, band, mask, headgear, CPAP, pad, sleeve, interface

ESPACENET and GOOGLE PATENTS: Keywords: plenum chamber, therapeutic pressure, seal, patient, face, airways, friction, coefficient of friction, cheek, positioning and stabilising structure, strap, tie, band, mask, headgear, CPAP

Applicant(s)/Inventor(s) name searched in PATENW, DOCDB, DWPI and internal databases provided by IP Australia.

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
	Documents are listed in the continuation of Box C	

[X] Further documents are listed in the continuation of Box C [X] See patent family annex

* Special categories of cited documents:

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

"D" document cited by the applicant in the international application

"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	Date of mailing of the international search report
19 May 2023	19 May 2023
Name and mailing address of the ISA/AU	**Authorised officer**
AUSTRALIAN PATENT OFFICE PO BOX 200, WODEN ACT 2606, AUSTRALIA Email address: pct@ipaustralia.gov.au	Ashen Fernando AUSTRALIAN PATENT OFFICE (ISO 9001 Quality Certified Service) Telephone No. +61262108429

INTERNATIONAL SEARCH REPORT C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT		International application No. **PCT/AU2023/050141**
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 2018220535 A1 (FISHER & PAYKEL HEALTHCARE LIMITED) 06 December 2018 Figure 5B, 10; Para 0310, 0364, 0386-0390, 0416-0417, 0430	1-21
X	EP 2022528 B1 (ResMed Limited) 09 March 2016 Figure 2-1, 5-24-1, 5-39, 5-41, 10-7-1, 10-7-2, 10-7-3, 12-5; Para 0038, 0040, 0121, 0431	1-13a, 14-16, 20-21
X	WO 2017042717 A1 (FISHER & PAYKEL HEALTHCARE LIMITED) 16 March 2017 Figure 2, 3, 8, 10; Para 0313, 0316, 0365	1-13a, 14-16, 20-21
X	WO 2016193859 A1 (KONINKLIJKE PHILIPS N.V.) 08 December 2016 Figure 1B, 10, 12A, 12B; Page 14, Line 5-17	17-20
A	WO 2012080887 A2 (KONINKLIJKE PHILIPS ELECTRONICS N.V.) 21 June 2012 Figure 7C, 9; Para 30-32	8-10
A	WO 2009148956 A2 (ACCUMED INNOVATIVE TECHNOLOGIES, INC.) 10 December 2009 Figure 1, 2; Para 0008, 0043	8-10
A	WO 2010066004 A1 (RESMED LTD) 17 June 2010 Figure 14A-14G; Para 0097, 0165	8-10

INTERNATIONAL SEARCH REPORT Information on patent family members	International application No. **PCT/AU2023/050141**

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Patent Document/s Cited in Search Report		Patent Family Member/s	
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		US 2017021121 A1	26 Jan 2017
		US 10675428 B2	09 Jun 2020

Due to data integration issues this family listing may not include 10 digit Australian applications filed since May 2001.

INTERNATIONAL SEARCH REPORT Information on patent family members	International application No. **PCT/AU2023/050141**

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Patent Document/s Cited in Search Report		Patent Family Member/s	
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		US 11642484 B2	09 May 2023
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Due to data integration issues this family listing may not include 10 digit Australian applications filed since May 2001.

INTERNATIONAL SEARCH REPORT Information on patent family members	International application No. **PCT/AU2023/050141**

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INTERNATIONAL SEARCH REPORT Information on patent family members	International application No. **PCT/AU2023/050141**

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Patent Document/s Cited in Search Report		Patent Family Member/s	
Publication Number	**Publication Date**	**Publication Number**	**Publication Date**
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		US 2021252245 A1	19 Aug 2021

End of Annex

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