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(72) Inventor; and
(71) Applicant: **YANG, Quangang** [AU/AU]; 12 York Rd, Kellyville, New South Wales 2155 (AU).

(72) Inventor: **YANG, Bill Jiahui**; 12 York Rd, Kellyville, New South Wales 2155 (AU).

(74) Agent: **ALDER IP PTY LTD**; Suite 504, 10 Help Street, Chatswood, NSW 2067 (AU).

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(54) **Title:** A DEVICE FOR RESPIRATORY SUPPORT

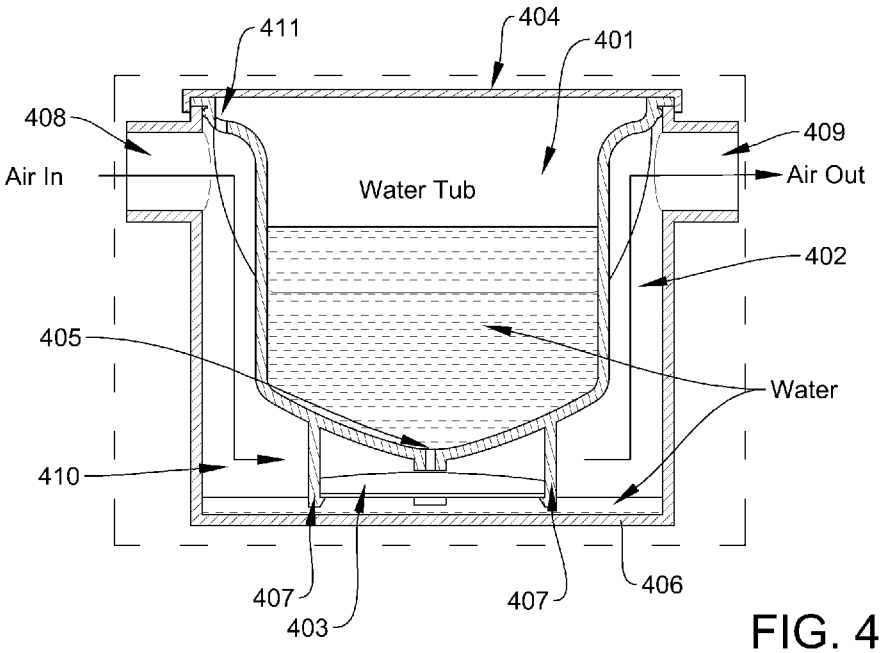

FIG. 4

(57) **Abstract:** A device for respiratory support, the device comprising: a flow generator supplying breathable gas from a breathable gas source to a breathing mask through an air path and wherein the air path includes a humidifier; and wherein the breathing mask is adapted to engage the face of a patient.

[Continued on next page]

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A device for respiratory support

TECHNICAL FIELD

[0001] The present invention relates to a device for respiratory support may include a humidifier and a mask assembly that may be implemented for a respiratory - support and oxygen concentrator for oxygen support.

BACKGROUND

[0002] The respiratory support normally requires a delivery of air or other breathable gas at pressures above atmospheric pressure to the user via a mask. Pressurised air flows to the mask and to the user via the nose and/or mouth. A washout vent in the mask may be implemented to discharge the exhaled gas from the mask to atmosphere.

[0003] Respiratory support apparatus may include a flow generator, an air filter, an air delivery conduit connecting the flow generator to the mask, various sensors, a controller, a humidifier and/or heating elements. The flow generator may include a motor and an impeller, may also include a valve capable of discharging air to atmosphere as a means for altering the pressure delivered to the user as an alternative to motor speed control. The sensors may measure gas volumetric flow rate and outlet pressure, such as with a pressure transducer, flow sensor, thermal sensor or the like. The controller may also include data storage capacity with or without integrated data retrieval/transfer and display functions. Positive airway pressure may be delivered in many forms.

[0004] Respiratory support may maintain a support pressure across the inspiratory and expiratory levels of the user's breathing cycle at an approximately constant level. Alternatively, pressure levels may be adjusted to change synchronously with the user's breathing cycle. For example, pressure may be set at one level during inspiration and another lower level during expiration for patient comfort. Alternatively, the pressure levels may be continuously adjusted to smoothly replicate changes in the user's breathing cycle. In U.S. Patent No. 4,944,310 positive airway pressure treatments typically provide gas under pressures to the user in the range of 4 to 15 cmH_20 from the device and may involve

flow rates of at about 120 litres/minute. Some of the air may escape via an end restriction or vent and not be delivered to the user. These pressure settings may also be adjusted based on the detection of conditions of the user's airway or respiration. For example, treatment pressure may be increased in the detection of partial obstruction or snoring. In some cases, positive airway pressure may be adapted to provide ventilation support. For example, a user's ventilatory needs may be supported on a breath-by-breath basis by automatically calculating a target ventilation and adjusting the pressure support generated by an apparatus, such as a bilevel pressure treatment apparatus, so as to achieve the target ventilation.

[0005] Respiratory treatment apparatus is sometimes provided with accessory components for comfort conditioning of the flow or pressurized breathable gas supplied by the flow generator. For example, the supplied air may be applied to a humidifier to humidify and warm the treatment gas prior to its delivery to a user.

[0006] The relative humidity of the air that people breath affects how comfortable the user feels. The common type of humidifier is designed so that the dry air is drawn into the humidifier passing through a water reservoir from where the water is vapourised. The air then travels through the chamber picking up water vapour and travels out of the humidifier. One of the problems of this type of humidifier is that large amount of the water in the reservoir is heated, which may result in excessive energy consumption and prolonged time for the device in response to humidification. This invention provides a humidifier with a significantly reduced humidification response time and energy savings by producing instant water vapour through vaporising only small amount of water constantly when in use.

[0007] Other issues with the traditional humidifier include that the water needs to be heated up by a heating element and the water surface area for the evaporation is limited. The present invention first provides a solution by preheating the breathing gas to an elevated temperature to enhance the water evaporation without the need of directly heating on the water. Another solution is to utilise the hydrophilic material to make wicks to draw off the

water and to arrange the wicks in a pattern, such as zig zag pattern, to increase the gas travel distance and time to pick up the water vapour.

[0008] Respiratory support involves the use of a user interface, which is typically a nasal or oral mask having a frame supporting a mask on the face of a user to interface the ventilator or pressure support device with the airway of the user so that a flow of breathing gas can be delivered from the flow generating device to the user. It is common to maintain such masks on the face of a user by a headgear situated on top of the user's head. As such masks are typically worn for an extended period of time, it is important that the headgear maintains the mask seal against a user's face without discomfort. There are concerns over support for the masks and if these concerns are not addressed, the user may avoid wearing the masks. One concern is that the mask should be supported on the user in a stable fashion so that the mask does not shift on the user's face as the user moves during sleep. Another concern is that the user's mouth may be open during treatment if a nasal/pillow mask is used. Some users have thus to choose full face mask to cover both mouth and nose. A full face mask may be bulky to use, may require higher flow pressure and the treatment may be compromised as the user's jaw may be pushed backwards by the mask. Another concern is that the user does not perceive the mask to be suffocating.

[0009] US Patent No. 8,857,435 describes an interface assembly including a chin support attached to a head strap and rests just below the chin of the user. The '435 patent addresses some of the above concerns, for example, by maintaining the mask in a stable fashion during sleep, it does not prevent air flow delivered through user's mouth during the sleep. U.S. Pat. No. 2,241,535 describes an apparatus for delivering breathing gas to a patient including a nose piece joined by a transverse tubular member directly resting on the anterior portion of the user's chin. The transverse tubular member rests on or above the anterior portion of the mandible. The '535 patent addresses some of the above concerns, for example, by avoiding placing portions of the interface near the patient's eyes, but it does not provide a stable platform that supports the nose piece. Thus, there still a need for a mask that more completely addresses these concerns. The present invention provides lip support that disposed under and supported against user's lower lip, so that user's mouth is

restrained to be open. Thus, such lip support prevents mouth leaking of the user during treatment.

[0010] As mentioned previously, it is important that the headgear maintains the mask in a seal against a user's face without discomfort. A loose strap will result in gas leaking out of the user interface thus compromises the treatment. A tense strap however may cause discomfort or facial injury in extreme cases. There is a need for a tension indicator for the strap such as marks, numbers, letters, colour scheme, bump bars, dots or any other indicative features. The indication mechanism may include springs or other elastic components where the elasticity remains constant over the time.

[0011] Some forms of patient interface systems may include a vent to allow the washout of exhaled carbon dioxide. The advantage of the vented mask is to prevent re-breathing of carbon dioxide. Also, there is a need for preventing virus/bacteria from spreading into ambient through venting holes, especially during recent COVID-19 pandemic.

[0012] It is important to monitor the user's response to the respiratory support. Such response may be reflected by a ventilatory index which is calculated based on the minute volume and user's carbon dioxides and/or oxygen level. The device may be able to measure patient's carbon dioxides and/or oxygen level directly, or it is able to connect to an external device to measure the carbon dioxides and/or oxygen level. The device may display this index continuously, or in comparison, an expected ventilatory index may be displayed simultaneously to show whether the treatment is above or under the expectancy. In this invention, an algorithm may estimate user's production of carbon dioxide, detect the dead space volume, dead space/alveolar ventilation, and even other lung characteristics such as functional residual volume. It would be advantage that the information and monitoring can be remotely displayed and controlled.

[0013] For some of respiratory supports, breathable gas such as oxygen is commonly supplied from an oxygen cylinder. The present invention provides a Portable Oxygen Concentrator (POC) that is easy to be held by a hand, which also has a large port from which a user may inhale the oxygen through either mouth or nose. Condensation is one of

the major issues with the POCs due to the water vapour condensation after air compression, so that the liquid water may thus get into the sieve beds. On the other side, the oxygen from POC does not have water and may cause discomfort to the user due to the dryness. The present invention provides a mechanism that condenses the water vapour and collects condensed water from the compressed air prior to entering into the sieve bed and reintroduces the water vapour into dry oxygen. A device, such as a peristaltic pump, or a solenoid valve, will be activated periodically to drive the condensed water into the oxygen tank, where the dry gas is being re-humidified by the condensed water. The humidified gas is then delivered to the user. In addition, sieve bed deformation under high pressure is the main cause of zeolite fluidization in a POC. In this disclosure, a structural design integrating the oxygen tank and sieve bed will increase the strength of the sieve bed and consequently reduce the deformation when undergoing high pressure.

[0014] One of the issues with breathing mask assembly is that the attached tube/hose gets tangled especially for CPAP users during sleep. Some users use a rack on which flexible tube/hose rests. However, the problem with this arrangement is that the rack/hanger moves with the user when tossing and turning. In the presented invention, the device is designed to accept a detachable stiff tube which is extendable to a desired height so that a flexible tube/hose may connect to the stiff tube avoiding the flexible tube/hose to get tangled.

[0015] Accordingly, it is imperative to find a way to improve efficiency of heating and/or humidification and/or pressurised delivery of a breathable gas for respiratory supports.

[0016] It is also imperative to find a way to avoid water entering in the sieve beds.

[0017] Any discussion of the prior art throughout the specification should in no way be considered as an admission that such prior art is widely known or forms part of common general knowledge in the field.

SUMMARY

[0018] PROBLEMS TO BE SOLVED

[0019] It may be advantageous to provide a device with improved efficiency of heating and/or humidification and/or pressurised delivery of a breathable gas for respiratory supports.

[0020] It may be an advantage to provide a flow guiding feature to utilise the dynamic pressure/flow velocity to open and close the air path of the conduits configured for expiratory venting. It may be an advantage to provide a valve capable of reducing the leakage during inhalation or stop venting so that improve the efficiency of the motor and the humidifier.

[0021] It may be an advantage to provide a respiratory support device with accessory components for comfort conditioning of the flow or pressurised air supplied by the flow generator.

[0022] It may be an advantage to provide a lip holder or lip support that reduce the mouth leak of the user when in use during treatment to improve the treatment efficacy, avoid dry mouth and reduce the noise. The term 'lip holder' and 'lip support' have the same meaning in this specification.

[0023] It may be an advantage to provide tension indicator for a headgear and/or lip holder.

[0024] It may be an advantage to provide a mask with a port for adapting various type of the venting plugs and a viral filter comprising venting hole/s.

[0025] It may be an advantage to provide a venting plug that receiving a commercial filter.

[0026] It may be an advantage to provide a monitoring system that monitor the pressure of the breathing mask in remote mode.

[0027] It may be an advantage to provide a valve operated by a remote control.

[0028] It may be an advantage to provide a ventilatory index that reflects and shows the response of the user to the respiratory support.

[0029] It may be an advantage to provide a device capable of adjusting the settings based on the detection of conditions of the user's airway or respiratory characterisation.

[0030] It may be an advantage to provide a device that showing information of user's respiratory characteristics during the treatment.

[0031] It may be an advantage to provide a condensation system preventing condensed water entering into sieve beds of a portable oxygen concentrator.

[0032] It may be an advantage to provide a sieve bed design that may have stronger structure so that sieve bed has less deformation under high pressure.

[0033] The present invention seeks to ameliorate one or more of the abovementioned disadvantages and/or provide a new breathing apparatus.

[0034] MEANS FOR SOLVING THE PROBLEM

[0035] According to a first preferred aspect of the present invention, A preferred device for respiratory support, the device comprising: a flow generator supplying breathable gas from a breathable gas source to a breathing mask through an air path and wherein the air path includes a humidifier; and wherein the breathing mask is adapted to engage the face of a patient. Preferably, the humidifier comprising an inner container being fitted inside of an outer container, a chamber defined by the outer surface of the inner container and the inner surface of the outer container, an air inlet and an air outlet in gas communications with the chamber; wherein the air enter the chamber through the air inlet and exit through the air outlet; and a floating member inside of the chamber; wherein the floating member is configured to move to selectively block and open an aperture extending from the lower part of the inner container, so that fluid from the inner container flows to the outer container through the aperture when the aperture is in open configuration.

[0036] Preferably, floating member is in hollow or bowl structure or a hollow sealed structure. Preferably, wherein the floating member moves in vertical direction along one or more guide rails. The preferred humidifier further comprising a heater in heat communication with the outer container.

[0037] Preferably, humidifier may comprise a water container and a hydrophilic wick, wherein the hydrophilic wick configured to draw off liquid from the water container.

[0038] Also, the device may further comprise a heater for heating air wherein the heater is positioned in the air path so that the temperature of the air increased as the air traveling through the heater before entering into the humidifier. Preferably, the hydrophilic wick having concertina arrangement.

[0039] Preferably, the air path is coupled in gas communication with a pressure sensor and or a temperature sensor. Preferably, the water level within the humidifier is calculated and derived from the measurements outputted by at least one of the sensors and wherein at least one of the sensors is adapted to detect a fault state for humidifier. The preferred device may further comprise a conduit positioned in the air path, wherein the conduit is in gas communication with supplied air and the conduit is in gas communication with the breathing mask for a breathable gas delivers respiratory support and further wherein the conduit having: a first channel and a second channel, wherein the first channel is configured to conduct an inspiratory breathable gas and the second channel is configured to conduct both inspiratory gas and expiratory gas; a venting portion extended from the second channel; a flexible membrane positioned in between the first channel and the second channel configured to move to selectively block and open an aperture of the venting portion of the conduit; and a flow guiding means located in the first and or the second channel configured to guiding gas flow to a direction that create pressure on the membrane so that cause the membrane to open and or block the aperture.

[0040] Preferably, the flow guiding means is coupled in gas communication with a sensor, the sensor configured to sense a gas characteristic attributable to the conduit. The preferred

flow guiding means is selectively coupled to a further gas communication using an integrated port.

[0041] The preferred device may also further comprise a lip support assembly associated with the mask. The preferred lip support comprises: a lip support arm operatively coupled to the mask; and a lip support bracket configured to extend around a lower lip of the user and engage the lower lip, mounted on the lip support arm.

[0042] The preferred device may further comprise lip contacting means operatively coupled to the lip support for contacting a surface of a user. The preferred device may also further comprise an adjusting means for adjusting a relative position between the lip support and the user interface. The preferred lip support comprise a flexible strap made of a flexible material adapted to conform to a shape of a user's responsive to the user interface assembly being donned by the user.

[0043] Preferably, the mask further includes a chin strap member, the chin strap member being adapted to extend around a lower lip of the user responsive to the patient interface assembly being donned by the user. The preferred strap is coupled with a tension indicator, the indicator is adapted to be configured to provide information of the tension force of a headgear, when in use.

[0044] Preferably, the device further includes a computing module that calculates ventilation responses and respiratory characteristics based on minute ventilation and patient CO_2 level and patient O_2 level using: : $\dot{V}_A = \frac{-\dot{V}' \times P_{CO_2}}{P'_{CO_2}}$; $\dot{V}_D = \frac{\dot{V} \times P'_{CO_2} + \dot{V}' \times P_{CO_2}}{P'_{CO_2}}$; $\dot{V}_{CO_2} = \frac{-\dot{V}' \times (P_{CO_2})^2}{k \times P'_{CO_2}}$, $Y = \dot{V} \times P_{CO_2}$, $Yo = Y / Oxygen\ level.$

[0045] The preferred device may comprise a breathing mask/elbow/venting port assembly, wherein the mask is adapted to seal against the face of the patient, when in use, and comprising: an inlet first port connected to the flow generator; and a second output port, wherein the second port is adapted to receive one of the following assemblies engaged

inside the second port: a) plug assembly; b) viral filter assembly wherein the viral filter assembly includes an inlet with at least one opening adapted to be connected to the second port, when in use, and a viral filter and an outlet wherein the outlet formed by a series of apertures in the body of the viral filter assembly and the body has a larger diameter than the diameter of the second port; or c) vent assembly wherein the vent assembly includes an inlet adapted to be inserted into the second port and wherein the vent assembly includes a series of apertures at one end.

[0046] The preferred device may comprise: a portable oxygen concentrator; and wherein the portable oxygen concentrator further comprising: a compressor; an oxygen tank; and a condensation module positioned between the compressor and the oxygen tank, the condensation module is configured to condense the water vapour and collect condensed water from the compressed air and redistribute the condensed water to the oxygen tank. The preferred portable oxygen concentrator comprising a first sieve bed and a second sieve bed, each sieve bed has a first end and a second end, wherein the first end of the first sieve bed is in communication with a first inlet valve, the first end of the second sieve bed is in communication with a second inlet valve; and the inlet valves are connected to a compressor; and wherein the second ends of each sieve beds are connected to a first and a second diametrically opposed one way purge valves; and bi-directional balancing valve. Preferably, the portable oxygen concentrator further comprising an insert positioned within at least one of the sieve beds which configured to increase the travel distance and the time of the gas flow therethrough. The preferred insert is positioned within at least one of the sieve beds and is helical in shape.

[0047] Preferably, the sieve bed is integrated with the oxygen tank. The preferred sieve bed having a U-shaped wall and a vertical partition dividing the sieve bed into a first part and a second part such that the breathing gas enter the sieve bed through the upper end of the first part and exit the sieve bed through the upper end of the second part. Preferably, the portable oxygen concentrator further comprising: a mouth port configured to be attachable to a tube connectable with a mouth piece or an apparatus for a user to inhale through user's mouth; a nasal port positioned inside of the mouth port for connecting to a

nasal cannula and delivering breathable gas to the user; and an air entraining port configured to increase flow and pressure of the gas therethrough.

[0048] The preferred device further comprising a housing and a delivery tube wherein the delivery tube is rotably affixed to an outlet of the housing and wherein the delivery tube is rigid and telescopic and able to be selectively engaged at different preselected angles relative to the housing.

BRIEF DESCRIPTION OF THE FIGURES

[0049] Figure 1 is a schematic view of the device showing heating element, humidifier, pressure sensors and temperature sensors are used in the device.

[0050] Figure 2 (a) is an exploded perspective view of a wick humidifier. Figure 2 (b) is an illustration of zig zag wick pattern of a wick humidifier.

[0051] Figure 3 is a schematic view of a heater.

[0052] Figure 4 is a cross section view of a humidifier.

[0053] Figure 5(a) is a cross section view of a valve showing the gas flow push the valve to its closed position during inhalation process. Figure 5(b) is a cross section view of a valve showing the exhaled air flow push the valve to its open position to atmosphere during exhalation process. Figure 5(c) is a cross section view of a valve with two stages configured to be open and close during expiration and inhalation.

[0054] Figure 6 is a cross section view of three types of valves showing different guiding features and membranes of the valves.

[0055] Figure 7 is an illustration of three types of the lip support.

[0056] Figure 8 is a collection of two types of indicators that showing the tension level of the headgear of a mask.

[0057] Figure 9 depicts a breathing mask with various features.

[0058] Figure 10 shows a cross section view of a mask frame that integrated with venting features receives a plug or a viral filter on the top of venting features.

[0059] Figure 11 illustrates that a non-vented plug (a), venting features (b) and a viral filter (c) being received by an elbow of a mask.

[0060] Figure 12 is an imaginary ventilatory index that indicates how the user responds to the respiratory support.

[0061] Figure 13(a) is a perspective view of a Portable Oxygen Concentrator. Figure 13(b) is a view of the port section of a Portable Oxygen Concentrator. Figure 13(c) illustrates a mouth port connecting with a vented mask through a hose. Figure 13(d) is an example of a mouth piece attached to the nasal port via a tube.

[0062] Figure 14 is a diagram showing the working process of a Portable Oxygen Concentrator.

[0063] Figure 15 is a perspective view of a sieve bed insertion and a cross section view of sieve beds with an insertion.

[0064] Figure 16 (a) and (b) are perspective views of two sieve beds integrated with an oxygen tank; Figure 16(c) and (d) are illustrations of the direction of gas flow in a folded sieve bed design.

DESCRIPTION OF THE INVENTION

[0065] Preferred embodiments of the invention will now be described with reference to the accompanying drawings and non-limiting examples.

[0066] One of the embodiments shown in Figure 1 has a heater 101 for preheating the breathing gas before entering to humidifier 102. Temperature sensors 103, 104 and 105

provide temperature measurement at the points before the heating element, after the heating element and after the humidifier. The temperature difference measured by sensor 103 and 104 may be used to calculate flow rate as the temperature drop over the heating element varies with the flow rates when the supplied heat power keeps constant. There are also three pressure sensors 106, 107 and 108 for measuring the pressure at different points, and similarly the heating element may act as a flow element and the pressure drop over it may be used to calculate flow rate. More or less pressure and temperature sensors may be used in the airpath.

[0067] In one embodiment, the humidifier is a hydrophilic wick humidifier as shown in Figure 2, the wick humidifier has a water container 203 and hydrophilic wicks 202 that are used to pull the water up. The wick 202 may be corrugated to increase the surface area for evaporation. The wick 202 may be made from paper or any other material such as cloth. In this embodiment, a total of 7 wicks 202 are used. However, the number of the wicks 202 required may be less or more. As shown in Figure 2 (b), the wicks 202 may be arranged in a pattern that makes the air inside travel in a zig-zag fashion or concertina shape direction. The advantages of this arrangement may include increasing the distance the air travels, allowing more time to pick up moisture; acting as a turbulator to increase the mixture of the air during its travel; and exposing both sides of the wick 202 to the air, having twice the surface area. The wicks may be mounted onto the top lid 201 or at the bottom of the water container 203 or other mounting means. In some embodiments, a water delivery device, such as a pump, can be included to deliver the controlled amount of water to the wick so that the moisture added to the air and consequently the air humidity can be accurately controlled.

[0068] As one of the maintenance issues of a wick humidifier is that the scale deposits onto the wicks 202 of the humidifier 200. When a large amount of scale has been built up in the wicks 202, the scales will increase the flow resistance and therefore result in larger pressure drop, the scale will also reduce the hydrophilic capacity of the wick 202 and consequently, the efficiency of the water evaporation. As the result of less energy consumption for evaporation, the level of gas temperature drop is reduced. For maintenance purpose the

temperature sensors 104 and 105, and/or pressure sensors 107 and 108 are used to measure the temperature and/or pressure difference over the humidifier for indicating the level of scale deposition on the wicks 202. The small change of temperature and/or the big change in pressure may be a fault indication that the wicks 202 of the humidifier 200 may require maintenance and/or replacement. Similarly, if there is no water in the tank or water level is low at a certain level, less evaporation occurs, then the change in temperature in the humidifier will be very small. Therefore, the temperature difference may also be used to detect the no water or low water level in the humidifier tank and issue a warning.

[0069] In one embodiment, the humidifier as shown in Figure 4, consists of an inner container 401 for storing water, an outer container 402, a lid 404 and a float 403. An aperture 405 is located in the bottom of the inner container 401 from where the water in the inner container flows through into the outer container 402 to top up the water level in the outer container 402. The outer container 402 consists of heating elements or heat conductive plate 406 located at the bottom of the outer container 402. The water in the outer container is vaporised while it is heated up by the heating elements or heating plate 406. A float 403 that moves with the water level in the outer container 402, which may be made of light material or may have a hollow or bowl structure for reducing the weight, guided by one or more guiding feature 407 in between the lower end of the inner container 401 and the lower end of the outer container 402. The guiding feature, which may have varied design, confines the movement of the float 403 to upright and downright movement so that the float acts as a switch of allowing or stopping water flow through the aperture 405 when the water level in the outer container changes. The water from the inner container 401 stops going into the outer container 402 when the water level in the outer container 402 reaches a height which brings the float 403 to close the aperture 405. While the water level in the outer container 402 drops down, the float 403 moves down with the lowering water level and unblocked the aperture 405. The water in the inner container 401 flow through the aperture 405 and top up the water in the outer container 402. The purpose of this design is to keep the water level in the outer container the same at all time when in use, so that smaller amount of water is to be heated up compared with the traditional humidifier with one water container. The space between the inner side of the outer container and the

outer side of the inner container defines a chamber 410. On the top of the outer container 402, there is an air inlet 408 which allows the air entered into the chamber 410. The air in the chamber then takes the water vapor in the chamber and exit the chamber through an air outlet 409 that on the top of the outer container 402. In this embodiment, the air inlet 408 and air outlet 409 are on the opposite side of the top of the outer container 402. In some embodiments, where an air inlet 408 and an air outlet 409 not opposing to each other, a partition may be used in between the air inlet 408 and air outlet 409 for directing air flow to go around the chamber 410. A second aperture 411 may be included on the top of inner chamber communicating with the chamber 410 for equalising the pressure between the inner container 401 and the chamber 410.

[0070] Figure 5 (a) shows gas flow push the valve to its closed position during inhalation process. Figure 5(b) is a cross section view of a valve showing the exhaled air flow push the valve to its open position to atmosphere during exhalation process. Figure 5(c) is a cross section view of a valve with two stages configured to be open and closed during expiration and inhalation. The valve consists of a respiratory conduit having a first flow channel 501, a second flow channel 502 coupled with user's interface, a ring shape flexible membrane 503 in between the first channel 501 and the second channel 502, and a plurality of apertures 504. The membrane 503 may be made of soft elastic material and may have a flexible structure. The membrane 503 may have a fixed end 506 and a lip end 507, which may be configured to move to selectively block and open the apertures 504. The apertures 504 may be in any shape including trapezoid shape, cylindrical shape or square shape. The size of the openings of the apertures 504 on the atmosphere side may be larger than those on the side of second flow channel to facilitate the release of gas flow to the atmosphere. The valve also comprises a flow guiding feature 508 located in the first flow channel 501 and/or in the second flow channel 502, directing the gas flow in the respiratory channel. During inhalation, the supplied air flow from the first flow channel 501 to the second flow channel 502 will change direction by the flow guiding features 508 to create dynamic pressure that push up the lip end 507 of the membrane 503 so that the membrane 503 block the apertures 504 and stop the supplied air flow through the apertures 504 to the atmosphere. During exhalation, the dynamic pressure of the exhaled gas from the user in

the second flow channel 502 created by the flow guiding features 508 helps push down the lip end 507 of the flexible membrane 503 so that leaves the apertures 504 open to the atmosphere. The exhaled gas from the user thus flows to the atmosphere through the apertures 504. Figure 5(c) illustrate an embodiment having two stages of valves, consisting of a first valve connected to a second valve 509. In this example, the valve having same features with those of the valve 509.

[0071] In some embodiments, the flow guiding feature may locate in only one channel, and it may have a shape, such as a spindle, to guide both the inspiratory and expiratory flow, as shown in Figure 6(a). In some embodiments, a port 601 may attach to the flow guiding features for the tube connection as shown in Figure 6(a), so that a tube may be connected to this port 601 for measuring the proximal pressure or delivering gas, such as oxygen, to the user. In some embodiment, a sensor, such as pressure/temperature/humidity sensor 602 may be placed inside a flow guiding feature, where the sensor 602 may be connected to a device via wires or wireless such as Bluetooth™, as shown in Figure 6(b). The flow guiding feature may also act as a base for the flap 603. As shown in Figure 6(b), the flap 603 sits on the flow guiding feature during exhalation under the pressure by the exhaled gas. In some embodiments, a valve membrane may have one way valve, such as a duck bill valve 604, integrated in its centre, as shown in Figure 6(c).

[0072] A lip support according to a first embodiment of the present invention is shown in Figure 7(a) and (b) and includes a breathing nasal mask 701 coupled to a lip holding portion 702. The breathing mask 701 communicates a flow of breathing gas between a user's airway and a pressure/flow generating system. The breathing mask 701 is held in place on the user's head by an adjustable head strap as exemplary shown on Figure 8. Other head straps or connection pieces may be provided in addition to or in place of those shown to secure the breathing mask to the user.

[0073] The lip support may be made from any flexible material, any semi-rigid or rigid material. The lip holding portion 702 is adjustably connected to the breathing mask 701 by a connecting portion 703. In an exemplary embodiment of the present invention,

connecting portion 703 is a hard plastic part, which also provides rigidity. In a preferred embodiment, each end of lip holding portion 702 coupled to breathing mask 701 is also adjustable relative to the breathing mask 701. The connecting portion 703 is rotatable and allow the lip holding portion 702 to be adjustable in a number of positions/angles relative to the breathing mask 701.

[0074] The lip holding portion 702 is configured such that the lip holding portion 702 is disposed on/under or supported against user's lower lip. This configuration stops mouth opening by preventing the relaxed lower lip from dropping down, and consequently provides a relatively secure prevention of gas leaking from user's mouth during treatment. The lip holding portion 702 may include a relatively rigid shell 704 and a cushion 705. The shell 704 is preferably formed from rigid plastic. The cushion 705 may be attached to the shell 704 by a locking tab or any other techniques or overmolded to the shell 704. Cushion 705 is configured to contact with user's lower lip. The cushion 705 may be formed from foam, fabric or any other conventional cushion material, which is relatively soft to provide a comfortable contact to the user and to contour to the lip profile of the user. The lip holder may be integrated with the mask 701.

[0075] In another preferred embodiment, the lip holder may be part of the cushion and on both ends there are features which can be used to attach the lip holder to the headgear with straps, as shown in Figure 7(b).

[0076] . In some further embodiments, the lip holder connected to the existing the head gear for engaging the mask on the face of the patient (not shown).

[0077] Further, the lip holder 706 may be formed by a strap/part of a strap attached to the chin strap 707. On both ends of the lip holder 706 there are features which can be used to attach the lip holder to the chin strap 707. The tension and position/angle of the lip holder 706 can be adjusted by the connecting straps. In some embodiments, the lip support may be integrated with or attached to a chin/strap support, as shown in Figure 7(c). The tension and position of the lip support may be adjusted independently of the chin/strap support. In

some embodiments the lip support may be an independent part, which is separated from the mask and headgear, and has its own mechanism to be held in place on user's head.

[0078] In some embodiments, the lip support may be used together or integrated with a full-face mask to encourage or train the nose breathing. The headgear (not shown in figure 7) or chin strap 707 may include a tension adjustment means which may be Velcro™ or hook and loop style fasteners 708.

[0079] As discussed previously, a loose strap may compromise the treatment due to gas/air leaking out of the airpath, a tense strap however may cause discomfort or facial injury in extreme cases, therefore a tension indicator for the strap may be an advantage to guide the user to have the right headgear tension. In one embodiment, indicative features, such as marks, numbers, letters, colour scheme, bump bars, dots, holes or any other features may be added into headgear and chin/lip strap to help the user to understand the headgear tension or buckling position, examples, such as the numbers 801 and/or the bars 802, are illustrated in Figure 8(a) and Figure 8(b). In some other embodiments, the indication mechanism may include springs or other elastic components, that have constant elasticity over the time, in mask, head gear, or other locations, such as the spring 803 as shown in Figure 8(c). As shown in Figure 8(c), the spring 803 is mounted within a spring housing in a lateral direction to apply a constant pulling force on the headgear straps, when in use. The spring housing comprises an upper string housing 805 and a lower spring housing 806 wherein the upper and lower housing portions are slidably connected to each with the spring 803 mounted laterally within the gap between the interior walls of the upper and lower housing portions 805 and 806. A headgear strap is adapted to be receive and secured through the slot 804 in the tail end of upper housing portion 805. This configuration is adapted to allow the headgear strap received by slot 804 to be tightened by the user in use and wherein the spring 803 is adapted be compressed within the spring housing and equalise the load of tightened strap. The advantage mounting the spring 803 in this manner is that, when in use, the headgear straps are constantly tensioning to a preset tension level as determined by the strength of the spring 803. The elastic properties of the spring 803 may not deteriorate with age as the headgear straps may overtime. Typically, headgear straps are constructed on

fabric material or neoprene which generally losses elasticity over extended or repeated use by a user.

[0080] Figure 8(d) depicts an alternate embodiment of the headgear assembly 809, wherein the headgear assembly 809 includes multiple straps adapted to engage the aforementioned face mask using a fastener 808. At least one of the straps includes a concertina or zigzag section 807 wherein this concertina section 807 is adapted to extend laterally or in a lateral direction along the length of the strap and apply a pulling force onto to face mask against the user's face. The concertina section includes an elastic property allowing it to stretch but to return to it original position when resting.

[0081] The breathing mask may include a venting port. which may be located on the mask frame, elbow, tube or an independent jig. As illustrated in Figure 9, the port 903 may receive a non-venting plug 902 so that the mask will become a non-vented mask. The port 903 may also receive venting plugs 901 so that the mask will become a vented mask. A venting plug 901 may have the first end and the second end, the first end has venting hole/holes 905 which constructed and arranged to allow for the washout of exhaled gas; there may be a set of venting plugs with different aperture shapes, dimensions, or numbers to get different mask flow-pressure characteristics; the second end 906 may be configured to receive a commercial filter to filter the exhaled gas. The port 903 may receive a viral filter 904 integrated with venting hole/holes 905. The vent may be integrated or integrally formed in one piece with an assembly 903.

[0082] The venting feature 905 may be integrated with the port 903 in mask frame as shown in Figure 10 (a). Figure 10 (b) shows a plug 1002 fit into the port 1001 to convert the mask into a non-vented mask, while Figure 10 (c) shows a filter 1003 fitted into the port 1001 to filter the exhaled gas.

[0083] In alternative examples as illustrated in Figure 11, the vent port may be located on an elbow1104: a non-venting plug 1102 in an elbow1104, a venting plug 1101 in an elbow 1104; and a viral filter 1103 in an elbow 1104. Similarly, the venting feature may be

integrated with the elbow 1104, and the port may receive a non-vented plug 1102 to make a non-vented mask, or receive a viral filter 1103 to filter the air going atmosphere.

[0084] Figure 12 is an imaginary diagram of the estimated and actual ventilatory index for comparison. A ventilatory index, which is calculated from the minute volume and patient CO2 level and tells how the patient responds to the treatment, may be presented in mechanical ventilation. To enable this index, the device may facilitate measuring patient's carbon dioxides and/or oxygen level directly, or the device may have connectivity with the external device, such as Sentec™, to measure patient's carbon dioxides and oxygen level externally. The Ventilatory Index (VI) can be simply calculated as the product of minute ventilation and CO2 partial pressure, that is:

$$Y = \dot{V} \times P_{CO_2} \qquad \text{Eq. 1}$$

where Y is the ventilatory index, $\dot{V}$ is the minute ventilation, and P_{CO_2} is the partial pressure of CO_2. This index may be scaled or adjusted to get a different number, for example, dividing by 100 to get a smaller number.

The minute ventilation is the sum of the alveolar ventilation and the dead space ventilation:

$$\dot{V} = \dot{V}_A + \dot{V}_D \qquad \text{Eq. 2}$$

where $\dot{V}_A$ is the minute alveolar ventilation and $\dot{V}_D$ is the minute dead space ventilation. Thus, the index Y can be expressed as:

$$Y = \dot{V}_A \times P_{CO_2} + \dot{V}_D \times P_{CO_2} \qquad \text{Eq. 3}$$

On the other hand, the alveolar ventilation equation can be written as either

$$P_{CO_2} = (\dot{V}_{CO_2} \times k)/\dot{V}_A \qquad \text{Eq. 4}$$

or

$$\dot{V}_A \times P_{CO_2} = \dot{V}_{CO_2} \times k \qquad \text{Eq. 5}$$

where k is the conversion constant, $\dot{V}_{CO_2}$ is the carbon dioxides removed by the lung and it equals to the carbon dioxides production from metabolism in the steady state condition. Substituting Eq. 4 and Eq. 5 into Eq. 3, and rearranging the equation to get:

$$Y = k \times \dot{V}_{CO_2} \times (1 + \dot{V}_D/\dot{V}_A) \qquad \text{Eq. 6}$$

This equation suggests that the ventilatory index Y is directly proportional to the amount of patient's carbon dioxides production. It is also related to the ratio of dead space ventilation over the alveolar ventilation.

To take the oxygen into consideration, a variant of the index, which may also be called state ventilation, is obtained by dividing it by patient's oxygen level:

$$Y_O = Y/O_2\ level$$

Oxygen level may be either the oxygen partial pressure PO_2 if available, or oxygen saturation $SpO2$ measured by a pulse oximetry. Oxygen adjusted index provides a better indication of the effectiveness of ventilatory support, as a patient with a good response will normally have a higher O_2 level, thus resulting in a smaller index.

Rewrite the Eq. 6 by substituting Eq. 1 into it:

$$\dot{V} \times P_{CO_2} = k \times \dot{V}_{CO_2} \times (1 + \dot{V}_D/\dot{V}_A) \qquad \text{Eq. 7}$$

Assuming a patient is in stable condition, and his/her dead space ventilation $\dot{V}_D$ and CO_2 production $\dot{V}_{CO_2}$ are constant. Differentiating both sides of this equation:

$$\dot{V}' \times P_{CO_2} + \dot{V} \times P'_{CO_2} = k \times \dot{V}_{CO_2} \times \dot{V}_D \times (-1/\dot{V}_A^2) \times \dot{V}_A' \qquad \text{Eq. 8}$$

Again, with constant $\dot{V}_D$, differentiating Eq. 2 to get:

$$\dot{V}' = \dot{V}_A' \qquad \text{Eq. 9}$$

Substituting Eq. 9 and Eq. 5 into Eq. 8 and rearranging the equation, we have:

$$\dot{V}_D/\dot{V}_A = (-\dot{V} \times P'_{CO_2})/(\dot{V}' \times P_{CO_2}) - 1 \quad \text{Eq. 10}$$

Solving Eq. 2 and Eq. 10 simultaneously to get the dead space ventilation and alveolar ventilation:

$$\dot{V}_A = -\dot{V}' \times P_{CO_2}/P'_{CO_2} \quad \text{Eq. 11}$$

$$\dot{V}_D = (\dot{V} \times P'_{CO_2} + \dot{V}' \times P_{CO_2})/P'_{CO_2} \quad \text{Eq. 12}$$

Substituting Eq. 10 into Eq. 7 to obtain CO_2 production:

$$\dot{V}_{CO_2} = -\dot{V}' \times (P_{CO_2})^2/k \times P'_{CO_2} \quad \text{Eq. 13}$$

With these three equations, dead space and alveolar ventilation and CO2 production can be computed at any point, and the dead space volume can be obtained once $\dot{V}_D$ is known:

$$V_D = \dot{V}_D/f \quad \text{Eq. 14}$$

where f is the respiratory rate.

[0085] In one embodiment illustrated in Figure 13, a Portable Oxygen Concentrator (POC) is used in the respiratory treatment for supplying oxygen to the user. As illustrated in Figure 13, a POC includes a combined outlet comprising a nasal cannula port 1302 located inside of a mouth port 1301. A large hose may connect the mouth port 1301 to a user interface such as a vented mask or a mouthpiece. If a vented mask is used, a one-way valve may be placed between the mask and the hose to avoid rebreathing in carbon dioxides. There may be four ways to deliver oxygen from a POC to the user with this invention. A user may hold a POC and breath in oxygen through mouth directly from the outer mouth port 1301; a user may inhale oxygen through nose from the nasal cannula connected to nasal port 1302; The oxygen may be delivered to a user through a large hose that attached to a breathing mask and connected to a mouth port 1301; A detached mouth piece 1304, like a jet in a venturi mask, may be used via a tube connecting to the nasal port for a user to inhale oxygen through the mouth. During inhalation, the pressure difference may be detected by a sensor in the gas pathway, in response to the pressure change, the POC may release oxygen from the nasal port 1302 where high velocity oxygen may then entrain air from the

large air entraining port 1303. Air entrainment will increase the ventilation flow, which will also result in a positive mouth pressure, reducing work of breathing and increasing alveolar recruitment.

[0086] Figure 14 shows the working principle of the POC schematically. An active purging valve or an orifice is normally used in most of the POCs to purge one sieve bed with oxygen from the other sieve bed and vice versa. In this disclosure, the active purging valve or orifice is replaced with two passive one-way purge valves 1405 and 1406. which may be duck bill valve or umbrella valve. The one- way valve 1405 will open to purge sieve bed 1404 when the pressure in sieve bed 1403 is higher than the pressure in sieve bed 1404 by a predetermined value, the one way valve 1406 will open to purge sieve bed 1403 when the pressure in sieve bed 1404 is higher than the pressure in sieve bed 1403 by a predetermined value. The predetermined pressure difference may be the valve's cracking pressure in the system. However, the purging may not occur if the POC is running at low setting due to the pressure difference cannot reach the valve's cracking pressure.

[0087] Condensation is one of the major issues with the POCs. Water vapour inside the compressed air may be condensed, so that the liquid water may get into the sieve bed. On the other side, the oxygen from POC does not have water and may cause discomfort to the user due to the dryness. The present invention provides a mechanism that condenses the water vapour and collects condensed water from the compressed air prior to entering the sieve bed and reintroduce the water vapour into dry oxygen as shown in Figure 14. The condensation unit 1408 comprises a volume connected to air path after the compressor with stagnant air, which helps to extract water from the compressed gas so that the dry compressed gas entered the sieve beds through the valves. The condensation module also comprises one or more pumps or valves 1409, such as a peristaltic pump, or solenoid valve, which will be activated periodically to pump the condensed water into the oxygen tank 1410 to provide water vapor to the dry oxygen. The humidified oxygen then delivers to the user from the oxygen tank.

[0088] Figure 15(a) shows an insert 1501 for a sieve bed. Fig 15(b) is a cross section view of an insert 1501 inside a sieve bed. The insert 1501 may have a design, such as a spiral or

helical design, so that the time and distance for gas to travel inside of the sieve bed may be increased, which may help producing better effect of absorption. The sieve bed insert is constructed to reduce dead space/corners in the sieve bed to maximize the zeolite usage. The zeolite inside of the sieve bed may be divided into two separated halves by the insert as constructed in Figure 15, all zeolite may be kept together and may move as whole under periodic pressurization and depressurization. Therefore, it may reduce zeolite fluidisation. The inserts 1501 may be integrated with other components, for example, diffuser or buffer.

[0089] In one embodiment illustrated in Figure 16(a) and (b), a sieve bed 1601 is integrated with an oxygen tank 1602. The pressure in the oxygen tank may assist to reduce the deformation of the wall of the sieve bed due to reduced pressure difference across the wall. The oxygen tank has two volumes on opposite sides of the sieve bed so that it may provide flexibility to the layout of the oxygen tank. For example, one is used as a dead-head volume and the other used as a go-through volume, as shown in Figure 14. Other embodiments may include a design in which the sieve bed(s) may be completely surrounded by the oxygen tank, or the sieve beds may not be joined together.

[0090] Figure 16(c) and (d) shows a design of a folded sieve bed, in which the inlet and outlet ports of the sieve bed will be located on the same side. This design of folded sieve bed will be generally less slender and have a mid wall or partition. Hence, the sieve bed will be structurally stronger and have less deformation when undergoing high pressure. In some embodiments, the zeolite in a folded sieve bed may be separated into two halves, as shown Figure 16(c), while in some other embodiments, the zeolite may not be separated as shown in Figure 16(d). The folded sieve bed may also be varied in term of other parts such as lid, diffuser, buffer, and spring. Two folded sieve beds may also integrate together.

[0091] Although the invention has been described with reference to specific examples, it will be appreciated by those skilled in the art that the invention may be embodied in many other forms, in keeping with the broad principles and the spirit of the invention described herein.

[0092] The present invention and the described preferred embodiments specifically include at least one feature that is industrial applicable.

THE CLAIMS DEFINING THE INVENTION ARE AS FOLLOWS:

1. A device for respiratory support, the device comprising: a flow generator supplying breathable gas from a breathable gas source to a breathing mask through an air path and wherein the air path includes a humidifier; and wherein the breathing mask is adapted to engage the face of a patient.

2. The device of claim 1, wherein the humidifier comprising an inner container being fitted inside of an outer container, a chamber defined by the outer surface of the inner container and the inner surface of the outer container, an air inlet and an air outlet in gas communications with the chamber; wherein the air enter the chamber through the air inlet and exit through the air outlet; and a floating member inside of the chamber; wherein the floating member is configured to move to selectively block and open an aperture extending from the lower part of the inner container, so that fluid from the inner container flows to the outer container through the aperture when the aperture is in open configuration.

3. The device of claim 2, wherein the floating member is in a hollow sealed structure.

4. The device of any one of claims 2-3, wherein the floating member moves in vertical direction along one or more guide rails.

5. The device of any one of the preceding claims, wherein the humidifier further comprising a heater in heat communication with the outer container.

6. The device of claim 1, wherein the humidifier comprising a water container and a hydrophilic wick, wherein the hydrophilic wick configured to draw off liquid from the water container.

7. The device of claims 6, wherein the device further comprising a heater for heating air wherein the heater is positioned in the air path so that the temperature of the air increased as the air traveling through the heater before entering into the humidifier.

8. The device of claim 6 or 7, wherein the hydrophilic wick having concertina arrangement.

9. The device of any one of the preceding claims, wherein the air path is coupled in gas communication with a pressure sensor and or a temperature sensor.

10. The device of claim 9, wherein the water level within the humidifier is calculated and derived from the measurements outputted by at least one of the sensors and wherein at least one of the sensors is adapted to detect a fault state for humidifier.

11. The device of any one of preceding claims, wherein the device further comprising a conduit positioned in the air path, wherein the conduit is in gas communication with supplied air and the conduit is in gas communication with the breathing mask for a breathable gas delivers respiratory support and further wherein the conduit having:

a first channel and a second channel, wherein the first channel is configured to conduct an inspiratory breathable gas and the second channel is configured to conduct both inspiratory gas and expiratory gas;

a venting portion extended from the second channel;

a flexible membrane positioned in between the first channel and the second channel configured to move to selectively block and open an aperture of the venting portion of the conduit; and

a flow guiding means located in the first and or the second channel configured to guiding gas flow to a direction that create pressure on the membrane so that cause the membrane to open and or block the aperture.

12. The device of claim 11, wherein the flow guiding means is coupled in gas communication with a sensor, the sensor configured to sense a gas characteristic attributable to the conduit.

13. The device of any one of claims 11 to 12, wherein the flow guiding means is selectively coupled to a further gas communication using an integrated port.

14. The device of any one of preceding claims, wherein the device further comprising a lip support assembly associated with the mask.

15. The device of claim 14, wherein the lip support comprises: a lip support arm operatively coupled to the mask; and a lip support bracket configured to extend around a lower lip of the user and engage the lower lip, mounted on the lip support arm.

16. The device of any one of claims 14-15, further comprising lip contacting means operatively coupled to the lip support for contacting a surface of a user.

17. The device of claim 14-16, further comprising adjusting means for adjusting a relative position between the lip support and the user interface.

18. The device of any one of claims 14-17, wherein the lip support comprise a flexible strap made of a flexible material adapted to conform to a shape of a user's responsive to the user interface assembly being donned by the user.

19. The device of any one of preceding claims, wherein the mask further includes a chin strap member, the chin strap member being adapted to extend around a lower

lip of the user responsive to the patient interface assembly being donned by the user.

20. The device of any one of the preceding claims, wherein the strap is coupled with a tension indicator, the indicator is adapted to be configured to provide information of the tension force of a headgear, when in use, and wherein the tension indicator includes a spring adapted to allow for constant elasticity during extended use of the strap.

21. The device of any one of preceding claims, wherein the device further includes a computing module that calculates ventilation responses and respiratory characteristics based on minute ventilation and patient CO_2 level and patient O_2 level using: : $\dot{V}_A = \frac{-\dot{V}' \times P_{CO_2}}{P'_{CO_2}}$; $\dot{V}_D = \frac{\dot{V} \times P'_{CO_2} + \dot{V}' \times P_{CO_2}}{P'_{CO_2}}$; $\dot{V}_{CO_2} = \frac{-\dot{V}' \times (P_{CO_2})^2}{k \times P'_{CO_2}}$, $Y = \dot{V} \times P_{CO_2}$, $Yo = Y / Oxygen\ level$

22. The device of any one of preceding claims, wherein the breathing mask, wherein the mask is adapted to seal against the face of the patient, when in use, and comprising: an inlet first port connected to the flow generator; and a second output port, wherein the second port is adapted to receive one of the following assemblies engaged inside the second port: a) plug assembly; b) viral filter assembly wherein the viral filter assembly includes an inlet with at least one opening adapted to be connected to the second port, when in use, and a viral filter and an outlet wherein the outlet formed by a series of apertures in the body of the viral filter assembly and the body has a larger diameter than the diameter of the second port; or c) vent assembly wherein the vent assembly includes an inlet adapted to be inserted into the second port and wherein the vent assembly includes a series of apertures.

23. A device for respiratory support, the device comprising: a portable oxygen concentrator; and wherein the portable oxygen concentrator further comprising: a compressor; an oxygen tank; and a condensation module positioned between the

compressor and the oxygen tank, the condensation module is configured to condense the water vapour and collect condensed water from the compressed air and redistribute the condensed water to the oxygen tank.

24. The device of claim 23, wherein the portable oxygen concentrator comprising a first sieve bed and a second sieve bed, each sieve bed has a first end and a second end, wherein the first end of the first sieve bed is in communication with a first inlet valve, the first end of the second sieve bed is in communication with a second inlet valve; and the inlet valves are connected to a compressor; and wherein the second ends of each sieve beds are connected to a first and a second diametrically opposed one way purge valves; and bi-directional balancing valve.

25. The device of any one of the claims 23-24, wherein the portable oxygen concentrator further comprising an insert positioned within one sieve bed which configured to increase the travel distance and the time of the gas flow therethrough.

26. The device of claim 25, wherein the insert positioned within one sieve bed is helical in shape.

27. The device of any one of claims 23-26, wherein the sieve bed is integrated with the oxygen tank.

28. The device of any one of claims 23-27, wherein the sieve bed having a U-shaped wall and a vertical partition dividing the sieve bed into a first part and a second part such that the breathing gas enter the sieve bed through the upper end of the first part and exit the sieve bed through the upper end of the second part.

29. The device of any one of claims 23-28, wherein the portable oxygen concentrator further comprising:

a mouth port configured to be attachable to a tube connectable with a mouth piece or an apparatus for a user to inhale through user's mouth;

a nasal port positioned inside of the mouth port for connecting to a nasal cannula and delivering breathable gas to the user; and

an air entraining port configured to increase flow and pressure of the gas therethrough.

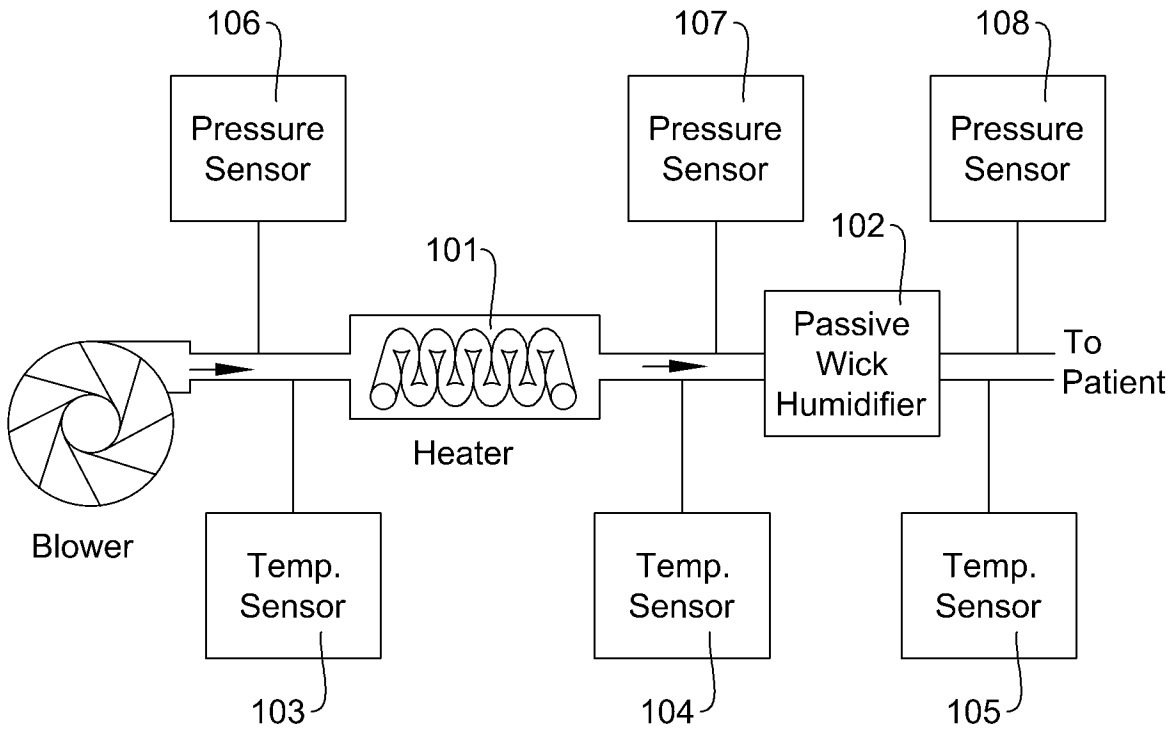
106
Pressure Sensor
107
Pressure Sensor
108
Pressure Sensor
101
102
Passive Wick Humidifier
To Patient
Heater
Blower
Temp. Sensor
Temp. Sensor
Temp. Sensor
103
104
105

FIG. 1

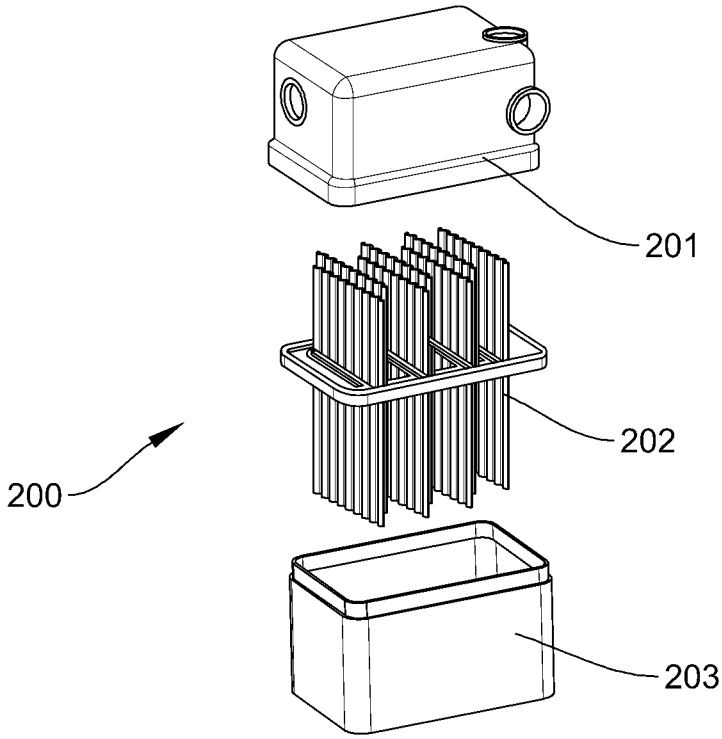

FIG. 2A

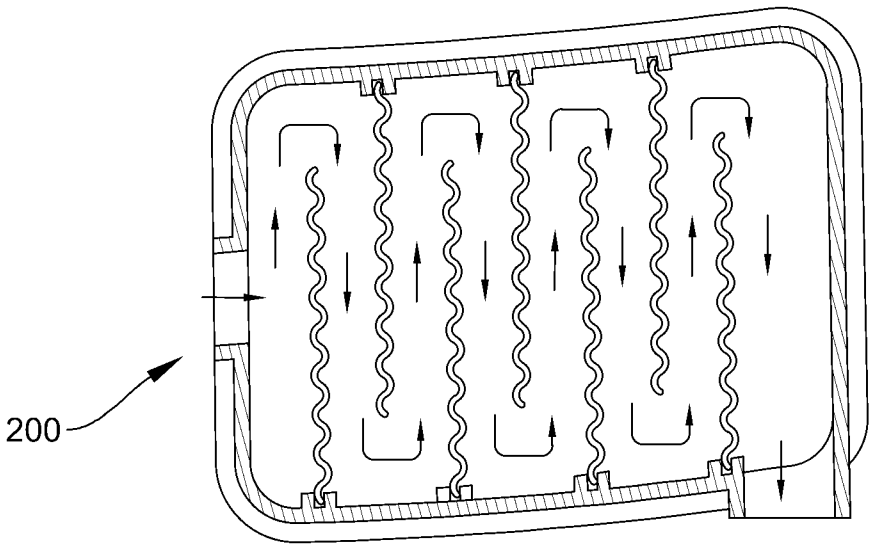

FIG. 2B

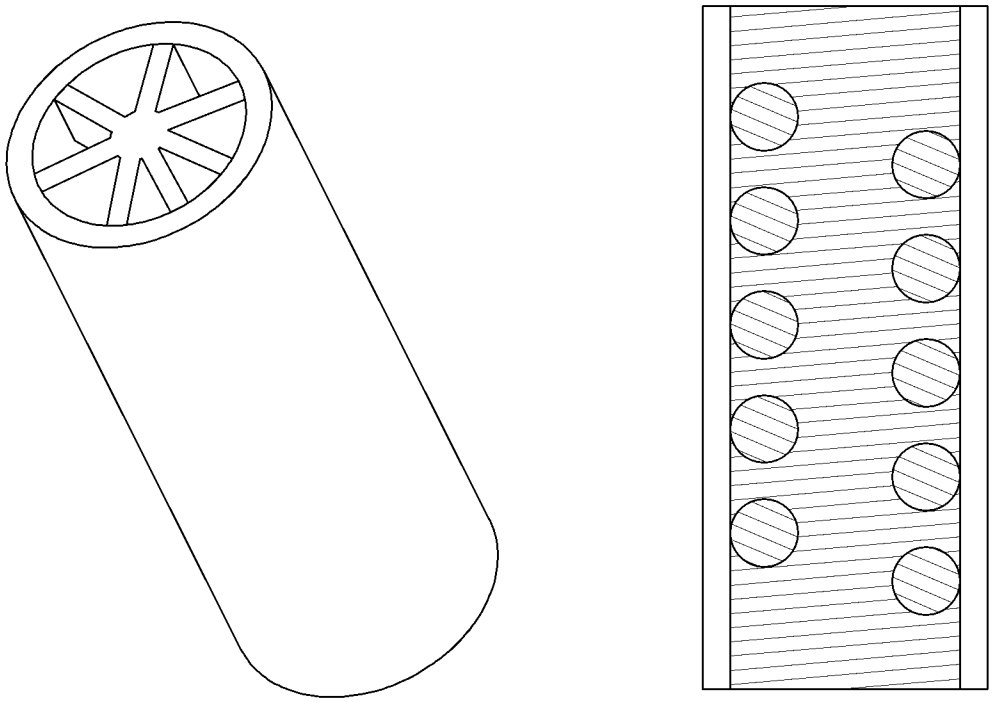

FIG. 3

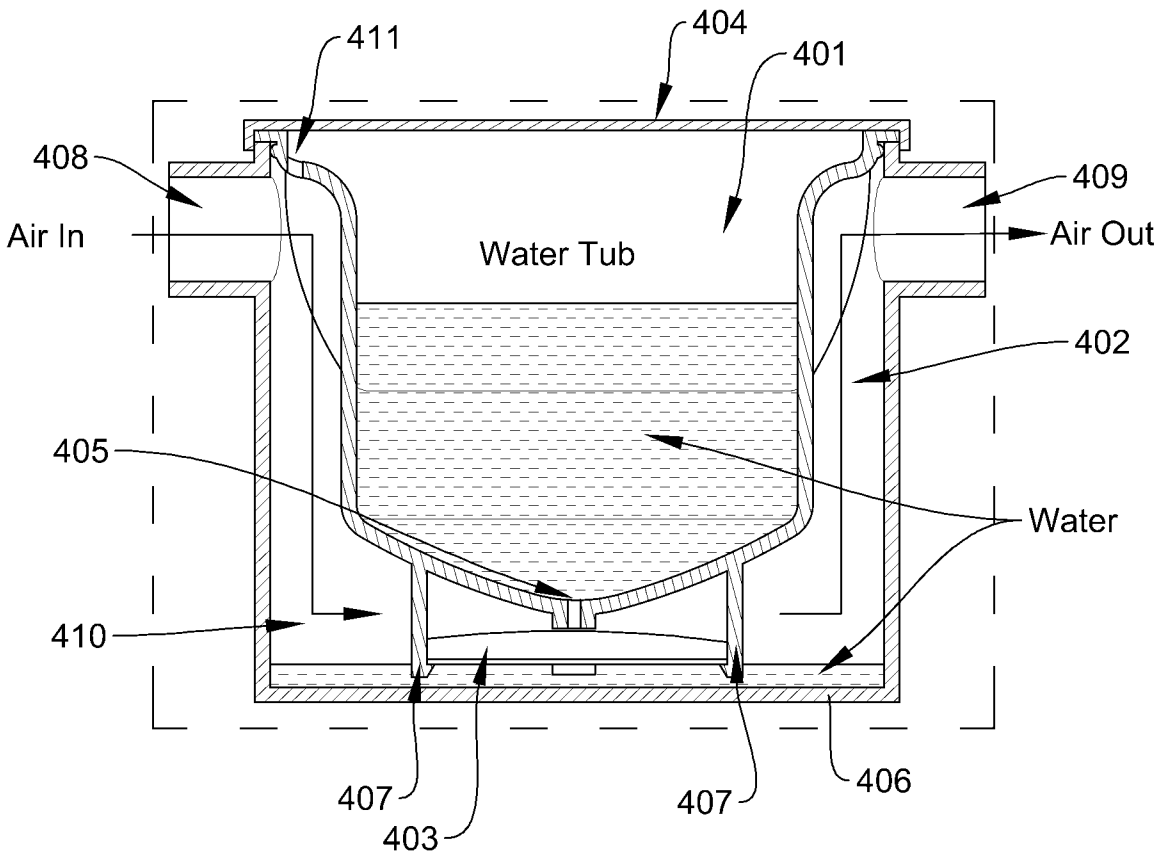
411
404
401
408
409
Air In
Water Tub
Air Out
402
405
Water
410
407
403
407
406

FIG. 4

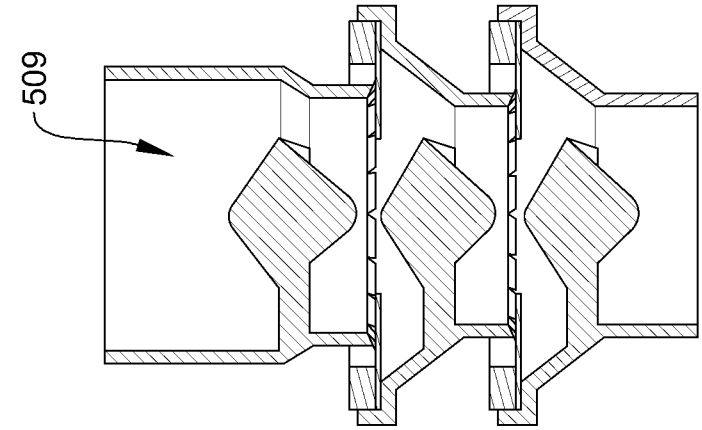

FIG. 5C

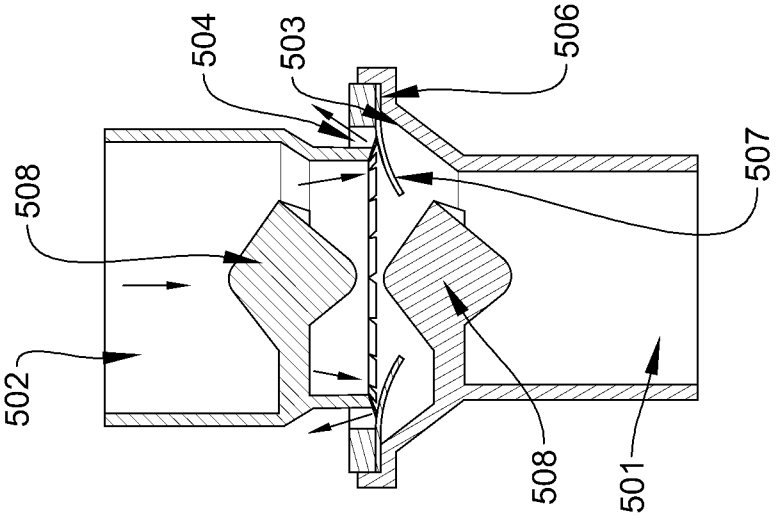

FIG. 5B

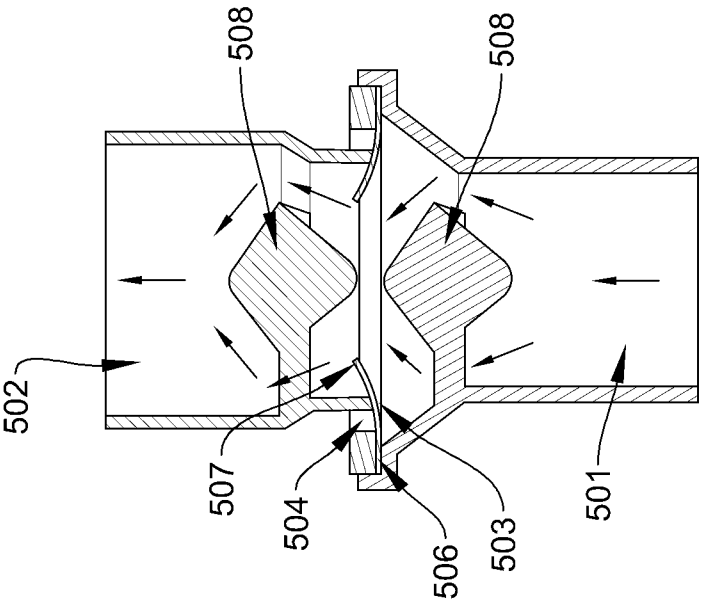

FIG. 5A

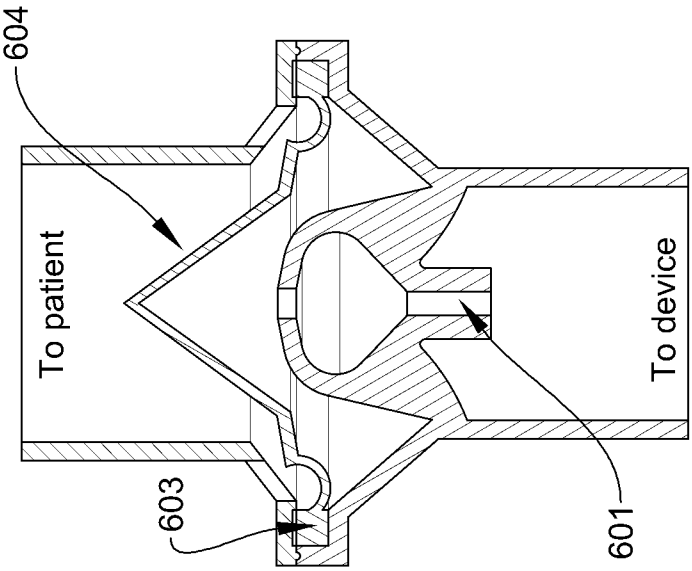

FIG. 6C

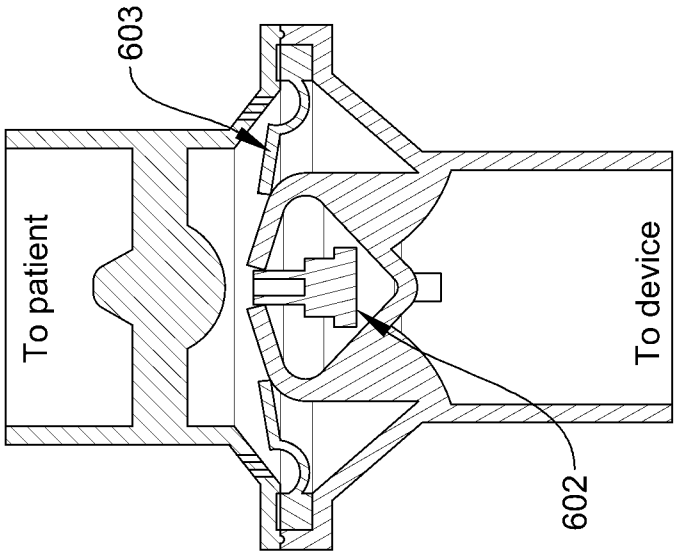

FIG. 6B

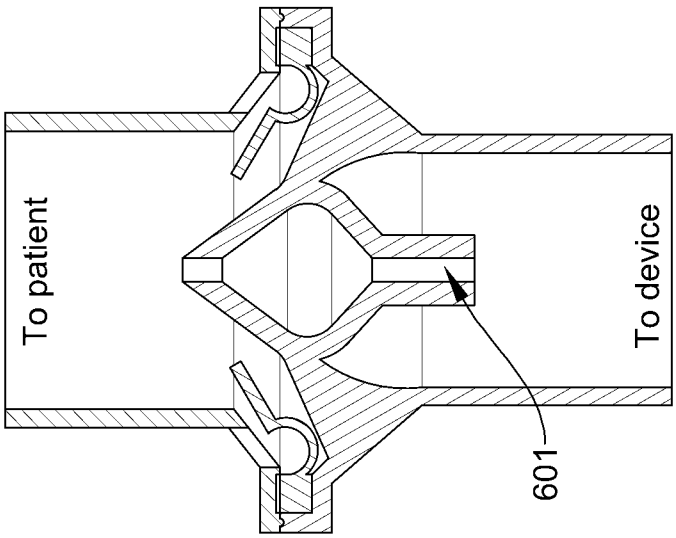

FIG. 6A

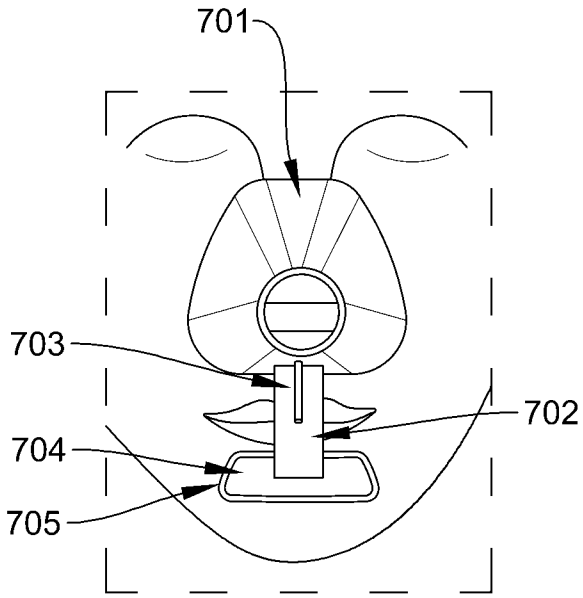

FIG. 7A

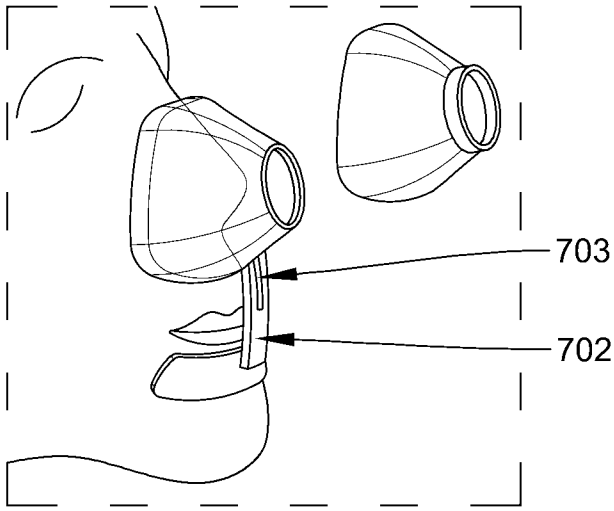

FIG. 7B

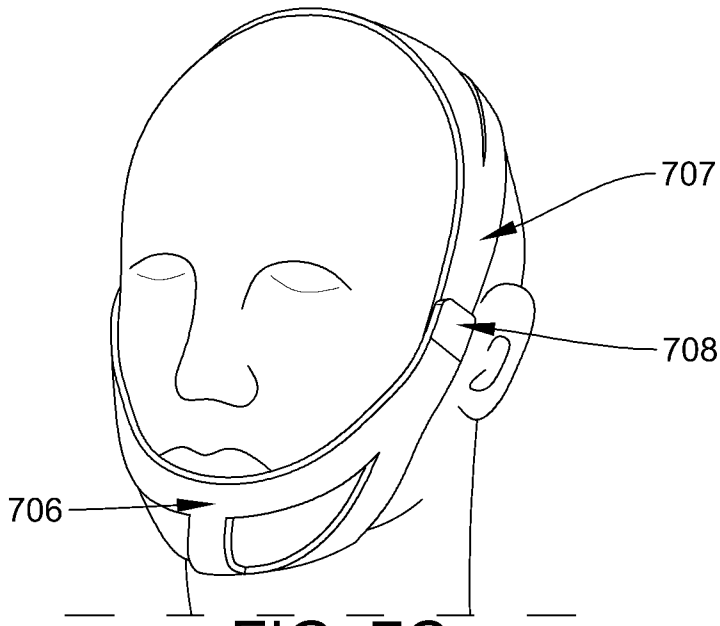

FIG. 7C

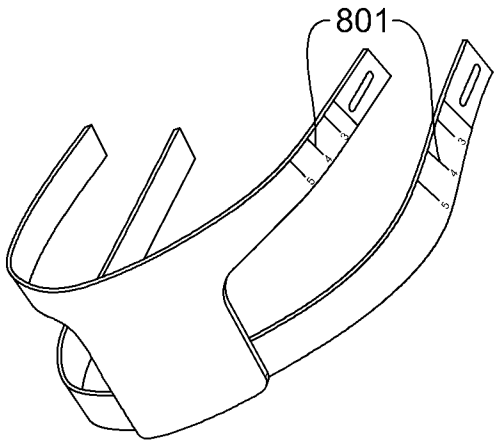

FIG. 8A

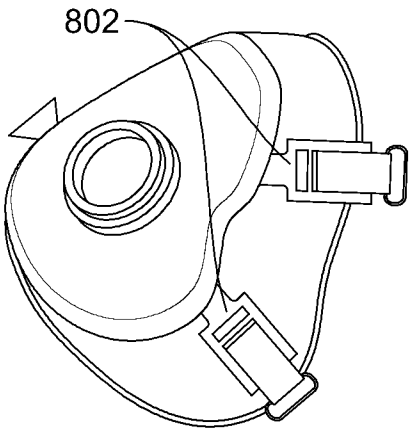

FIG. 8B

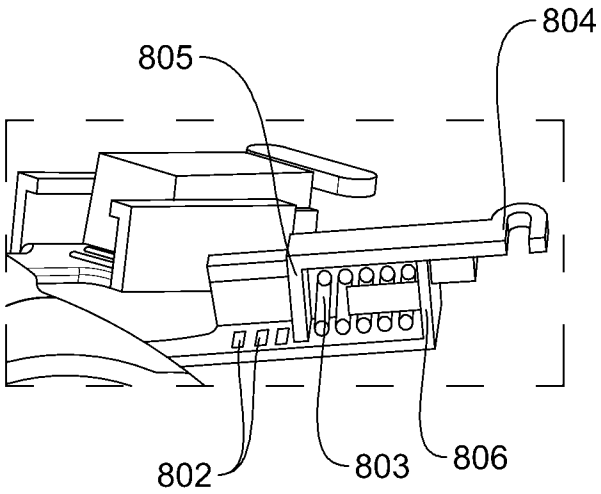

FIG. 8C

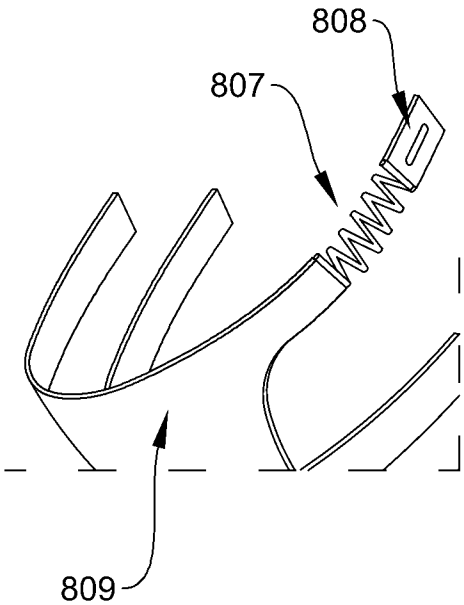

FIG. 8D

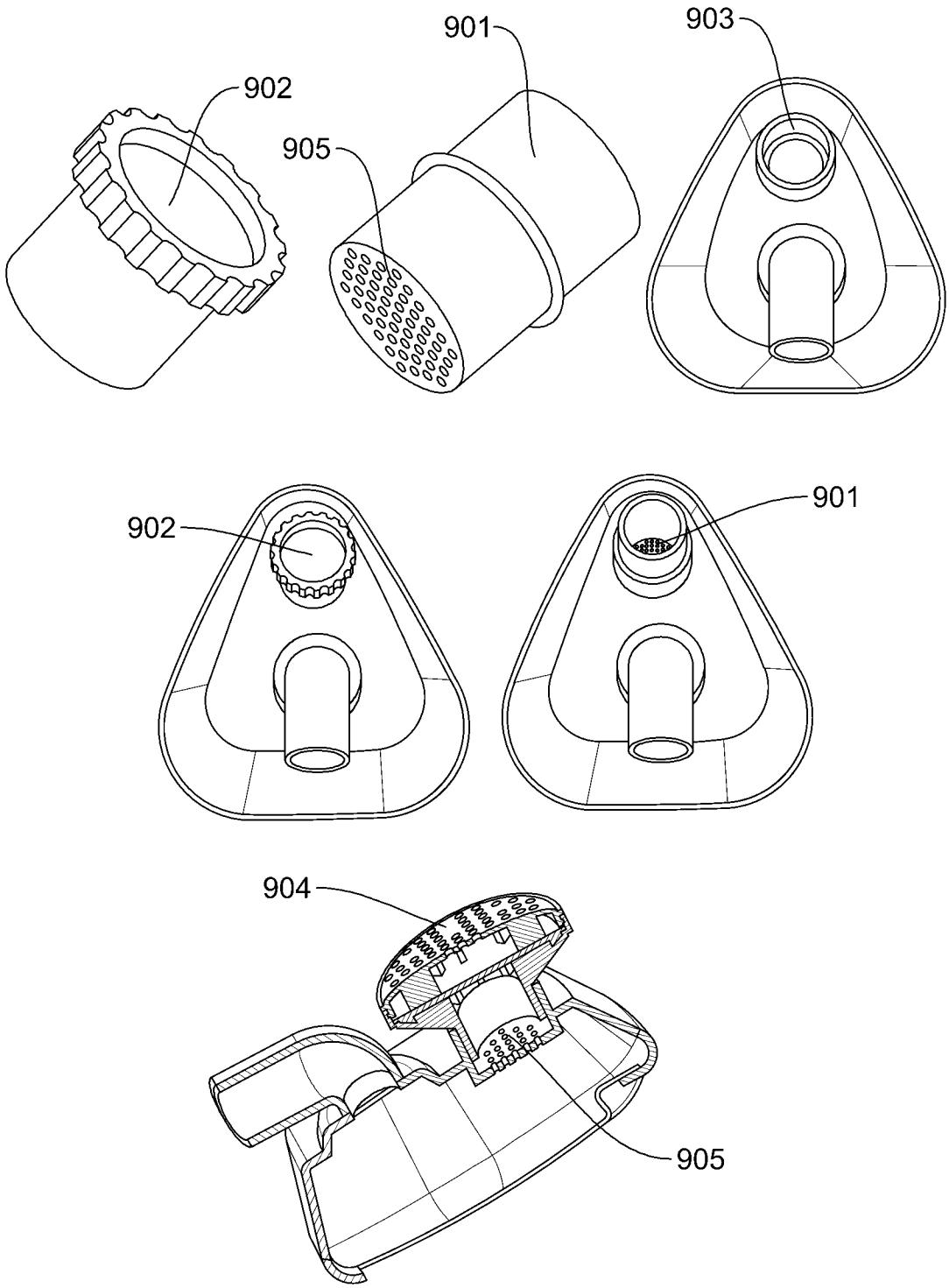

FIG. 9

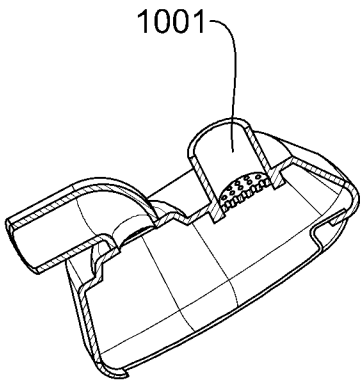

FIG. 10A

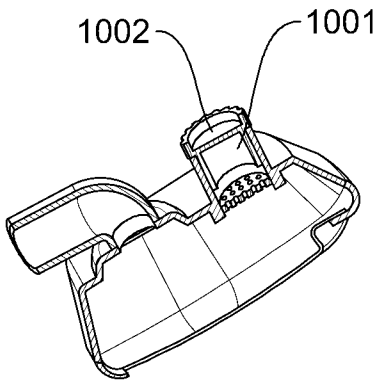

FIG. 10B

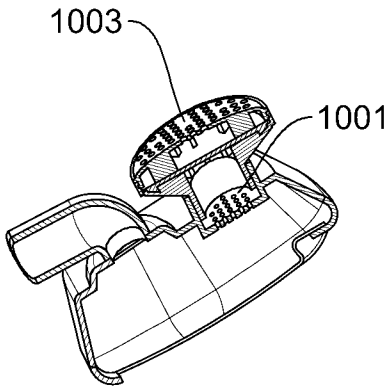

FIG. 10C

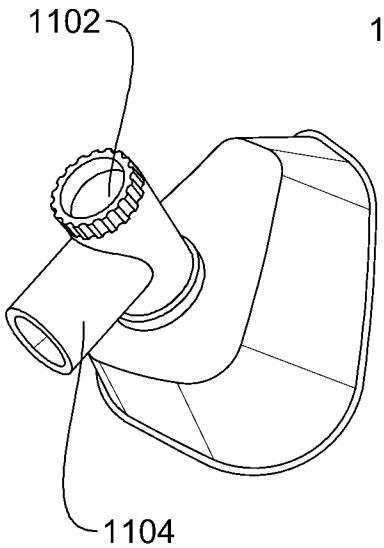

FIG. 11A

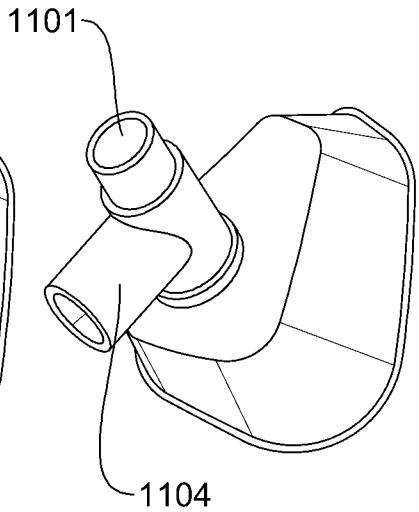

FIG. 11B

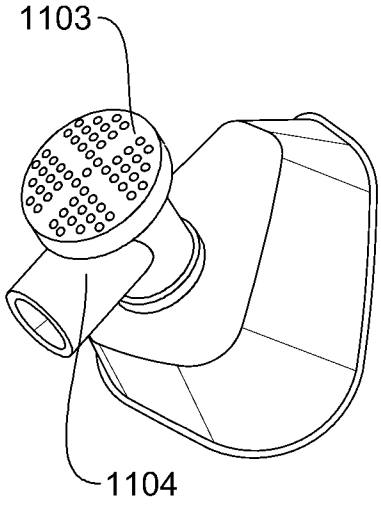

FIG. 11C

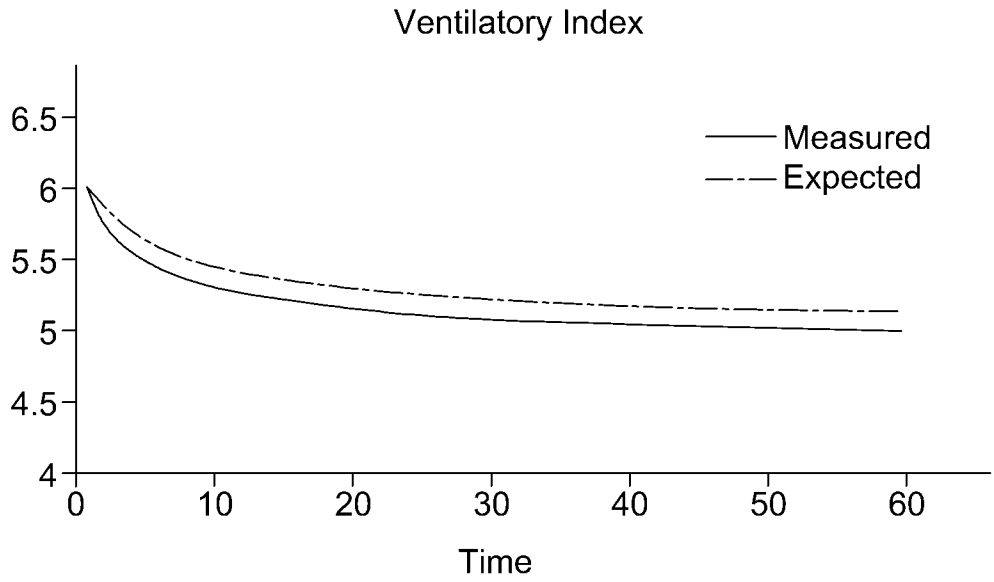
Ventilatory Index
6.5
6
5.5
5
4.5
4
0
10
20
30
40
50
60
Time
Measured
Expected

FIG. 12

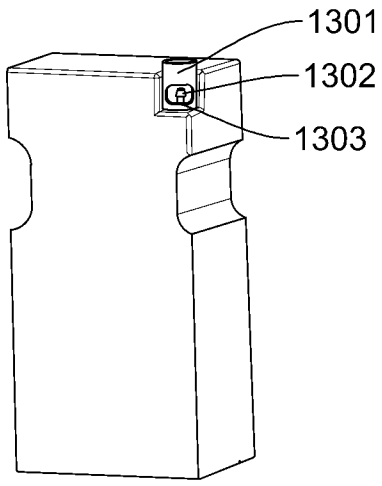

FIG. 13A

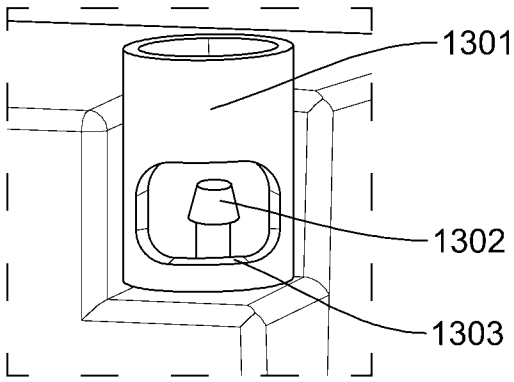

FIG. 13B

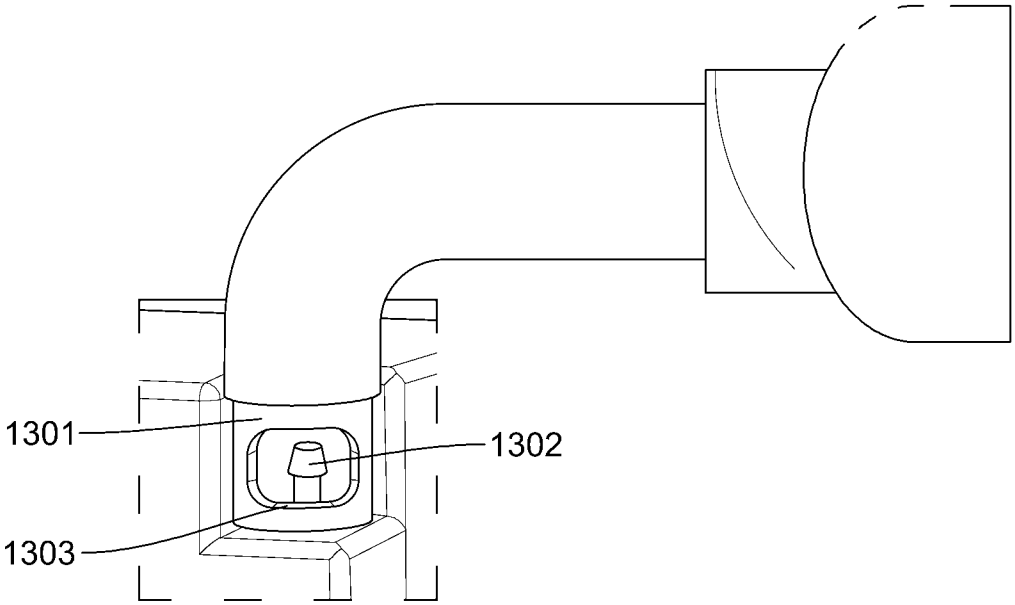

FIG. 13C

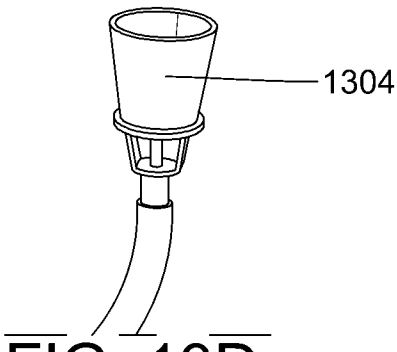

FIG. 13D

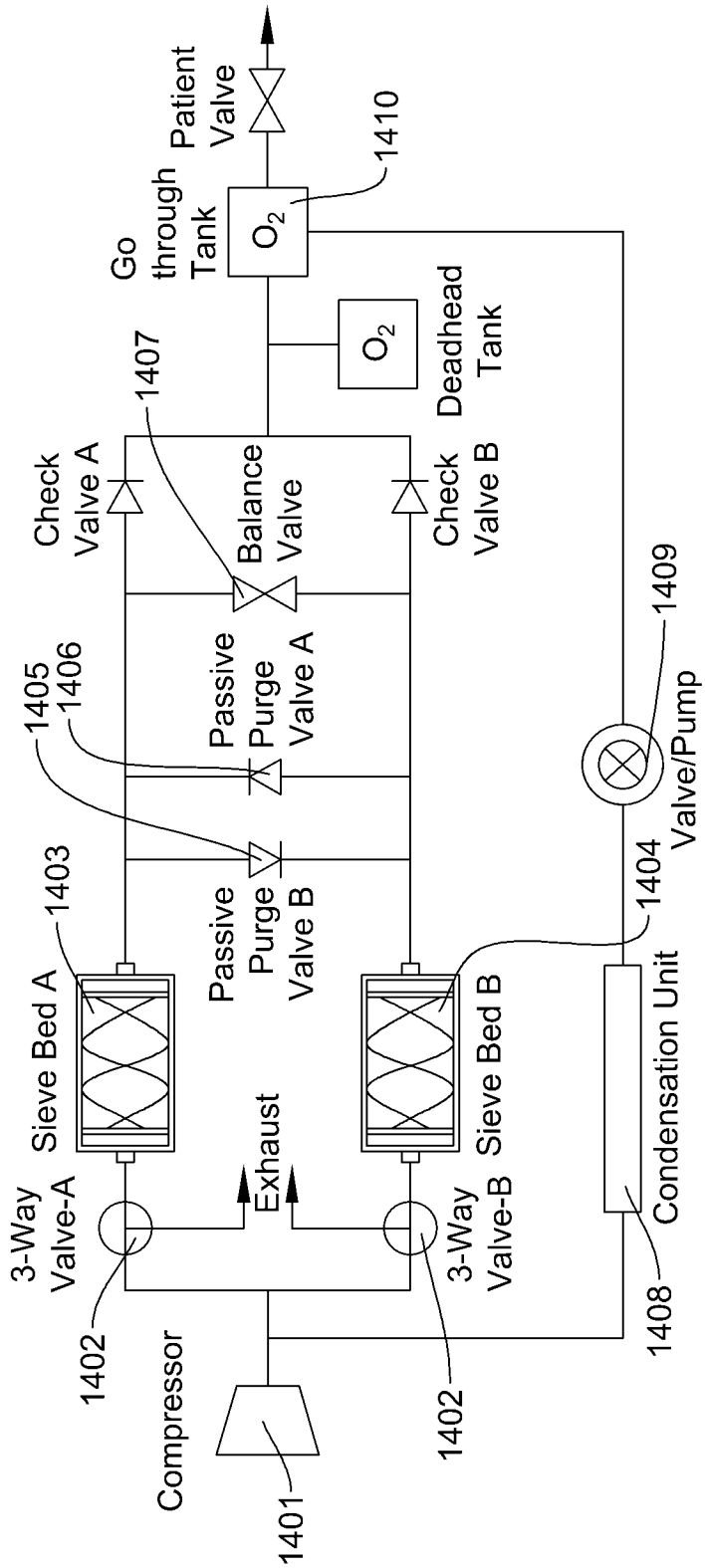
Patient Valve
Go through Tank
O_2
1410
O_2
Deadhead Tank
1407
Check Valve A
Balance Valve
Check Valve B
1405
1406
Passive Purge Valve A
1409
Valve/Pump
Passive Purge Valve B
1403
1404
Sieve Bed A
Sieve Bed B
Condensation Unit
Exhaust
3-Way Valve-A
3-Way Valve-B
1402
1402
1408
Compressor
1401

FIG. 14

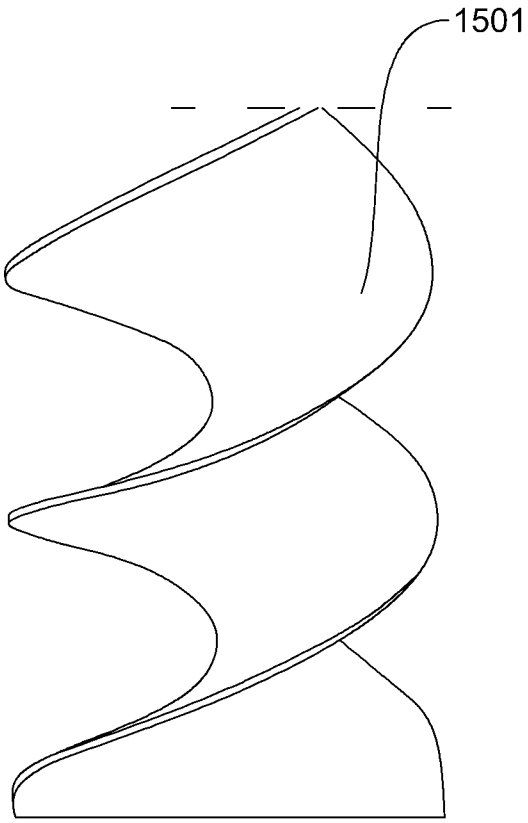

FIG. 15A

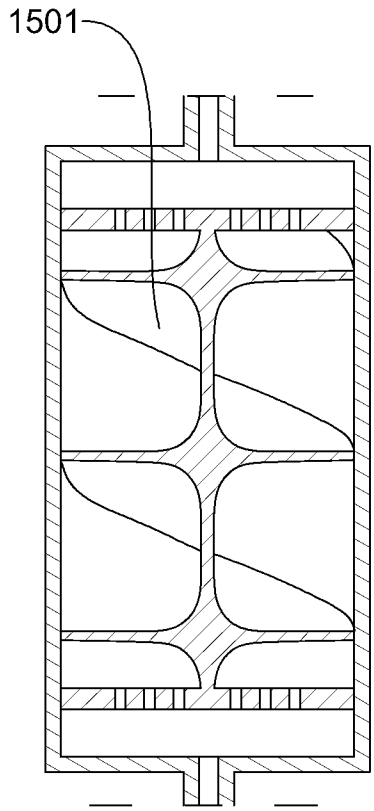

FIG. 15B

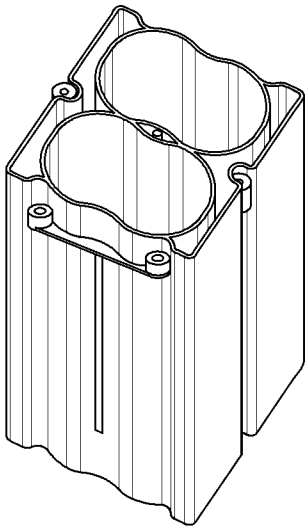

FIG. 16A

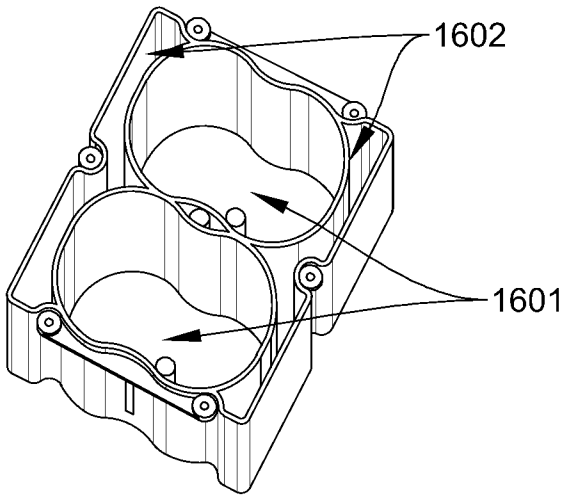

FIG. 16B

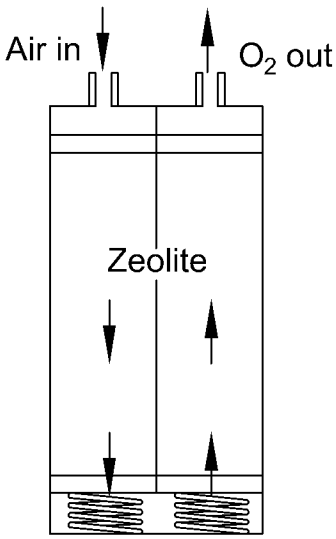

FIG. 16C

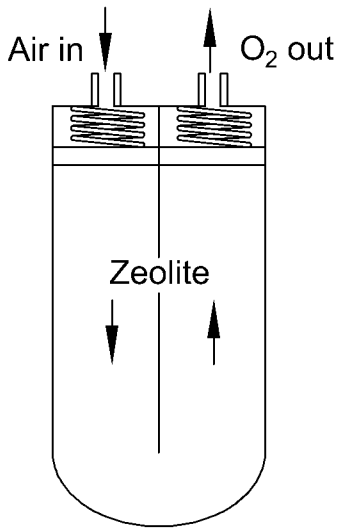

FIG. 16D

INTERNATIONAL SEARCH REPORT

International application No.
PCT/AU2022/050481

A. CLASSIFICATION OF SUBJECT MATTER

A61M 16/00 (2006.01) ***A61M 16/06 (2006.01)*** ***A61M 16/08 (2006.01)*** ***A61M 16/10 (2006.01)*** ***A61M 16/12 (2006.01)*** ***A61M 16/16 (2006.01)*** ***A61M 16/20 (2006.01)***

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

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

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

Applicant and inventor names searched in DOCDB, DWPI and IP Australia internal databases. PATENW: CPC A61M16/167, A61M16/165/LOW, A61M16/108, A61M16/1045, A61M16/16/LOW, A61M2016/0021, A61M2016/0027, A61M2205/3331/LOW, A61M2205/3365, A61M2205/3379/LOW; IPC A61M16/16/LOW with keywords (internal, chamber, tub, valve, outlet, passage, air_path, hydrophilic, wick, concertina, preheat, level, minimum, sensor, temperature, pressure) 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.
	Documents are listed in the continuation of Box C	

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

* Special categories of cited documents:

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

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

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

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

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

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

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

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

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

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
8 August 2022	08 August 2022

Name and mailing address of the ISA/AU	**Authorised officer**
AUSTRALIAN PATENT OFFICE PO BOX 200, WODEN ACT 2606, AUSTRALIA Email address: pct@ipaustralia.gov.au	John Schweitzer AUSTRALIAN PATENT OFFICE (ISO 9001 Quality Certified Service) Telephone No. +61 2 6283 2400

INTERNATIONAL SEARCH REPORT C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT		International application No. **PCT/AU2022/050481**
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2020/0030565 A1 (FISHER & PAYKEL HEALTHCARE LIMITED) 30 January 2020 fig. 1; par 0105	1
X	US 2016/0129212 A1 (KONINKLIJKE PHILIPS N.V.) 12 May 2016 fig. 1; par 0041, 0054	1
X	US 2018/0021539 A1 (BMC MEDICAL CO., LTD.) 25 January 2018 fig. 1, 3, 4; par 0031, 0040-0044, 0046-0048	1-5
X	US 4051205 A (GRANT) 27 September 1977 abstract; fig. 3; col. 3, lines 20-25; col. 4, lines 29-42, 55-62; col. 7 lines 23-39; col. 8, lines 17-30	1-5, 9-10
X	US 4676237 A (WOOD et al.) 30 June 1987 figs. 1-3 and col. 3, line 5 to col. 4, line 52; col. 7, lines 18-25	1, 6, 9-10
X	EP 0885623 B1 (FISHER & PAYKEL HEALTHCARE LIMITED) 03 November 2004 fig. 5 and par 0007-0010, 0046-0047	1, 9-10
X	US 2020/0069904 A1 (FISHER & PAYKEL HEALTHCARE LIMITED) 05 March 2020 fig. 15; par 0131-0134	1, 6-8
A	WO 2002/000284 A2 (NORTHGATE TECHNOLOGIES INC.) 03 January 2002 fig. 4; page 8, lines 19-21	8

INTERNATIONAL SEARCH REPORT

International application No.
PCT/AU2022/050481

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

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

1. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:
the subject matter listed in Rule 39 on which, under Article 17(2)(a)(i), an international search is not required to be carried out, including

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

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

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

This International Searching Authority found multiple inventions in this international application, as follows:

See Supplemental Box for Details

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying additional fees, this Authority did not invite payment of additional fees.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:

4. ☒ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:
1-10

Remark on Protest

☐ The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.

☐ The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.

☐ No protest accompanied the payment of additional search fees.

Supplemental Box

Continuation of: **Box III**

This International Application does not comply with the requirements of unity of invention because it does not relate to one invention or to a group of inventions so linked as to form a single general inventive concept.

This Authority has found that there are different inventions based on the following features that separate the claims into distinct groups:

- Claims 1 to 5 are directed to a respiratory support device having a humidifier comprising an inner container fitted in an outer container, with a floating member in a chamber defined between the containers to selectively open an aperture. A humidifier with the defined features is specific to this group of claims.
- Claims 1 and 6 to 8 are directed to a respiratory support device humidifier comprising a hydrophilic wick and a heater in the air path before the humidifier. A humidifier with the defined features is specific to this group of claims.
- Claims 1 and 9 to 10 are directed to a respiratory support device comprising a pressure sensor or temperature sensor in a flow path. A respiratory support device with the defined sensors is specific to this group of claims.
- Claims 1 and 11 to 13 are directed to a respiratory support device conduit having a first channel for inspiratory gas and a second channel for both inspiratory and expiratory gas with a flexible membrane positioned between the channels that selectively blocks an aperture of a venting portion. A conduit with the defined features is specific to this group of claims.
- Claims 1 and 14 to 20 are directed to a lip support assembly of a mask of a respiratory support device. A lip support assembly is specific to this group of claims.
- Claims 1 and 21 are directed to a respiratory support device including a computing module calculating ventilation based on a defined algorithm. A computing module as defined is specific to this group of claims.
- Claims 1 and 22 are directed to a respiratory support device having a breathing mask an inlet port and an output port, the output port adapted to receive one of a plug assembly, a viral filter assembly or a vent assembly. A breathing mask having the defined features is specific to this group of claims.
- Claims 23 to 29 are directed to a respiratory support device comprising a portable oxygen concentrator. An oxygen concentrator is specific to this group of claims.

PCT Rule 13.2, first sentence, states that unity of invention is only fulfilled when there is a technical relationship among the claimed inventions involving one or more of the same or corresponding special technical features. PCT Rule 13.2, second sentence, defines a special technical feature as a feature which makes a contribution over the prior art.

When there is no special technical feature common to all the claimed inventions there is no unity of invention.

In the above groups of claims, the identified features may have the potential to make a contribution over the prior art but are not common to all the claimed inventions and therefore cannot provide the required technical relationship. Therefore there is no special technical feature common to all the claimed inventions and the requirements for unity of invention are consequently not satisfied *a priori*.

This Opinion relates to the first to third inventions (claims 1 to 10), because the International Searching Authority considered that a search and examination for the second and third inventions would require a negligible additional search and examination effort over that for the first invention.

INTERNATIONAL SEARCH REPORT Information on patent family members	International application No. **PCT/AU2022/050481**

This Annex lists known patent family members relating to the patent documents cited in the above-mentioned international search report. The Australian Patent Office is in no way liable for these particulars which are merely given for the purpose of information.

Patent Document/s Cited in Search Report		Patent Family Member/s	
Publication Number	**Publication Date**	**Publication Number**	**Publication Date**
US 2020/0030565 A1	30 January 2020	US 2020030565 A1	30 Jan 2020
		AU 2013281354 A1	22 Jan 2015
		AU 2013281354 B2	22 Mar 2018
		AU 2018201175 A1	08 Mar 2018
		AU 2018201175 B2	20 Feb 2020
		AU 2020203251 A1	11 Jun 2020
		AU 2020203251 B2	09 Jun 2022
		AU 2022202872 A1	19 May 2022
		CN 104540540 A	22 Apr 2015
		CN 104540540 B	14 Jul 2017
		CN 105228680 A	06 Jan 2016
		CN 105228680 B	13 Feb 2018
		CN 107596522 A	19 Jan 2018
		CN 107596522 B	31 Aug 2021
		CN 107596529 A	19 Jan 2018
		CN 107596529 B	08 Feb 2022
		CN 107596530 A	19 Jan 2018
		CN 107596530 B	31 Aug 2021
		CN 108310574 A	24 Jul 2018
		CN 108310574 B	27 Jul 2021
		CN 108310575 A	24 Jul 2018
		CN 108310575 B	22 Jun 2021
		CN 108325043 A	27 Jul 2018
		CN 108325043 B	21 Jan 2022
		EP 2863975 A1	29 Apr 2015
		EP 2863975 B1	28 Nov 2018
		EP 2968830 A1	20 Jan 2016
		EP 2968830 B1	06 Mar 2019
		EP 3498327 A1	19 Jun 2019
		EP 3498327 B1	15 Sep 2021
		EP 3546004 A1	02 Oct 2019
		EP 3546004 B1	17 Nov 2021
		EP 3909633 A1	17 Nov 2021
		EP 3960226 A1	02 Mar 2022
		GB 2517381 A	18 Feb 2015
		GB 2517381 B	17 Jul 2019

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

INTERNATIONAL SEARCH REPORT Information on patent family members	International application No. **PCT/AU2022/050481**

This Annex lists known patent family members relating to the patent documents cited in the above-mentioned international search report. The Australian Patent Office is in no way liable for these particulars which are merely given for the purpose of information.

Patent Document/s Cited in Search Report		Patent Family Member/s	
Publication Number	**Publication Date**	**Publication Number**	**Publication Date**
		GB 2527226 A	16 Dec 2015
		GB 2527226 B	13 May 2020
		GB 2567082 A	03 Apr 2019
		GB 2567082 B	31 Jul 2019
		GB 2568409 A	15 May 2019
		GB 2568409 B	31 Jul 2019
		GB 2571443 A	28 Aug 2019
		GB 2571443 B	20 Nov 2019
		JP 2015521520 A	30 Jul 2015
		JP 6313294 B2	18 Apr 2018
		JP 2016511052 A	14 Apr 2016
		JP 6490602 B2	27 Mar 2019
		JP 2019048079 A	28 Mar 2019
		JP 6787967 B2	18 Nov 2020
		JP 2018126536 A	16 Aug 2018
		JP 7005405 B2	21 Jan 2022
		JP 2020116405 A	06 Aug 2020
		JP 2021035522 A	04 Mar 2021
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