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(54) Title: PATIENT INTERFACE AND COMPONENTS THEREOF

(57) Abstract: 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. The present technology also relates to components formed from nonwoven composites for use in medical devices or apparatus.

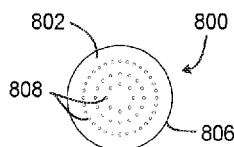


FIG. 8C



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PATIENT INTERFACE AND COMPONENTS THEREOF

1 CROSS-REFERENCE TO RELATED APPLICATIONS

[0001] This application claims the benefit of Singapore Provisional Patent Application No. 10202011925X, filed November 30, 2020, the entire contents of which is incorporated herein by reference in its entirety.

2 STATEMENT REGARDING FEDERALLY SPONSORED RESEARCH OR DEVELOPMENT

[0002] Not Applicable

3 THE NAMES OF PARTIES TO A JOINT RESEARCH DEVELOPMENT

[0003] Not Applicable

4 SEQUENCE LISTING

[0004] Not Applicable

5 BACKGROUND OF THE TECHNOLOGY

5.1 FIELD OF THE TECHNOLOGY

[0005] 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.

5.2 DESCRIPTION OF THE RELATED ART

5.2.1 Human Respiratory System and its Disorders

[0006] The respiratory system of the body facilitates gas exchange. The nose and mouth form the entrance to the airways of a patient.

[0007] 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.

[0008] A range of respiratory disorders exist. Certain disorders may be characterised by particular events, e.g. apneas, hypopneas, and hyperpneas.

[0009] Examples of respiratory disorders include Obstructive Sleep Apnea (OSA), Cheyne-Stokes Respiration (CSR), respiratory insufficiency, Obesity Hypoventilation Syndrome (OHS), Chronic Obstructive Pulmonary Disease (COPD), Neuromuscular Disease (NMD) and Chest wall disorders.

[0010] 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).

[0011] 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).

[0012] 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.

[0013] A patient with respiratory insufficiency (a form of respiratory failure) may experience abnormal shortness of breath on exercise.

[0014] 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.

[0015] 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.

[0016] 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.

[0017] 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.

[0018] 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.

5.2.2 Therapies

[0019] 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.

5.2.2.1 Respiratory pressure therapies

[0020] 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).

[0021] 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.

[0022] 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.

[0023] 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.

5.2.2.2 Flow therapies

[0024] 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.

[0025] 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.

5.2.2.3 Supplementary oxygen

[0026] For certain patients, oxygen therapy may be combined with a respiratory pressure therapy or HFT by adding supplementary oxygen to the pressurised flow of air. When oxygen is added to respiratory pressure therapy, this is referred to as RPT with supplementary oxygen. When oxygen is added to HFT, the resulting therapy is referred to as HFT with supplementary oxygen.

5.2.3 Respiratory Therapy Systems

[0027] 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.

[0028] 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.

[0029] Another form of therapy system is a mandibular repositioning device.

5.2.3.1 Patient Interface

[0030] 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 cmH₂O 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 cmH₂O. 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.

[0031] 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.

[0032] 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.

[0033] 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.

[0034] 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.

[0035] 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.

[0036] 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.

[0037] 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.

[0038] 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.

[0039] For these reasons, patient interfaces for delivery of CPAP during sleep form a distinct field.

5.2.3.1.1 Seal-forming structure

[0040] 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.

[0041] 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.

[0042] 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.

[0043] Certain seal-forming structures may be designed for mass manufacture such that one design 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.

[0044] 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.

[0045] 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.

[0046] 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.

[0047] Another form of seal-forming structure may use adhesive to achieve a seal. Some patients may find it inconvenient to constantly apply and remove an adhesive to their face.

[0048] 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.

[0049] 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.

[0050] 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).

5.2.3.1.2 Positioning and stabilising

[0051] 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.

[0052] One technique is the use of adhesives. See for example US Patent Application Publication No. US 2010/0000534. However, the use of adhesives may be uncomfortable for some.

[0053] Another technique is the use of one or more straps and/or stabilising harnesses. Many such harnesses suffer from being one or more of ill-fitting, bulky, uncomfortable and awkward to use.

5.2.3.2 Respiratory Pressure Therapy (RPT) Device

[0054] 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.

[0055] Air pressure generators are known in a range of applications, e.g. industrial-scale ventilation systems. However, air pressure generators for medical applications have particular requirements not fulfilled by more generalised air pressure generators, such as the reliability, size and weight requirements of medical devices. In addition, even devices designed for medical treatment may suffer from shortcomings, pertaining to one or more of: comfort, noise, ease of use, efficacy, size, weight, manufacturability, cost, and reliability.

[0056] An example of the special requirements of certain RPT devices is acoustic noise.

[0057] Table of noise output levels of prior RPT devices (one specimen only, measured using test method specified in ISO 3744 in CPAP mode at 10 cmH₂O).

RPT Device name	A-weighted sound pressure level dB(A)	Year (approx.)
C-Series Tango TM	31.9	2007
C-Series Tango TM with Humidifier	33.1	2007
S8 Escape TM II	30.5	2005
S8 Escape TM II with H4i TM Humidifier	31.1	2005
S9 AutoSet TM	26.5	2010
S9 AutoSet TM with H5i Humidifier	28.6	2010

[0058] One known RPT device used for treating sleep disordered breathing is the S9 Sleep Therapy System, manufactured by ResMed Limited. Another example of an RPT device is a ventilator. Ventilators such as the ResMed Stellar™ Series of Adult and Paediatric Ventilators may provide support for invasive and non-invasive non-dependent ventilation for a range of patients for treating a number of conditions such as but not limited to NMD, OHS and COPD.

[0059] The ResMed Elisée™ 150 ventilator and ResMed VS III™ ventilator may provide support for invasive and non-invasive dependent ventilation suitable for adult or paediatric patients for treating a number of conditions. These ventilators provide volumetric and barometric ventilation modes with a single or double limb circuit. RPT devices typically comprise a pressure generator, such as a motor-driven blower or a compressed gas reservoir, and are configured to supply a flow of air to the airway of a patient. In some cases, the flow of air may be supplied to the airway of the patient at positive pressure. The outlet of the RPT device is connected via an air circuit to a patient interface such as those described above.

[0060] The designer of a device may be presented with an infinite number of choices to make. Design criteria often conflict, meaning that certain design choices are far from routine or inevitable. Furthermore, the comfort and efficacy of certain aspects may be highly sensitive to small, subtle changes in one or more parameters.

5.2.3.3 Air circuit

[0061] 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.

5.2.3.4 Humidifier

[0062] 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.

[0063] A range of artificial humidification devices and systems are known, however they may not fulfil the specialised requirements of a medical humidifier.

[0064] Medical humidifiers are used to increase humidity and/or temperature of the flow of air in relation to ambient air when required, typically where the patient may be asleep or resting (e.g. at a hospital). A medical humidifier for bedside placement may be small. A medical humidifier may be configured to only humidify and/or heat the flow of air delivered to the patient without humidifying and/or heating the patient's surroundings. Room-based systems (e.g. a sauna, an air conditioner, or an evaporative cooler), for example, may also humidify air that is breathed in by the patient, however those systems would also humidify and/or heat the entire room, which may cause discomfort to the occupants. Furthermore, medical humidifiers may have more stringent safety constraints than industrial humidifiers

[0065] While a number of medical humidifiers are known, they can suffer from one or more shortcomings. Some medical humidifiers may provide inadequate humidification, some are difficult or inconvenient to use by patients.

5.2.3.5 Heat and moisture exchanger

[0066] Heat and Moisture Exchangers are devices used in mechanically ventilated patients intended to help prevent complications due to drying of the respiratory mucosa, such as mucus plugging and endotracheal tube occlusion. The basic components of heat and moisture exchangers are foam, paper, or a substance which acts as a condensation and absorption surface. The material is often impregnated with hygroscopic salts such as calcium chloride, to enhance the water-retaining capacity.

[0067] For example, electrostatic filters tend to collect water vapour by means of electrostatic attraction.

[0068] Pleated filters tend to collect water vapour by exposing the gas to a large surface area. However, these tend to be thicker, fluffier, more foam-like, and they offer greater resistance to gas flow.

[0069] A problem with using such heat and moisture exchanger is that its component cost is high, and it is a laborious process to fabricate these exchangers. Further, current heat and moisture exchangers in the market is not suitable for long term use, deteriorates over use, and has a limited lifespan of less than about 30 days. These heat and moisture exchangers also does not allow for multifunctional features, produces inconsistent performance, is not washable, is difficult to shape and integrate into mask, is not adjustable and there is no means to control the level of humidity. It also has a bulky geometry and can be noisy. Different levels of humidification requirements may also be required based on country and patient. Overall, it leads to a poor user experience.

5.2.3.6 Oxygen source

[0070] Experts in this field have recognized that exercise for respiratory failure patients provides long term benefits that slow the progression of the disease, improve quality of life and extend patient longevity. Most stationary forms of exercise like tread mills and stationary bicycles, however, are too strenuous for these patients. As a result, the need for mobility has long been recognized. Until recently, this mobility has been facilitated by the use of small compressed oxygen tanks or cylinders mounted on a cart with dolly wheels. The disadvantage of these tanks is that they contain a finite amount of oxygen and are heavy, weighing about 50 pounds when mounted.

[0071] Oxygen concentrators have been in use for about 50 years to supply oxygen for respiratory therapy. Traditional oxygen concentrators have been bulky and heavy making ordinary ambulatory activities with them difficult and impractical. Recently, companies that manufacture large stationary oxygen concentrators began developing portable oxygen concentrators (POCs). The advantage of POCs is that they can produce a theoretically endless supply of oxygen. In order to make these devices small for mobility, the various systems necessary for the production of oxygen enriched gas are condensed. POCs seek to utilize their produced oxygen as efficiently as possible, in order to minimise weight, size, and power consumption. This may be achieved by delivering the oxygen as series of pulses, each pulse or “bolus” timed to coincide with the onset of inhalation. This therapy mode is known as

pulsed oxygen delivery (POD) or demand mode, in contrast with traditional continuous flow delivery more suited to stationary oxygen concentrators.

5.2.3.7 Data Management

[0072] There may be clinical reasons to obtain data to determine whether the patient prescribed with respiratory therapy has been “compliant”, e.g. that the patient has used their RPT device according to one or more “compliance rules”. One example of a compliance rule for CPAP therapy is that a patient, in order to be deemed compliant, is required to use the RPT device for at least four hours a night for at least 21 of 30 consecutive days. In order to determine a patient's compliance, a provider of the RPT device, such as a health care provider, may manually obtain data describing the patient's therapy using the RPT device, calculate the usage over a predetermined time period, and compare with the compliance rule. Once the health care provider has determined that the patient has used their RPT device according to the compliance rule, the health care provider may notify a third party that the patient is compliant.

[0073] There may be other aspects of a patient's therapy that would benefit from communication of therapy data to a third party or external system.

[0074] Existing processes to communicate and manage such data can be one or more of costly, time-consuming, and error-prone.

5.2.3.8 Mandibular repositioning

[0075] A mandibular repositioning device (MRD) or mandibular advancement device (MAD) is one of the treatment options for sleep apnea and snoring. It is an adjustable oral appliance available from a dentist or other supplier that holds the lower jaw (mandible) in a forward position during sleep. The MRD is a removable device that a patient inserts into their mouth prior to going to sleep and removes following sleep. Thus, the MRD is not designed to be worn all of the time. The MRD may be custom made or produced in a standard form and includes a bite impression portion designed to allow fitting to a patient's teeth. This mechanical protrusion of the lower jaw expands the space behind the tongue, puts tension on the pharyngeal walls to reduce collapse of the airway and diminishes palate vibration.

[0076] In certain examples a mandibular advancement device may comprise an upper splint that is intended to engage with or fit over teeth on the upper jaw or maxilla and a lower splint that is intended to engage with or fit over teeth on the upper jaw or mandible. The upper and lower splints are connected together laterally via a pair of connecting rods. The pair of connecting rods are fixed symmetrically on the upper splint and on the lower splint.

[0077] In such a design the length of the connecting rods is selected such that when the MRD is placed in a patient's mouth the mandible is held in an advanced position. The length of the connecting rods may be adjusted to change the level of protrusion of the mandible. A dentist may determine a level of protrusion for the mandible that will determine the length of the connecting rods.

[0078] Some MRDs are structured to push the mandible forward relative to the maxilla while other MADs, such as the ResMed Narval CC™ MRD are designed to retain the mandible in a forward position. This device also reduces or minimises dental and temporo-mandibular joint (TMJ) side effects. Thus, it is configured to minimise or prevent any movement of one or more of the teeth.

5.2.3.9 Vent technologies

[0079] 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.

[0080] 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.

[0081] 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.

[0082] Table of noise of prior masks (ISO 17510-2:2007, 10 cmH₂O pressure at 1m)

Mask name	Mask type	A-weighted sound power level dB(A) (uncertainty)	A-weighted sound pressure dB(A) (uncertainty)	Year (approx.)
Glue-on (*)	nasal	50.9	42.9	1981
ResCare standard (*)	nasal	31.5	23.5	1993
ResMed Mirage™ (*)	nasal	29.5	21.5	1998
ResMed UltraMirage™ M	nasal	36 (3)	28 (3)	2000
ResMed Mirage Activa™	nasal	32 (3)	24 (3)	2002
ResMed Mirage Micro™	nasal	30 (3)	22 (3)	2008
ResMed Mirage™ SoftGel	nasal	29 (3)	22 (3)	2008
ResMed Mirage™ FX	nasal	26 (3)	18 (3)	2010
ResMed Mirage Swift™ (*)	nasal pillows	37	29	2004
ResMed Mirage Swift™ II	nasal pillows	28 (3)	20 (3)	2005
ResMed Mirage Swift™ LT	nasal pillows	25 (3)	17 (3)	2008
ResMed AirFit P10	nasal pillows	21 (3)	13 (3)	2014

[0083] (* one specimen only, measured using test method specified in ISO 3744 in CPAP mode at 10 cmH₂O)

[0084] Sound pressure values of a variety of objects are listed below

Object	A-weighted sound pressure dB(A)	Notes
Vacuum cleaner: Nilfisk Walter Broadly Litter Hog: B+ Grade	68	ISO 3744 at 1m distance
Conversational speech	60	1m distance
Average home	50	
Quiet library	40	
Quiet bedroom at night	30	
Background in TV studio	20	

5.2.4 Screening, Diagnosis, and Monitoring Systems

[0085] Polysomnography (PSG) is a conventional system for diagnosis and monitoring of cardio-pulmonary disorders, and typically involves expert clinical staff to apply the system. PSG typically involves the placement of 15 to 20 contact sensors on a patient in order to record various bodily signals such as electroencephalography (EEG), electrocardiography (ECG), electrooculography (EOG), electromyography (EMG), etc. PSG for sleep disordered breathing has involved two nights of observation of a patient in a clinic, one night of pure diagnosis and a second night of titration of treatment parameters by a clinician. PSG is therefore expensive and inconvenient. In particular, it is unsuitable for home screening / diagnosis / monitoring of sleep disordered breathing.

[0086] Screening and diagnosis generally describe the identification of a condition from its signs and symptoms. Screening typically gives a true / false result indicating whether or not a patient’s SDB is severe enough to warrant further investigation, while diagnosis may result in clinically actionable information. Screening and diagnosis tend to be one-off processes, whereas monitoring the progress of a condition can continue indefinitely. Some screening / diagnosis systems are suitable only for screening / diagnosis, whereas some may also be used for monitoring.

[0087] Clinical experts may be able to screen, diagnose, or monitor patients adequately based on visual observation of PSG signals. However, there are circumstances where a clinical expert may not be available, or a clinical expert may

not be affordable. Different clinical experts may disagree on a patient's condition. In addition, a given clinical expert may apply a different standard at different times.

6 BRIEF SUMMARY OF THE TECHNOLOGY

[0088] 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. The present invention is also directed to components for use in the medical devices.

[0089] A first aspect of the present technology relates to apparatus used in the screening, diagnosis, monitoring, amelioration, treatment or prevention of a respiratory disorder.

[0090] Another aspect of the present technology relates to methods used in the screening, diagnosis, monitoring, amelioration, treatment or prevention of a respiratory disorder.

[0091] 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.

[0092] One form of the present technology is a patient interface comprising a plenum chamber pressurizable to a therapeutic pressure, a seal-forming structure constructed and arranged to form a seal with a region of the patient's face, and a positioning and stabilising structure to provide a force to hold the seal-forming structure in a therapeutically effective position.

[0093] In some forms, a heat and moisture exchanger may be positioned (e.g., removably or permanently) within the plenum chamber in order to improve humidification performance.

[0094] One form of the present technology is a patient interface comprising: a plenum chamber pressurisable to a therapeutic pressure of at least 4 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.

[0095] In some forms, a heat and moisture exchanger may be positioned (e.g., removably or permanently) within the plenum chamber in order to improve humidification performance.

[0096] One form of the present technology comprises a heat and moisture exchanger for a patient interface. The heat and moisture exchanger comprises a nonwoven composite having a first planar surface, an opposite second planar surface and a sidewall, and at least one vent on the first planar surface. The nonwoven composite is bidirectionally permeable to air through the first planar surface and the second planar surface. The vent allows a flow of gas through the first planar surface.

[0097] Advantageously, the nonwoven composite can improve humidification performance of the patient interface when used as a heat and moisture exchanger. The nonwoven composite is also durable, and can provide for consistency in results.

[0098] Another aspect of one form of the present technology is a heat and moisture exchanger for a patient interface, comprising: a nonwoven composite having a first planar surface, an opposite second planar surface and a sidewall; and at least one vent on the first planar surface; wherein the nonwoven composite is permeable to air; and wherein the vent allows a flow of gas through the first planar surface.

[0099] Another aspect of one form of the present technology is a heat and moisture exchanger for a patient interface, comprising a heat and moisture exchanger for a patient interface, comprising: a nonwoven composite formed from a fibrous material having a first planar surface, an opposite second planar surface and a sidewall positioned between the first planar surface and the opposite second planar surface; and at least one vent on the first planar surface, the at least one vent extending at least partially toward the second planar surface, and a wall of the at least

one vent being formed from the fibrous material; wherein the nonwoven composite is permeable to air; and wherein the nonwoven composite including a first impedance and the vent including a second impedance less than the first impedance to allow a flow of gas through the first planar surface.

[0100] In some forms, a) the nonwoven composite is permeable to air through the first planar surface from the sidewall; b) the nonwoven composite is permeable to air through the first planar surface from the second planar surface; c) the vent allows air to flow through the first planar surface to the second planar surface; and/or d) the vent allows air to flow through the first planar surface to the sidewall.

[0101] In some forms, a) the vent is one of a plurality of vents; and/or b) the plurality of vents are arranged in at least one concentric pattern or spiral pattern.

[0102] In some forms, a) the vent has a diameter of about 0.1 mm to 2 mm; b) the nonwoven composite is a multi-layered composite; c) the nonwoven composite is an at least three layered composite; and/or d) the nonwoven composite comprises a combination of spunbond fibers, meltblown fibers, melt extrusion fibres and/or natural fibres.

[0103] In some forms, a) the heat and moisture exchanger has a thickness of about 3 mm to about 15 mm; b) the nonwoven composite has a water contact angle of less than 90°; c) the nonwoven composite has a mass change of at least 20% at a relative humidity of 50% (when measured using dynamic vapour sorption); d) the nonwoven composite has a porosity of at least 20%; e) the nonwoven composite has a density of at least 50 fibers/cm; f) the nonwoven composite has a surface area of about 5 m²/g to about 100 m²/g; g) the nonwoven composite is formed from a web of fibers selected from polyethylene, polypropylene, polyethylene terephthalate, polyester, rayon, cotton, or a combination thereof; and/or h) the nonwoven composite is formed from a web of fibers functionalised with hydrophilic moieties selected from hydroxyl, carboxyl, amino, sulfinyl, sulfonyl, phosphoryl, or a combination thereof.

[0104] In some forms, a) the nonwoven composite further comprises a hydrophilic coating on the first planar surface and/or the second planar surface; b) the nonwoven composite further comprises an anti-bacterial coating or anti-bacterial filter

layer; and/or c) the nonwoven composite further comprises an olfactory coating or olfactory layer.

[0105] In some forms, a) multiple heat and moisture exchangers are positioned adjacent to each other; b) attachment means selectively aligns and stacks two or more heat and moisture exchangers; and/or c) the attachment means is a polymer spacer.

[0106] In some forms, a patient interface comprising a plenum chamber pressurizable to a therapeutic pressure, a seal-forming structure constructed and arranged to form a seal with a region of the patient's face, and a positioning and stabilising structure to provide a force to hold the seal-forming structure in a therapeutically effective position; wherein the heat and moisture exchanger of any of the previous forms is inserted into the plenum chamber.

[0107] Another aspect of one form of the present technology is a heat and moisture exchanger for a patient interface.

[0108] Another aspect of one form of the present technology is a patient interface comprising: a plenum chamber pressurisable to a therapeutic pressure of at least 4 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; the heat and moisture exchanger positioned within the plenum chamber, the heat and moisture exchanger comprising: a body constructed from a permeable, nonwoven composite formed with a fibrous material, the body having a first surface and a second surface; a passageway extending between the first surface and the second surface, the fibrous material forming the wall of the passageway; 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; and wherein the body includes a first impedance and the passageway includes a second impedance less than the first

impedance; wherein the fibrous material configured to absorb water vapor from exhaled air; and wherein the nonwoven composite of the body configured to transfer the absorbed water vapor to inhaled air and increase the humidity of the flow.

[0109] In some forms, a) the body has a disk shape; b) the first surface is a first planar surface and the second surface is a second planar surface opposite to the first planar surface; c) the passageway extends along a single axis between the first surface and the second surface; d) wherein the first surface is a first planar surface and the second surface is a sidewall oriented substantially perpendicularly to the first surface; and/or e) the passageway is elbow shaped and extends along two axes.

[0110] In some forms, a) the body is a first body, the patient interface further comprising a second body, the first body and the second body being alignable and stackable on top of each other; b) attachment means is included for aligning and stacking the first body and the second body; and/or c) the attachment means is a polymer spacer.

[0111] Another aspect of one form of the present technology includes a patient interface comprising: a heat and moisture exchanger having at least one body formed from a permeable material, the body having at least one vent configured to allow airflow, the vent having a permeability greater than the permeability of the body.

[0112] In some forms, a) the body is formed from a nonwoven composite; b) the body is formed from a fibrous material; c) the body is formed from multiple layers of nonwoven composites; and/or d) fibrous material forms the wall of the at least one vent.

[0113] 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.

[0114] An aspect of one form of the present technology is a method of manufacturing apparatus.

[0115] An aspect of one form of the present technology is a method of assembling a heat and moisture exchanger for use with a patient interface, the method

comprises selectively stacking one or more nonwoven composite bodies in an attachment means. In some forms, the method further comprises providing the attachment means.

[0116] In some forms, the method further comprises a) aligning at least one vent of a first body with at least one vent of the second body; b) positioning the first body adjacent to the second body; and/or c) securing the one or more bodies to the attachment means with a locking mechanism.

[0117] 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.

[0118] 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.

[0119] 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.

[0120] 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.

[0121] 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.

[0122] Other features of the technology will be apparent from consideration of the information contained in the following detailed description, abstract, drawings and claims.

7 BRIEF DESCRIPTION OF THE DRAWINGS

[0123] 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:

7.1 RESPIRATORY THERAPY SYSTEMS

[0124] 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.

[0125] 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.

[0126] 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.

7.2 RESPIRATORY SYSTEM AND FACIAL ANATOMY

[0127] 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.

[0128] 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.

[0129] 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.

[0130] 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.

[0131] 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.

[0132] 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.

[0133] Fig. 2G shows a side view of the superficial features of a nose.

[0134] Fig. 2H shows subcutaneous 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.

[0135] 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.

[0136] 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.

[0137] 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.

[0138] Fig. 2L shows an anterolateral view of a nose.

7.3 PATIENT INTERFACE

[0139] Fig. 3A shows a patient interface in the form of a nasal mask in accordance with one form of the present technology.

[0140] 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.

[0141] 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.

[0142] 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.

[0143] 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.

[0144] 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.

[0145] 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.

[0146] 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.

[0147] 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.

[0148] 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.

[0149] 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.

[0150] Fig. 3L shows a mask having an inflatable bladder as a cushion.

[0151] 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.

[0152] Fig. 3N shows a further cross-section through the mask of Fig. 3L. The interior surface is also indicated.

[0153] Fig. 3O illustrates a left-hand rule.

[0154] Fig. 3P illustrates a right-hand rule.

[0155] Fig. 3Q shows a left ear, including the left ear helix.

[0156] Fig. 3R shows a right ear, including the right ear helix.

[0157] Fig. 3S shows a right-hand helix.

[0158] 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.

[0159] Fig. 3U shows a view of a plenum chamber 3200 showing a sagittal plane and a mid-contact plane.

[0160] 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.

[0161] 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.

[0162] 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.

[0163] Fig. 3Y shows a patient interface in the form of a nasal cannula in accordance with one form of the present technology.

7.4 RPT DEVICE

[0164] Fig. 4A shows an RPT device in accordance with one form of the present technology.

[0165] Fig. 4B is a schematic diagram of the pneumatic path of an RPT device in accordance with one form of the present technology. The directions of upstream and downstream are indicated with reference to the blower and the patient interface. The blower is defined to be upstream of the patient interface and the patient interface is defined to be downstream of the blower, regardless of the actual flow direction at any particular moment. Items which are located within the pneumatic path between the blower and the patient interface are downstream of the blower and upstream of the patient interface.

7.5 HUMIDIFIER

[0166] Fig. 5A shows an isometric view of a humidifier in accordance with one form of the present technology.

[0167] Fig. 5B shows an isometric view of a humidifier in accordance with one form of the present technology, showing a humidifier reservoir 5110 removed from the humidifier reservoir dock 5130.

7.6 BREATHING WAVEFORMS

[0168] Fig. 6A shows a model typical breath waveform of a person while sleeping.

7.7 SCREENING, DIAGNOSIS AND MONITORING SYSTEMS

[0169] Fig. 7A shows a patient undergoing polysomnography (PSG). The patient is sleeping in a supine sleeping position.

[0170] Fig. 7B shows a monitoring apparatus for monitoring the condition of a patient. The patient is sleeping in a supine sleeping position.

7.8 HEAT AND MOISTURE EXCHANGER

[0171] Fig. 8A shows a perspective view of a first example of a first version of a heat and moisture exchanger.

[0172] Fig. 8B shows a side view of the heat and moisture exchanger of Fig. 8A.

[0173] Fig. 8C shows a front view of the heat and moisture exchanger of Fig. 8A.

[0174] Fig. 9A shows a perspective view of a second example of a first version of a heat and moisture exchanger.

[0175] Fig. 9B shows a side view of the heat and moisture exchanger of Fig. 9A.

[0176] Fig. 9C shows a front view of the heat and moisture exchanger of Fig. 9A.

[0177] Fig. 10A shows a perspective view of a third example of a first version of a heat and moisture exchanger.

[0178] Fig. 10B shows a side view of the heat and moisture exchanger of Fig. 10A.

[0179] Fig. 10C shows a front view of the heat and moisture exchanger of Fig. 10A.

[0180] Fig. 11 shows a schematic view of the heat and moisture exchanger of any one of the first example of Fig. 8A, the second example of Fig. 9A, or the third example of Fig. 10A.

[0181] Fig. 12A shows a perspective view of a first example of a second version of a heat and moisture exchanger.

[0182] Fig. 12B shows a side view of the heat and moisture exchanger of Fig. 12A.

[0183] Fig. 12C shows a front view of the heat and moisture exchanger of Fig. 12A.

[0184] Fig. 12D shows a detail view of the heat and moisture exchanger of Fig. 12A.

[0185] Fig. 13 shows a schematic view of the heat and moisture exchanger in Fig. 12A.

[0186] Fig. 14A shows a perspective view of a single heat and moisture exchanger connected to an attachment means.

[0187] Fig. 14B shows a perspective view of a pair of heat and moisture exchangers stackable within an attachment means.

[0188] Fig. 14C shows a perspective view of multiple heat and moisture exchangers stackable within an attachment means.

[0189] Fig. 14D shows a front view of an alternate form of the attachment means containing at least one heat and moisture exchanger.

[0190] Fig 14E shows a view perspective view of the attachment means of Fig. 14D.

[0191] Fig. 15 shows an example of a heat and moisture exchanger with an antibacterial filter.

[0192] Fig. 16 shows an example of the placement of the heat and moisture exchanger (HMX) in the patient interface.

[0193] Fig. 17 shows a perspective view of the attachment means of Fig. 14D connected from a patient interface.

[0194] Fig. 18 shows a rear view of the patient interface of Fig. 17 connected to the attachment means.

[0195] Fig. 19 shows a rear view of another patient interface connected to the attachment means of Fig. 14D.

8 DETAILED DESCRIPTION OF EXAMPLES OF THE TECHNOLOGY

[0196] 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.

[0197] 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.

8.1 THERAPY

[0198] 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.

[0199] 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.

[0200] In certain examples of the present technology, mouth breathing is limited, restricted or prevented.

8.2 RESPIRATORY THERAPY SYSTEMS

[0201] 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.

8.3 PATIENT INTERFACE

[0202] A non-invasive patient interface 3000 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.

[0203] 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.

[0204] 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.

[0205] 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 6 cmH₂O with respect to ambient.

[0206] 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.

[0207] 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.

8.3.1 Seal-forming structure

[0208] 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.

[0209] In one form the target seal-forming region is located on an outside surface of the seal-forming structure 3100.

[0210] In certain forms of the present technology, the seal-forming structure 3100 is constructed from a biocompatible material, e.g. silicone rubber.

[0211] A seal-forming structure 3100 in accordance with the present technology may be constructed from a soft, flexible, resilient material such as silicone.

[0212] 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.

8.3.1.1 Sealing mechanisms

[0213] 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.

[0214] 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.

[0215] 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.

[0216] 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.

[0217] In one form, the seal-forming structure comprises a region having a tacky or adhesive surface.

[0218] 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.

8.3.1.2 Nose bridge or nose ridge region

[0219] 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.

[0220] 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.

8.3.1.3 Upper lip region

[0221] 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.

[0222] 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.

8.3.1.4 Chin-region

[0223] 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.

[0224] 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.

8.3.1.5 Forehead region

[0225] 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.

8.3.1.6 Nasal pillows

[0226] In one form the seal-forming structure of the non-invasive patient interface 3000 comprises a pair of nasal puffs, or nasal pillows, each nasal puff or nasal pillow being constructed and arranged to form a seal with a respective naris of the nose of a patient.

[0227] Nasal pillows in accordance with an aspect of the present technology include: a frusto-cone, at least a portion of which forms a seal on an underside of the patient's nose, a stalk, a flexible region on the underside of the frusto-cone and connecting the frusto-cone to the stalk. In addition, the structure to which the nasal pillow of the present technology is connected includes a flexible region adjacent the base of the stalk. The flexible regions can act in concert to facilitate a universal joint structure that is accommodating of relative movement both displacement and angular of the frusto-cone and the structure to which the nasal pillow is connected. For

example, the frusto-cone may be axially displaced towards the structure to which the stalk is connected.

8.3.2 Plenum chamber

[0228] 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.

[0229] 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.

[0230] 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.

[0231] 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.

8.3.3 Positioning and stabilising structure

[0232] 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.

[0233] 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.

[0234] 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.

[0235] In one form the positioning and stabilising structure 3300 provides a retention force as a safety margin to overcome the potential effect of disrupting forces on the patient interface 3000, such as from tube drag, or accidental interference with the patient interface.

[0236] 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.

[0237] 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.

[0238] 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.

[0239] 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.

[0240] 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.

[0241] 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.

[0242] 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.

[0243] 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.

[0244] 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.

[0245] 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.

[0246] 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,

[0247] 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.

8.3.4 Vent

[0248] 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.

[0249] 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.

[0250] 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.

[0251] 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.

8.3.5 Decoupling structure(s)

[0252] In one form the patient interface 3000 includes at least one decoupling structure, for example, a swivel or a ball and socket.

8.3.6 Connection port

[0253] Connection port 3600 allows for connection to the air circuit 4170.

8.3.7 Forehead support

[0254] In one form, the patient interface 3000 includes a forehead support 3700.

8.3.8 Anti-asphyxia valve

[0255] In one form, the patient interface 3000 includes an anti-asphyxia valve.

8.3.9 Ports

[0256] 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.

8.3.10 Heat and moisture exchanger

[0257] A heat and moisture exchanger can be included in the patient interface. The heat and moisture exchanger is a component that is intended to help humidify and warm air flowing into the airways of the patient. This helps prevent complications due to drying of the respiratory mucosa.

[0258] The heat and moisture exchanger may be designed in order to capture exhaled water vapor in order to improve humidity during use of the patient interface 3000. Accordingly, the heat and moisture exchanger increases the impedance of the airflow through the plenum chamber 3200. The increased impedance may assist in allowing greater moisture retention. But as described below, increased impedance may also decrease carbon dioxide washout. Accordingly, a heat and moisture exchanger may be designed in order to increase moisture capture without substantially decreasing gas washout (e.g., in order to limit carbon dioxide build-up in the plenum chamber 3200).

[0259] In one form of the present technology, the heat and moisture exchanger 800 comprises a nonwoven composite having a first planar surface 802, an opposite second planar surface 804 and a sidewall 806. The heat and moisture exchanger also

comprises at least one vent 808 on the first planar surface 802. The nonwoven composite is formed such that it is air permeable to all the directions. In other words, the nonwoven composite is bidirectionally permeable to air through the first planar surface and the second planar surface. The vent 808 allows a flow of gas through the first planar surface, that is, it allows air to flow in both directions through the first planar surface.

[0260] Figs. 8A to 10C show examples of a heat and moisture exchanger 800. A cross-sectional schematic is shown as 810 in Fig. 11. Air from an air source can, for example, flow 812 into the heat and moisture exchanger 800. Air can flow 812 at an angle through the heat and moisture exchanger 800 via the second planar surface 804 to be received by a patient at the first planar surface 802. For example, the illustrated schematic 810 shows the flow 812 may be substantially perpendicular with respect to the second planar surface 804. However, the flow 812 may also be oriented at an oblique angle with respect to the second surface. In some forms, an angle between the flow 812 and the second surface 804 may be at least about $\pm 1^\circ$. In some forms, an angle between the flow 812 and the second surface 804 may be at least about $\pm 10^\circ$. In some forms, an angle between the flow 812 and the second surface 804 may be at least about $\pm 25^\circ$. In some forms, an angle between the flow 812 and the second surface 804 may be about $\pm 45^\circ$. The angle may depend on the orientation of the air circuit 4170. The air can then flow 814 out of the heat and moisture exchanger 800 through the first planar surface 802 to be received by the patient. Similarly, as shown in Fig. 13, air can flow 852 through the heat and moisture exchanger 840 (illustrated as schematic 850) perpendicularly with respect from an inlet tubing to a plenum chamber via the second planar surface 844 to the first planar surface 842 and thus flow 854 out from the heat and moisture exchanger to be received by the patient. Alternatively, the flow 852 and/or flow 854 may be oriented at an oblique angle (e.g., at least about $\pm 1^\circ$, $\pm 10^\circ$, $\pm 25^\circ$, or $\pm 45^\circ$) with respect to the first or second planar surfaces 842, 844. The angle may similarly depend on the orientation of the air circuit 4170.

[0261] Advantageously, as the nonwoven composite is a porous material, air permeability across the heat and moisture exchanger can be obtained. Further, as fibre

arrangements can be tuned, the permeability can be controlled to regulate the flow of air.

[0262] The vent 808 allows a flow 816 of gas through the first planar surface 802. As shown in Fig. 11, the vent 808 allows a flow 816 of air between the first planar surface 802 and the second planar surface 804. The gas or exhaled air from the patient passes through the nonwoven composite via the vent 808 and exits 818 via the second planar surface 804. In this regard, the vent 808 allows gas to flow in an opposite direction 816 to the air 814 from the air source.

[0263] Advantageously, the vent 808 facilitates the flow of air from a high pressure region to a low pressure region. When a patient breathes out, a high pressure region is created within the plenum chamber. The high pressure region can be quickly de-pressurised through the flow of air via the vent 808. In this way, carbon dioxide that is breathed out by the patient can be quickly removed from the plenum chamber.

[0264] For example, the vents 808 may decrease the impedance by allowing the exhaled air to more freely flow through the nonwoven composite. However, the fibrous material of the nonwoven composite may form the boundary of the vents 808 through the heat and moisture exchanger 800. Thus, flow 816 may still contact the nonwoven composite, which may absorb water vapor in the exhaled gas, even while not traveling directly through the solid nonwoven composite. The carbon dioxide may be able to exit 818 without substantial build up in a plenum chamber, while also maintaining sufficient levels of moisture capture.

[0265] Advantageously, the combination of these two features act synergistically to retain heat and moisture in the heat and moisture exchanger. When gas is expelled from the airways of a patient and exits the heat and moisture exchanger 800 via the vent 808, heat and moisture can be captured within the nonwoven composite. This is due to the high surface area and structure created by the web of fibres. As air from the air source pass through the heat and moisture exchanger 800 to be breathe in by the patient, heat and moisture which are trapped within the nonwoven composite is carried out by this air, and can be delivered to the patient's airways. In this regard, the heat and moisture content of the air that is delivered can be regulated and an external humidifier and/or heating element is not required.

[0266] Figs. 12A to 13 show another example of the heat and moisture exchanger 840. The heat and moisture exchanger 840 comprises a nonwoven composite having a first planar surface 842, an opposite second planar surface 844 and a sidewall 846. The heat and moisture exchanger 840 also comprises at least one vent 848 on the first planar surface 842. The nonwoven composite is formed such that it is bidirectionally permeable to air through the first planar surface 842 and the second planar surface 844. The vent 848 allows a flow of gas through the first planar surface 842, that is, it allows air to flow in both directions through the first planar surface 842.

[0267] A cross-sectional schematics is shown as 850 in Fig. 13. Air from an air source can flow 852 into the heat and moisture exchanger 840 via the second planar surface 844. The air can then flow 854 out of the heat and moisture exchanger 840 through the first planar surface 842. The vent 848 allows a flow 856 of gas through the first planar surface 842. The gas or exhaled air from the patient passes through the nonwoven composite via the vent 848 and exits 858 via the sidewall 846.

[0268] In some forms, the sidewall 846 may include at least one opening 847. For example, a plurality of openings 847 may be disposed around the perimeter of the heat and moisture exchanger 840. The exit flow 858 may exhaust through the openings 847 in a direction substantially perpendicularly to the flow 852.

[0269] In certain forms, the one or more openings 847 may assist in diffusing airflow (e.g., the flow 858) that exits the heat and moisture exchanger 840. The diffusion of the flow 858 may assist with sound dampening related to airflow through the heat and moisture exchanger 840 (e.g., by reducing or eliminating whistling or other sounds that could disturb a patient's sleep).

[0270] In one form, forming a vent 848 with a tortuous path (e.g., by angling the pathway 849 of the vent 848 such that a through-hole configuration is avoided), may cause sound to be more readily transmitted through the non-woven fabric and to be absorbed by the material. The sound is also diffused (redirected or scattered) into a wider space which may make the sound less coherent and may reduce echos.

[0271] In some forms, the sidewall 846 may be formed from a permeable material and may allow air flow (e.g., the exit flow 858 in Fig. 13) to pass through the

sidewall 846. In this example, the sidewall 846 may have a greater permeability than the planar surfaces 842, 844 in order to assist in exhausting carbon dioxide.

[0272] This arrangement advantageously minimises the mixing of the inhalable air and the exhaled air. Further, as a portion of the vent 848 is substantially parallel to the first and second planar surfaces 842, 844, and the exhaled air travels a greater distance within the heat and moisture exchanger 840, more heat and moisture can be trapped within.

[0273] In certain forms the vent 848 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.

[0274] One form of vent of a heat and moisture exchanger 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.

[0275] The vent (e.g., vent 808) can allow the passage of gas between the first planar surface 802 and the second planar surface 804 as illustrated in Fig. 11. Alternatively (or additionally), the vent (e.g., vent 848) can allow the passage of gas between the first planar surface 842 and the sidewall 846 as illustrated in Fig. 12D.

[0276] For example, a pathway 849 may be formed through the body of the heat and moisture exchanger 840 in order to connect a vent 848 to an opening 847 in the sidewall 846. In the illustrated example, the pathway 849 may connect a single vent 848 to a single opening 847, although in other examples, multiple vents 848 and/or multiple openings 847 may be connected to a single pathway 849. For example, vents 848 oriented in concentric patterns (see e.g., Figs. 8C and 9C) may include a single pathway 849 connecting both vents 848 to a single opening 847.

[0277] In certain forms, the pathway 849 may be formed with a substantially elbow shape extending between the first planar surface 842 and the sidewall 846.

[0278] In some forms, the pathways 849 and the vents 848 may be similar to the vents 808 described above. The nonwoven composite may line (e.g., form the boundary of) the pathway 849. Thus, the nonwoven composite may not substantially interfere (e.g., provide an elevated impedance) to carbon dioxide in the flow 856. However, the airflow flowing through the pathways 849 may contact the fibrous material of the nonwoven composite, which may absorb the water vapor in the airflow (e.g., thereby maintaining absorption but limiting impedance).

[0279] The heat and moisture exchanger can comprise a plurality of vents. The vents may be arranged in any suitable pattern, and may be uniformly or randomly dispersed. For example, the vents can be arranged in at least one concentric pattern on the heat and moisture exchanger. Figs. 10A to 10C and 12A to 12D show an example of the vents 808, 848 being arrayed as a concentric pattern (e.g., a singular circular pattern) on the heat and moisture exchanger 800, 840. Figs. 8A to 9C show other examples of vents 808 being arranged in two concentric patterns (see e.g., Figs. 9A and 9C) or three concentric patterns (see e.g., Figs. 8A and 8C) on the heat and moisture exchanger 800. Alternatively, the vents can be arranged in a spiral pattern, or in any other patterns that is suitable for use.

[0280] The vents can have a diameter of about 0.1 mm to about 2 mm.

[0281] The pattern and number of vents can be selected such that it reduces a flow resistance of air. For example, the air flow resistance can be defined as $R_f = \frac{\Delta p}{\mu S}$, where Δp is the air pressure difference (Pa) across the heat and moisture exchanger, μ is the linear air velocity (m/s) and S is the cross sectional area of the heat and moisture exchanger perpendicular to the direction of the flow (m^2).

[0282] When combined with the nonwoven composite, the flow resistance (or impedance) of the heat and moisture exchanger can be such that the patient feels no or minimal resistance to breathing in and out. This provides a therapeutically effective air pressure to a patient when the heat and moisture exchanger is incorporated in the patient interface.

[0283] The heat and moisture exchanger can have a low through impedance. The impedance can be less than about 150 L/min at 3cm H₂O. The impedance of the

nonwoven composite (first impedance) can be less than about 150 L/min at 3cm H₂O. The impedance of the vent (second impedance) can be less than about 120 L/min at 3cm H₂O, or preferably less than about 80 L/min at 3cm H₂O. The heat and moisture exchanger can add about 18 mg/L to about 25 mg/L absolute humidity at 10cm H₂O therapy pressure. Advantageously, after being saturated with water, humidification performance does not decrease and impedance does not increase.

[0284] The heat and moisture exchanger can have a moisture exchange rate of at least about 1 mg/s. The heat and moisture exchanger can have a moisture exchange rate of at least about 3 mg/s. In other examples, the moisture exchange rate is at least about 5 mg/s. The heat and moisture exchanger can have a moisture exchange rate of at least about 7 mg/s.

[0285] The heat and moisture exchanger can have an air permeability of more than about 1 mL/s/mm². The heat and moisture exchanger can have an air permeability of more than about 3 mL/s/mm². In other embodiments, the air permeability is more than about 5 mL/s/mm². The heat and moisture exchanger can have an air permeability of more than about 7 mL/s/mm².

[0286] The heat and moisture exchanger can have a suitable heat conductivity as defined by $\lambda = \frac{QL}{At(T_1 - T_2)}$, where Q is the heat flow (W) passing in time t (h) through an area A (m²) of the composite thickness L (m) at a temperature difference (T₁-T₂) (°C).

[0287] The heat and moisture exchanger can have a thickness of about 2 mm to about 20 mm. In other embodiments, the thickness is about 3 mm to about 15 mm. This provides the heat and moisture exchanger with sufficient rigidity to facilitate its insertion into, for example, the patient interface.

[0288] As illustrated in Figs. 14A to 14C, two or more of the heat and moisture exchangers (e.g., heat and moisture exchanger 800 and/or heat and moisture exchanger 840) can also be alignable and stackable on top of each other. In other words, two or more heat and moisture exchangers may be positioned adjacent to each other. This allows a patient to adjust and control the amount of heat and moisture to be delivered into the airways of the patient. To this end, when two or more heat and

moisture exchangers are stacked together, the amount of heat and moisture retained in the heat and moisture exchanger can be increased. When the heat and moisture exchangers (e.g., heat and moisture exchanger(s) 800 and/or heat and moisture exchanger(s) 840) are stacked such that the vents can be aligned, the impedance can at least be maintained. Figures 14A to 14C illustrate the heat and moisture exchanger 800, but the description and figures may be equally applicable for the heat and moisture exchanger 840.

[0289] The heat and moisture exchanger 800(or alternatively the heat and moisture exchanger 840) can further comprise an attachment means 900 for aligning and stacking the two or more heat and moisture exchangers 800. The attachment means 900 can be a bayonet connector or can be an adhesive. The attachment means 900 can also be a polymer spacer. The attachment means 900 can also provide a physical space between the adjacent heat and moisture exchangers. This may eliminate, or at least reduce, the need for alignment of the vents.

[0290] For example, as illustrated in Fig. 14A, a single heat and moisture exchanger 800 may be connected to the attachment means 900. A patient may selectively add additional heat and moisture exchangers 800 as illustrated in Figs. 14B (e.g., two total heat and moisture exchangers 800) and Figs. 14C (e.g., three total heat and moisture exchangers 800). In some forms, the combined structure connected to the attachment means 900 may be the heat and moisture exchanger 800, which is made up of multiple nonwoven components (e.g., singular heat and moisture exchangers 800). As mentioned above, the heat and moisture exchanger 800 may be replaced with the heat and moisture exchanger 840, or the heat and moisture exchangers 800, 840 may be used in combination with one another.

[0291] In Figs. 14A to 14C, the heat and moisture exchanger(s) (e.g., one or more heat and moisture exchangers 800, one or more heat and moisture exchangers 840, or a combination of both heat and moisture exchangers 800, 840) may be secured to the attachment means 900 so that the heat and moisture exchanger(s) is not movable relative to the attachment means 900 in use.

[0292] Figs. 14D and 14E illustrates another form of an attachment means 940. The attachment means 940 may have an outer body 942 holding one or more heat and

moisture exchangers 800, 840. Opposing ends 944 of the outer body 942 may include an interface for allowing the patient to handle the attachment means 940.

[0293] As shown in Figs. 16 to 19, the heat and moisture exchanger(s) 800 (or alternatively the heat and moisture exchanger 840) may be positioned in the plenum chamber 3200 proximate to the air circuit 4170 so that pressurized air flowing into the plenum chamber is directed through the heat and moisture exchanger(s) 800, 840.

[0294] As shown in Fig. 14E, one side of the outer body 942 may include one or more tabs 946, which may engage with the connection port 3600 of the plenum chamber 3200.

[0295] As shown in Figs. 17 and 18, the attachment means 940 may be inserted into the plenum chamber 3200 prior to use, and connected to the connection port 3600. For example, the tabs 946 face away from the patient in use, and connect to the connection port 3600 so that the heat and moisture exchanger 800 is positioned within the plenum chamber 3200. The outer body 942 (via the tabs 946) may mechanically engage the connection port 3600 (e.g., using a snap fit, friction fit, and/or press fit). Once the outer body 942 is connected to the connection port 3600, the heat and moisture exchanger 800 (and/or 840 – not shown) may be positioned proximate to the connection port 3600 so that airflow entering the plenum chamber 3200 via the air circuit 4170 passes through the heat and moisture exchanger 800. The attachment means 900 may be similarly connected to the plenum chamber 3200.

[0296] As shown in Fig. 19, the outer body 942 may be similarly connected to the connection port 3600 (see e.g., Fig. 18 illustrating a similar connection port of the patient interface 3000) of a nasal patient interface 6000 with a plenum chamber 6200 that provides pressurized air only to the patient's nares.

[0297] In some forms, the pressurized air from the air circuit 4170 may be directed through the heat and moisture exchanger(s) 800 and into the plenum chamber 3200. The pressurized air may pass through the nonwoven composite and “pick up” the trapped water vapor, thereby humidifying the flow of air entering the plenum chamber 3200. The patient may then inhale this humidified air.

[0298] In some forms, the patient may exhale water vapor as part of the normal respiratory process. The nonwoven composite may assist in trapping the water vapor from exhausting to ambient so that the water vapor can be reintroduced into the patient's lungs.

[0299] In certain forms, the heat and moisture exchanger(s)' position proximate to an interface between the air circuit 4170 and an opening of the plenum chamber 3200 may allow the heat and moisture exchanger(s) 800 to act as a vent to exhaust exhaled air to ambient. However, as described above, the nonwoven material, while permeable, may have a relatively high impedance that slows airflow through the material. In order to limit the build-up of carbon dioxide, the vents 808, 848 may allow the carbon dioxide to more easily exhaust to ambient through a lower impedance opening.

[0300] As described above, the high pressure in the plenum chamber 3200 (e.g., as a result of the flow of air from the air circuit 4170 and the exhaled air from the patient's lungs) may assist the exhaled air to flow through the vents 808 (or vents 848 when the heat and moisture exchanger 840 is used) and exit the plenum chamber 3200.

[0301] In certain forms, the exhaled, humidified air (e.g., as a result of natural respiration) exhausts through the vents 808 and/or 848 which are formed directly through the nonwoven composite. In either form (e.g., the vent 808 between the first and second surfaces 802, 804 in Figs. 8A to 11, or the vent 848 between the first surface 842 and the sidewall 846 in Figs. 12A to 13), the wall of the vent 808, 848 (e.g., the pathway 849) is formed by the nonwoven composite. The flow of air through the vents 808, 848 thus contacts the nonwoven composite even without substantially experiencing the impedance of the composite. The fibrous material of the nonwoven composite may absorb water vapor from the exhausted air so that the water vapor can be returned to the plenum chamber 3200 and eventually the patient's lungs.

8.3.11 Nonwoven composite for heat and moisture exchanger

[0302] The heat and moisture exchanger can be formed from a nonwoven composite as disclosed herein.

[0303] For example, the nonwoven composite can be a multi-layered nonwoven composite. The multi-layered composite can comprise at least two layers, and can be up to 10 layers.

[0304] For example, the heat and moisture exchanger can comprise a first nonwoven composite and a second nonwoven composite, the first nonwoven composite and the second nonwoven composite may be positioned adjacent to each other. Alternatively, the first nonwoven composite and the second nonwoven composite may be aligned and stacked on top of each other. The first nonwoven composite and the second nonwoven composite can be stacked such that the vents in the first and second nonwoven composites are aligned.

[0305] The nonwoven composite can have a water contact angle of less than about 90 °.

[0306] The nonwoven composite can have a mass change of at least 20% at a relative humidity of 50%. The mass change can be measured using dynamic vapour sorption.

[0307] The nonwoven composite can have a porosity of at least 20%.

[0308] The nonwoven composite can have a density of at least 50 fibres/cm.

[0309] The nonwoven composite can have an internal surface area of about 5 m²/g to about 100 m²/g.

[0310] The nonwoven composite can be treated with a wetting agent for allowing rapid moisture penetration. The wetting agent can be applied to an inner layer of a multi-layered composite. Alternatively, an inner layer can be composed of rayon fibres for improving the moisture absorbent property of the heat and moisture exchanger.

[0311] As shown in Fig. 15, the heat and moisture exchanger 800 (or the heat and moisture exchanger 840; not shown) can further comprise a filter layer 910. The filter layer 910 can be an anti-bacterial filter layer. The filter layer 910 can be formed within the heat and moisture exchanger 800 during the fabrication thereof, or can be sandwiched between a plurality of heat and moisture exchangers 800 and/or 840. For

example, the filter layer 910 may be separate from the heat and moisture exchangers 800, and may be positioned between adjacent heat and moisture exchangers 800 within an attachment means 900 (e.g., similar to Figs. 14B and 14C).

8.3.12 Nonwoven composite in general

[0312] The nonwoven composite can be a multi-layered nonwoven composite. The multi-layered composite can comprise at least two layers, and can be up to 10 layers. One of the layers can comprise microfibers. The layer comprising microfibers can be a patient-contacting layer of the nonwoven composite.

[0313] The nonwoven composite can be formed from fibres which are spunbond, meltblown, or from a combination thereof.

[0314] The fibres can be a single component fibre or a bi-component fibre. A multi-component fibre is also envisioned. Bi-component fibres are fibres which are extruder with two different types of polymer within a single fibre. The components do not mix with each other, but by changing the physical relationship of the two components within the fibre, and by changing the composition of the components, the properties of the final fibre can be altered. Examples of bi-component fibres include side-by-side, eccentric sheath/core, citrus, island-in-the-sea, segmented pie, segmented circle, segmented ribbon, trilobal sheath/core and trilobal side-by-side.

[0315] The non-woven composite may comprise fine fibres and/or fibres with high surface area. Advantageously, the non-woven composite is capable of effectively absorbing moisture. Fibres with high surface area may include engineered fibres having various cross-sectional geometry, such as trilobal or multilobal. Preferably, the non-woven material may comprise fine fibres which leads to a higher surface area and therefore better moisture absorption.

[0316] The fibres can have a combination of hydrophilic and hydrophobic components. The ratio of hydrophilic to hydrophobic component can be tuned to regulate the retention of heat and/or moisture. For example, the ratio can be from about 1:99 to about 99:1, about 10:90 to about 90:10, about 20:80 to about 80:20, about 30:70 to about 70:30, about 40:60 to about 60:40, or about 50:50.

- [0317] The nonwoven fibres can have a diameter of about 0.5 μm to about 50 μm .
- [0318] The nonwoven composite can be moulded to give it surface texturisation. For example, the texture can be of at least 1 cm deep.
- [0319] The nonwoven composite can have a thickness of about 1 mm to about 5 cm.
- [0320] The nonwoven composite can have a density of about 0.05 g/cm^3 to 5.0 g/cm^3 .
- [0321] The nonwoven composite can be formed from a web of fibres. The fibres can be a synthetic polymer fibre and/or a natural plant or animal fibre such as seed fibre, leaf fibre, bast fibre, fruit fibre, stalk fibre, chitin, chitosan, collagen or keratin. Examples of natural plant fibres are cotton (or other cellulose fibres), kapok, coir, flax, hemp, jute, ramie, abaca, henequen, and sisal. Examples of synthetic polymer fibres are polyamides, polyacrylonitrile, polyethylene, polypropylene, polyethylene terephthalate, polyester, regenerated cellulose fibres, or rayon and their co-polymer derivatives such as co-polyester, co-polypropylene etc. In some embodiments, the fibres can be selected from polyethylene, polypropylene, polyethylene terephthalate, polyester, rayon, viscose, cotton, or a combination thereof.
- [0322] The fibres can be further functionalised with a functional coating on the fibres. For example, the fibres can be functionalised with hydrophilic moieties selected from hydroxyl, carboxyl, amino, sulfinyl, sulfonyl, phosphoryl, or a combination thereof.
- [0323] Advantageously, the nonwoven composite can be washed and re-used.
- [0324] Alternatively, the nonwoven composite can further comprise a hydrophilic coating on the first planar surface and/or the second planar surface. The hydrophilic coating can be selected from various cross-linking polymers such as derivatives of polysiloxanes or it can be achieved by other treatments like plasma.
- [0325] Alternatively, the nonwoven composite can further comprise a hydrophobic coating on the first planar surface and/or the second planar surface. The

hydrophobic coating can be selected from combination of chemicals such as polydimethylsiloxane (PDMS).

[0326] The nonwoven composite can further comprises an anti-bacterial coating. The anti-bacterial coating can be based on silicone based softeners, silver salts, zinc pyrithione, silane quarternary ammonia compounds, Polyhexamethylene Buguanide (PHMB), or the likes. Alternatively, the nonwoven composite can comprise a filter layer, the filter layer is an anti-bacterial layer. In this way, the fabrication process does not have to be substantially modified and the anti-bacterial substance will not adversely affect the properties of the fibres.

[0327] Alternatively, as illustrated in Fig. 15, the Meltblown nonwoven membrane can be sandwiched between two or more nonwoven composites in order to achieve air filtration and bacterial filtration.

[0328] The nonwoven composite further comprises an olfactory coating or layer. The olfactory coating can be selected from various essential oils. The essential oils can be used as a form of aromatherapy for inducing relaxation and/or restful sleep. Examples of essential oils include, but not limited to, sweet orange, peppermint, menta arvensis, cedarwood, lemon, eucalyptus globulus, spearmint, lavender, bergamot, rose, chamomile, ylang-ylang, tea tree, jasmine, or a combination thereof. The olfactory coating can be coated on the fibres or impregnated into the fibres. This can be done during the fabrication of the nonwoven composite. Alternatively, the nonwoven composite can comprise a layer, the layer is an olfactory layer. In this way, the fabrication process does not have to be substantially modified and the olfactory substance will not adversely affect the properties of the fabric fibers. Further, the layer can be switched out when all or most of the olfactory substance has defused off.

8.4 RPT DEVICE

[0329] 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 4300, 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.

[0330] In one form, the RPT device 4000 is constructed and arranged to be capable of delivering a flow of air in a range of -20 L/min to +150 L/min while maintaining a positive pressure of at least 6 cmH₂O, or at least 10cmH₂O, or at least 20 cmH₂O.

[0331] The RPT device may have an external housing 4010, formed in two parts, an upper portion 4012 and a lower portion 4014. Furthermore, the external housing 4010 may include one or more panel(s) 4015. The RPT device 4000 comprises a chassis 4016 that supports one or more internal components of the RPT device 4000. The RPT device 4000 may include a handle 4018.

[0332] The pneumatic path of the RPT device 4000 may comprise one or more air path items, e.g., an inlet air filter 4112, an inlet muffler 4122, a pressure generator 4140 capable of supplying air at positive pressure (e.g., a blower 4142), an outlet muffler 4124 and one or more transducers 4270, such as pressure sensors 4272 and flow rate sensors 4274.

[0333] One or more of the air path items may be located within a removable unitary structure which will be referred to as a pneumatic block 4020. The pneumatic block 4020 may be located within the external housing 4010. In one form a pneumatic block 4020 is supported by, or formed as part of the chassis 4016.

[0334] The RPT device 4000 may have an electrical power supply, one or more input devices, a central controller, a therapy device controller, a pressure generator 4140, one or more protection circuits, memory, transducers, data communication interface and one or more output devices. Electrical components may be mounted on a single Printed Circuit Board Assembly (PCBA). In an alternative form, the RPT device 4000 may include more than one PCBA.

8.4.1 RPT device mechanical & pneumatic components

[0335] An RPT device may comprise one or more of the following components in an integral unit. In an alternative form, one or more of the following components may be located as respective separate units.

8.4.1.1 Air filter(s)

[0336] An RPT device in accordance with one form of the present technology may include an air filter 4110, or a plurality of air filters 4110.

[0337] In one form, an inlet air filter 4112 is located at the beginning of the pneumatic path upstream of a pressure generator 4140.

[0338] In one form, an outlet air filter 4114, for example an antibacterial filter, is located between an outlet of the pneumatic block 4020 and a patient interface 3000 or 3800.

8.4.1.2 Muffler(s)

[0339] An RPT device in accordance with one form of the present technology may include a muffler 4120, or a plurality of mufflers 4120.

[0340] In one form of the present technology, an inlet muffler 4122 is located in the pneumatic path upstream of a pressure generator 4140.

[0341] In one form of the present technology, an outlet muffler 4124 is located in the pneumatic path between the pressure generator 4140 and a patient interface 3000 or 3800.

8.4.1.3 Pressure generator

[0342] In one form of the present technology, a pressure generator 4140 for producing a flow, or a supply, of air at positive pressure is a controllable blower 4142. For example, the blower 4142 may include a brushless DC motor 4144 with one or more impellers. The impellers may be located in a volute. The blower may be capable of delivering a supply of air, for example at a rate of up to about 120 litres/minute, at a positive pressure in a range from about 4 cmH₂O to about 20 cmH₂O, or in other forms up to about 30 cmH₂O when delivering respiratory pressure therapy. The blower may be as described in any one of the following patents or patent applications the contents of which are incorporated herein by reference in their entirety: U.S. Patent No. 7,866,944; U.S. Patent No. 8,638,014; U.S. Patent No. 8,636,479; and PCT Patent Application Publication No. WO 2013/020167.

[0343] The pressure generator 4140 may be under the control of the therapy device controller.

[0344] In other forms, a pressure generator 4140 may be a piston-driven pump, a pressure regulator connected to a high pressure source (e.g. compressed air reservoir), or a bellows.

8.4.1.4 Transducer(s)

[0345] Transducers may be internal of the RPT device, or external of the RPT device. External transducers may be located for example on or form part of the air circuit, e.g., the patient interface. External transducers may be in the form of non-contact sensors such as a Doppler radar movement sensor that transmit or transfer data to the RPT device.

[0346] In one form of the present technology, one or more transducers 4270 are located upstream and/or downstream of the pressure generator 4140. The one or more transducers 4270 may be constructed and arranged to generate signals representing properties of the flow of air such as a flow rate, a pressure or a temperature at that point in the pneumatic path.

[0347] In one form of the present technology, one or more transducers 4270 may be located proximate to the patient interface 3000 or 3800.

[0348] In one form, a signal from a transducer 4270 may be filtered, such as by low-pass, high-pass or band-pass filtering.

8.4.1.5 Anti-spill back valve

[0349] In one form of the present technology, an anti-spill back valve 4160 is located between the humidifier 5000 and the pneumatic block 4020. The anti-spill back valve is constructed and arranged to reduce the risk that water will flow upstream from the humidifier 5000, for example to the motor 4144.

8.4.2 RPT device electrical components

8.4.2.1 Power supply

[0350] A power supply 4210 may be located internal or external of the external housing 4010 of the RPT device 4000.

[0351] In one form of the present technology, power supply 4210 provides electrical power to the RPT device 4000 only. In another form of the present technology, power supply 4210 provides electrical power to both RPT device 4000 and humidifier 5000.

8.4.2.2 Input devices

[0352] In one form of the present technology, an RPT device 4000 includes one or more input devices 4220 in the form of buttons, switches or dials to allow a person to interact with the device. The buttons, switches or dials may be physical devices, or software devices accessible via a touch screen. The buttons, switches or dials may, in one form, be physically connected to the external housing 4010, or may, in another form, be in wireless communication with a receiver that is in electrical connection to the central controller.

[0353] In one form, the input device 4220 may be constructed and arranged to allow a person to select a value and/or a menu option.

8.5 AIR CIRCUIT

[0354] An air circuit 4170 in accordance with an aspect of the present technology is a conduit or a tube constructed and arranged to allow, in use, a flow of air to travel between two components such as RPT device 4000 and the patient interface 3000 or 3800.

[0355] In particular, the air circuit 4170 may be in fluid connection with the outlet of the pneumatic block 4020 and the patient interface. The air circuit may be referred to as an air delivery tube. In some cases there may be separate limbs of the circuit for inhalation and exhalation. In other cases a single limb is used.

[0356] In some forms, the air circuit 4170 may comprise one or more heating elements configured to heat air in the air circuit, for example to maintain or raise the

temperature of the air. The heating element may be in a form of a heated wire circuit, and may comprise one or more transducers, such as temperature sensors. In one form, the heated wire circuit may be helically wound around the axis of the air circuit 4170. The heating element may be in communication with a controller such as a central controller. One example of an air circuit 4170 comprising a heated wire circuit is described in United States Patent 8,733,349, which is incorporated herewithin in its entirety by reference.

8.5.1 Supplementary gas delivery

[0357] In one form of the present technology, supplementary gas, e.g. oxygen, 4180 is delivered to one or more points in the pneumatic path, such as upstream of the pneumatic block 4020, to the air circuit 4170, and/or to the patient interface 3000 or 3800.

8.6 HUMIDIFIER

8.6.1 Humidifier overview

[0358] In one form of the present technology there is provided a humidifier 5000 (e.g. as shown in Fig. 5A) 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.

[0359] The humidifier 5000 may comprise a humidifier reservoir 5110, a humidifier inlet 5002 to receive a flow of air, and a humidifier outlet 5004 to deliver a humidified flow of *air*. In some forms, as shown in Fig. 5A and Fig. 5B, an inlet and an outlet of the humidifier reservoir 5110 may be the humidifier inlet 5002 and the humidifier outlet 5004 respectively. The humidifier 5000 may further comprise a humidifier base 5006, which may be adapted to receive the humidifier reservoir 5110 and comprise a heating element 5240.

8.6.2 Humidifier components

8.6.2.1 Water reservoir

[0360] According to one arrangement, the humidifier 5000 may comprise a water reservoir 5110 configured to hold, or retain, a volume of liquid (e.g. water) to be evaporated for humidification of the flow of air. The water reservoir 5110 may be configured to hold a predetermined maximum volume of water in order to provide adequate humidification for at least the duration of a respiratory therapy session, such as one evening of sleep. Typically, the reservoir 5110 is configured to hold several hundred millilitres of water, e.g. 300 millilitres (ml), 325 ml, 350 ml or 400 ml. In other forms, the humidifier 5000 may be configured to receive a supply of water from an external water source such as a building's water supply system.

[0361] According to one aspect, the water reservoir 5110 is configured to add humidity to a flow of air from the RPT device 4000 as the flow of air travels therethrough. In one form, the water reservoir 5110 may be configured to encourage the flow of air to travel in a tortuous path through the reservoir 5110 while in contact with the volume of water therein.

[0362] According to one form, the reservoir 5110 may be removable from the humidifier 5000, for example in a lateral direction as shown in Fig. 5A and Fig. 5B.

[0363] The reservoir 5110 may also be configured to discourage egress of liquid therefrom, such as when the reservoir 5110 is displaced and/or rotated from its normal, working orientation, such as through any apertures and/or in between its sub-components. As the flow of air to be humidified by the humidifier 5000 is typically pressurised, the reservoir 5110 may also be configured to prevent losses in pneumatic pressure through leak and/or flow impedance.

8.6.2.2 Conductive portion

[0364] According to one arrangement, the reservoir 5110 comprises a conductive portion 5120 configured to allow efficient transfer of heat from the heating element 5240 to the volume of liquid in the reservoir 5110. In one form, the conductive portion 5120 may be arranged as a plate, although other shapes may also be suitable. All or a part of the conductive portion 5120 may be made of a thermally conductive

material such as aluminium (e.g. approximately 2 mm thick, such as 1 mm, 1.5 mm, 2.5 mm or 3 mm), another heat conducting metal or some plastics. In some cases, suitable heat conductivity may be achieved with less conductive materials of suitable geometry.

8.6.2.3 Humidifier reservoir dock

[0365] In one form, the humidifier 5000 may comprise a humidifier reservoir dock 5130 (as shown in Fig. 5B) configured to receive the humidifier reservoir 5110. In some arrangements, the humidifier reservoir dock 5130 may comprise a locking feature such as a locking lever 5135 configured to retain the reservoir 5110 in the humidifier reservoir dock 5130.

8.6.2.4 Water level indicator

[0366] The humidifier reservoir 5110 may comprise a water level indicator 5150 as shown in Fig. 5A-5B. In some forms, the water level indicator 5150 may provide one or more indications to a user such as the patient 1000 or a care giver regarding a quantity of the volume of water in the humidifier reservoir 5110. The one or more indications provided by the water level indicator 5150 may include an indication of a maximum, predetermined volume of water, any portions thereof, such as 25%, 50% or 75% or volumes such as 200 ml, 300 ml or 400ml.

8.6.2.5 Humidifier transducer(s)

[0367] The humidifier 5000 may comprise one or more humidifier transducers (sensors) instead of, or in addition to, transducers 4270 described above. Humidifier transducers may include one or more of an air pressure sensor, an air flow rate transducer, a temperature sensor, or a humidity sensor. A humidifier transducer may produce one or more output signals which may be communicated to a controller such as the central controller and/or the humidifier controller. In some forms, a humidifier transducer may be located externally to the humidifier 5000 (such as in the air circuit 4170) while communicating the output signal to the controller.

8.6.2.5.1 Pressure transducer

[0368] One or more pressure transducers may be provided to the humidifier 5000 in addition to, or instead of, a pressure sensor provided in the RPT device 4000.

8.6.2.5.2 Flow rate transducer

[0369] One or more flow rate transducers may be provided to the humidifier 5000 in addition to, or instead of, a flow rate sensor provided in the RPT device 4000.

8.6.2.5.3 Temperature transducer

[0370] The humidifier 5000 may comprise one or more temperature transducers 5216. The one or more temperature transducers 5216 may be configured to measure one or more temperatures such as of the heating element 5240 and/or of the flow of air downstream of the humidifier outlet 5004. In some forms, the humidifier 5000 may further comprise a temperature sensor 5216 to detect the temperature of the ambient air.

8.6.2.5.4 Humidity transducer

[0371] In one form, the humidifier 5000 may comprise one or more humidity sensors 5218 to detect a humidity of a gas, such as the ambient air. The humidity sensor 5218 may be placed towards the humidifier outlet 5004 in some forms to measure a humidity of the gas delivered from the humidifier 5000. The humidity sensor may be an absolute humidity sensor or a relative humidity sensor.

8.6.2.6 Heating element

[0372] A heating element 5240 may be provided to the humidifier 5000 in some cases to provide a heat input to one or more of the volume of water in the humidifier reservoir 5110 and/or to the flow of air. The heating element 5240 may comprise a heat generating component such as an electrically resistive heating track. One suitable example of a heating element 5240 is a layered heating element such as one described in the PCT Patent Application Publication No. WO 2012/171072, which is incorporated herewith by reference in its entirety.

[0373] In some forms, the heating element 5240 may be provided in the humidifier base 5006 where heat may be provided to the humidifier reservoir 5110 primarily by conduction as shown in Fig. 5B.

8.7 BREATHING WAVEFORMS

[0374] Fig. 6A shows a model typical breath waveform of a person while sleeping. The horizontal axis is time, and the vertical axis is respiratory flow rate.

While the parameter values may vary, a typical breath may have the following approximate values: tidal volume V_t 0.5L, inhalation time T_i 1.6s, peak inspiratory flow rate Q_{peak} 0.4 L/s, exhalation time T_e 2.4s, peak expiratory flow rate Q_{peak} -0.5 L/s. The total duration of the breath, T_{tot} , is about 4s. The person typically breathes at a rate of about 15 breaths per minute (BPM), with Ventilation $Vent$ about 7.5 L/min. A typical duty cycle, the ratio of T_i to T_{tot} , is about 40%.

8.8 SCREENING, DIAGNOSIS, MONITORING SYSTEMS

8.8.1 Polysomnography

[0375] Fig. 7A shows a patient 1000 undergoing polysomnography (PSG). A PSG system comprises a headbox 2000 which receives and records signals from the following sensors: an EOG electrode 2015; an EEG electrode 2020; an ECG electrode 2025; a submental EMG electrode 2030; a snore sensor 2035; a respiratory inductance plethysmogram (respiratory effort sensor) 2040 on a chest band; a respiratory inductance plethysmogram (respiratory effort sensor) 2045 on an abdominal band; an oro-nasal cannula 2050 with oral thermistor; a photoplethysmograph (pulse oximeter) 2055; and a body position sensor 2060. The electrical signals are referred to a ground electrode (ISOG) 2010 positioned in the centre of the forehead.

8.8.2 Non-obtrusive monitoring system

[0376] One example of a monitoring apparatus 7100 for monitoring the respiration of a sleeping patient 1000 is illustrated in Fig. 7B. The monitoring apparatus 7100 contains a contactless motion sensor generally directed toward the patient 1000. The motion sensor is configured to generate one or more signals representing bodily movement of the patient 1000, from which may be obtained a signal representing respiratory movement of the patient.

8.9 PORTABLE OXYGEN CONCENTRATOR (POC)

[0377] Portable oxygen concentrators may take advantage of pressure swing adsorption (PSA). Pressure swing adsorption may involve using one or more compressors to increase gas pressure inside a canister that contains particles of a gas separation adsorbent arranged in a "sieve bed". As the pressure increases, certain molecules in the gas may become adsorbed onto the gas separation adsorbent. Removal of a portion of the gas in the canister under the pressurized conditions allows

separation of the non-adsorbed molecules from the adsorbed molecules. The gas separation adsorbent may be regenerated by reducing the pressure, which reverses the adsorption of molecules from the adsorbent. Further details regarding oxygen concentrators may be found, for example, in U.S. Published Patent Application No. 2009-0065007, published March 12, 2009, and entitled “Oxygen Concentrator Apparatus and Method”, which is incorporated herein by reference.

[0378] Ambient air usually includes approximately 78% nitrogen and 21% oxygen with the balance comprised of argon, carbon dioxide, water vapor and other trace gases. If a gas mixture such as air, for example, is passed under pressure through a canister containing a gas separation adsorbent bed that attracts nitrogen more strongly than it does oxygen, part or all of the nitrogen will stay in the bed, and the gas coming out of the canister will be enriched in oxygen. When the bed reaches the end of its capacity to adsorb nitrogen, it can be regenerated by reducing the pressure, thereby releasing the adsorbed nitrogen. It is then ready for another cycle of producing oxygen enriched air. By alternating canisters in a two-canister system, one canister can be separating oxygen while the other canister is being purged (resulting in a continuous separation of the oxygen from the nitrogen). In this manner, oxygen enriched air can be accumulated, such as in a storage container or other pressurizable vessel or conduit coupled to the canisters, for a variety of uses including providing supplemental oxygen to patients.

8.10 RESPIRATORY THERAPY MODES

[0379] Various respiratory therapy modes may be implemented by the disclosed respiratory therapy system. For example, the system may implement CPAP therapy, bi-level therapy, and/or high flow therapy.

8.11 GLOSSARY

[0380] 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.

8.11.1 General

[0381] *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.

[0382] *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.

[0383] 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.

[0384] In another example, ambient pressure may be the pressure immediately surrounding or external to the body.

[0385] 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.

[0386] *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.

[0387] *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.

[0388] *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'.

[0389] 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, Q_d , is the flow rate of air leaving the RPT device. Total flow rate, Q_t , is the flow rate of air and any supplementary gas reaching the patient interface via the air circuit. Vent flow rate, Q_v , is the flow rate of air leaving a vent to allow washout of exhaled gases. Leak flow rate, Q_l , is the flow rate of leak from a patient interface system or elsewhere. Respiratory flow rate, Q_r , is the flow rate of air that is received into the patient's respiratory system.

[0390] *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.

[0391] *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.

[0392] *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.

[0393] *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.

[0394] *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.

[0395] *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.

[0396] *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".

[0397] *Medical Oxygen*: Medical oxygen is defined as oxygen enriched air with an oxygen concentration of 80% or greater.

[0398] *Patient*: A person, whether or not they are suffering from a respiratory condition.

[0399] *Pressure*: Force per unit area. Pressure may be expressed in a range of units, including cmH₂O, g-f/cm² and hectopascal. 1 cmH₂O is equal to 1 g-f/cm² and is approximately 0.98 hectopascal (1 hectopascal = 100 Pa = 100 N/m² = 1 millibar ~ 0.001 atm). In this specification, unless otherwise stated, pressure is given in units of cmH₂O.

[0400] The pressure in the patient interface is given the symbol *P_m*, while the treatment pressure, which represents a target value to be achieved by the interface pressure *P_m* at the current instant of time, is given the symbol *P_t*.

[0401] *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.

[0402] *Ventilator*: A mechanical device that provides pressure support to a patient to perform some or all of the work of breathing.

8.11.1.1 Materials

[0403] *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.

[0404] *Polycarbonate*: a thermoplastic polymer of Bisphenol-A Carbonate.

8.11.1.2 Mechanical properties

[0405] *Resilience*: Ability of a material to absorb energy when deformed elastically and to release the energy upon unloading.

[0406] *Resilient*: Will release substantially all of the energy when unloaded. Includes e.g. certain silicones, and thermoplastic elastomers.

[0407] *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.

[0408] *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.

[0409] *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.

[0410] *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.

[0411] 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.

8.11.2 Respiratory cycle

[0412] *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.

[0413] *Breathing rate*: The rate of spontaneous respiration of a patient, usually measured in breaths per minute.

[0414] *Duty cycle*: The ratio of inhalation time, T_i to total breath time, T_{tot} .

[0415] *Effort* (breathing): The work done by a spontaneously breathing person attempting to breathe.

[0416] *Expiratory portion* of a breathing cycle: The period from the start of expiratory flow to the start of inspiratory flow.

[0417] *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.

[0418] 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.

[0419] *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.

[0420] *Hyperpnea*: An increase in flow to a level higher than normal.

[0421] *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.

[0422] *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).

[0423] *Positive End-Expiratory Pressure (PEEP)*: The pressure above atmosphere in the lungs that exists at the end of expiration.

[0424] *Peak flow rate (Q_{peak})*: The maximum value of flow rate during the inspiratory portion of the respiratory flow waveform.

[0425] *Respiratory flow rate, patient airflow rate, respiratory airflow rate (Q_r)*: 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.

[0426] *Tidal volume (V_t)*: The volume of air inhaled or exhaled during normal breathing, when extra effort is not applied. In principle the inspiratory volume V_i (the volume of air inhaled) is equal to the expiratory volume V_e (the volume of air exhaled), and therefore a single tidal volume V_t may be defined as equal to either quantity. In practice the tidal volume V_t is estimated as some combination, e.g. the mean, of the inspiratory volume V_i and the expiratory volume V_e .

[0427] *Inhalation Time (T_i)*: The duration of the inspiratory portion of the respiratory flow rate waveform.

[0428] *Exhalation Time (T_e)*: The duration of the expiratory portion of the respiratory flow rate waveform.

[0429] *Total Time (T_{tot})*: 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.

[0430] *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.

[0431] *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).

[0432] *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.

8.11.3 Ventilation

[0433] *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.

[0434] *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.

[0435] *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.

[0436] *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.

[0437] *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.

[0438] Inspiratory positive airway pressure (IPAP): Maximum desired interface pressure which the ventilator will attempt to achieve during the inspiratory portion of the breath.

[0439] 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.

[0440] 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.

[0441] 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.

[0442] Swing: Equivalent term to pressure support.

[0443] 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.

8.11.4 Anatomy

8.11.4.1 Anatomy of the face

[0444] Ala: the external outer wall or "wing" of each nostril (plural: alar)

[0445] Alare: The most lateral point on the nasal ala.

[0446] 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.

[0447] Auricle: The whole external visible part of the ear.

[0448] (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.

[0449] (nose) Cartilaginous framework: The cartilaginous framework of the nose comprises the septal, lateral, major and minor cartilages.

[0450] Columella: the strip of skin that separates the nares and which runs from the pronasale to the upper lip.

[0451] 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.

[0452] 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.

[0453] Glabella: Located on the soft tissue, the most prominent point in the midsagittal plane of the forehead.

[0454] 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.

[0455] 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.

[0456] 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.

[0457] 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.

[0458] Naso-labial angle: The angle between the columella and the upper lip, while intersecting subnasale.

[0459] Otobasion inferior: The lowest point of attachment of the auricle to the skin of the face.

[0460] Otobasion superior: The highest point of attachment of the auricle to the skin of the face.

[0461] 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.

[0462] Philtrum: the midline groove that runs from lower border of the nasal septum to the top of the lip in the upper lip region.

[0463] Pogonion: Located on the soft tissue, the most anterior midpoint of the chin.

[0464] Ridge (nasal): The nasal ridge is the midline prominence of the nose, extending from the Sellion to the Pronasale.

[0465] 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.

[0466] Sellion: Located on the soft tissue, the most concave point overlying the area of the frontonasal suture.

[0467] Septal cartilage (nasal): The nasal septal cartilage forms part of the septum and divides the front part of the nasal cavity.

[0468] Subalare: The point at the lower margin of the alar base, where the alar base joins with the skin of the superior (upper) lip.

- [0469] Subnasal point: Located on the soft tissue, the point at which the columella merges with the upper lip in the midsagittal plane.
- [0470] Supramenton: The point of greatest concavity in the midline of the lower lip between labrale inferius and soft tissue pogonion
- [0471] Anatomy of the skull
- [0472] Frontal bone: The frontal bone includes a large vertical portion, the squama frontalis, corresponding to the region known as the forehead.
- [0473] Mandible: The mandible forms the lower jaw. The mental protuberance is the bony protuberance of the jaw that forms the chin.
- [0474] 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.
- [0475] 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.
- [0476] 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.
- [0477] 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.
- [0478] Orbit: The bony cavity in the skull to contain the eyeball.
- [0479] Parietal bones: The parietal bones are the bones that, when joined together, form the roof and sides of the cranium.
- [0480] 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.

[0481] 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.

8.11.4.2 Anatomy of the respiratory system

[0482] 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.

[0483] Larynx: The larynx, or voice box houses the vocal folds and connects the inferior part of the pharynx (hypopharynx) with the trachea.

[0484] 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.

[0485] 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.

[0486] 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).

8.11.5 Patient interface

[0487] 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.

[0488] 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.

[0489] 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.

[0490] Functional dead space: (description to be inserted here)

[0491] 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.

[0492] 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.

[0493] 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.

[0494] 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.

[0495] 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.

[0496] 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.

[0497] 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.

[0498] 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.

[0499] Tie (noun): A structure designed to resist tension.

[0500] 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.

8.11.6 Shape of structures

[0501] 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.

[0502] 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.

8.11.6.1 Curvature in one dimension

[0503] The curvature of a plane curve at p may be described as having a sign (e.g. positive, negative) and a magnitude (e.g. $1/\text{radius}$ of a circle that just touches the curve at p).

[0504] 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.

[0505] 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.

[0506] 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.

8.11.6.2 Curvature of two dimensional surfaces

[0507] 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.

[0508] 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.

[0509] 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.

[0510] 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).

[0511] 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”).

[0512] 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.

[0513] Planar region: A region of a surface where both of the principal curvatures are zero (or, for example, zero within manufacturing tolerances).

[0514] Edge of a surface: A boundary or limit of a surface or region.

[0515] 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).

[0516] 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).

[0517] 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'.)

8.11.6.3 Space curves

[0518] 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.

[0519] 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.

[0520] 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.

[0521] 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).

[0522] Osculating plane: The plane containing the unit tangent vector and the unit principal normal vector. See Figures 3O and 3P.

[0523] 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 $T_2 > T_1$, 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

[0524] 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).

[0525] 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.

8.11.6.4 Holes

[0526] 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.

[0527] 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.

8.12 OTHER REMARKS

[0528] 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.

[0529] 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.

[0530] 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.

[0531] 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.

[0532] 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.

[0533] 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.

[0534] 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.

[0535] 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.

[0536] 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.

[0537] 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.

[0538] 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.

8.13 REFERENCE SIGNS LIST

moisture exchanger	800
first planar surface	802
second planar surface	804
sidewall	806
vent	808
angle	812
flow	814

flow	816
exit	818
moisture exchanger	840
first planar surface	842
second planar surface	844
sidewall	846
opening	847
vent	848
pathway	849
flow	852
flow	854
flow	856
exit flow	858
attachment means	900
filter layer	910
attachment means	940
outer body	942
opposing ends	944
tabs	946
patient	1000
bed partner	1100
headbox	2000
ground electrode ISOG	2010
EOG electrode	2015
EEG electrode	2020
ECG electrode	2025
submental EMG electrode	2030
snore sensor	2035
respiratory inductance plethysmogram respiratory effort sensor	2040
respiratory inductance plethysmogram respiratory effort sensor	2045
oro - nasal cannula	2050
photoplethysmograph pulse oximeter	2055
body position sensor	2060
patient interface	3000
seal - forming structure	3100
plenum chamber	3200
chord	3210
superior point	3220
inferior point	3230
structure	3300
vent	3400
connection port	3600
forehead support	3700
ISO	3744

unsealed patient interface	3800
nasal prong	3810a
nasal prong	3810b
lumen	3820a
lumen	3820b
RPT device	4000
external housing	4010
upper portion	4012
portion	4014
panel	4015
chassis	4016
handle	4018
pneumatic block	4020
air filter	4110
air filters	4110
inlet air filter	4112
outlet air filter	4114
muffler	4120
inlet muffler	4122
outlet muffler	4124
pressure generator	4140
blower	4142
controllable blower	4142
motor	4144
brushless DC motor	4144
anti - spill back valve	4160
air circuit	4170
power supply	4210
input device	4220
transducer	4270
pressure sensors	4272
flow rate sensors	4274
algorithms	4300
humidifier	5000
humidifier inlet	5002
humidifier outlet	5004
humidifier base	5006
reservoir	5110
conductive portion	5120
humidifier reservoir dock	5130
locking lever	5135
water level indicator	5150
temperature sensor	5216
humidity sensor	5218

heating element	5240
patient interface	6000
plenum chamber	6200
monitoring apparatus	7100

9 CLAIMS

1. A heat and moisture exchanger for a patient interface, comprising:
 - a) a nonwoven composite formed from a fibrous material having a first planar surface, an opposite second planar surface and a sidewall positioned between the first planar surface and the opposite second planar surface; and
 - b) at least one vent on the first planar surface, the at least one vent extending at least partially toward the second planar surface, and a wall of the at least one vent being formed from the fibrous material;wherein the nonwoven composite is permeable to air; and

wherein the nonwoven composite including a first impedance and the vent including a second impedance less than the first impedance to allow a flow of gas through the first planar surface.
2. The heat and moisture exchanger according to claim 1, wherein the nonwoven composite is permeable to air through the first planar surface from the sidewall.
3. The heat and moisture exchanger according to claim 1, wherein the nonwoven composite is permeable to air through the first planar surface from the second planar surface.
4. The heat and moisture exchanger according to claim 1 or 2, wherein the vent allows air to flow through the first planar surface to the second planar surface.
5. The heat and moisture exchanger according to claim 1 or 3, wherein the vent allows air to flow through the first planar surface to the sidewall.
6. The heat and moisture exchanger according to any one of claims 1 to 5, wherein the vent is one of a plurality of vents.
7. The heat and moisture exchanger according to claim 6, wherein the plurality of vents are arranged in at least one concentric pattern or spiral pattern.
8. The heat and moisture exchanger according to any one of claims 1 to 7, wherein the vent has a diameter of about 0.1 mm to 2 mm.

9. The heat and moisture exchanger according to any one of claims 1 to 8, wherein the nonwoven composite is a multi-layered composite.
10. The heat and moisture exchanger according to any one of claims 1 to 9, wherein the nonwoven composite is an at least three layered composite.
11. The heat and moisture exchanger according to any one of claims 1 to 10, wherein the fibrous material of the nonwoven composite comprises a combination of spunbond fibers, meltblown fibers, melt extrusion fibres and/or natural fibres.
12. The heat and moisture exchanger according to any one of claims 1 to 11, having a thickness of about 3 mm to about 15 mm.
13. The heat and moisture exchanger according to any one of claims 1 to 12, wherein the nonwoven composite has a water contact angle of less than 90°.
14. The heat and moisture exchanger according to any one of claims 1 to 13, wherein the nonwoven composite has a mass change of at least 20% at a relative humidity of 50% when measured using dynamic vapour sorption.
15. The heat and moisture exchanger according to any one of claims 1 to 14, wherein the nonwoven composite has a porosity of at least 20%.
16. The heat and moisture exchanger according to any one of claims 1 to 15, wherein the nonwoven composite has a density of at least 50 fibers/cm.
17. The heat and moisture exchanger according to any one of claims 1 to 16, wherein the nonwoven composite has a surface area of about 5 m²/g to about 100 m²/g.
18. The heat and moisture exchanger according to any one of claims 1 to 17, wherein the fibrous material of the nonwoven composite is formed from a web of fibers selected from polyethylene, polypropylene, polyethylene terephthalate, polyester, rayon, cotton, or a combination thereof.
19. The heat and moisture exchanger according to any one of claims 1 to 18, wherein fibrous material of the nonwoven composite is formed from a web of fibers

functionalised with hydrophilic moieties selected from hydroxyl, carboxyl, amino, sulfinyl, sulfonyl, phosphoryl, or a combination thereof.

20. The heat and moisture exchanger according to any one of claims 1 to 19, wherein the nonwoven composite further comprises a hydrophilic coating on the first planar surface and/or the second planar surface.

21. The heat and moisture exchanger according to any one of claims 1 to 20, wherein the nonwoven composite further comprises an anti-bacterial coating or anti-bacterial filter layer.

22. The heat and moisture exchanger according to any one of claims 1 to 21, wherein the nonwoven composite further comprises an olfactory coating or olfactory layer.

23. The heat and moisture exchanger according to any one of claims 1 to 22, wherein the nonwoven composite is a first nonwoven composite, the heat and moisture exchanger further comprising a second nonwoven composite, the first nonwoven composite and the second nonwoven composite being positioned adjacent to each other.

24. The heat and moisture exchanger according to claim 23, further comprising attachment means for aligning and stacking the first nonwoven composite and the second nonwoven composite.

25. The heat and moisture exchanger according to claim 24, wherein the attachment means is a polymer spacer.

26. A patient interface comprising:

a plenum chamber pressurisable to a therapeutic pressure of at least 4 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;

the heat and moisture exchanger of any one of claims 1 to 25 positioned within the plenum chamber;

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.

27. A patient interface comprising:

a plenum chamber pressurisable to a therapeutic pressure of at least 4 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;

the heat and moisture exchanger positioned within the plenum chamber, the heat and moisture exchanger comprising:

a body constructed from a permeable, nonwoven composite formed with a fibrous material, the body having a first surface and a second surface;

a passageway extending between the first surface and the second surface, the fibrous material forming a wall of the passageway;

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; and

wherein the body includes a first impedance and the passageway includes a second impedance less than the first impedance;

wherein the fibrous material configured to absorb water vapor from exhaled air; and

wherein the nonwoven composite of the body configured to transfer the absorbed water vapor to inhaled air and increase the humidity of the flow.

28. The patient interface of claim 27, wherein the body has a disk shape.
29. The patient interface of claim 27 or claim 28, wherein the first surface is a first planar surface and the second surface is a second planar surface opposite to the first planar surface.
30. The patient interface of claim 29, wherein the passageway extends along a single axis between the first surface and the second surface.
31. The patient interface of claim 27 or claim 28, wherein the first surface is a first planar surface and the second surface is a sidewall oriented substantially perpendicularly to the first surface.
32. The patient interface of claim 31, wherein the passageway is elbow shaped and extends along two axes.
33. The patient interface of any one of claims 27 to 32, wherein the body is a first body, the patient interface further comprising a second body, the first body and the second body being alignable and stackable on top of each other.
34. The patient interface of claim 33, further comprising attachment means for aligning and stacking the first body and the second body.
35. The heat and moisture exchanger according to claim 34, wherein the attachment means is a polymer spacer.

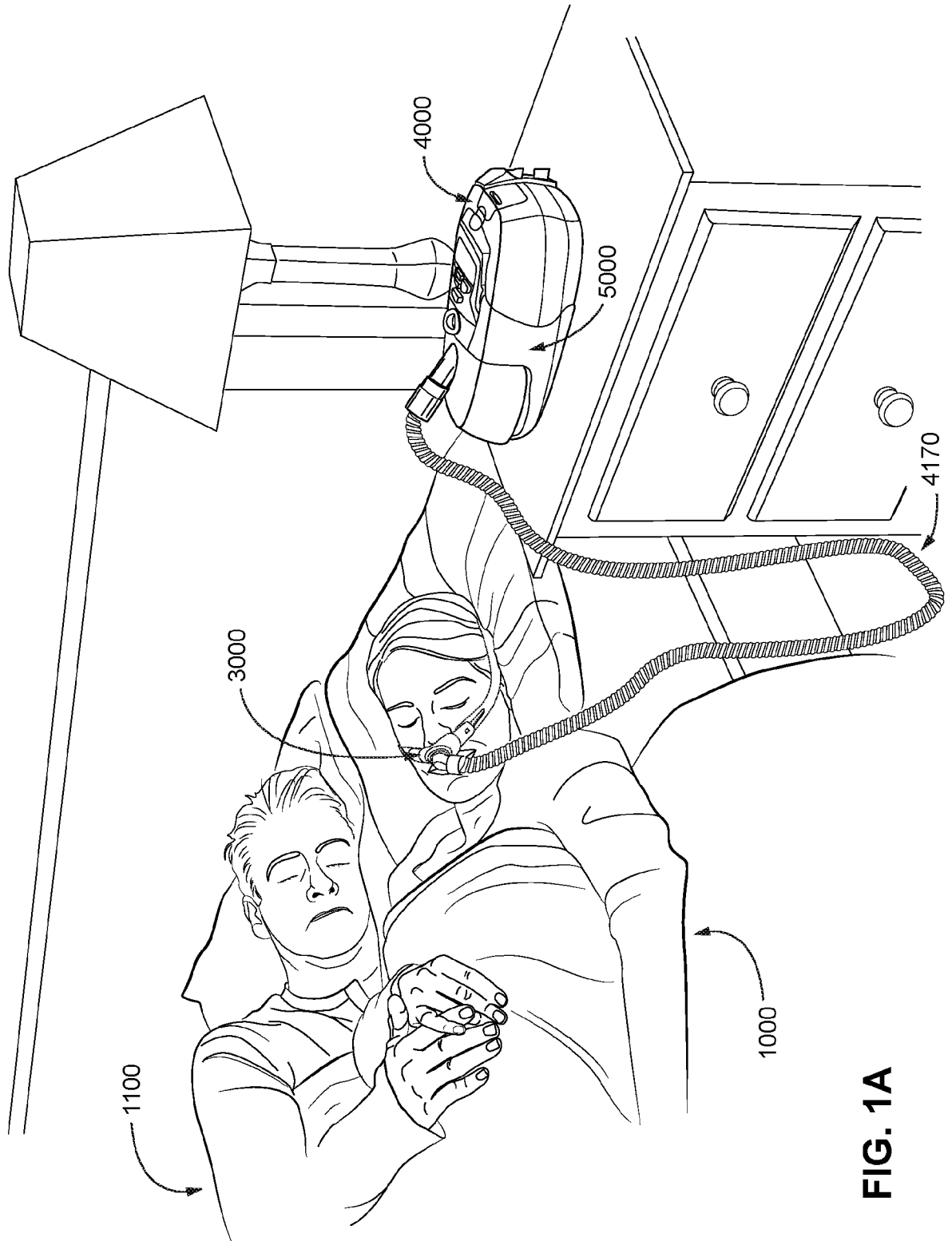


FIG. 1A

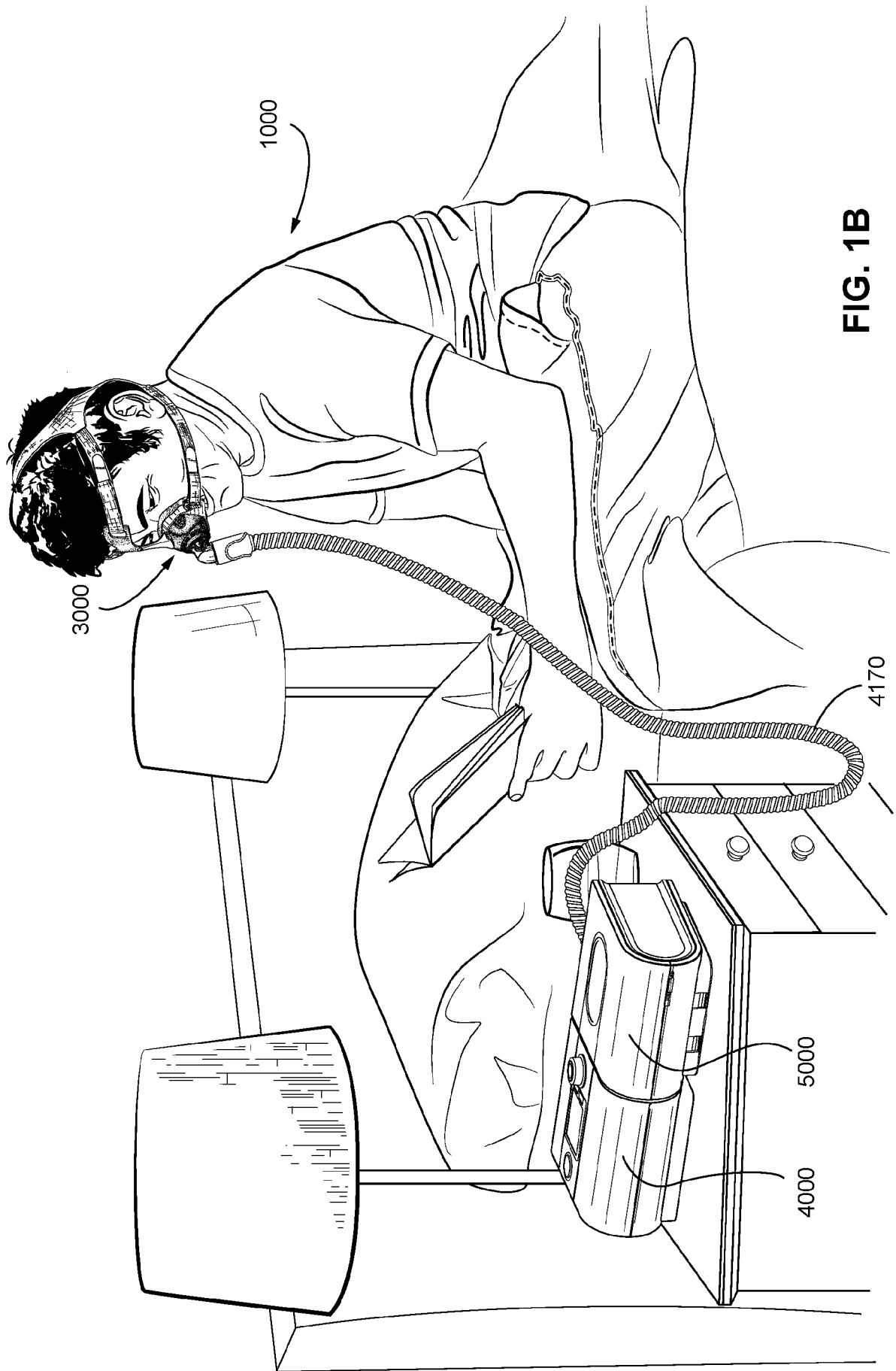


FIG. 1B



FIG. 1C

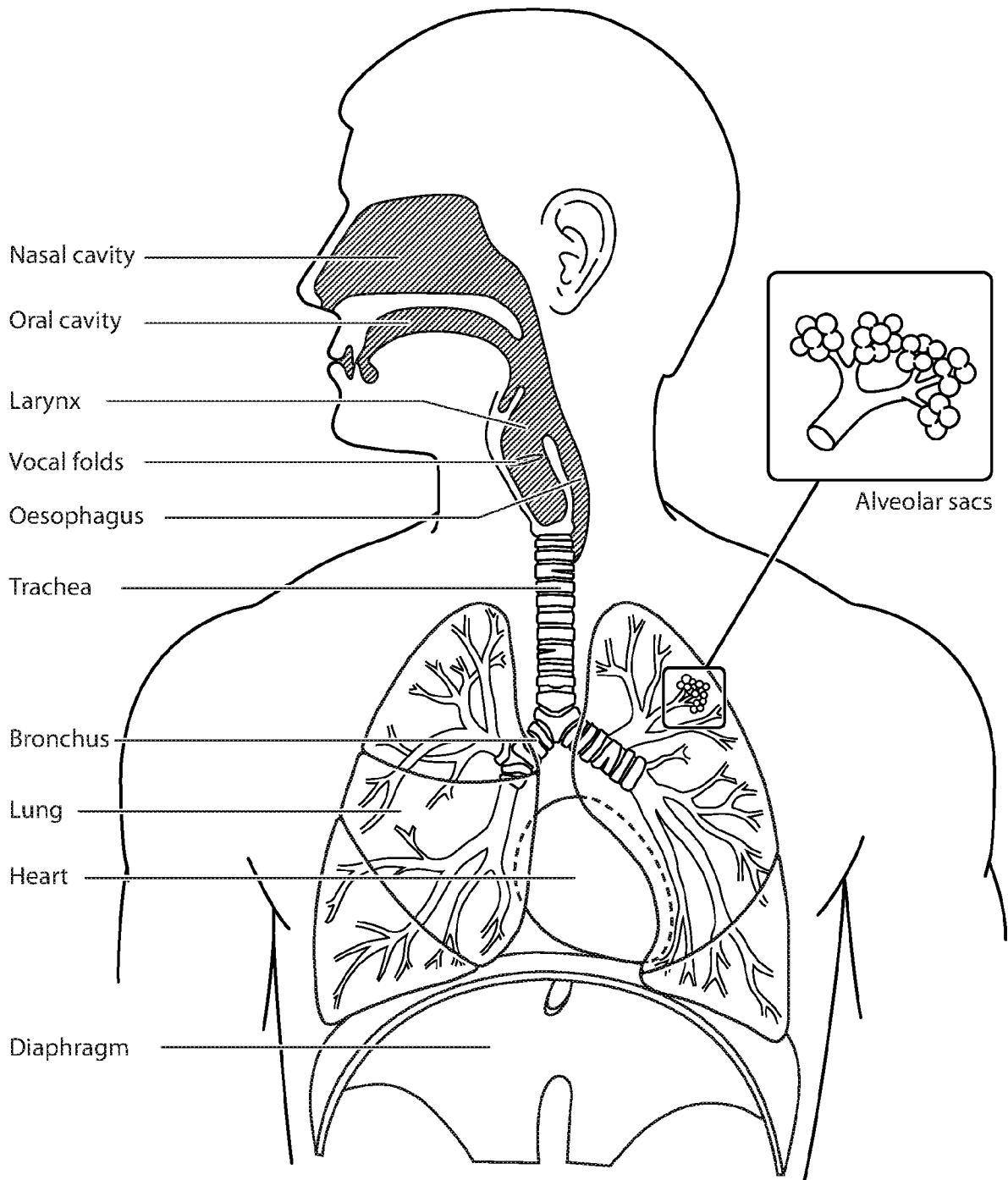


FIG. 2A

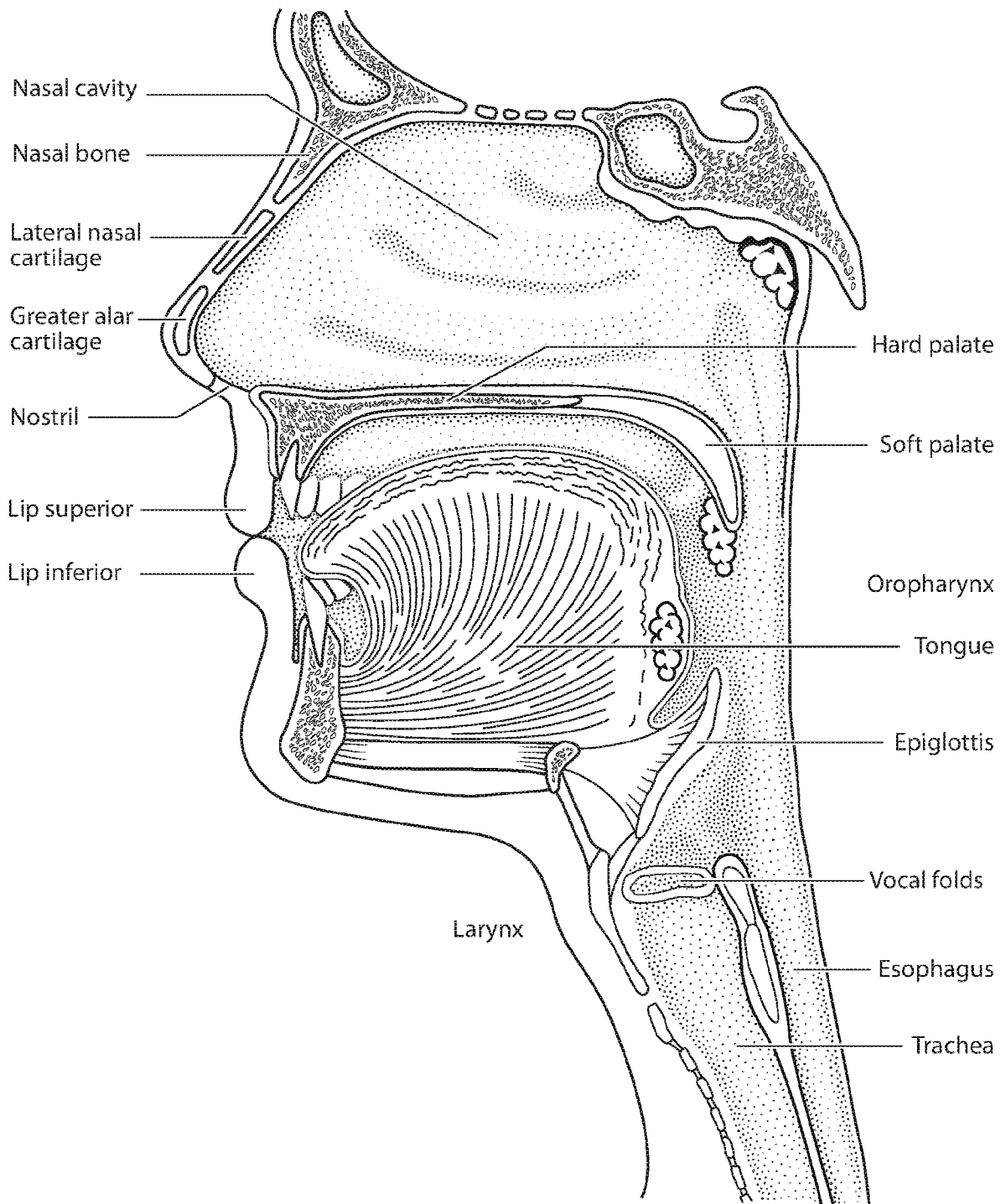
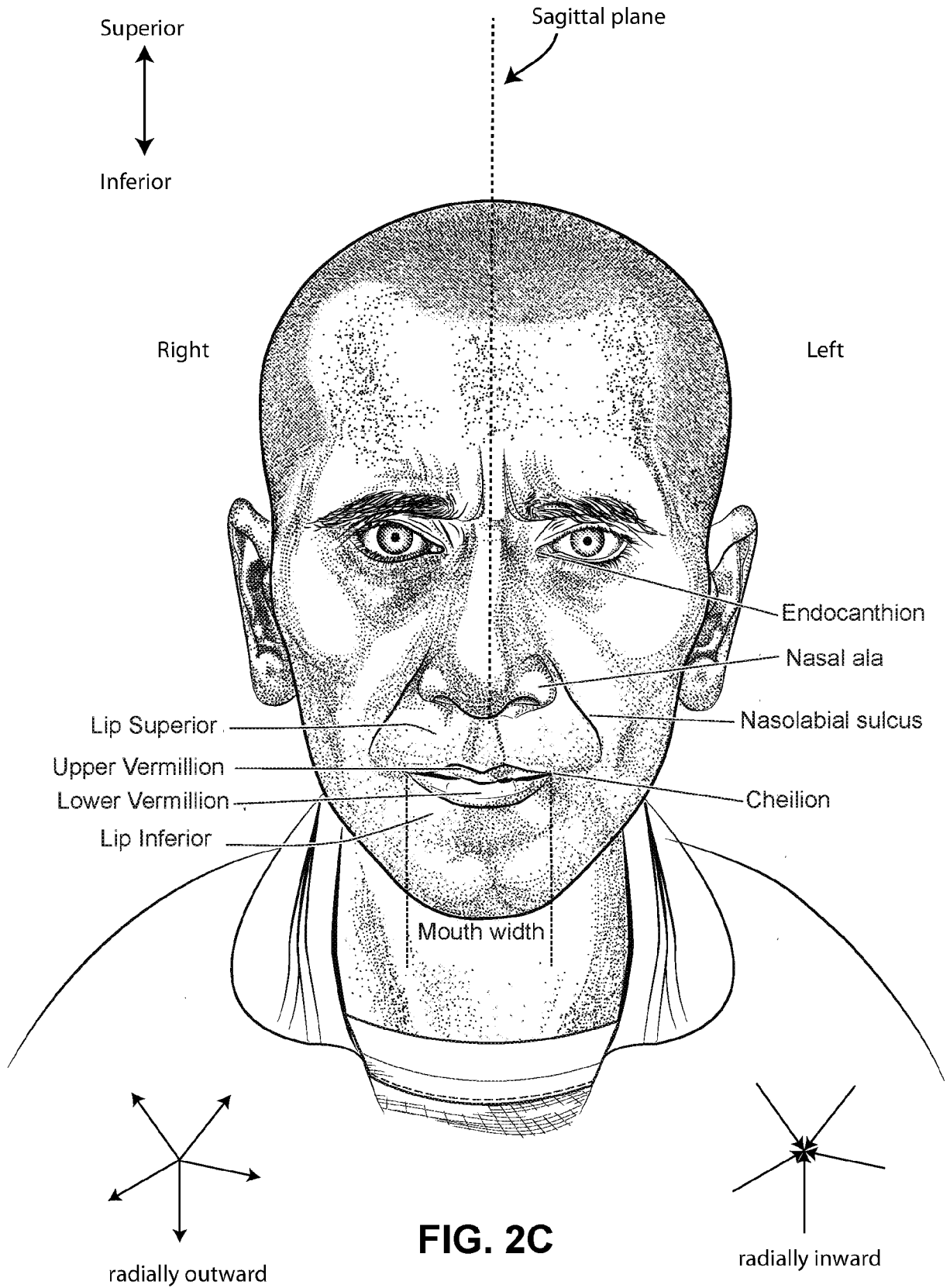


FIG. 2B



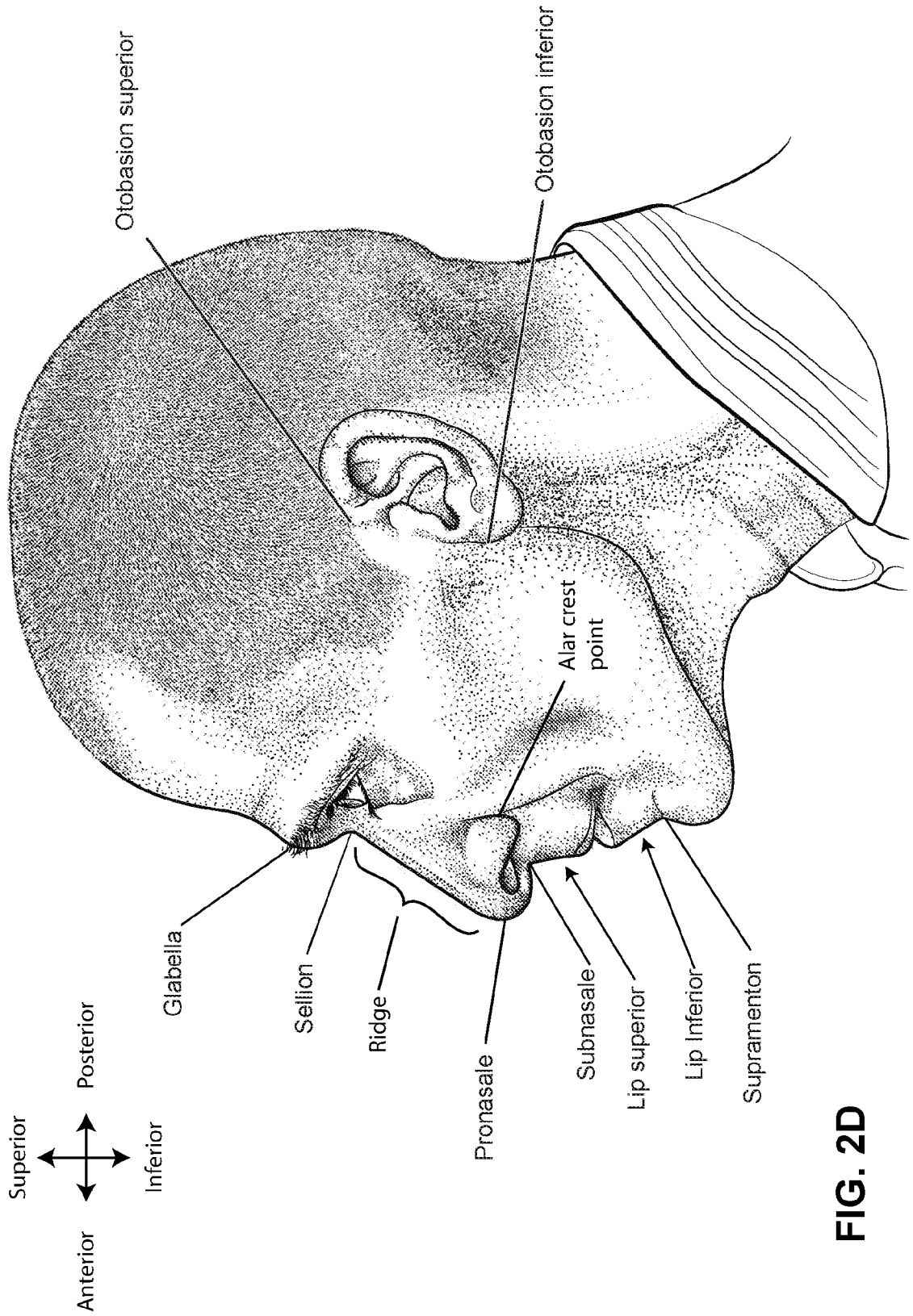


FIG. 2D

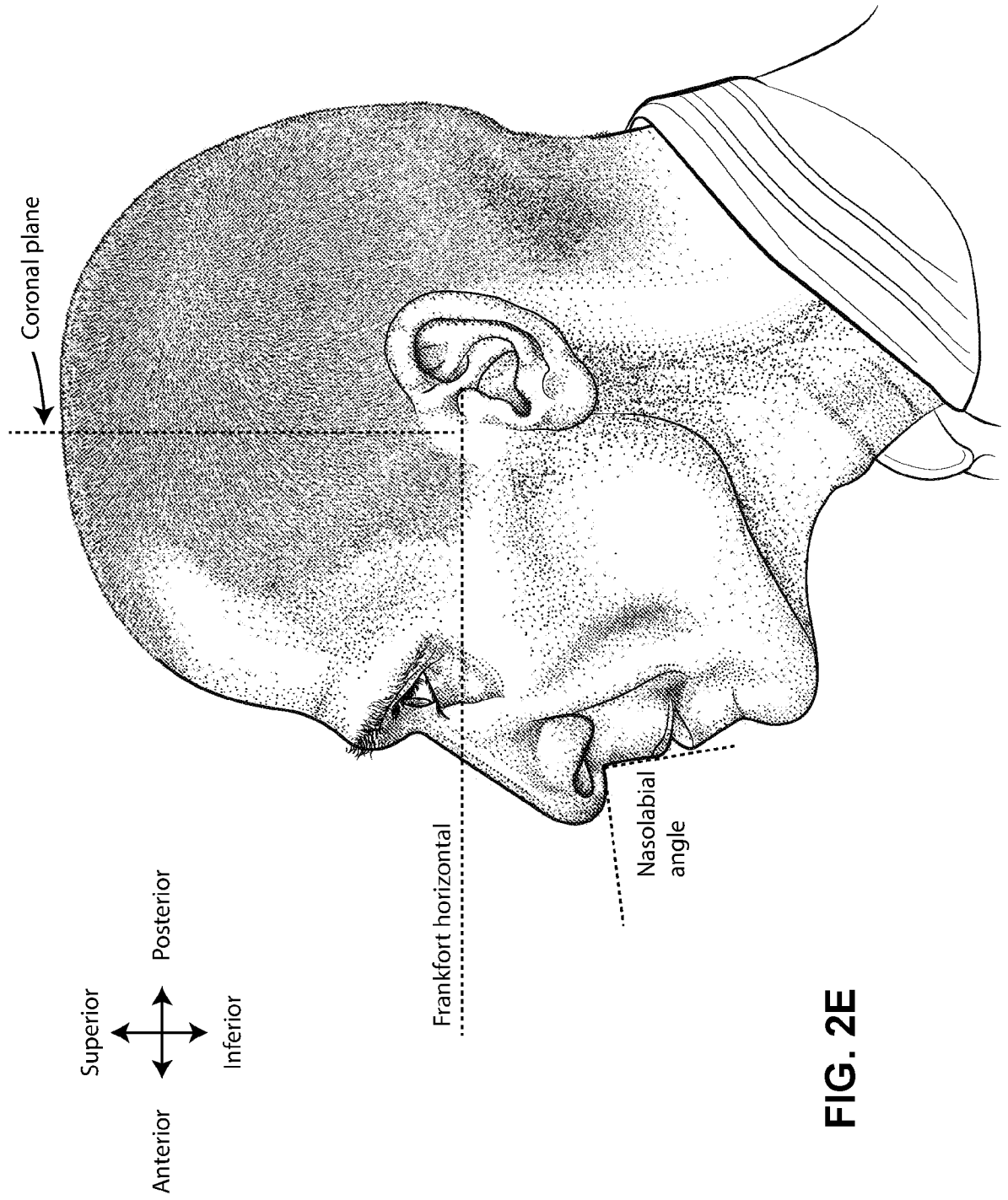
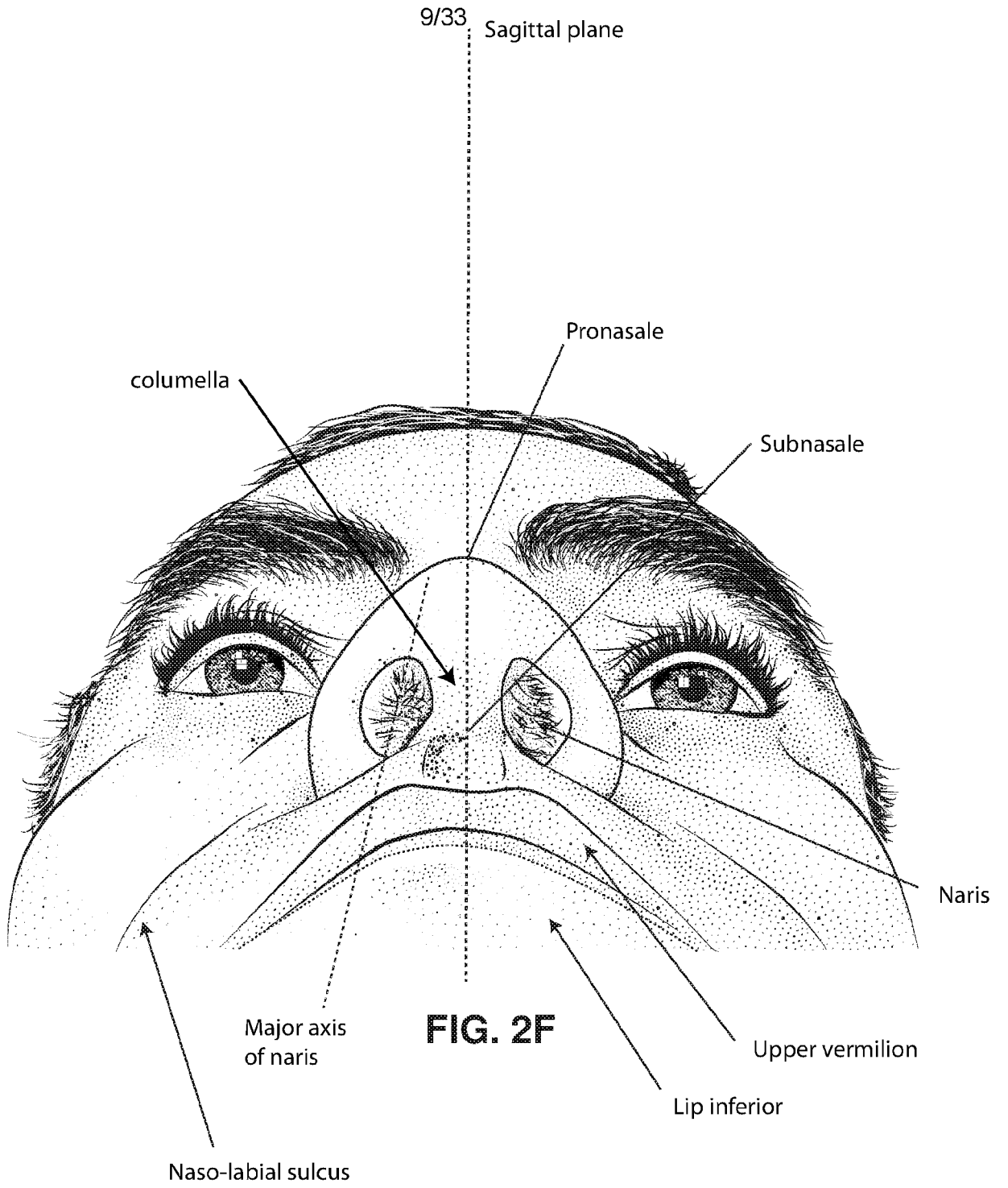


FIG. 2E



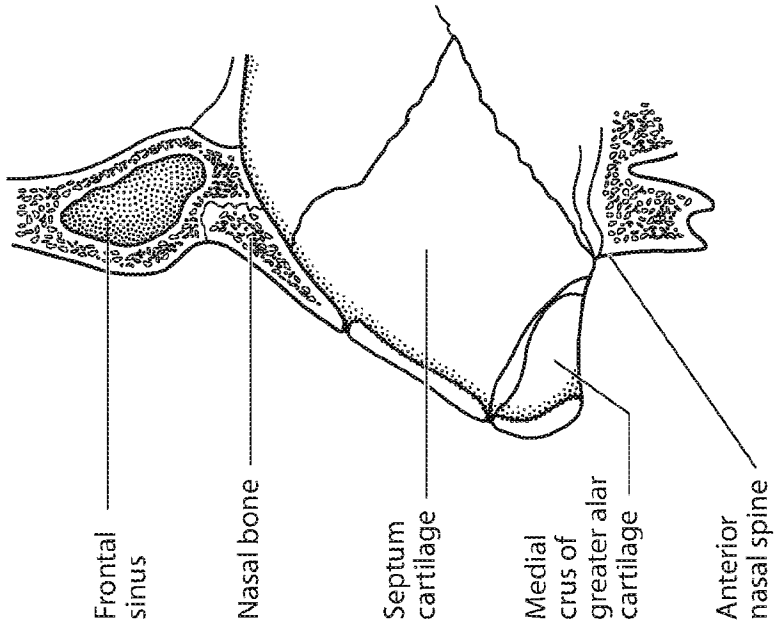


FIG. 2I

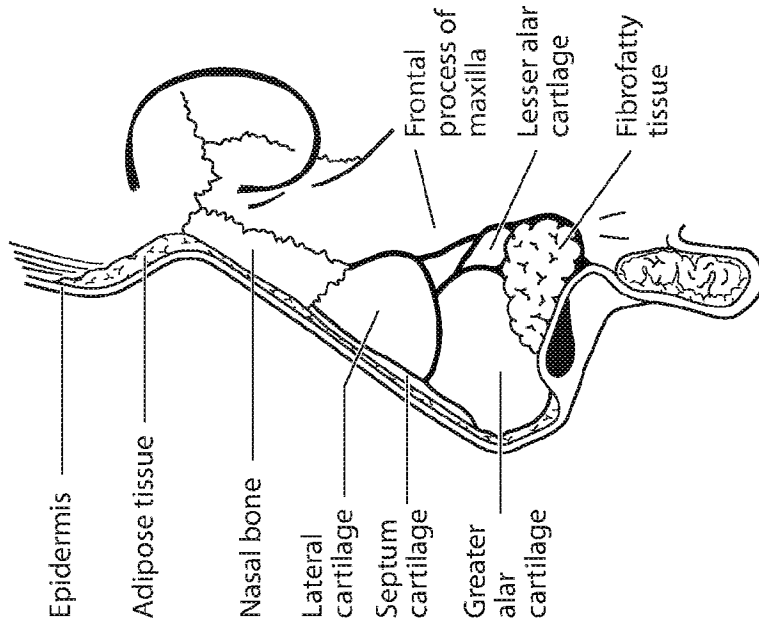


FIG. 2H



FIG. 2G

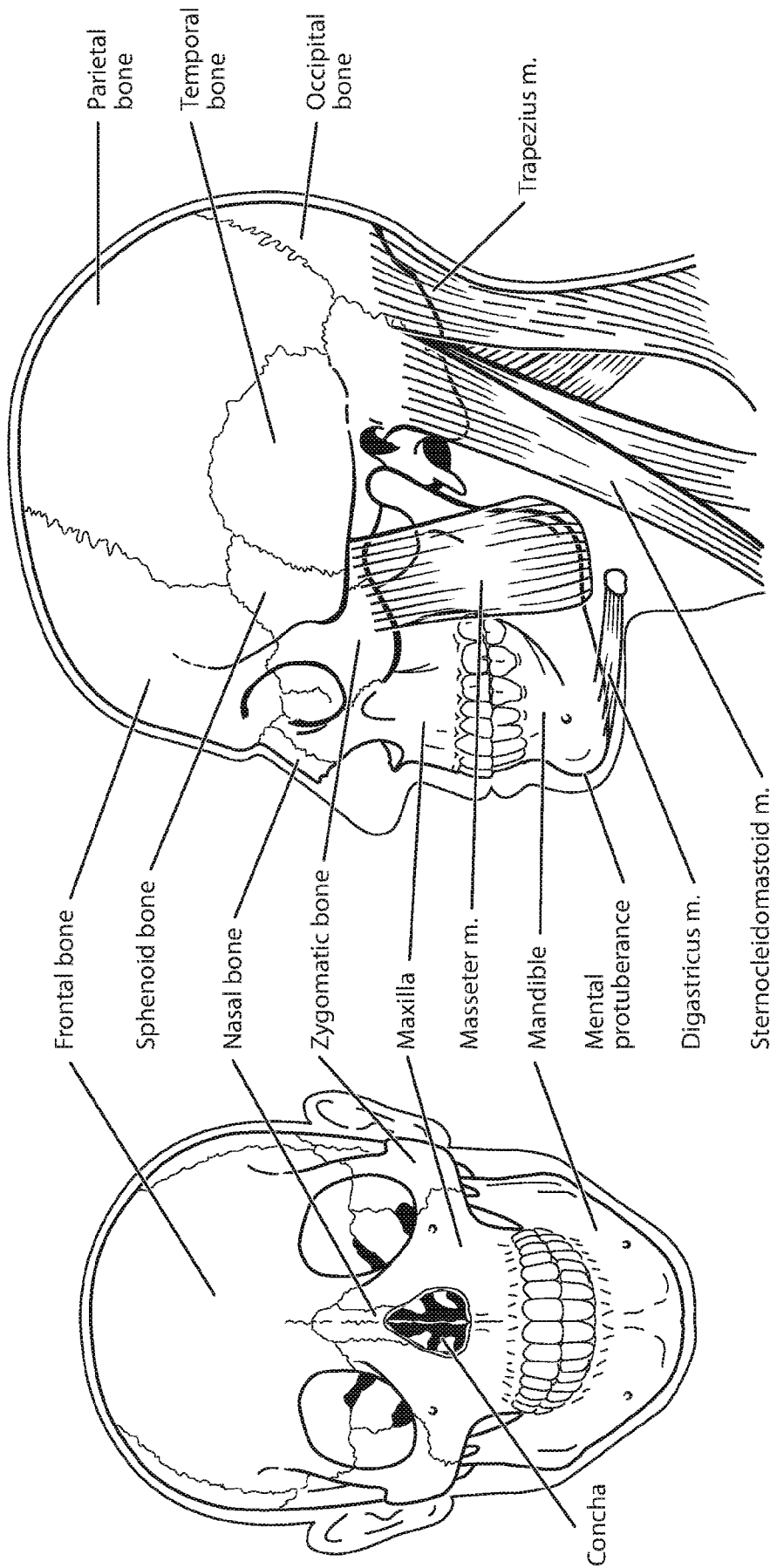


FIG. 2J

FIG. 2K

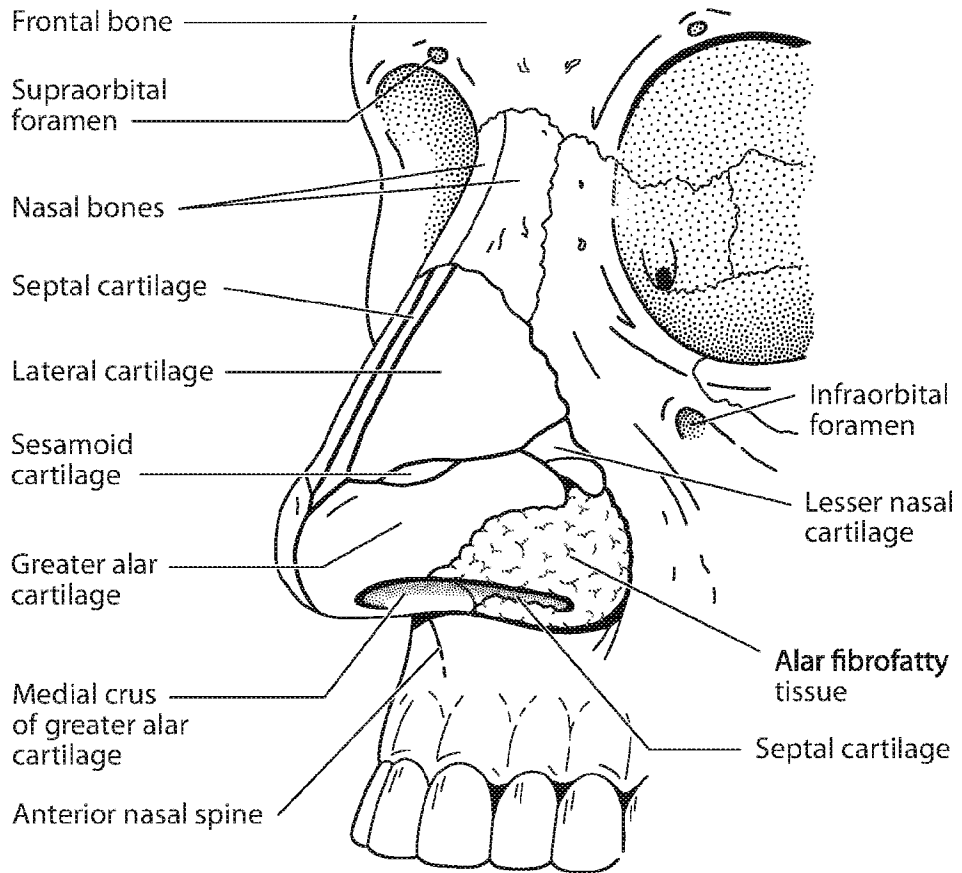


FIG. 2L

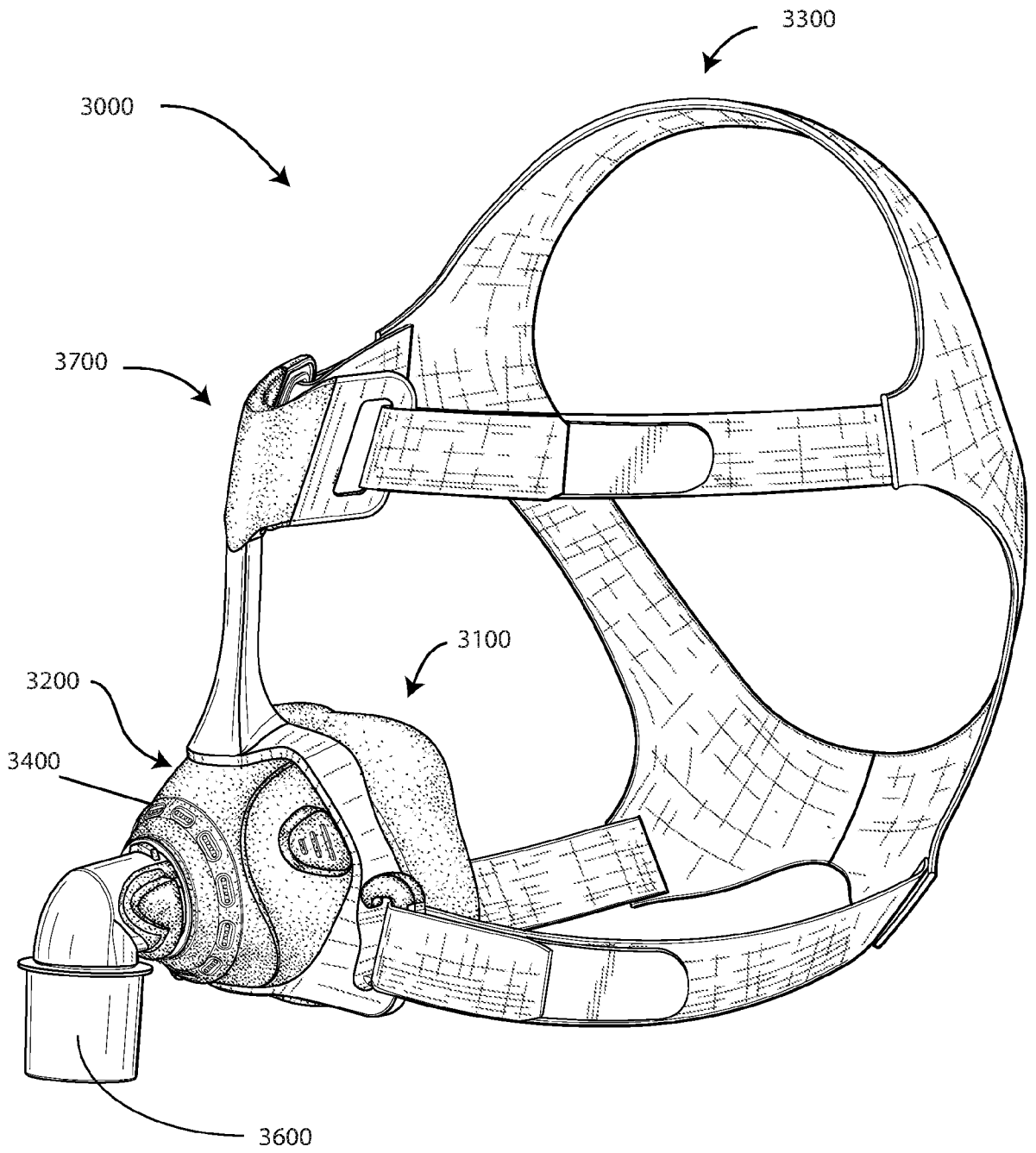
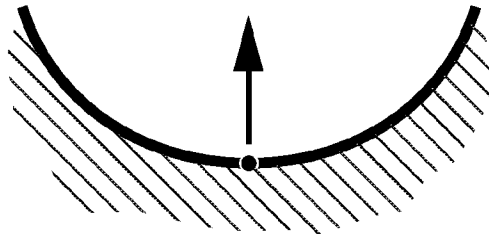


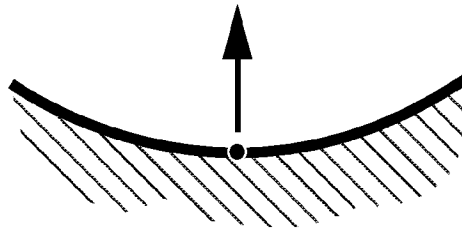
FIG. 3A

FIG. 3B



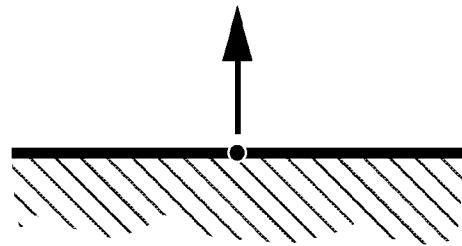
Relatively Large
Positive Curvature

FIG. 3C



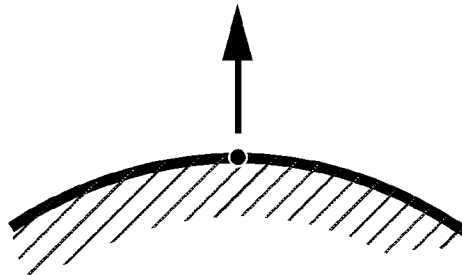
Relatively Small
Positive Curvature

FIG. 3D



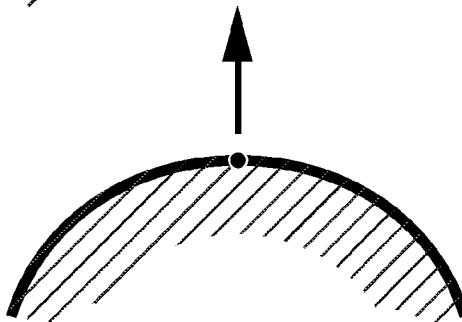
Zero Curvature

FIG. 3E



Relatively Small
Negative Curvature

FIG. 3F



Relatively Large
Negative Curvature

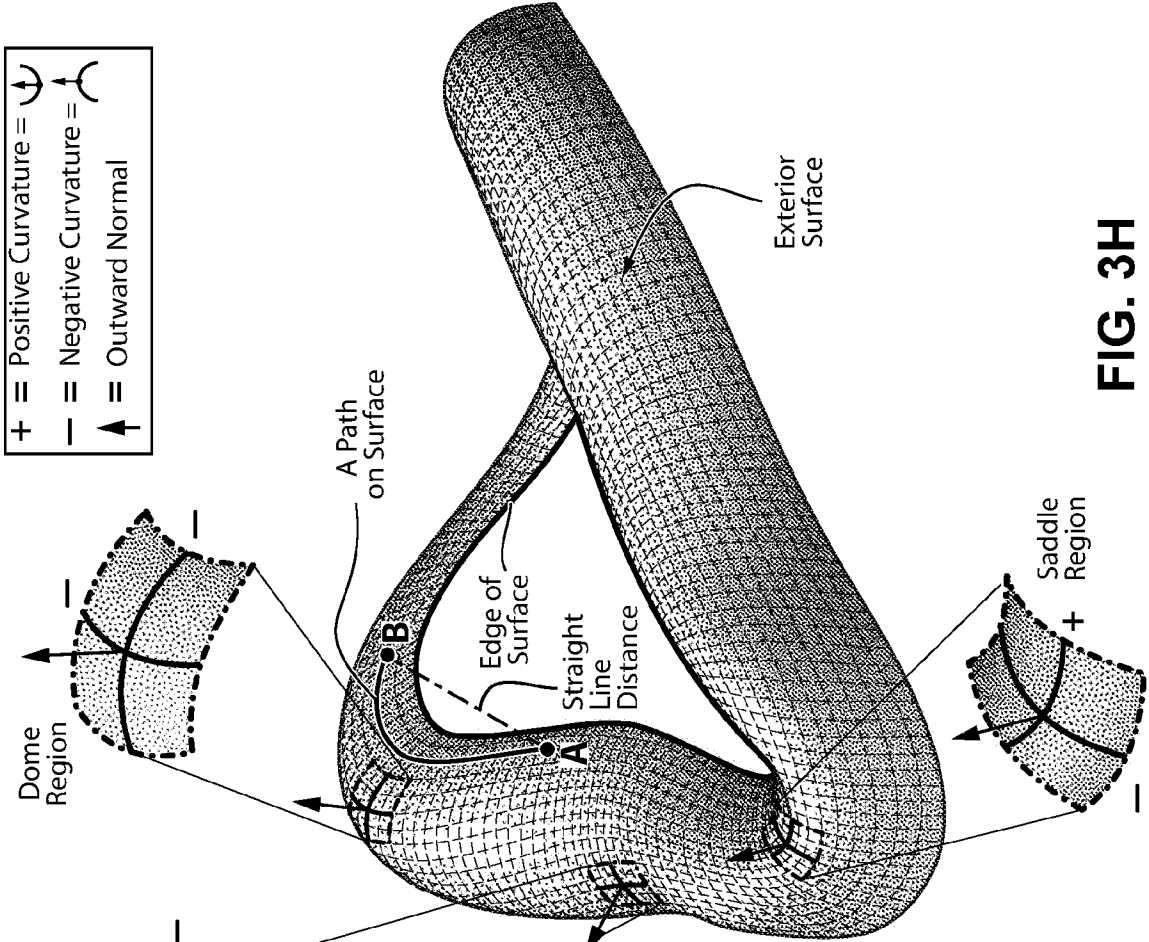


FIG. 3H

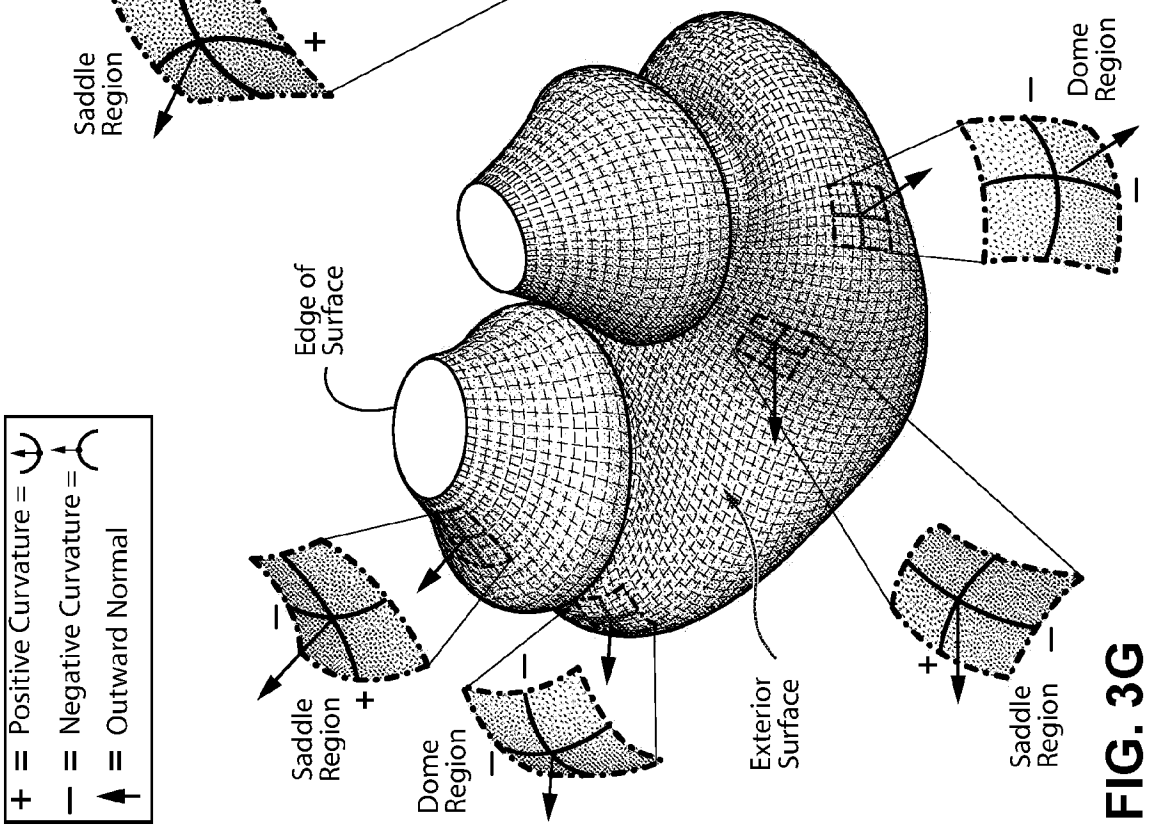


FIG. 3G

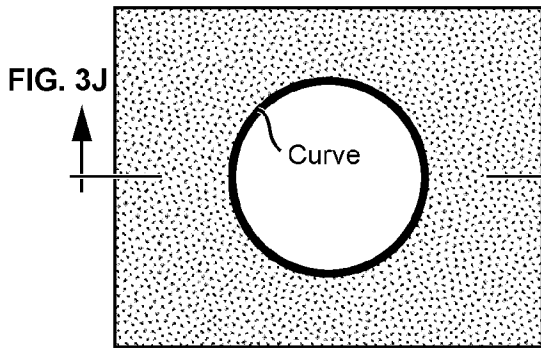


FIG. 3I

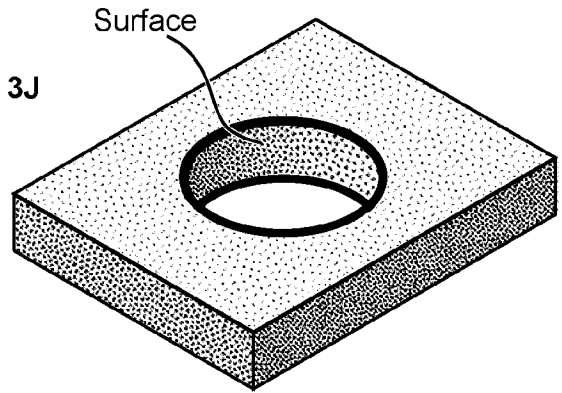


FIG. 3K

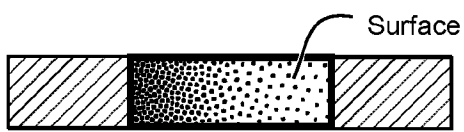


FIG. 3J

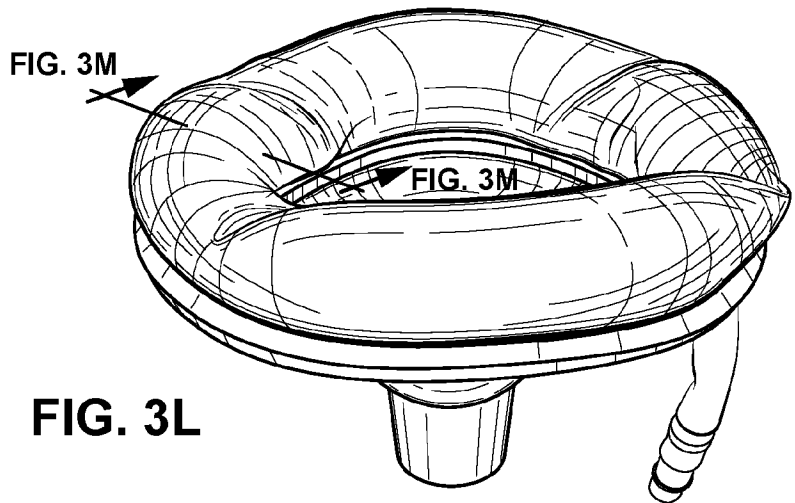


FIG. 3L

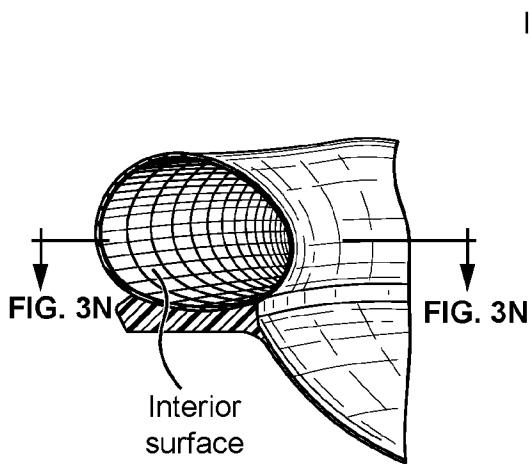


FIG. 3M

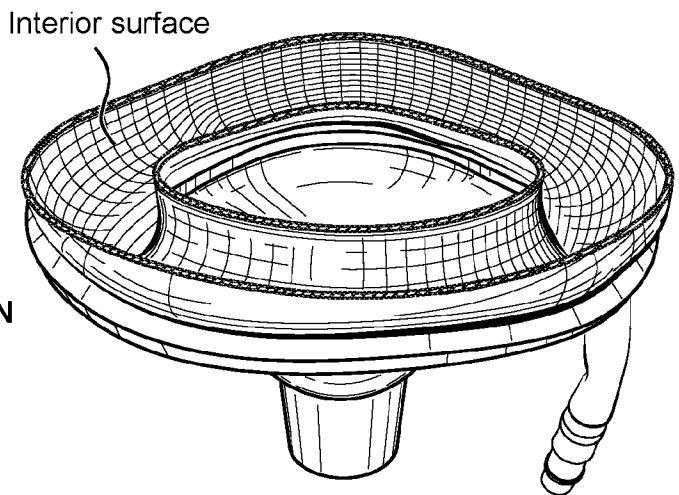


FIG. 3N

Left-hand rule

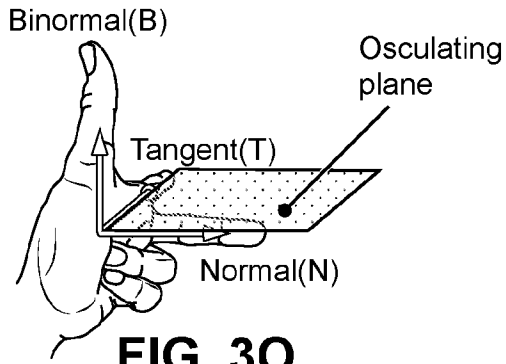


FIG. 30

Right-hand rule

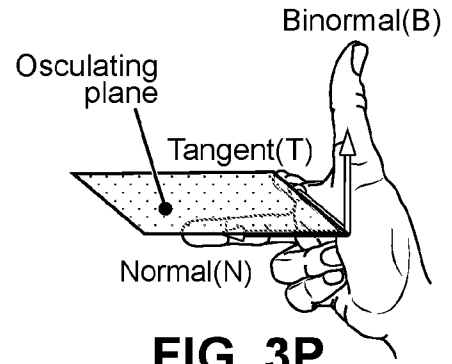


FIG. 3P

Left ear helix

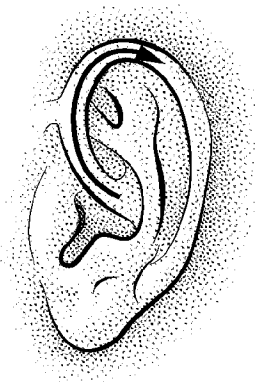
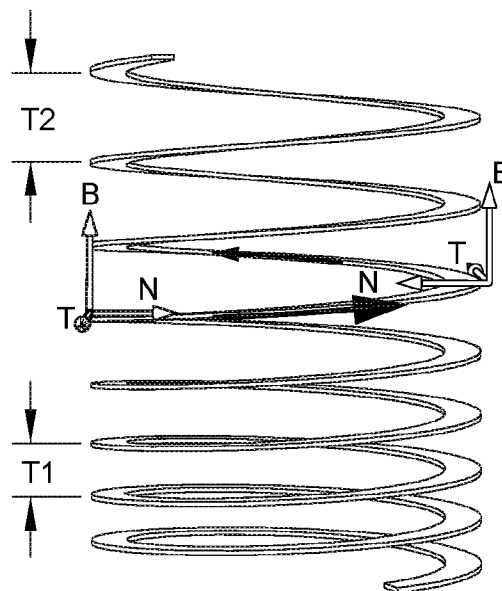


FIG. 3Q



**Right-hand helix
Right-hand positive**

Right ear helix



FIG. 3R

FIG. 3S

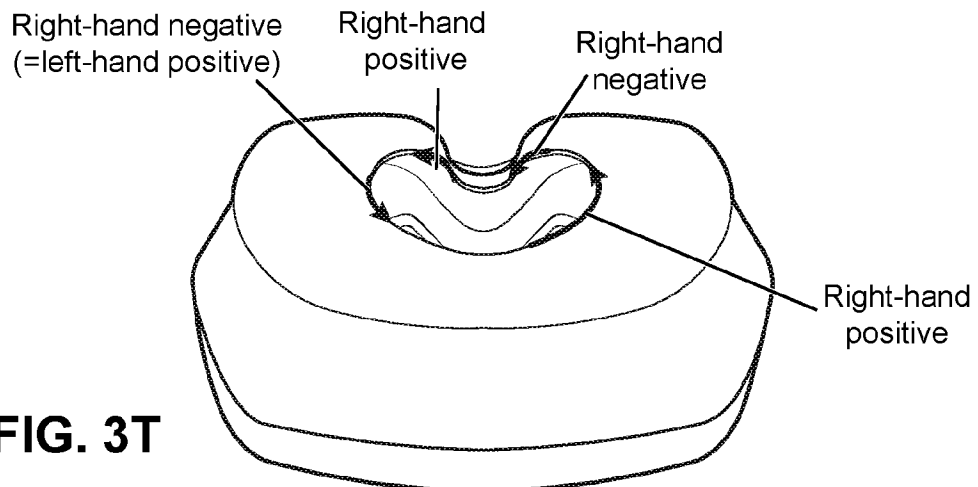


FIG. 3T

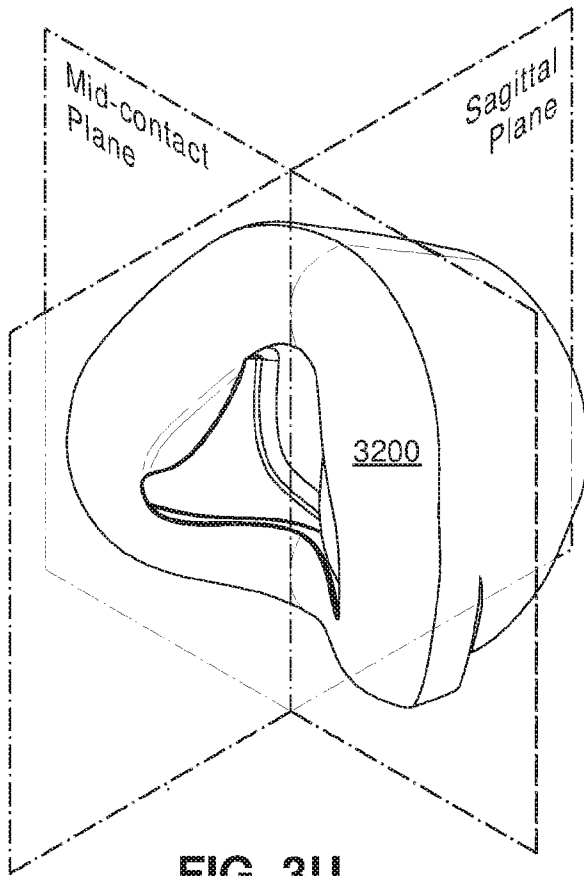


FIG. 3U

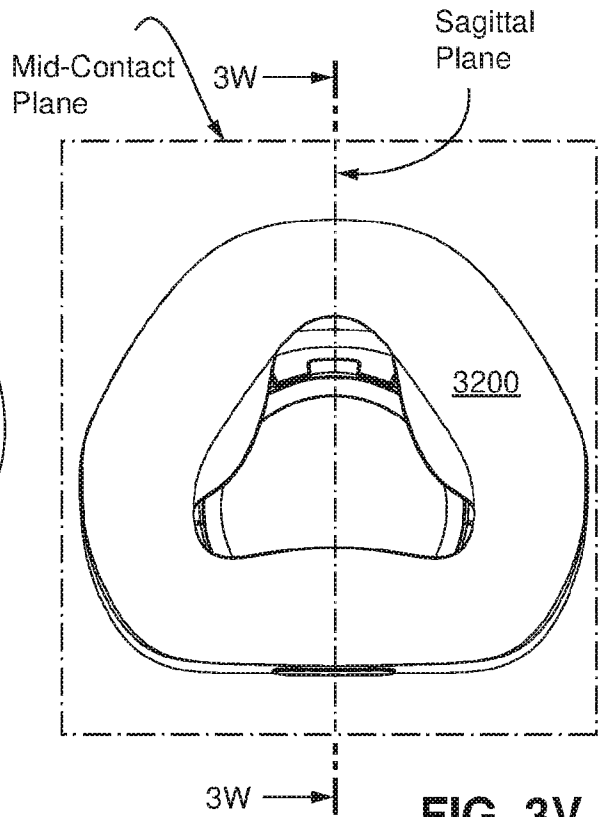


FIG. 3V

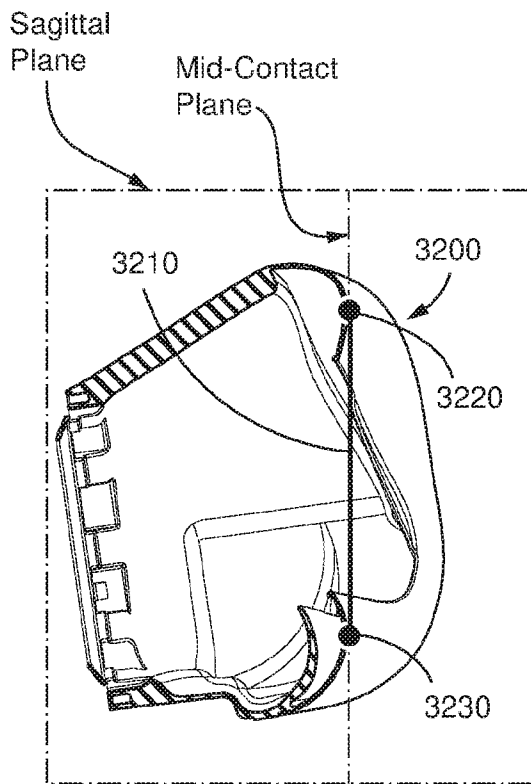


FIG. 3W

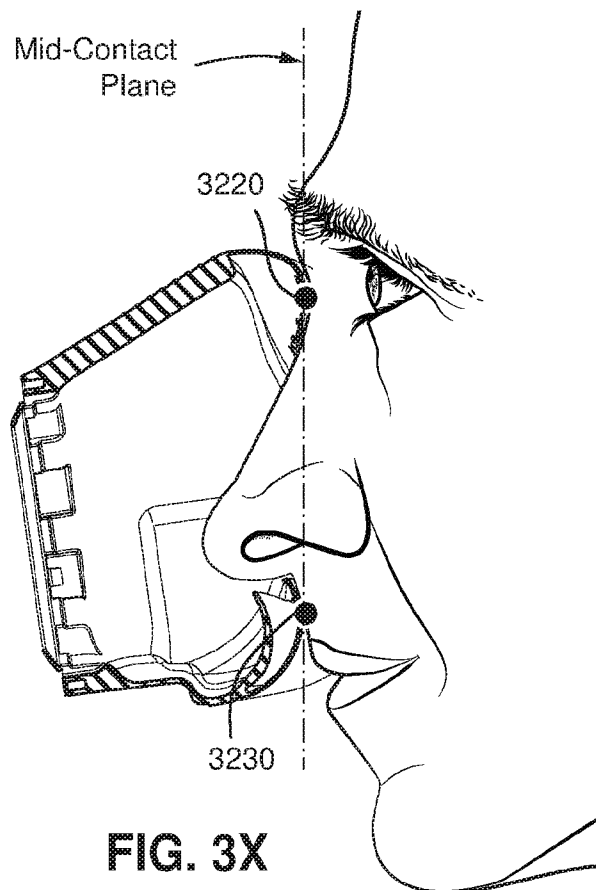


FIG. 3X

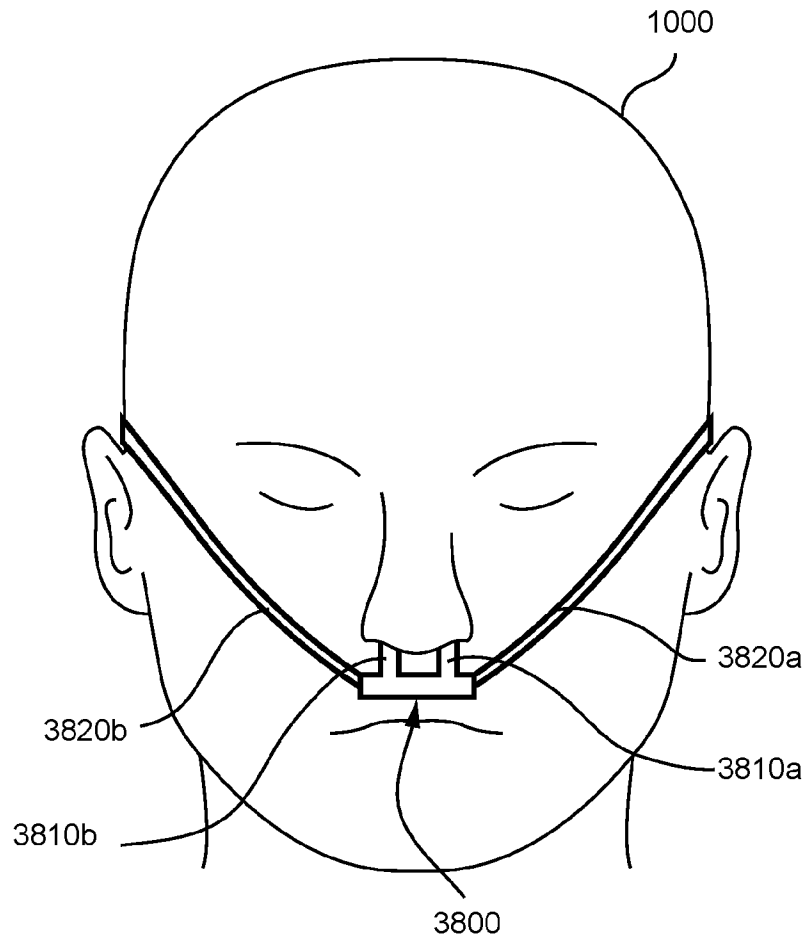
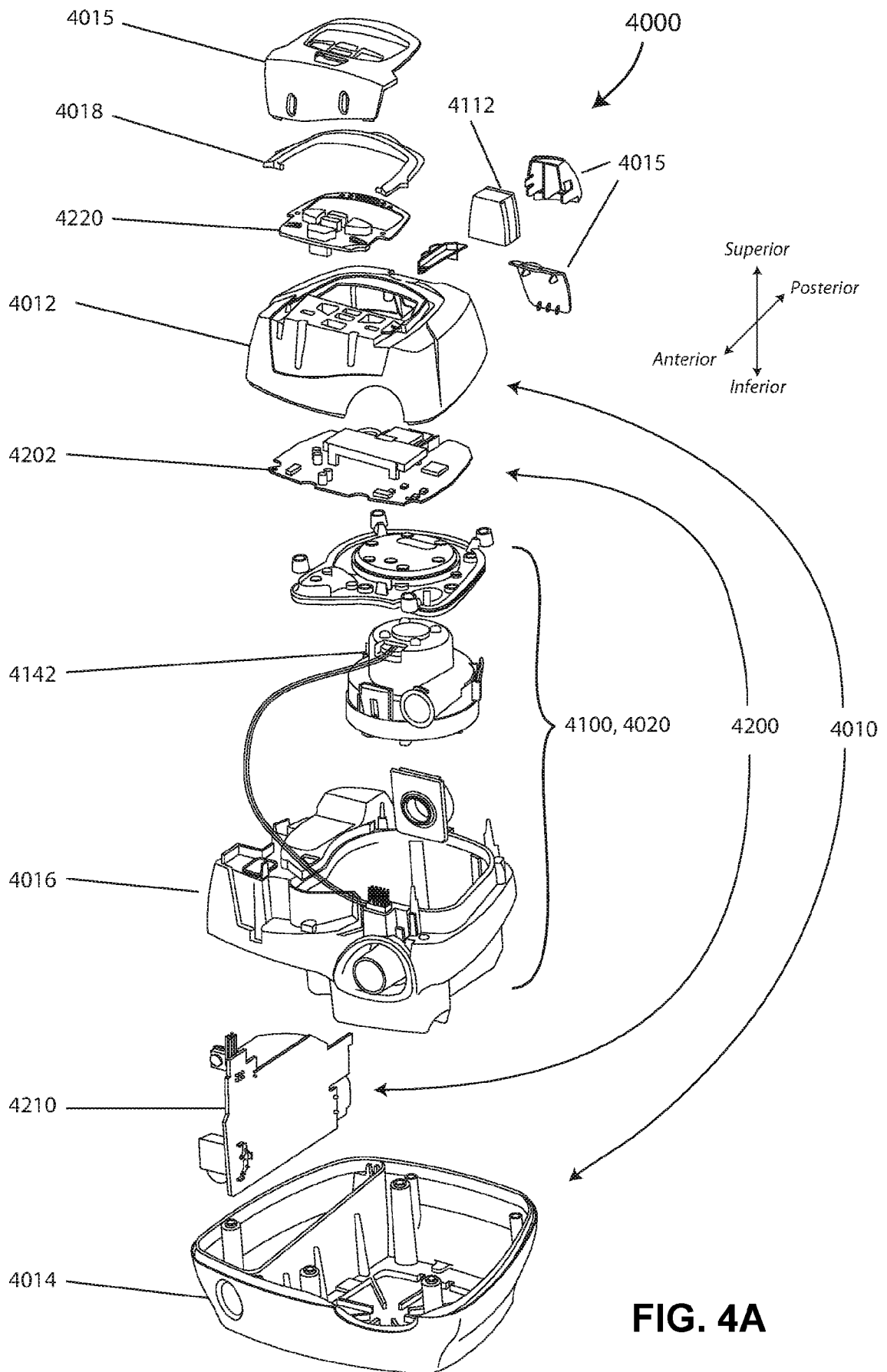


FIG. 3Y



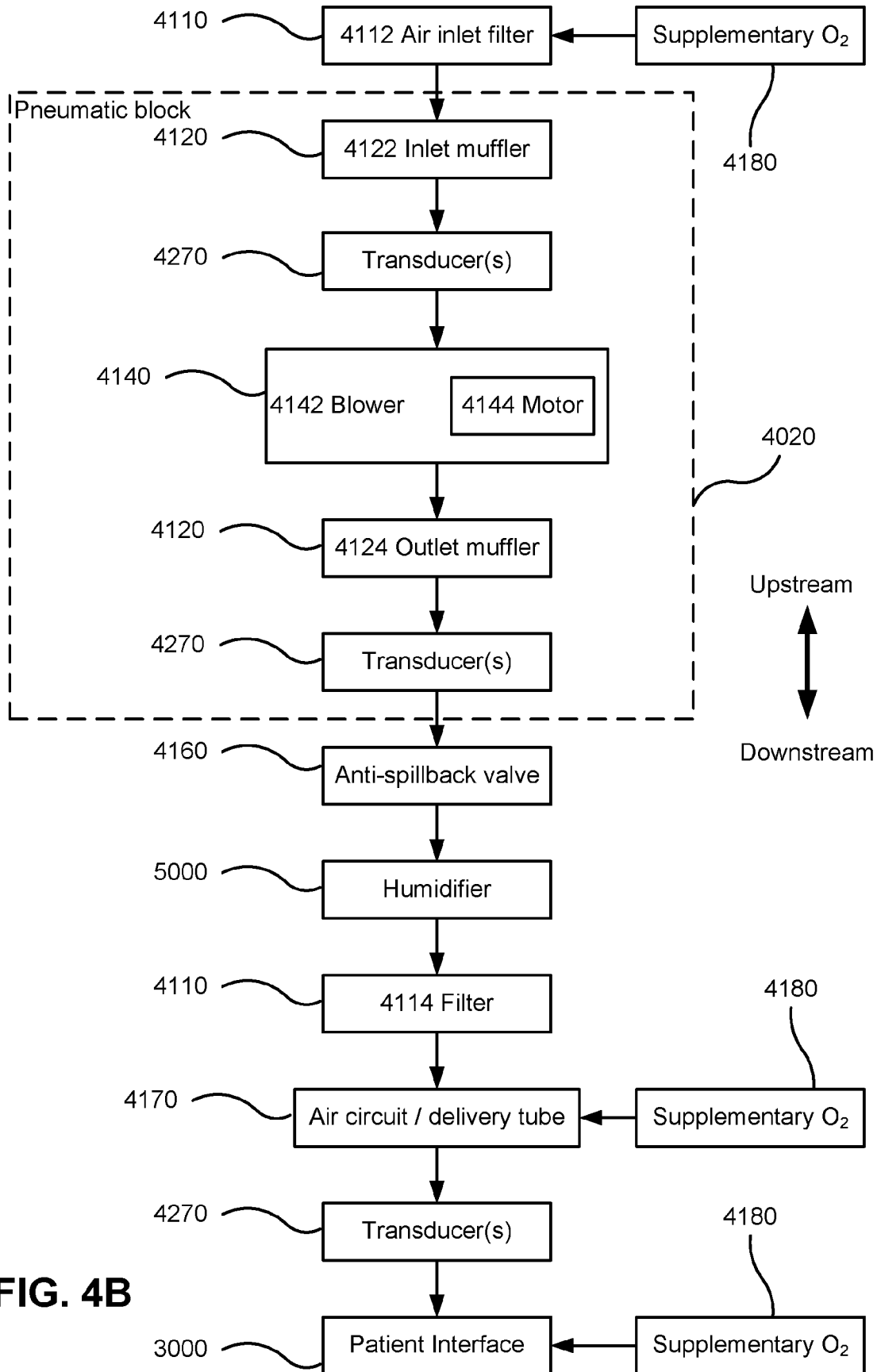
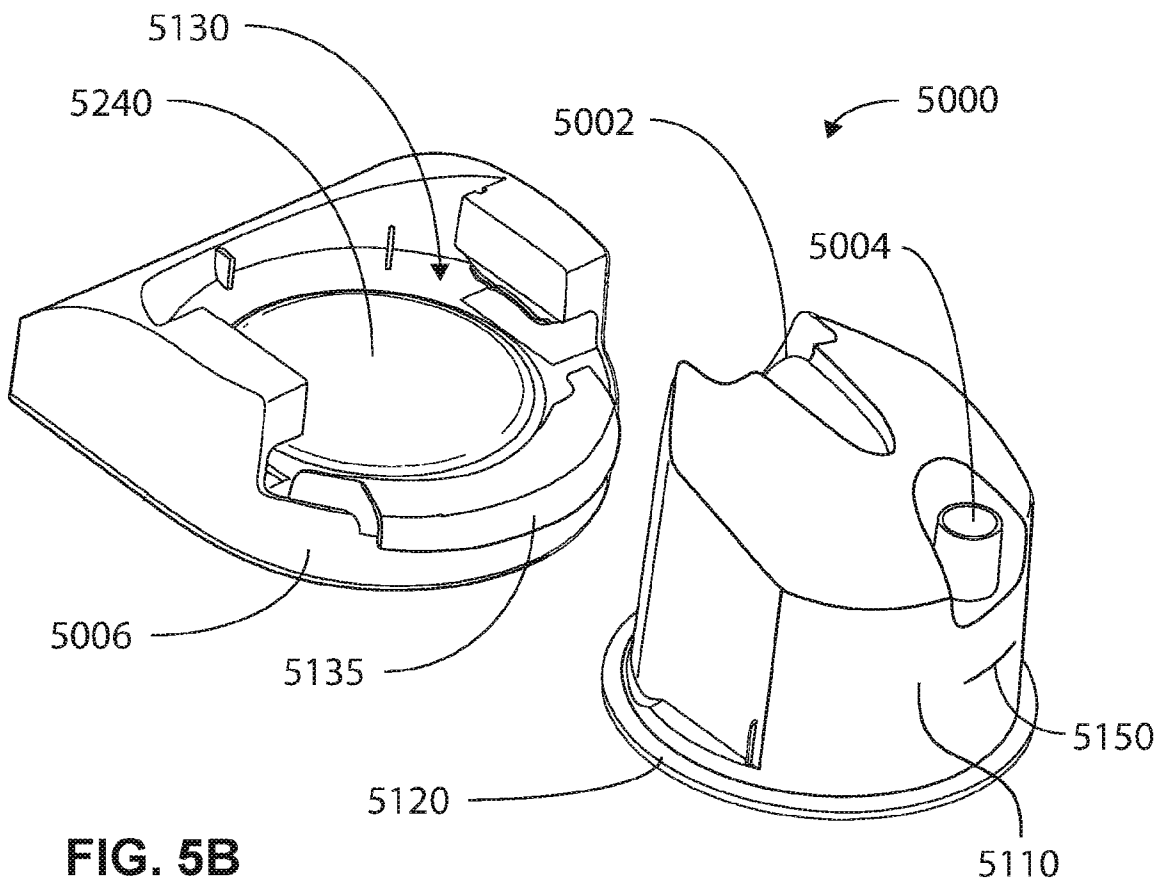
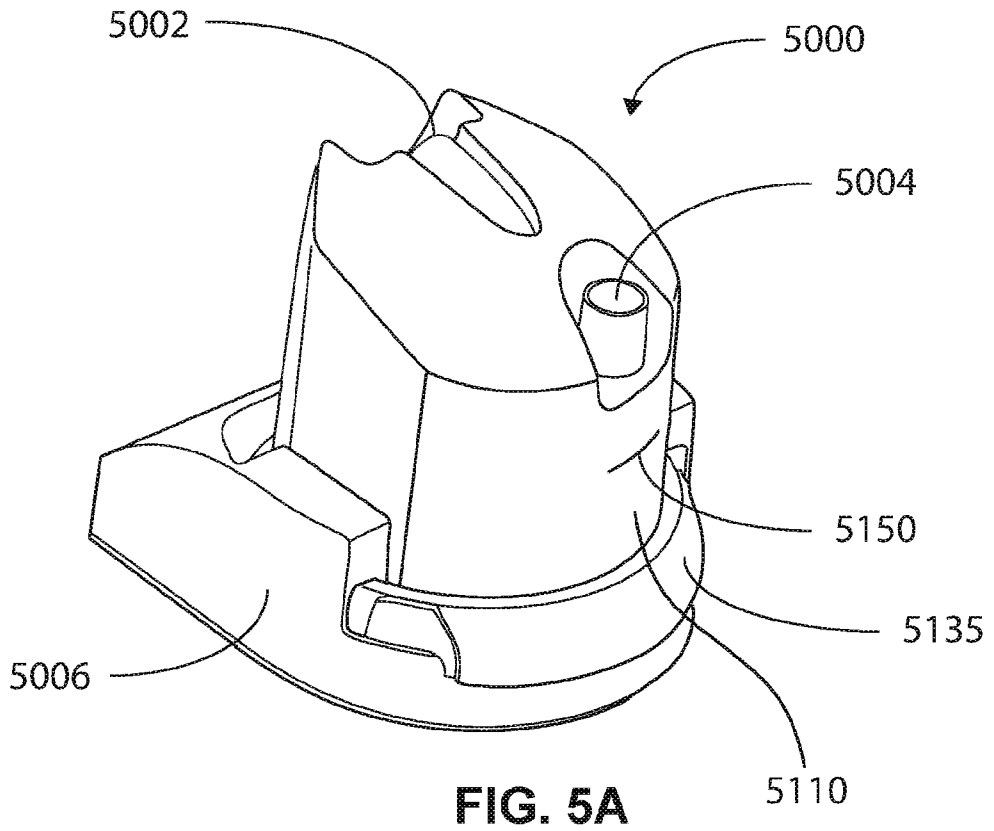


FIG. 4B



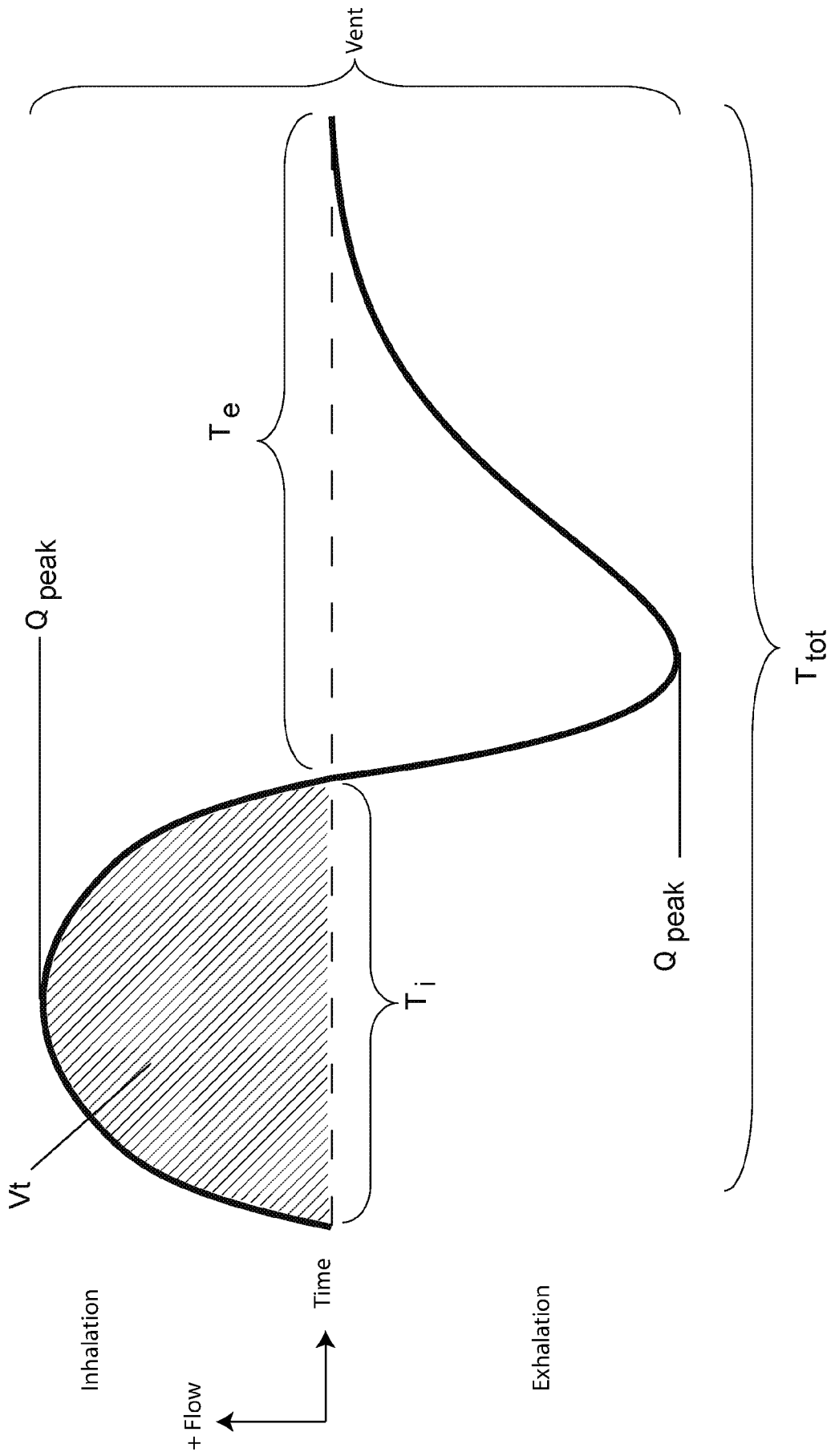
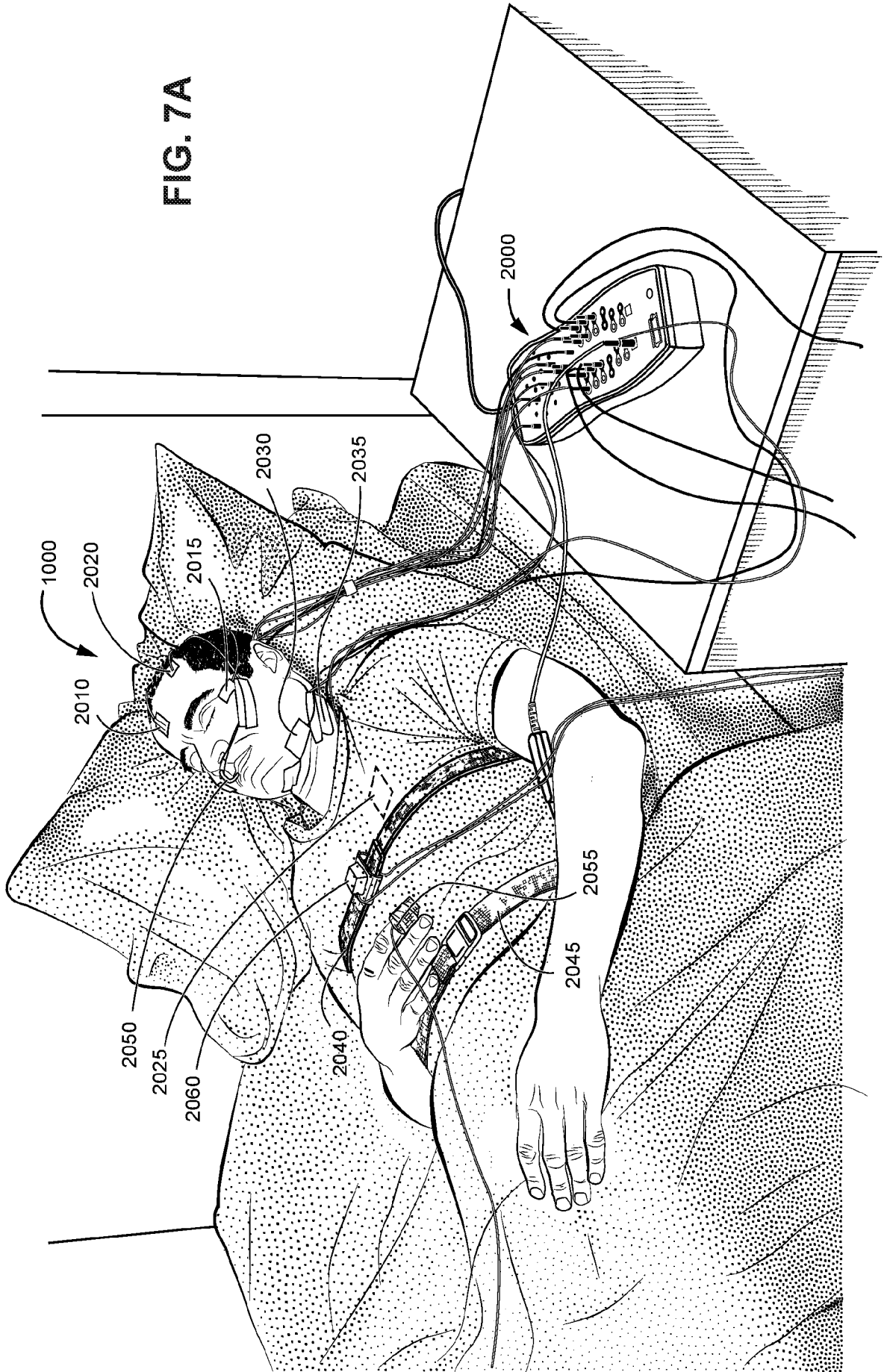


FIG. 6A

FIG. 7A



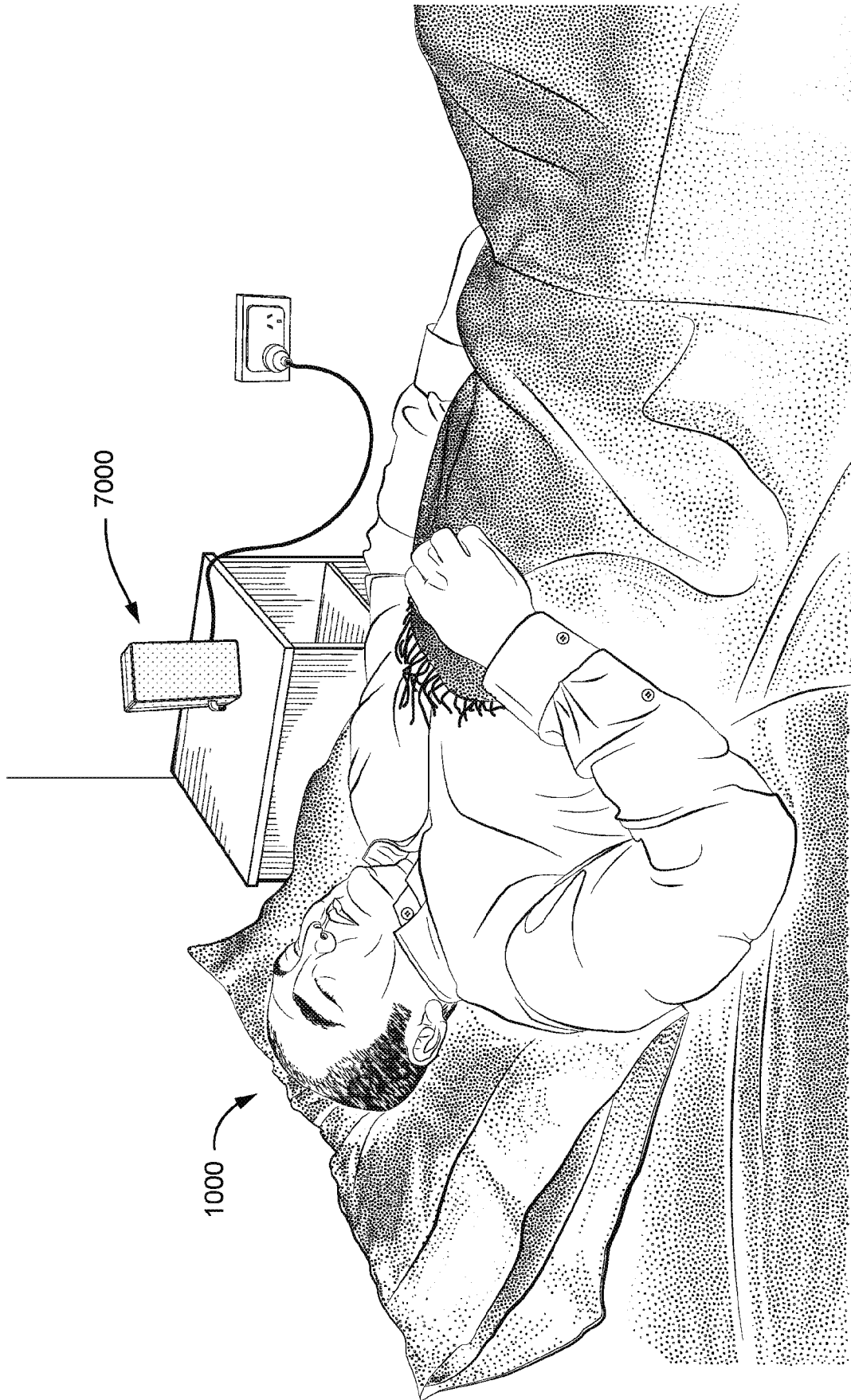


FIG. 7B

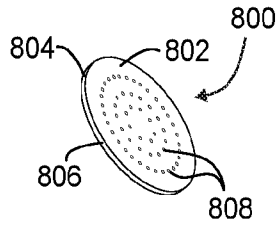


FIG. 8A

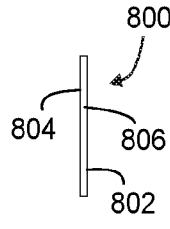


FIG. 8B

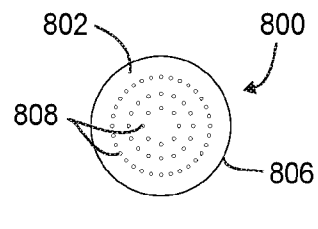


FIG. 8C

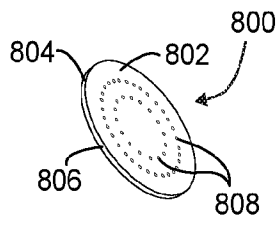


FIG. 9A

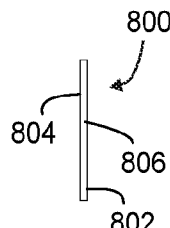


FIG. 9B

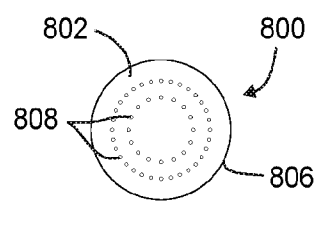


FIG. 9C

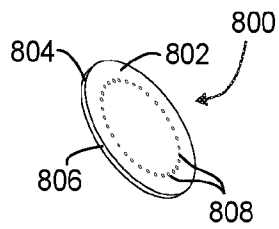


FIG. 10A

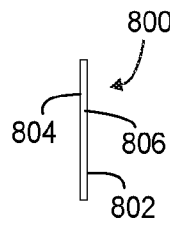


FIG. 10B

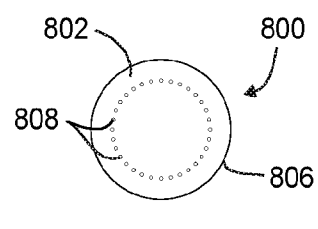


FIG. 10C

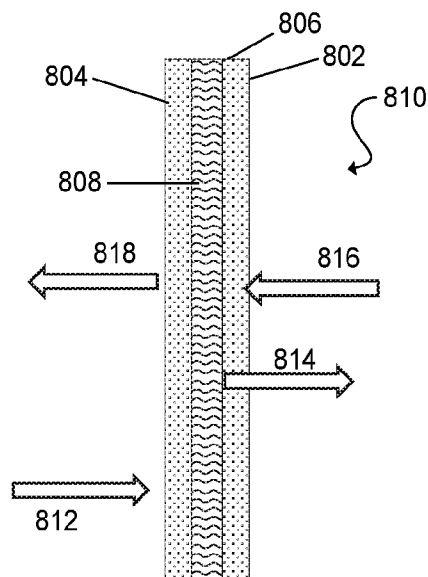


FIG. 11

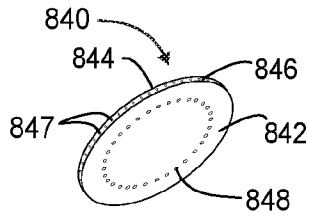


FIG. 12A

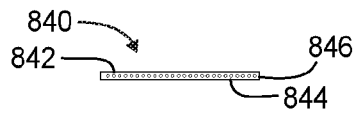


FIG. 12B

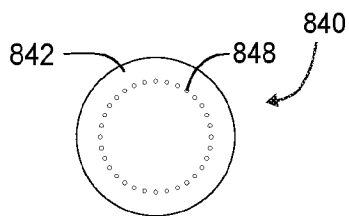


FIG. 12C

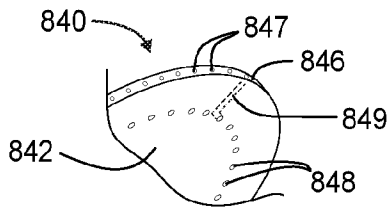


FIG. 12D

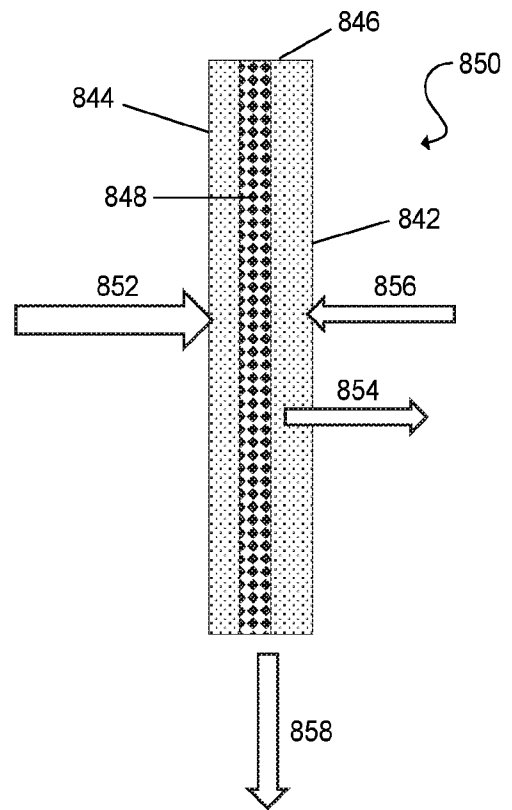


FIG. 13

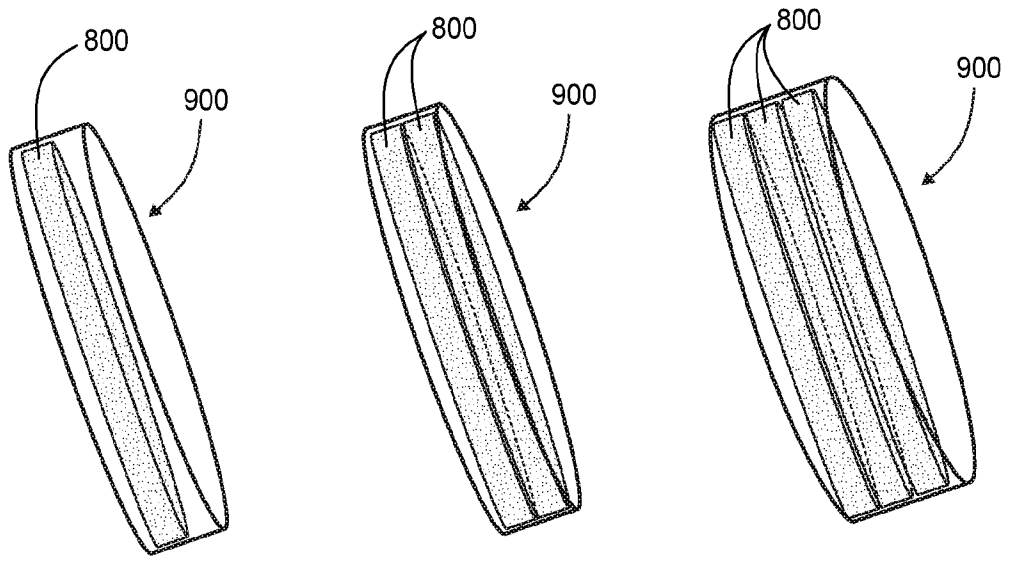


FIG. 14A

FIG. 14B

FIG. 14C

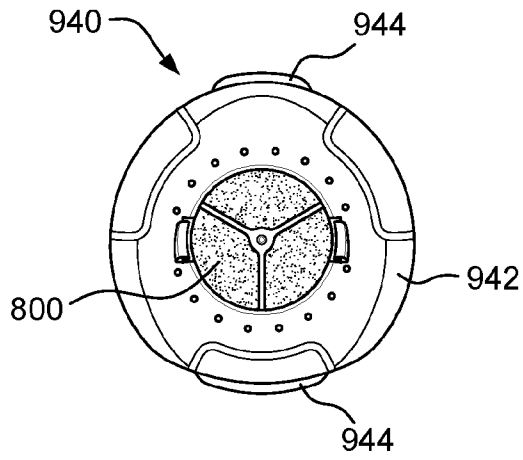


FIG. 14D

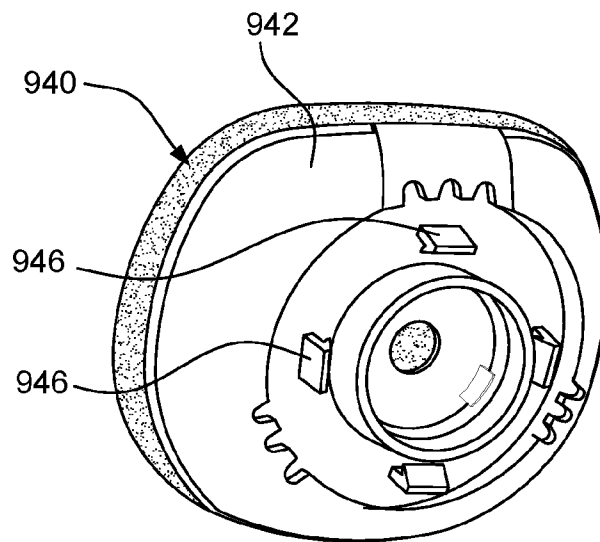


FIG. 14E

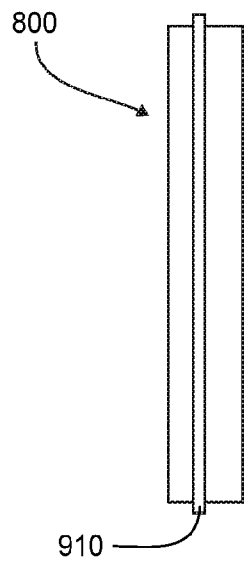


FIG. 15

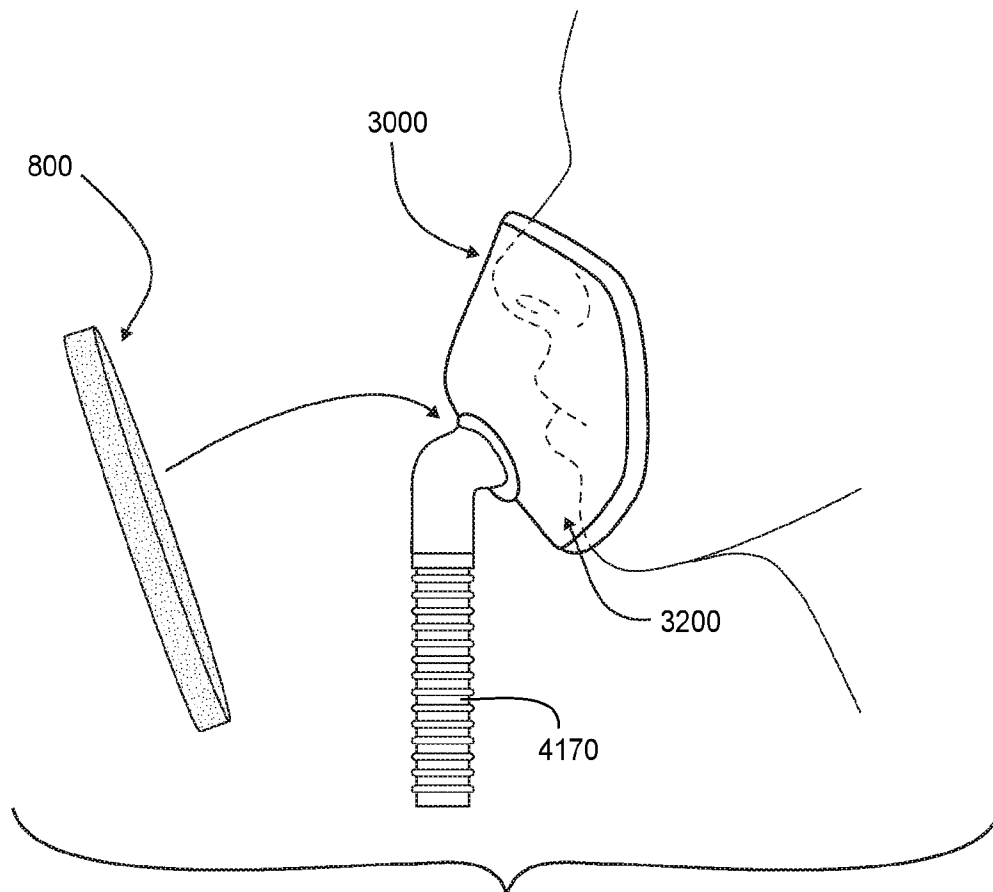


FIG. 16

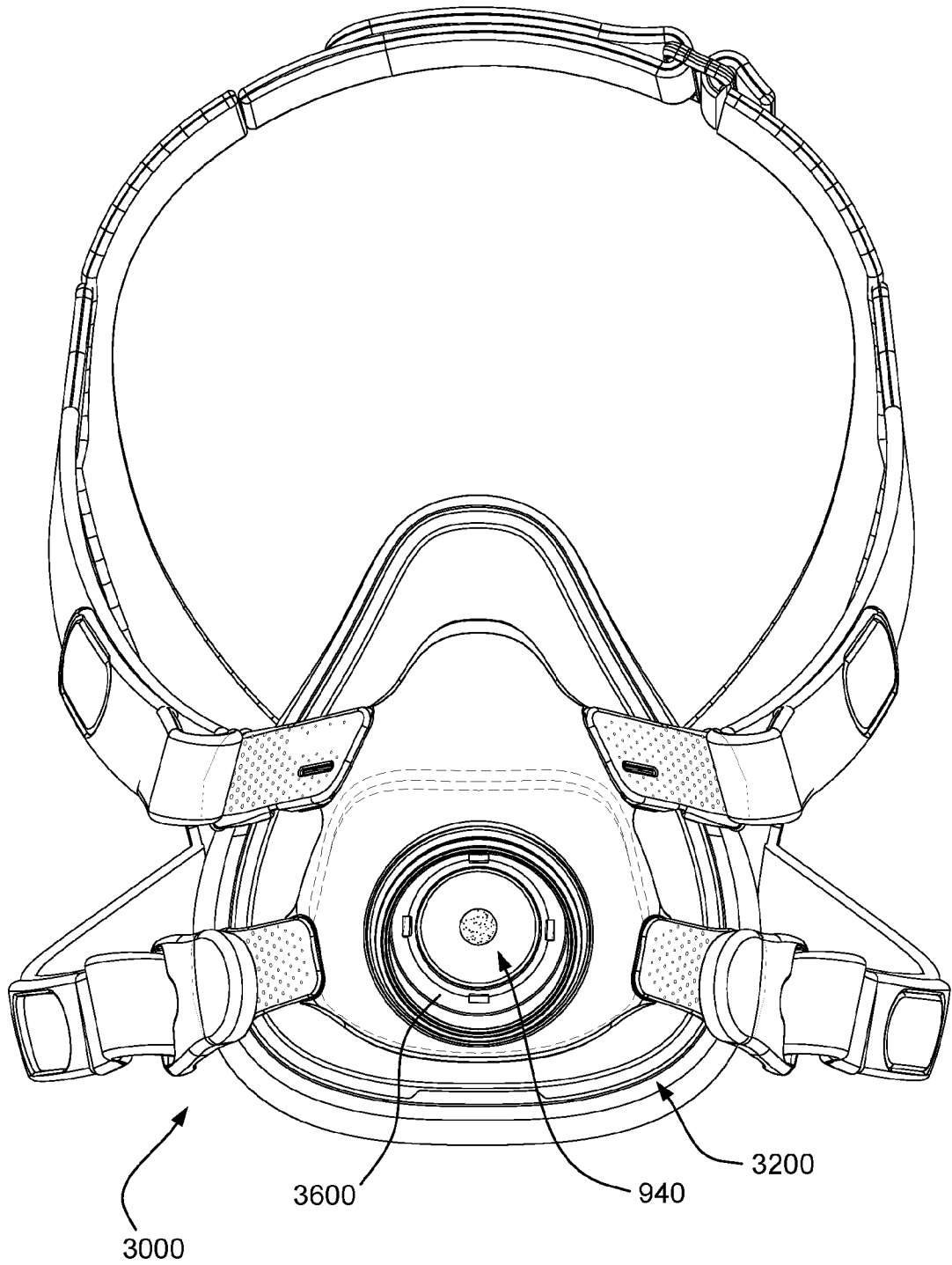


FIG. 17

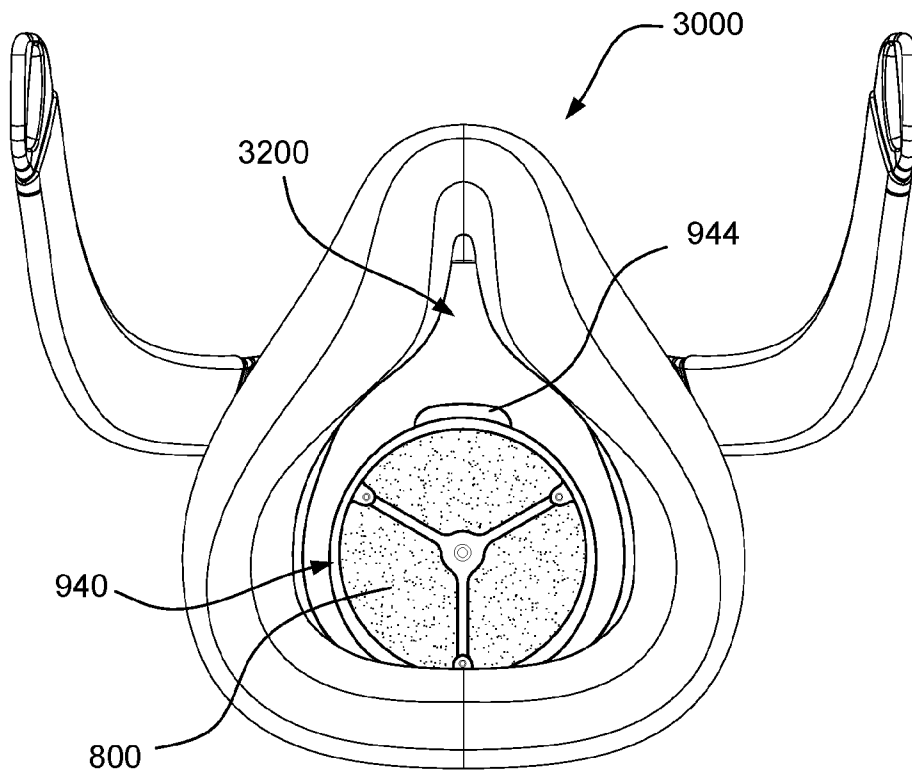


FIG. 18

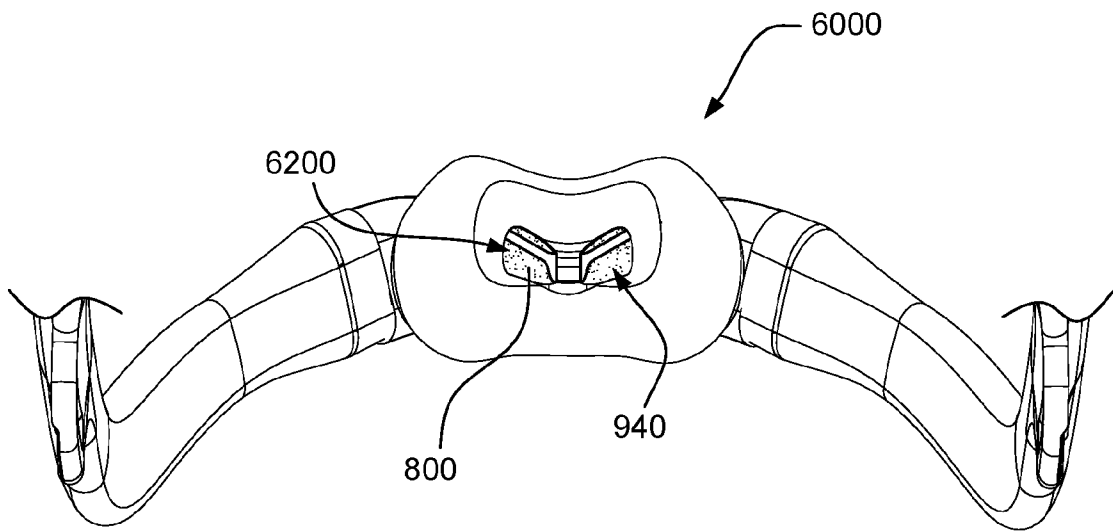


FIG. 19

A. CLASSIFICATION OF SUBJECT MATTER

A61M 16/00 (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)

Applicant and inventor names searched in DOCDB, DWPI, IP Australia internal databases and PATENW. PATENW: CPC A61M16/06/LOW, A61M16/1045, A61M16/106/low, A61M2205/7527 and IPC/CPC A61M16/00/low with keywords (non_woven, composite, combination, mixture, HME, fibre, vent, disk, layered, reduced, thickness, conserve, store, heat, moisture, filter, cartridge) and similar terms. Ultracombi search of documents US 2020/0368476, US 2020/0269005, WO 2020/188495 with keywords (HME, exchange, heat, moisture) and similar terms.

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
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Date of the actual completion of the international search
16 February 2022

Date of mailing of the international search report
16 February 2022

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Telephone No. +61262832400

INTERNATIONAL SEARCH REPORT C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT		International application No. PCT/SG2021/050736
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 2020188495 A1 (RESMED PTY LTD) 24 September 2020 figs. 99, 127-130; par 0078-0079, 0353, 0379, 0383	1-30, 33-35
A	Paper as a Composite Material [Retrieved from the internet on 5 February 2022] URL< https://cool.culturalheritage.org/jaic/articles/jaic26-01-001_2.html#:~:text=Paper%20is%20a%20composite%20material,lignin%20content%2C%20and%20extractives%20chemistry.&text=4%20Most%20papers%20are%20composed%20of%20a%20combination%20of%20several%20fiber%20types. > Published 1987. page 1 lines 4-6	1
X	US 2012/0097156 A1 (BOWMAN et al.) 26 April 2012 figs. 13A-14C; par 0093-0096, 0100	1-5, 9-11, 13-21, 23-25
X	US 2020/0368476 A1 (RESMED PTY LTD) 26 November 2020 figs. 3, 8A-8C, 9A-9B; par 0059, 0189-0193, 0197-0200	1-8, 12-17, 20, 26, 27, 29, 30
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INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No.

PCT/SG2021/050736

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

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Publication Number	Publication Date	Publication Number	Publication Date
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End of Annex