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(54) Title: SYSTEMS AND METHODS FOR HYPOXIC GAS DELIVERY FOR ALTITUDE TRAINING AND ATHLETIC CONDITIONING

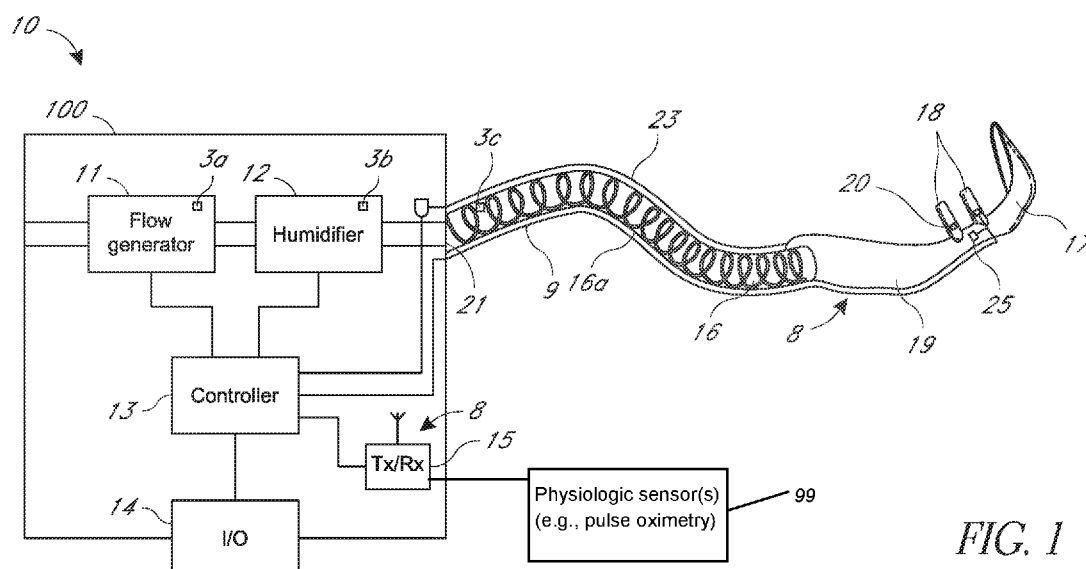


FIG. 1

(57) Abstract: A flow therapy apparatus can provide a hypoxic flow of gases to a user, for altitude training, athletic performance training, and other indications. The system can include an apparatus that can include a gas conduit, an ambient air inlet, and a hypoxic gas source inlet configured to connect to a hypoxic gas source and configured to create a hypoxic gas composition upon mixing of ambient air and the hypoxic gas. The system can also include a user interface, and a gas flow generation element configured to deliver the hypoxic gas composition to nares of the user at a predetermined flow rate of at least about 10 liters/minute. Methods are also disclosed.

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SYSTEMS AND METHODS FOR HYPOXIC GAS DELIVERY FOR ALTITUDE TRAINING AND ATHLETIC CONDITIONING

[0001] This application claims the benefit under 35 U.S.C. § 120 as a nonprovisional application of U.S. Prov. App. No. 62/569,147 filed on October 6, 2017, which is hereby incorporated by reference in its entirety.

FIELD OF THE DISCLOSURE

[0002] The present disclosure relates in some aspects to systems and methods for high flow hypoxic gas delivery to a user via a nasal conduit. The gas delivery can be for a wide variety of indications, including but not limited to altitude training and improving cardiovascular conditioning and athletic performance.

BACKGROUND

[0003] Altitude effects can influence athletic performance. Some athletes have found it advantageous to spend time, such as live and/or train, at relatively high altitudes to gain a competitive edge, commonly known as altitude training. Not to be limited by theory, altitude training has several beneficial potential physiological effects. At high altitude the partial pressure of oxygen is reduced due to the reduced barometric pressure, even though the actual concentration of oxygen remains relatively constant. Over the course of multiple weeks, a person's body may adapt to this relatively low oxygen environment by increasing mass of red blood cells and hemoglobin, and/or by altering muscle metabolism. These physiological changes can be shown to have follow up positive effects, particularly in terms of a raised VO_2 max, which is the maximum rate at which oxygen can be used be consumed by the body. VO_2 max is strongly linked to aerobic capacity, and in turn has effects on speed, strength, endurance and recovery.

[0004] There can be a large number of variables associated with altitude training, not limited to types of exercise, levels of altitude/oxygen concentration, length of therapy sessions, total length of therapy regime, length of time since leaving altitude, whether or not to remain at altitude for training sessions, whether or not to remain at altitude outside of training sessions, efficacy of simulated altitude, optimum ways to deliver simulated altitude, whether to control to inspired oxygen or blood oxygen saturation, as well as determining the

exact underlying mechanism behind the physiological changes. As actually being at altitude poses multiple challenges in terms of cost, inconvenience and difficulty to alter the exact altitude as noted above, methods of generating an artificial high altitude environment have been investigated. As one theory for the effects of altitude training is the reduced partial pressure of oxygen, this could be accurately mimicked by adding one, two, or more hypoxic gases, such as nitrogen or other gases to ambient air, resulting in a gas with a reduced oxygen concentration. Generating a hypoxic environment can be shown to artificially replicate the effects of being at altitude. Systems and methods that can more efficiently, effectively, safely, and conveniently replicate such altitude and other effects are needed.

SUMMARY

[0005] In some configurations, disclosed herein are methods of providing a hypoxic flow of gases to a user. The methods can include providing a hypoxic gas composition. The methods can also include delivering the hypoxic gas composition to the user, such as via an airway such as the nares and/or the mouth. The hypoxic gas composition can be provided to the airway via a nasal cannula or a mask, for example. The flow rate of the hypoxic gas composition to the user can be, for example, less than about, about, or at least about 10 liters/minute.

[0006] In some configurations, methods of providing a hypoxic flow of gases to a user can include providing a hypoxic gas composition; heating the hypoxic gas composition to a desired temperature, e.g., between about 30°C and about 45°C; and delivering the heated, hypoxic gas composition via a user interface in proximity to the airway, e.g., nares or mouth of a user.

[0007] In some configurations, methods of providing a hypoxic flow of gases to a user can include providing a hypoxic gas composition; humidifying the hypoxic gas composition; and delivering the humidified, hypoxic gas composition via a user interface in proximity to the airway, e.g., nares or mouth of a user.

[0008] The hypoxic gas composition can include one or more physiologically inert gases, such as nitrogen. The hypoxic gas composition can be delivered continuously at a desired flow rate, such as, for example, about or at least about 10, 20, 30, 40, 50, or more liters/minute. The method can also include delivering (e.g., synchronizing in some cases) the

hypoxic gas composition with an inspiratory phase of breathing of the user, for example, at a flow rate of at least about 10 liters/minute during inspiration. Synchronizing can include increasing the flow on inspiration and reducing the flow on expiration. Synchronization of a control signal of the device with a breath cycle of a user can be achieved by identifying a phase of the breath cycle waveform, and iteratively updating a phase of the control signal to achieve a determined phase difference between the control signal and the breath cycle waveform, such that the control signal can be configured to adjust a speed of the blower motor based upon the patient's inspiration and expiration. Synchronizing can further include phase-shifting the control signal based upon a system delay between the control signal being received by the blower motor and the resulting air flow being sensed by a patient. Synchronizing can also further include phase-shifting the control signal, such that the control signal can pre-empt the breath cycle waveform by a set amount of time. Delivering the hypoxic gas can be sufficient to meet peak inspiratory demand of the user. In some configurations, the method can include synchronizing the hypoxic gas composition with a phase of breathing of the user; delivery of the hypoxic gas composition can be at a flow rate of, for example, less than about 10 liters/minute during at least a portion of expiration.

[0009] The method can also include heating the hypoxic gas composition prior to reaching the user's airway (e.g., the nares and/or mouth). Heating can be sufficient to inactivate a pathogen of interest, such as human rhinovirus or influenza, among others. The hypoxic gas composition can be heated to any desired temperature, such as, for example, between about 30°C and about 45°C, between about 30°C and about 43°C, between about 37°C and about 43°C, or about 41°C. The method can also include humidifying the hypoxic gas composition prior to reaching the nares and/or mouth of the user. Humidifying can be to any desired relative humidity, such as about or at least about 80%, 90%, or 95% in some cases. The method can also include mixing ambient air with a source of enriched nitrogen to create the hypoxic gas composition. In some configurations, the peak inspiratory demand of the user can optionally be measured; and the flow rate adjusted based upon the measured peak inspiratory demand.

[0010] The oxygen concentration of the hypoxic gas composition can be, for example, between about 10% and about 20%, between about 15% and about 20%, between about 10.2% and about 20.9%, between about 11.9% and about 17.4%, between about 13.8%

and about 17.4%, or between about 15.7% and about 16.7%. The method can also include sensing the oxygen concentration of the hypoxic gas composition after mixing, and/or measuring at least one physiological parameter of the user; and automatically controlling the delivery of the hypoxic gas composition based on the measured physiological parameter. The measured physiological parameter can be, for example, blood oxygen saturation, heart rate, respiratory rate, heart rate variability, and/or blood pressure. Automatically controlling the delivery of the hypoxic gas composition can include adjusting an amount of hypoxic gas, such as enriched nitrogen, mixed into the hypoxic gas composition. Automatically controlling the delivery of the hypoxic gas can include titrating the composition of the hypoxic gas composition to achieve a predetermined blood oxygen saturation, e.g., of less than about 95%, between about 80% and about 94%, between about 85% and about 92%, between about 87% and about 90%, or between about 80% and about 85%. Titrating the composition of the hypoxic gas composition can include altering a flow rate of nitrogen into the hypoxic gas composition. The sensed oxygen concentration can be outputted, such as in real time, to a display, and/or correlated with an altitude equivalent via a processor, which can also be outputted to a display. The result of one or more sensed physiological parameters can also be outputted to a display.

[0011] The method can also include notifying the user (e.g., via a visual, auditory, or tactile alarm) when the physiological parameter deviates from a pre-selected range for at least a pre-determined period of time, and/or altering the pre-selected range based upon individual characteristics of the user. The method can be used for a time period sufficient to improve the user's conditioning at high altitude, and/or stimulate erythropoiesis such that the user's hemoglobin level increases by at least about 5%, 10%, 15%, 20%, or more compared to before starting the method.

[0012] Also disclosed herein is a system configured for providing a hypoxic flow of gases to a user. The system can include an apparatus that includes a gas conduit and an ambient air inlet. The system can also include a hypoxic gas source inlet configured to connect to a hypoxic gas source and configured to create a hypoxic gas composition upon mixing of ambient air and the hypoxic gas. The system can also include a user interface comprising a nasal cannula comprising nasal prongs. The system can also include a gas flow generation element configured to deliver the hypoxic gas composition.

[0013] In some configurations, a system configured for providing a hypoxic flow of gases to a user can include an apparatus that includes a gas conduit and an ambient air inlet, and a hypoxic gas source inlet configured to connect to a hypoxic gas source and configured to create a hypoxic gas composition upon mixing of ambient air and the hypoxic gas; a user interface; a gas flow generation element configured to deliver the hypoxic gas composition to comprising a nasal cannula comprising nasal prongs; and/or a heating element within the gas conduit configured to heat the hypoxic gas composition to a temperature of between about 30°C and about 45°C. In some configurations, the heating element can comprise a heater plate. In some configurations, the heating element can comprise a heater wire.

[0014] In some configurations, a system configured for providing a hypoxic flow of gases to a user can include an apparatus that includes a gas conduit and an ambient air inlet, and a hypoxic gas source inlet configured to connect to a hypoxic gas source and configured to create a hypoxic gas composition upon mixing of ambient air and the hypoxic gas; a user interface; a gas flow generation element configured to deliver the hypoxic gas composition to an airway of the user; and a humidification element within the gas conduit configured to humidify the hypoxic gas composition prior to reaching the airway of the user. The humidification element may be a humidification chamber.

[0015] The hypoxic gas composition can be delivered to the airway, e.g., nares and/or mouth of the user at a predetermined flow rate. The flow rate can be, for example, at least about 10, 20, 30, 40, 50, or more liters/minute. The system can include the hypoxic gas source, such as a hypoxic gas reservoir. The hypoxic gas can be, for example, enriched nitrogen. The gas flow generation element can be configured to deliver the hypoxic gas composition sufficient to meet the inspiratory demand of the user. The system can also include a heating element configured to heat the hypoxic gas composition prior to reaching the nares of the user. In some configurations, the heating element can comprise a heater plate. In some configurations, the heating element can comprise a heater wire. The heating element can be configured, for example, to heat the hypoxic gas composition to a predetermined temperature. The temperature can be, for example, between about 30°C and about 45°C, between about 30°C and about 43°C, between about 37°C and about 43°C, or about 41°C in some cases. The system can also include a humidification element configured to humidify the

hypoxic gas composition prior to reaching the nares of the user, such as to a relative humidity of at least about 80%, 90%, 95%, or more. The humidification element may be a humidification chamber. The system can also include a sensor configured to measure a peak inspiratory demand of the user. The system can be configured to adjust the flow rate based upon the measured peak inspiratory demand. The system can be configured to deliver the hypoxic gas in an oxygen concentration of, for example, between about 10% and about 20%, between about 15% and about 20%, between about 10.2% and about 20.9%, between about 11.9% and about 17.4%, between about 13.8% and about 17.4%, or between about 15.7% and about 16.7%. The system can also include a sensor configured to sense the oxygen concentration of the hypoxic gas composition. The system can also include a sensor configured to measure a physiological parameter of the user. The system can include a controller configured to automatically control the delivery of the hypoxic gas composition based on the measured physiological parameter. The controller can be configured to automatically controlling the delivery of the hypoxic gas composition by adjusting an amount of hypoxic gas, such as enriched nitrogen, mixed into the hypoxic gas composition. The physiological parameter can be, for example, blood oxygen saturation, heart rate, respiratory rate, heart rate variability, and/or blood pressure.

[0016] The system can also include an alarm (e.g., a visual, auditory, or tactile alarm) configured to notify the user when the physiological parameter deviates from a pre-selected range for at least a pre-determined period of time. The controller can also be configured to titrate the composition of the hypoxic gas composition to achieve a predetermined blood oxygen saturation, e.g., of less than about 95%, between about 80% and about 94%, between about 85% and about 92%, between about 87% and about 90%, or between about 80% and about 85%. The controller can also be configured to alter the flow rate of the hypoxic gas into the hypoxic gas composition. The system can also include a display. The controller can be configured to output the sensed oxygen concentration in real time to the display. The system can also be configured to correlate the sensed oxygen concentration to an altitude equivalent using a processor, and output the altitude equivalent in real time to a display.

[0017] The above examples are intended to be within the scope of the disclosure herein. These and other examples will become readily apparent to those skilled in the art

from the following detailed description having reference to the attached figures, the disclosure not being limited to any particular disclosed example(s).

[0018] In some configurations, a method of providing a hypoxic flow of gases to a user can include providing a hypoxic gas composition; delivering the hypoxic gas composition to the nares of a user via a nasal cannula at a flow rate of at least about 10 liters/minute; measuring at least one physiological parameter of the user; and automatically controlling the delivery of the hypoxic gas composition based on the measured physiological parameter, wherein the measured physiological parameter can be blood oxygen saturation.

[0019] In some configurations, the hypoxic gas composition can comprise at least one physiologically inert gas. In some configurations, the hypoxic gas composition can comprise nitrogen.

[0020] In some configurations, the method can include delivering the hypoxic gas composition continuously at a flow rate of at least about 10 liters/minute.

[0021] In some configurations, the method can include synchronizing delivering the hypoxic gas composition with an inspiratory phase of breathing of the user, wherein the delivering of the hypoxic gas composition can be at a flow rate of at least about 10 liters/minute during inspiration.

[0022] In some configurations, synchronizing can comprise increasing the flow rate on inspiration and reducing the flow rate on expiration.

[0023] In some configurations, delivering the hypoxic gas can be sufficient to meet peak inspiratory demand of the user.

[0024] In some configurations, the method can include heating the hypoxic gas composition prior to reaching the nares of the user.

[0025] In some configurations, heating the hypoxic gas composition can be sufficient to inactivate a pathogen of interest.

[0026] In some configurations, the pathogen of interest can be a human rhinovirus or influenza.

[0027] In some configurations, heating the hypoxic gas composition can comprise heating the hypoxic gas composition to between about 30°C and about 43°C. Heating the hypoxic gas composition can comprise heating the hypoxic gas composition to between

about 37°C and about 43°C. Heating the hypoxic gas composition can comprise heating the hypoxic gas composition to about 41°C.

[0028] In some configurations, the method can include humidifying the hypoxic gas composition prior to reaching the nares of the user.

[0029] In some configurations, the method can include humidifying and heating the hypoxic gas composition to a dew point temperature between about 30°C and about 43°C. The method can include humidifying and heating the hypoxic gas composition to a dew point temperature between about 37°C and about 43°C. The method can include humidifying and heating the hypoxic gas composition to a dew point temperature about 41°C.

[0030] In some configurations, humidifying the hypoxic gas composition can comprise humidifying the hypoxic gas composition to a relative humidity of at least about 80%. Humidifying the hypoxic gas composition can comprise humidifying the hypoxic gas composition to a relative humidity of at least about 90%. Humidifying the hypoxic gas composition can comprise humidifying the hypoxic gas composition to a relative humidity of at least about 95%. Humidifying the hypoxic gas composition can comprise humidifying the hypoxic gas composition to a relative humidity of at least about 99%. Humidifying the hypoxic gas composition can comprise humidifying the hypoxic gas composition to a relative humidity of at least about 100%.

[0031] In some configurations, the method can include mixing ambient air with a source of the hypoxic gas to create the hypoxic gas composition.

[0032] In some configurations, the method can include measuring inspiratory peak demand of the user; and adjusting the flow rate based upon the measured peak inspiratory demand.

[0033] In some configurations, an oxygen concentration of the hypoxic gas composition can be between about 10% and about 20%. An oxygen concentration of the hypoxic gas composition can be between about 15% and about 20%. An oxygen concentration of the hypoxic gas composition can be between about 10.2% and about 20.9%. An oxygen concentration of the hypoxic gas composition can be between about 11.9% and about 17.4%. An oxygen concentration of the hypoxic gas composition can be between about

13.8% and about 17.4%. An oxygen concentration of the hypoxic gas composition can be between about 15.7% and about 16.7%.

[0034] In some configurations, the method can include outputting the measured physiological parameter in real time to the display.

[0035] In some configurations, the measured physiological parameter can further comprise at least one selected from the group consisting of: heart rate, respiratory rate, heart rate variability, and blood pressure.

[0036] In some configurations, automatically controlling the delivery of the hypoxic gas composition can comprise adjusting an amount of hypoxic gas mixed into the hypoxic gas composition.

[0037] In some configurations, the method can include notifying the user when the physiological parameter deviates from a pre-selected range for at least a pre-determined period of time.

[0038] In some configurations, the method can include altering the pre-selected range based upon individual characteristics of the user.

[0039] In some configurations, notifying the user can comprise activating a visual, auditory, or tactile alarm.

[0040] In some configurations, automatically controlling the delivery of the hypoxic gas can comprise titrating the composition of the hypoxic gas composition to achieve a blood oxygen saturation of less than about 95%. Automatically controlling the delivery of the hypoxic gas can comprise titrating the composition of the hypoxic gas composition to achieve a blood oxygen saturation of between about 80% and about 94%. Automatically controlling the delivery of the hypoxic gas can comprise titrating the composition of the hypoxic gas composition to achieve a blood oxygen saturation of between about 85% and about 92%. Automatically controlling the delivery of the hypoxic gas can comprise titrating the composition of the hypoxic gas composition to achieve a blood oxygen saturation of between about 87% and about 90%. Automatically controlling the delivery of the hypoxic gas can comprise titrating the composition of the hypoxic gas composition to achieve a blood oxygen saturation of between about 80% and about 85%.

[0041] In some configurations, the method can include sensing the oxygen concentration of the hypoxic gas composition after mixing.

[0042] In some configurations, the method can include outputting the sensed oxygen concentration in real time to a display.

[0043] In some configurations, the method can include correlating the sensed oxygen concentration to an altitude equivalent using a processor, and outputting the altitude equivalent in real time to the display.

[0044] In some configurations, the method can include obtaining a target oxygen concentration of the hypoxic gas composition based on the blood oxygen saturation.

[0045] In some configurations, the method can include achieving the target oxygen concentration by controlling a hypoxic gas inlet valve.

[0046] In some configurations, the method can include achieving the target oxygen concentration based on the sensed oxygen concentration after mixing.

[0047] In some configurations, automatically controlling the delivery of the hypoxic gas can comprise titrating the composition of the hypoxic gas composition to achieve a simulated altitude.

[0048] In some configurations, the simulated altitude can be between about 0 m and about 5,950 m. The simulated altitude can be between about 1,000 m and about 5,000 m. The simulated altitude can be between about 1,250 m and about 4,800 m. The simulated altitude can be between about 1,500 m and about 3,500 m. The simulated altitude can be between about 1,600 m and about 3,000 m. The simulated altitude can be between about 2,000 m and about 2,500 m.

[0049] In some configurations, titrating the composition of the hypoxic gas composition can comprise altering a flow rate of nitrogen into the hypoxic gas composition.

[0050] In some configurations, the hypoxic gas composition can be delivered to the user at a flow rate of at least about 20 liters/minute. The hypoxic gas composition can be delivered to the user at a flow rate of at least about 30 liters/minute. The hypoxic gas composition can be delivered to the user at a flow rate of at least about 40 liters/minute. The hypoxic gas composition can be delivered to the user at a flow rate of at least about 50 liters/minute. The hypoxic gas composition can be delivered to the user at a flow rate of at least about 60 liters/minute. The hypoxic gas composition can be delivered to the user at a flow rate of at least about 70 liters/minute.

[0051] In some configurations, the method can be used for a time period sufficient to improve the user's conditioning at high altitude.

[0052] In some configurations, the method can be used for a time period sufficient to stimulate erythropoiesis such that the user's hemoglobin level increases by at least 5% compared to before starting the method.

[0053] In some configurations, the method can be used for a time period sufficient to stimulate erythropoiesis such that the user's hemoglobin level increases by at least 10% compared to before starting the method.

[0054] In some configurations, the method can include controlling the delivery of the hypoxic gas using a mobile device in electrical communication with the device.

[0055] In some configurations, a system configured for providing a hypoxic flow of gases to a user can include an apparatus comprising a gas flow path, an ambient air inlet, and a hypoxic gas source inlet configured to connect to a hypoxic gas source and configured to create a hypoxic gas composition upon mixing of ambient air and the hypoxic gas; a user interface comprising a nasal cannula comprising nasal prongs; a gas flow generation element configured to deliver the hypoxic gas composition to nares of the user at a predetermined flow rate of at least about 10 liters/minute; a sensor configured to measure a physiological parameter of the user, wherein the physiological parameter is blood oxygen saturation; and a controller configured to automatically control the delivery of the hypoxic gas composition based on the measured physiological parameter.

[0056] In some configurations, the gas flow generation element can comprise one or more of a blower, a compressor, a pressurized tank, or a gas source in the wall.

[0057] In some configurations, the system can further include the hypoxic gas source.

[0058] In some configurations, the hypoxic gas source can comprise a hypoxic gas reservoir.

[0059] In some configurations, the hypoxic gas can comprise enriched nitrogen.

[0060] In some configurations, the gas flow generation element can be configured to deliver the hypoxic gas composition sufficient to meet the peak inspiratory demand of the user.

[0061] In some configurations, the system can further include a heating element configured to heat the hypoxic gas composition prior to reaching the nares of the user. In some configurations, the heating element can comprise a heater plate. In some configurations, the heating element can comprise a heater wire.

[0062] In some configurations, the heating element can be configured to heat the hypoxic gas composition to between about 30°C and about 43°C. The heating element can be configured to heat the hypoxic gas composition to between about 37°C and about 43°C. The heating element can be configured to heat the hypoxic gas composition to about 41°C.

[0063] In some configurations, the system can further include a humidification element configured to humidify the hypoxic gas composition prior to reaching the nares of the user. The humidification element may be a humidification chamber.

[0064] In some configurations, the heating element and the humidification element can be configured to heat and humidify the hypoxic gas composition to a dew point temperature between about 30°C and about 43°C. The heating element and the humidification element can be configured to heat and humidify the hypoxic gas composition to a dew point temperature between about 37°C and about 43°C. The heating element and the humidification element can be configured to heat and humidify the hypoxic gas composition to a dew point temperature about 41°C.

[0065] In some configurations, the humidification element can be configured to humidify the hypoxic gas composition to a relative humidity of at least about 80%. The humidification element can be configured to humidify the hypoxic gas composition to a relative humidity of at least about 90%. The humidification element can be configured to humidify the hypoxic gas composition to a relative humidity of at least about 95%. The humidification element can be configured to humidify the hypoxic gas composition to a relative humidity of at least about 99%. The humidification element can be configured to humidify the hypoxic gas composition to a relative humidity of at least about 100%.

[0066] In some configurations, the system can further include a sensor configured to measure a peak inspiratory demand of the user; and the system can be configured to adjust the flow rate based upon the measured peak inspiratory demand.

[0067] In some configurations, the system can be configured to deliver the hypoxic gas in an oxygen concentration of between about 10% and about 20%. The system

can be configured to deliver the hypoxic gas in an oxygen concentration of between about 15% and about 20%. The system can be configured to deliver the hypoxic gas in an oxygen concentration of between about 10.2% and about 20.9%. The system can be configured to deliver the hypoxic gas in an oxygen concentration of between about 11.9% and about 17.4%. The system can be configured to deliver the hypoxic gas in an oxygen concentration of between about 13.8% and about 17.4%. The system can be configured to deliver the hypoxic gas in an oxygen concentration of between about 15.7% and about 16.7%.

[0068] In some configurations, the controller can be configured to automatically controlling the delivery of the hypoxic gas composition by adjusting an amount of hypoxic gas mixed into the hypoxic gas composition. In some configurations, the controller can be configured to automatically controlling the delivery of the hypoxic gas composition by adjusting an amount of enriched nitrogen mixed into the hypoxic gas composition.

[0069] In some configurations, the physiological parameter can further comprise at least one selected from the group consisting of: heart rate, respiratory rate, heart rate variability, and blood pressure.

[0070] In some configurations, the system can further include an alarm configured to notify the user when the physiological parameter deviates from a pre-selected range for at least a pre-determined period of time.

[0071] In some configurations, the alarm can comprise one of a visual, auditory, or tactile alarm.

[0072] In some configurations, the controller can be configured to titrate the composition of the hypoxic gas composition to achieve a blood oxygen saturation of the user of less than about 95%. The controller can be configured to titrate the composition of the hypoxic gas composition to achieve a blood oxygen saturation of the user of between about 80% and about 94%. The controller can be configured to titrate the composition of the hypoxic gas composition to achieve a blood oxygen saturation of the user of between about 85% and about 92%. The controller can be configured to titrate the composition of the hypoxic gas composition to achieve a blood oxygen saturation of the user of between about 87% and about 90%. The controller can be configured to titrate the composition of the hypoxic gas composition to achieve a blood oxygen saturation of the user of between about 80% and about 85%.

[0073] In some configurations, the system can further include a sensor configured to sense the oxygen concentration of the hypoxic gas composition.

[0074] In some configurations, the system can further include a display, wherein the system is configured to output the sensed oxygen concentration in real time to the display.

[0075] In some configurations, the system can be further configured to correlate the sensed oxygen concentration to an altitude equivalent using a processor, and outputting the altitude equivalent in real time to the display.

[0076] In some configurations, the system can be further configured to obtain a target oxygen concentration of the hypoxic gas composition based on the blood oxygen saturation.

[0077] In some configurations, the system can be further configured to achieve the target oxygen concentration based on the sensed oxygen concentration.

[0078] In some configurations, the controller can be configured to achieve the target oxygen concentration by controlling a hypoxic gas inlet valve.

[0079] In some configurations, the controller can be configured to alter a flow rate of the hypoxic gas into the hypoxic gas composition.

[0080] In some configurations, the gas flow generation element can be configured to deliver the hypoxic gas composition to the nares of the user at a predetermined flow rate of at least about 20 liters/minute. The gas flow generation element can be configured to deliver the hypoxic gas composition to the nares of the user at a predetermined flow rate of at least about 30 liters/minute. The gas flow generation element can be configured to deliver the hypoxic gas composition to the nares of the user at a predetermined flow rate of at least about 40 liters/minute. The gas flow generation element can be configured to deliver the hypoxic gas composition to the nares of the user at a predetermined flow rate of at least about 50 liters/minute. The gas flow generation element can be configured to deliver the hypoxic gas composition to the nares of the user at a predetermined flow rate of at least about 60 liters/minute. The gas flow generation element can be configured to deliver the hypoxic gas composition to the nares of the user at a predetermined flow rate of at least about 70 liters/minute.

[0081] In some configurations, the nasal cannula can be non-sealed.

[0082] In some configurations, the system can be a high flow device.

[0083] In some configurations, the high flow device can be portable.

[0084] In some configurations, the humidification element can comprise a humidification chamber.

[0085] In some configurations, the heating element can comprise a heater plate.

[0086] In some configurations, the heating element can comprise a heater wire.

[0087] In some configurations, a method of providing a hypoxic flow of gases to a user can include providing a hypoxic gas composition; humidifying and heating the hypoxic gas composition to a dew point temperature of between about 30°C and about 45°C prior to reaching the airway of the user; and delivering the heated, humidified hypoxic gas composition via a user interface in proximity to an airway of the user.

[0088] In some configurations, the method can include delivering the heated, hypoxic gas composition via a nasal cannula to the user's nares. The method can include delivering the heated, hypoxic gas composition via a nasal cannula to the user's nares.

[0089] In some configurations, the hypoxic gas composition can comprise at least one physiologically inert gas. In some configurations, the hypoxic gas composition can comprise nitrogen.

[0090] In some configurations, the method can include delivering the hypoxic gas composition continuously at a flow rate of at least about 10 liters/minute.

[0091] In some configurations, the method can include delivering the hypoxic gas composition continuously at a flow rate that meets the user's inspiratory demand.

[0092] In some configurations, the method can include synchronizing delivering the hypoxic gas composition with an inspiratory phase of breathing of the user, wherein the delivering of the hypoxic gas composition can be at a flow rate of at least about 10 liters/minute during inspiration.

[0093] In some configurations, the method can include synchronizing delivering the hypoxic gas composition with an inspiratory phase of breathing of the user, wherein the delivering of the hypoxic gas composition can be at a flow rate that meets the user's inspiratory demand.

[0094] In some configurations, synchronizing can comprise increasing the flow rate on inspiration and reducing the flow rate on expiration.

[0095] In some configurations, the method can include heating the hypoxic gas composition prior to reaching the nares of the user.

[0096] In some configurations, heating the hypoxic gas composition can be sufficient to inactivate a pathogen of interest.

[0097] In some configurations, the pathogen of interest can be a human rhinovirus or influenza.

[0098] In some configurations, humidifying and heating the hypoxic gas composition can comprise humidifying and heating the hypoxic gas composition to a dew point temperature of between about 37°C and about 45°C. Humidifying and heating the hypoxic gas composition can comprise humidifying and heating the hypoxic gas composition to a dew point temperature of between about 37°C and about 43°C. Humidifying and heating the hypoxic gas composition can comprise humidifying and heating the hypoxic gas composition to a dew point temperature of between about 43°C and about 45°C. Humidifying and heating the hypoxic gas composition can comprise humidifying and heating the hypoxic gas composition to a dew point temperature of between about 40°C and about 43°C. Humidifying and heating the hypoxic gas composition can comprise humidifying and heating the hypoxic gas composition to a dew point temperature of about 41°C.

[0099] In some configurations, humidifying the hypoxic gas composition can comprise humidifying the hypoxic gas composition to a relative humidity of at least about 80%. Humidifying the hypoxic gas composition can comprise humidifying the hypoxic gas composition to a relative humidity of at least about 90%. Humidifying the hypoxic gas composition can comprise humidifying the hypoxic gas composition to a relative humidity of at least about 95%. Humidifying the hypoxic gas composition can comprise humidifying the hypoxic gas composition to a relative humidity of at least about 99%. Humidifying the hypoxic gas composition can comprise humidifying the hypoxic gas composition to a relative humidity of at least about 100%.

[0100] In some configurations, the method can include mixing ambient air with a source of enriched nitrogen to create the hypoxic gas composition.

[0101] In some configurations, the method can include measuring inspiratory peak demand of the user; and adjusting the flow rate based upon the measured peak inspiratory demand.

[0102] In some configurations, an oxygen concentration of the hypoxic gas composition can be between about 10% and about 20%. An oxygen concentration of the hypoxic gas composition can be between about 15% and about 20%. An oxygen concentration of the hypoxic gas composition can be between about 10.2% and about 20.9%. An oxygen concentration of the hypoxic gas composition can be between about 11.9% and about 17.4%. An oxygen concentration of the hypoxic gas composition can be between about 13.8% and about 17.4%. An oxygen concentration of the hypoxic gas composition can be between about 15.7% and about 16.7%.

[0103] In some configurations, the method can include measuring at least one physiological parameter of the user; and automatically controlling the delivery of the hypoxic gas composition based on the measured physiological parameter.

[0104] In some configurations, the method can include outputting the measured physiological parameter in real time to the display.

[0105] In some configurations, the measured physiological parameter can further comprise at least one selected from the group consisting of: heart rate, respiratory rate, heart rate variability, and blood pressure.

[0106] In some configurations, automatically controlling the delivery of the hypoxic gas composition can comprise adjusting an amount of hypoxic gas mixed into the hypoxic gas composition.

[0107] In some configurations, the method can include notifying the user when the physiological parameter deviates from a pre-selected range for at least a pre-determined period of time.

[0108] In some configurations, the method can include altering the pre-selected range based upon individual characteristics of the user.

[0109] In some configurations, notifying the user can comprise activating a visual, auditory, or tactile alarm.

[0110] In some configurations, automatically controlling the delivery of the hypoxic gas can comprise titrating the composition of the hypoxic gas composition to achieve a blood oxygen saturation of less than about 95%. Automatically controlling the delivery of the hypoxic gas can comprise titrating the composition of the hypoxic gas composition to achieve a blood oxygen saturation of between about 80% and about 94%.

Automatically controlling the delivery of the hypoxic gas can comprise titrating the composition of the hypoxic gas composition to achieve a blood oxygen saturation of between about 85% and about 92%. Automatically controlling the delivery of the hypoxic gas can comprise titrating the composition of the hypoxic gas composition to achieve a blood oxygen saturation of between about 87% and about 90%. Automatically controlling the delivery of the hypoxic gas can comprise titrating the composition of the hypoxic gas composition to achieve a blood oxygen saturation of between about 80% and about 85%.

[0111] In some configurations, the method can include sensing the oxygen concentration of the hypoxic gas composition after mixing.

[0112] In some configurations, the method can include outputting the sensed oxygen concentration in real time to a display.

[0113] In some configurations, the method can include correlating the sensed oxygen concentration to an altitude equivalent using a processor, and outputting the altitude equivalent in real time to the display.

[0114] In some configurations, the method can include obtaining a target oxygen saturation of the hypoxic gas composition based on the blood oxygen saturation.

[0115] In some configurations, the method can include achieving the target oxygen concentration based on the sensed oxygen concentration after mixing.

[0116] In some configurations, the method can include achieving the target oxygen concentration by controlling a hypoxic gas inlet valve.

[0117] In some configurations, titrating the composition of the hypoxic gas composition can comprise altering a flow rate of nitrogen into the hypoxic gas composition.

[0118] In some configurations, the hypoxic gas composition can be delivered to the user at a flow rate of at least about 20 liters/minute. The hypoxic gas composition can be delivered to the user at a flow rate of at least about 30 liters/minute. The hypoxic gas composition can be delivered to the user at a flow rate of at least about 40 liters/minute. The hypoxic gas composition can be delivered to the user at a flow rate of at least about 50 liters/minute. The hypoxic gas composition can be delivered to the user at a flow rate of at least about 60 liters/minute. The hypoxic gas composition can be delivered to the user at a flow rate of at least about 70 liters/minute.

[0119] In some configurations, the method can be used for a time period sufficient to improve the user's conditioning at high altitude.

[0120] In some configurations, the method can be used for a time period sufficient to stimulate erythropoiesis such that the user's hemoglobin level increases by at least 5% compared to before starting the method.

[0121] In some configurations, the method can be used for a time period sufficient to stimulate erythropoiesis such that the user's hemoglobin level increases by at least 10% compared to before starting the method.

[0122] In some configurations, the user interface can comprise a nasal cannula.

[0123] In some configurations, the nasal cannula can be non-sealed.

[0124] In some configurations, a system configured for providing a hypoxic flow of gases to a user can include an apparatus comprising a gas flow path, an ambient air inlet, and a hypoxic gas source inlet configured to connect to a hypoxic gas source and configured to create a hypoxic gas composition upon mixing of ambient air and the hypoxic gas; a gas flow generation element configured to deliver the hypoxic gas composition; a humidification element configured to humidify the hypoxic gas composition prior to reaching the nares of the user; a heating element within the gas flow path, wherein the humidification element and the heating element are configured to heat and humidify the hypoxic gas composition to a dew point temperature of between about 30°C and about 45°C; and a user interface.

[0125] In some configurations, the humidification element can comprise a humidification chamber.

[0126] In some configurations, the gas flow generation element can comprise one or more of a blower, a compressor, a pressurized tank, or a gas source in the wall.

[0127] In some configurations, the heating element can comprise a heater plate.

[0128] In some configurations, the heating element can comprise a heater wire.

[0129] In some configurations, the user interface can comprise nasal prongs. The user interface can comprise a mask.

[0130] In some configurations, the gas flow generation element can be configured to deliver the hypoxic gas composition to the user at a predetermined flow rate of at least about 10 liters/minute.

[0131] In some configurations, the gas flow generation element can be configured to deliver the hypoxic gas composition sufficient to meet the peak inspiratory demand of the user.

[0132] In some configurations, the system can further include the hypoxic gas source.

[0133] In some configurations, the hypoxic gas source can comprise a reservoir.

[0134] In some configurations, the hypoxic gas comprises a physiologically inert gas. The hypoxic gas can comprise enriched nitrogen.

[0135] In some configurations, the heating element and the humidification element can be configured to heat and humidify the hypoxic gas composition to a dew point temperature of between about 37°C and about 43°C. The heating element and the humidification element can be configured to heat and humidify the hypoxic gas composition to a dew point temperature of between about 37°C and about 43°C. The heating element and the humidification element can be configured to heat and humidify the hypoxic gas composition to a dew point temperature of between about 43°C and about 45°C. The heating element and the humidification element can be configured to heat and humidify the hypoxic gas composition to a dew point temperature of between about 40°C and about 43°C. The heating element and the humidification element can be configured to heat and humidify the hypoxic gas composition to a dew point temperature of about 41°C.

[0136] In some configurations, the humidification element can be configured to humidify the hypoxic gas composition to a relative humidity of at least about 80%. The humidification element can be configured to humidify the hypoxic gas composition to a relative humidity of at least about 90%. The humidification element can be configured to humidify the hypoxic gas composition to a relative humidity of at least about 95%. The humidification element can be configured to humidify the hypoxic gas composition to a relative humidity of at least about 99%. The humidification element can be configured to humidify the hypoxic gas composition to a relative humidity of at least about 100%.

[0137] In some configurations, the system can further include a sensor configured to measure a peak inspiratory demand of the user; and the system can be configured to adjust the flow rate based upon the measured peak inspiratory demand.

[0138] In some configurations, the system can be configured to deliver the hypoxic gas in an oxygen concentration of between about 10% and about 20%. The system can be configured to deliver the hypoxic gas in an oxygen concentration of between about 15% and about 20%. The system can be configured to deliver the hypoxic gas in an oxygen concentration of between about 10.2% and about 20.9%. The system can be configured to deliver the hypoxic gas in an oxygen concentration of between about 11.9% and about 17.4%. The system can be configured to deliver the hypoxic gas in an oxygen concentration of between about 13.8% and about 17.4%. The system can be configured to deliver the hypoxic gas in an oxygen concentration of between about 15.7% and about 16.7%.

[0139] In some configurations, the system can further include a sensor configured to measure a physiological parameter of the user; and a controller configured to automatically control the delivery of the hypoxic gas composition based on the measured physiological parameter.

[0140] In some configurations, the controller can be configured to automatically controlling the delivery of the hypoxic gas composition by adjusting an amount of hypoxic gas mixed into the hypoxic gas composition. In some configurations, the controller can be configured to automatically controlling the delivery of the hypoxic gas composition by adjusting an amount of enriched nitrogen mixed into the hypoxic gas composition.

[0141] In some configurations, the physiological parameter can be blood oxygen saturation.

[0142] In some configurations, the physiological parameter can further comprise at least one selected from the group consisting of: heart rate, respiratory rate, heart rate variability, and blood pressure.

[0143] In some configurations, the system can further include an alarm configured to notify the user when the physiological parameter deviates from a pre-selected range for at least a pre-determined period of time.

[0144] In some configurations, the alarm can comprise one of a visual, auditory, or tactile alarm.

[0145] In some configurations, the controller can be configured to titrate the composition of the hypoxic gas composition to achieve a blood oxygen saturation of the user of less than about 95%. The controller can be configured to titrate the composition of the

hypoxic gas composition to achieve a blood oxygen saturation of the user of between about 80% and about 94%. The controller can be configured to titrate the composition of the hypoxic gas composition to achieve a blood oxygen saturation of the user of between about 85% and about 92%. The controller can be configured to titrate the composition of the hypoxic gas composition to achieve a blood oxygen saturation of the user of between about 87% and about 90%. The controller can be configured to titrate the composition of the hypoxic gas composition to achieve a blood oxygen saturation of the user of between about 80% and about 85%.

[0146] In some configurations, the system can further include a sensor configured to sense the oxygen concentration of the hypoxic gas composition.

[0147] In some configurations, the system can further include a display, wherein the system is configured to output the sensed oxygen concentration in real time to the display.

[0148] In some configurations, the system can be further configured to correlate the sensed oxygen concentration to an altitude equivalent using a processor, and outputting the altitude equivalent in real time to the display.

[0149] In some configurations, the system can be further configured to obtain a target oxygen concentration of the hypoxic gas composition based on the blood oxygen saturation.

[0150] In some configurations, the system can be further configured to achieve the target oxygen concentration based on the sensed oxygen concentration.

[0151] In some configurations, the system can be further configured to achieve the target oxygen concentration by controlling a hypoxic gas inlet valve.

[0152] In some configurations, the controller can be configured to alter a flow rate of the hypoxic gas into the hypoxic gas composition.

[0153] In some configurations, the gas flow generation element can be configured to deliver the hypoxic gas composition to the nares of the user at a predetermined flow rate of at least about 20 liters/minute. The gas flow generation element can be configured to deliver the hypoxic gas composition to the nares of the user at a predetermined flow rate of at least about 30 liters/minute. The gas flow generation element can be configured to deliver the hypoxic gas composition to the nares of the user at a predetermined flow rate of at least about

40 liters/minute. The gas flow generation element can be configured to deliver the hypoxic gas composition to the nares of the user at a predetermined flow rate of at least about 50 liters/minute. The gas flow generation element can be configured to deliver the hypoxic gas composition to the nares of the user at a predetermined flow rate of at least about 60 liters/minute. The gas flow generation element can be configured to deliver the hypoxic gas composition to the nares of the user at a predetermined flow rate of at least about 70 liters/minute.

[0154] In some configurations, the user interface can comprise a nasal cannula.

[0155] In some configurations, the nasal cannula can be non-sealed.

[0156] In some configurations, the system can be a high flow device.

[0157] In some configurations, the high flow device can be portable.

[0158] In some configurations, a method of providing altitude or fitness training to a user can include simulating a higher altitude by providing a hypoxic gas composition; humidifying the hypoxic gas composition; and delivering the humidified, hypoxic gas composition via a user interface in proximity to an airway of a user.

[0159] In some configurations, a method of treating or preventing hypertension, obesity, hyperlipidemia, prediabetes or impaired glucose tolerance, diabetes mellitus type I or type II, metabolic syndrome, mitochondrial regeneration, aging, fatigue, inflammatory diseases, or anemia of a user can include providing a hypoxic gas composition; humidifying the hypoxic gas composition; and delivering the humidified, hypoxic gas composition via a user interface in proximity to an airway of a user so as to treat or prevent hypertension, obesity, hyperlipidemia, prediabetes or impaired glucose tolerance, diabetes mellitus type I or type II, metabolic syndrome, mitochondrial regeneration, aging, fatigue, inflammatory diseases, or anemia.

[0160] In some configurations, the method can include humidifying the hypoxic gas composition to a relative humidity of at least about 80%. The method can include humidifying the hypoxic gas composition to a relative humidity of at least about 90%. The method can include humidifying the hypoxic gas composition to a relative humidity of at least about 95%. The method can include humidifying the hypoxic gas composition to a relative humidity of at least about 99%. The method can include humidifying the hypoxic gas composition to a relative humidity of at least about 100%.

[0161] In some configurations, the method can include delivering the humidified, hypoxic gas composition via a nasal cannula to the user's nares. The method can include delivering the humidified, hypoxic gas composition via a mask. The method can include delivering the humidified, hypoxic gas composition via a mask.

[0162] In some configurations, the method can include heating the hypoxic gas composition prior to reaching the user.

[0163] In some configurations, the hypoxic gas composition can comprise at least one physiologically inert gas. In some configurations, the hypoxic gas composition can comprise nitrogen.

[0164] In some configurations, the method can include delivering the hypoxic gas composition continuously at a flow rate of at least about 10 liters/minute.

[0165] In some configurations, the method can include delivering the hypoxic gas composition continuously at a flow rate that meets the user's inspiratory demand.

[0166] In some configurations, the method can include synchronizing delivering the hypoxic gas composition with an inspiratory phase of breathing of the user, wherein the delivering of the hypoxic gas composition can be at a flow rate of at least about 10 liters/minute during inspiration.

[0167] In some configurations, the method can include synchronizing delivering the hypoxic gas composition with an inspiratory phase of breathing of the user, wherein the delivering of the hypoxic gas composition can be at a flow rate that meets the user's inspiratory demand.

[0168] In some configurations, synchronizing can comprise increasing the flow rate on inspiration and reducing the flow rate on expiration.

[0169] In some configurations, delivering the hypoxic gas can be sufficient to meet peak inspiratory demand of the user.

[0170] In some configurations, heating the hypoxic gas composition can comprise heating the hypoxic gas composition to a temperature of between about 30°C and about 45°C. Heating the hypoxic gas composition can comprise heating the hypoxic gas composition to between about 37°C and about 43°C. Heating the hypoxic gas composition can comprise heating the hypoxic gas composition to about 41°C.

[0171] In some configurations, the method can include heating and humidifying the hypoxic gas composition to a dew point temperature of between about 30°C and about 45°C. The method can include heating and humidifying the hypoxic gas composition to a dew point temperature of between about 37°C and about 45°C. The method can include heating and humidifying the hypoxic gas composition to a dew point temperature of about 41°C.

[0172] In some configurations, heating the hypoxic gas composition can be sufficient to inactivate a pathogen of interest.

[0173] In some configurations, the pathogen of interest can be a human rhinovirus or influenza.

[0174] In some configurations, the method can include mixing ambient air with a source of enriched nitrogen to create the hypoxic gas composition.

[0175] In some configurations, the method can include measuring inspiratory peak demand of the user; and adjusting the flow rate based upon the measured peak inspiratory demand.

[0176] In some configurations, an oxygen concentration of the hypoxic gas composition can be between about 10% and about 20%. An oxygen concentration of the hypoxic gas composition can be between about 15% and about 20%. An oxygen concentration of the hypoxic gas composition can be between about 10.2% and about 20.9%. An oxygen concentration of the hypoxic gas composition can be between about 11.9% and about 17.4%. An oxygen concentration of the hypoxic gas composition can be between about 13.8% and about 17.4%. An oxygen concentration of the hypoxic gas composition can be between about 15.7% and about 16.7%.

[0177] In some configurations, the method can include measuring at least one physiological parameter of the user; and automatically controlling the delivery of the hypoxic gas composition based on the measured physiological parameter.

[0178] In some configurations, the method can include outputting the measured physiological parameter in real time to the display.

[0179] In some configurations, the measured physiological parameter can be blood oxygen saturation.

[0180] In some configurations, the measured physiological parameter can further comprise at least one selected from the group consisting of: heart rate, respiratory rate, heart rate variability, and blood pressure.

[0181] In some configurations, automatically controlling the delivery of the hypoxic gas composition can comprise adjusting an amount of hypoxic gas mixed into the hypoxic gas composition.

[0182] In some configurations, the method can include notifying the user when the physiological parameter deviates from a pre-selected range for at least a pre-determined period of time.

[0183] In some configurations, the method can include altering the pre-selected range based upon individual characteristics of the user.

[0184] In some configurations, notifying the user can comprise activating a visual, auditory, or tactile alarm.

[0185] In some configurations, automatically controlling the delivery of the hypoxic gas can comprise titrating the composition of the hypoxic gas composition to achieve a blood oxygen saturation of less than about 95%. Automatically controlling the delivery of the hypoxic gas can comprise titrating the composition of the hypoxic gas composition to achieve a blood oxygen saturation of between about 80% and about 94%. Automatically controlling the delivery of the hypoxic gas can comprise titrating the composition of the hypoxic gas composition to achieve a blood oxygen saturation of between about 85% and about 92%. Automatically controlling the delivery of the hypoxic gas can comprise titrating the composition of the hypoxic gas composition to achieve a blood oxygen saturation of between about 87% and about 90%. Automatically controlling the delivery of the hypoxic gas can comprise titrating the composition of the hypoxic gas composition to achieve a blood oxygen saturation of between about 80% and about 85%.

[0186] In some configurations, the method can include sensing the oxygen concentration of the hypoxic gas composition after mixing.

[0187] In some configurations, the method can include outputting the sensed oxygen concentration in real time to a display.

[0188] In some configurations, the method can include correlating the sensed oxygen concentration to an altitude equivalent using a processor, and outputting the altitude equivalent in real time to the display.

[0189] In some configurations, the method can include obtaining a target oxygen concentration of the hypoxic gas composition based on the blood oxygen saturation.

[0190] In some configurations, the method can include achieving the target oxygen concentration based on the sensed oxygen concentration after mixing.

[0191] In some configurations, the method can include achieving the target oxygen concentration by controlling a hypoxic gas inlet valve.

[0192] In some configurations, titrating the composition of the hypoxic gas composition can comprise altering a flow rate of nitrogen into the hypoxic gas composition.

[0193] In some configurations, the hypoxic gas composition can be delivered to the user at a flow rate of at least about 20 liters/minute. The hypoxic gas composition can be delivered to the user at a flow rate of at least about 30 liters/minute. The hypoxic gas composition can be delivered to the user at a flow rate of at least about 40 liters/minute. The hypoxic gas composition can be delivered to the user at a flow rate of at least about 50 liters/minute. The hypoxic gas composition can be delivered to the user at a flow rate of at least about 60 liters/minute. The hypoxic gas composition can be delivered to the user at a flow rate of at least about 70 liters/minute.

[0194] In some configurations, the method can be used for a time period sufficient to improve the user's conditioning at high altitude.

[0195] In some configurations, the method can be used for a time period sufficient to stimulate erythropoiesis such that the user's hemoglobin level increases by at least 5% compared to before starting the method.

[0196] In some configurations, the method can be used for a time period sufficient to stimulate erythropoiesis such that the user's hemoglobin level increases by at least 10% compared to before starting the method.

[0197] In some configurations, the user interface can comprise a nasal cannula.

[0198] In some configurations, the nasal cannula can be non-sealed.

[0199] In some configurations, a system configured for providing altitude or fitness training to a user can include an apparatus comprising a gas flow path, an ambient air

inlet, and a hypoxic gas source inlet configured to connect to a hypoxic gas source and configured to create a hypoxic gas composition upon mixing of ambient air and the hypoxic gas; a gas flow generation element configured to deliver the hypoxic gas composition to an airway of the user so as to simulate a higher altitude; a humidification element within the gas flow path configured to humidify the hypoxic gas composition prior to reaching the airway of the user; and a user interface.

[0200] In some configurations, a system configured for or preventing hypertension, obesity, hyperlipidemia, prediabetes or impaired glucose tolerance, diabetes mellitus type I or type II, metabolic syndrome, mitochondrial regeneration, aging, fatigue, inflammatory diseases, or anemia of a user can include an apparatus comprising a gas flow path, an ambient air inlet, and a hypoxic gas source inlet configured to connect to a hypoxic gas source and configured to create a hypoxic gas composition upon mixing of ambient air and the hypoxic gas; a gas flow generation element configured to deliver the hypoxic gas composition to an airway of the user; a humidification element within the gas flow path configured to humidify the hypoxic gas composition prior to reaching the airway of the user, the gas flow configured to treat or prevent hypertension, obesity, hyperlipidemia, prediabetes or impaired glucose tolerance, diabetes mellitus type I or type II, metabolic syndrome, mitochondrial regeneration, aging, fatigue, inflammatory diseases, or anemia; and a user interface.

[0201] In some configurations, the humidification element can be configured to humidify the hypoxic gas composition to a relative humidity of at least about 80%. The humidification element can be configured to humidify the hypoxic gas composition to a relative humidity of at least about 90%. The humidification element can be configured to humidify the hypoxic gas composition to a relative humidity of at least about 95%. The humidification element can be configured to humidify the hypoxic gas composition to a relative humidity of at least about 99%. The humidification element can be configured to humidify the hypoxic gas composition to a relative humidity of at least about 100%.

[0202] In some configurations, the humidification element can comprise a humidification chamber.

[0203] In some configurations, the gas flow generation element can comprise one or more of a blower, a compressor, a pressurized tank, or a gas source in the wall.

[0204] In some configurations, the user interface can comprise nasal cannula including nasal prongs.

[0205] In some configurations, the nasal cannula can be non-sealed.

[0206] In some configurations, the user interface can comprise a mask.

[0207] In some configurations, the gas flow generation element can be configured to deliver the hypoxic gas composition to the user at a predetermined flow rate of at least about 10 liters/minute.

[0208] In some configurations, the gas flow generation element can be configured to deliver the hypoxic gas composition sufficient to meet the peak inspiratory demand of the user. The gas flow generation element can be configured to deliver the hypoxic gas composition sufficient to meet the peak inspiratory demand of the user.

[0209] In some configurations, the system can further include the hypoxic gas source.

[0210] In some configurations, the hypoxic gas source can comprise a reservoir.

[0211] In some configurations, the hypoxic gas comprises a physiologically inert gas. The hypoxic gas can comprise enriched nitrogen.

[0212] In some configurations, the system can further include a heating element configured to heat the hypoxic gas composition prior to reaching the airway of the user.

[0213] In some configurations, the heating element can comprise a heater plate.

[0214] In some configurations, the heating element can comprise a heater wire.

[0215] In some configurations, the heating element can be configured to heat the hypoxic gas composition to a temperature of between about 30°C and about 45°C. The heating element can be configured to heat the hypoxic gas composition to between about 30°C and about 43°C. The heating element can be configured to heat the hypoxic gas composition to between about 37°C and about 43°C. The heating element can be configured to heat the hypoxic gas composition to about 41°C.

[0216] In some configurations, the heating element and the humidification element can be configured to heat and humidify the hypoxic gas composition to a dew point temperature of between about 30°C and about 45°C. The heating element and the humidification element can be configured to heat and humidify the hypoxic gas composition to a dew point temperature of between about 30°C and about 43°C. The heating element and

the humidification element can be configured to heat and humidify the hypoxic gas composition to a dew point temperature of between about 37°C and about 43°C. The heating element and the humidification element can be configured to heat and humidify the hypoxic gas composition to a dew point temperature of about 41°C.

[0217] In some configurations, the system can further include a sensor configured to measure a peak inspiratory demand of the user; and the system can be configured to adjust the flow rate based upon the measured peak inspiratory demand.

[0218] In some configurations, the system can be configured to deliver the hypoxic gas in an oxygen concentration of between about 10% and about 20%. The system can be configured to deliver the hypoxic gas in an oxygen concentration of between about 15% and about 20%. The system can be configured to deliver the hypoxic gas in an oxygen concentration of between about 10.2% and about 20.9%. The system can be configured to deliver the hypoxic gas in an oxygen concentration of between about 11.9% and about 17.4%. The system can be configured to deliver the hypoxic gas in an oxygen concentration of between about 13.8% and about 17.4%. The system can be configured to deliver the hypoxic gas in an oxygen concentration of between about 15.7% and about 16.7%.

[0219] In some configurations, the system can further include a sensor configured to measure a physiological parameter of the user; and a controller configured to automatically control the delivery of the hypoxic gas composition based on the measured physiological parameter.

[0220] In some configurations, the controller can be configured to automatically controlling the delivery of the hypoxic gas composition by adjusting an amount of hypoxic gas mixed into the hypoxic gas composition. In some configurations, the controller can be configured to automatically controlling the delivery of the hypoxic gas composition by adjusting an amount of enriched nitrogen mixed into the hypoxic gas composition.

[0221] In some configurations, the physiological parameter can be blood oxygen saturation.

[0222] In some configurations, the physiological parameter can further comprise at least one selected from the group consisting of: heart rate, respiratory rate, heart rate variability, and blood pressure.

[0223] In some configurations, the system can further include an alarm configured to notify the user when the physiological parameter deviates from a pre-selected range for at least a pre-determined period of time.

[0224] In some configurations, the alarm can comprise one of a visual, auditory, or tactile alarm.

[0225] In some configurations, the controller can be configured to titrate the composition of the hypoxic gas composition to achieve a blood oxygen saturation of the user of less than about 95%. The controller can be configured to titrate the composition of the hypoxic gas composition to achieve a blood oxygen saturation of the user of between about 80% and about 94%. The controller can be configured to titrate the composition of the hypoxic gas composition to achieve a blood oxygen saturation of the user of between about 85% and about 92%. The controller can be configured to titrate the composition of the hypoxic gas composition to achieve a blood oxygen saturation of the user of between about 87% and about 90%. The controller can be configured to titrate the composition of the hypoxic gas composition to achieve a blood oxygen saturation of the user of between about 80% and about 85%.

[0226] In some configurations, the system can further include a sensor configured to sense the oxygen concentration of the hypoxic gas composition.

[0227] In some configurations, the system can further include a display, wherein the system is configured to output the sensed oxygen concentration in real time to the display.

[0228] In some configurations, the system can be further configured to correlate the sensed oxygen concentration to an altitude equivalent using a processor, and outputting the altitude equivalent in real time to the display.

[0229] In some configurations, the system can be further configured to obtain a target oxygen concentration of the hypoxic gas composition based on the blood oxygen saturation.

[0230] In some configurations, the system can be further configured to achieve the target oxygen concentration based on the sensed oxygen concentration.

[0231] In some configurations, the system can be further configured to achieve the target oxygen concentration by controlling a hypoxic gas inlet valve.

[0232] In some configurations, the controller can be configured to alter a flow rate of the hypoxic gas into the hypoxic gas composition.

[0233] In some configurations, the gas flow generation element can be configured to deliver the hypoxic gas composition to the nares of the user at a predetermined flow rate of at least about 20 liters/minute. The gas flow generation element can be configured to deliver the hypoxic gas composition to the nares of the user at a predetermined flow rate of at least about 30 liters/minute. The gas flow generation element can be configured to deliver the hypoxic gas composition to the nares of the user at a predetermined flow rate of at least about 40 liters/minute. The gas flow generation element can be configured to deliver the hypoxic gas composition to the nares of the user at a predetermined flow rate of at least about 50 liters/minute. The gas flow generation element can be configured to deliver the hypoxic gas composition to the nares of the user at a predetermined flow rate of at least about 60 liters/minute. The gas flow generation element can be configured to deliver the hypoxic gas composition to the nares of the user at a predetermined flow rate of at least about 70 liters/minute.

[0234] In some configurations, the system can be a high flow device.

[0235] In some configurations, the high flow device can be portable.

[0236] In some configurations, a method of providing a respiratory training session to a user can include providing a hypoxic gas composition; delivering the hypoxic gas composition via a user interface in proximity to an airway of the user; and varying an oxygen concentration of the hypoxic gas composition after a predetermined period of time.

[0237] In some configurations, varying can comprise reducing or increasing.

[0238] In some configurations, varying can comprise reducing followed by increasing the oxygen concentration of the hypoxic gas composition, or increasing followed by reducing the oxygen concentration of the hypoxic gas composition.

[0239] In some configurations, varying can comprise varying gradually. Varying can comprise varying in a series of step changes. Varying can comprise varying in a step change.

[0240] In some configurations, the hypoxic gas composition can comprise at least one physiologically inert gas. In some configurations, the hypoxic gas composition can comprise nitrogen.

[0241] In some configurations, the method can include delivering the hypoxic gas composition continuously at a flow rate of at least about 10 liters/minute.

[0242] In some configurations, the method can include delivering the hypoxic gas composition continuously at a flow rate that meets the user's inspiratory demand.

[0243] In some configurations, providing can comprise simulating a first altitude.

[0244] In some configurations, varying can comprise simulating a second altitude lower than the first altitude.

[0245] In some configurations, the method can include providing a gas composition substantially the same as ambient air prior to providing the hypoxic gas composition.

[0246] In some configurations, varying can be responsive to a change in the user's SpO₂.

[0247] In some configurations, the user interface can comprise a nasal cannula.

[0248] In some configurations, the nasal cannula can be non-sealed.

[0249] In some configurations, a system configured for providing a respiratory training session to a user can include an apparatus comprising a gas flow path, an ambient air inlet, and a hypoxic gas source inlet configured to connect to a hypoxic gas source and configured to create a hypoxic gas composition upon mixing of ambient air and the hypoxic gas; a gas flow generation element configured to deliver the hypoxic gas composition; a user interface; and a controller configured to: provide the hypoxic gas composition and vary an oxygen concentration of the hypoxic gas composition after a predetermined period of time.

[0250] In some configurations, the gas flow generation element can comprise one or more of a blower, a compressor, a pressurized tank, or a gas source in the wall.

[0251] In some configurations, to vary can comprise to reduce or to increase.

[0252] In some configurations, the system can include a screen configured to display an altitude equivalent of the altitude or fitness training.

[0253] In some configurations, the system can include a screen configured to display an SpO₂ of the user.

[0254] In some configurations, the screen can comprise a touchscreen.

[0255] In some configurations, the system can include user input devices for the user to select an altitude equivalent of the altitude or fitness training.

[0256] In some configurations, the altitude equivalent can be based on an oxygen concentration.

[0257] In some configurations, the oxygen concentration can be an FdO_2 set point or a sensed oxygen concentration.

[0258] In some configurations, the user input devices can comprise one or more buttons.

[0259] In some configurations, the user input devices can comprise a touchscreen.

[0260] In some configurations, to vary can comprise to reduce followed by to increase the oxygen concentration of the hypoxic gas composition, or to increase followed by to reduce the oxygen concentration of the hypoxic gas composition.

[0261] In some configurations, the controller can be configured to vary the oxygen concentration of the hypoxic gas composition gradually. The controller can be configured to vary the oxygen concentration of the hypoxic gas composition in a series of step changes. The controller can be configured to vary the oxygen concentration of the hypoxic gas composition in a step change.

[0262] In some configurations, the hypoxic gas composition can comprise at least one physiologically inert gas. In some configurations, the hypoxic gas composition can comprise nitrogen.

[0263] In some configurations, the gas flow generation element can be configured to deliver the hypoxic gas composition to the user at a predetermined flow rate of at least about 10 liters/minute.

[0264] In some configurations, the gas flow generation element can be configured to deliver the hypoxic gas composition sufficient to meet the peak inspiratory demand of the user.

[0265] In some configurations, the controller can be configured to provide the hypoxic gas composition to simulate a first altitude.

[0266] In some configurations, the controller can be configured to vary the oxygen concentration of the hypoxic gas composition to simulate a second altitude lower than the first altitude.

[0267] In some configurations, the controller can be configured to provide a gas composition substantially the same as ambient air prior to providing the hypoxic gas composition.

[0268] In some configurations, the controller can be configured to vary the oxygen concentration of the hypoxic gas composition responsive to a change in the user's SpO₂.

[0269] In some configurations, the system can comprise a sensor configured to measure the user's SpO₂.

[0270] In some configurations, the user interface can comprise a nasal cannula.

[0271] In some configurations, the nasal cannula can be non-sealed.

[0272] In some configurations, the system can be a high flow device.

[0273] In some configurations, the high flow device can be portable.

[0274] In some configurations, the system can comprise a humidification chamber.

[0275] In some configurations, the system can comprise a heating element.

[0276] In some configurations, the heating element can comprise a heater plate.

[0277] In some configurations, the heating element can comprise a heater wire.

BRIEF DESCRIPTION OF THE DRAWINGS

[0278] These and other features, aspects, and advantages of the present disclosure are described with reference to the drawings of certain embodiments, which are intended to schematically illustrate certain embodiments and not to limit the disclosure.

[0279] Figure 1 shows in diagrammatic form a hypoxic gas composition delivery apparatus in the form of a flow therapy apparatus.

[0280] Figure 2 is a front view of the flow therapy apparatus with a humidifier chamber in position and a raised handle/lever.

[0281] Figure 3 is a top view corresponding to Figure 2.

[0282] Figure 4 is a right side view corresponding to Figure 2.

[0283] Figure 5 is a left side view corresponding to Figure 2.

[0284] Figure 6 is a rear view corresponding to Figure 2.

[0285] Figure 7 is a front left perspective view corresponding to Figure 2.

[0286] Figure 8 is a front right perspective view corresponding to Figure 2.

[0287] Figure 9 is a bottom view corresponding to Figure 2.

[0288] Figure 10 shows a first configuration of an air and nitrogen inlet arrangement of the flow therapy apparatus.

[0289] Figure 11 shows a second configuration of an air and nitrogen inlet arrangement of the flow therapy apparatus.

[0290] Figure 12 is a transverse sectional view showing further detail of the air and nitrogen inlet arrangement of Figure 11.

[0291] Figure 13 is another transverse sectional view showing further detail of the air and nitrogen inlet arrangement of Figure 11.

[0292] Figure 14 is a longitudinal sectional view showing further detail of the air and nitrogen inlet arrangement of Figure 11.

[0293] Figure 15 is an exploded view of upper and lower chassis components of a main housing of the flow therapy apparatus.

[0294] Figure 16 is a front left side perspective view of the lower chassis of the main housing showing a housing for receipt of a motor/sensor module sub-assembly.

[0295] Figure 17A is a first underside perspective view of the main housing of the flow therapy apparatus showing a recess inside the housing for the motor/sensor module sub-assembly.

[0296] Figure 17B is a second underside perspective view of the main housing of the flow therapy apparatus showing the recess for the motor/sensor module sub-assembly.

[0297] Figures 18A-E illustrate various views of an example flow therapy apparatus.

[0298] Figure 19A illustrates a block diagram of a control system interacting with and/or providing control and direction to components of a respiratory assistance system.

[0299] Figure 19B illustrates a block diagram of an example controller.

[0300] Figure 20 illustrates a block diagram of a motor/sensor module.

[0301] Figure 21 illustrates a sensing chamber of an example removable motor/sensor module.

[0302] Figure 22 illustrates example block diagrams of a closed loop control system.

DETAILED DESCRIPTION

[0303] Although certain examples are described below, those of skill in the art will appreciate that the disclosure extends beyond the specifically disclosed examples and/or uses and obvious modifications and equivalents thereof. Thus, it is intended that the scope of the disclosure herein disclosed should not be limited by any particular examples described below.

[0304] In some configurations, systems and methods can reduce the oxygen content of inspired air as a mechanism of simulating being at a higher altitude, improving athletic performance, and other medical and/or wellness benefits. One objective of this is to stimulate the body to produce more red blood cells, and thus oxygen carrying capacity as a way of increasing cardiovascular endurance. In some cases, the systems and methods can be used for a time period sufficient to stimulate erythropoiesis such that the user's hemoglobin level increases by about or at least about 5%, 10%, 15%, 20%, or more compared with prior to initiation of therapy, or ranges including any two of the aforementioned values.

[0305] Conventional devices that provide a hypoxic atmosphere within an enclosure can suffer from several disadvantages. Such conventional setups can be quite costly due to the volume of gas that needs to be altered. Many systems are not portable, and the ones that are (such as a tent) can be both difficult to transport as well as quite small, limiting what a user can do while using it. The user can also be prevented/restricted from leaving the enclosure, and others who do not wish to use the device are unable to enter it, thus limiting the ability for interaction between participants and non-participants, especially during extended use. If the user needs to suddenly end the therapy they need to leave the enclosure, which would take significantly longer than simply removing a patient interface, such as a cannula (some devices provide a breathing device with normoxic air for use in an emergency, but this can just further add to the cost). The use of a room would also prevent individually adjusted therapy when used with others, as everyone would be required to breathe the same gas composition. The volume of the room would also make it difficult to make any quick changes to the composition of the gas. As such, it would be advantageous to limit the hypoxic atmosphere to a user interface proximate to, or directly attachable to a user.

[0306] Devices that use a mask can be disadvantageous in some cases by their obstructive nature. Using a nasal cannula (e.g., as the only conduit to the user) instead of and without using a mask means the user can still talk, eat and drink while the device is attached, making it more viable for longer therapy sessions, as the user would not need to remove it for such tasks. The portability of the cannula can also allow the user to move the device with them as they do various activities throughout the day. These factors combined allow such devices to advantageously implement a wide range of therapy regimes. The user could have a nasal cannula attached and connected to high flow systems as disclosed herein during a majority of day to day tasks, while sleeping, and while exercising on a spot (such as with a treadmill or weight training). The cannula could also be removed and reattached fairly easily, which could be useful if the therapy regime required regularly stopping and starting the administration of the hypoxic gases. The cannula can also be far more comfortable, and does not run the risk of the user developing pressure sores. Users may also in some cases find a mask somewhat claustrophobic due to the amount of their face it covers. A cannula can also be safer than a mask in some cases, as it would not obstruct breathing if the device were to fail, and can be removed more easily if needed.

[0307] Examples of systems and methods as disclosed herein can advantageously deliver high flow rates (e.g., greater than about 10 liters per minute in adults and/or in excess of peak inspiratory demand in some cases). However, some examples can be configured to deliver lower flow rates as well. Some conventional devices deliver a small dose of pure nitrogen upon inspiration that can mix with additional inspired air through the user's mouth and/or around the cannula to create the required hypoxic mixture. This method can have several disadvantages in some cases. One disadvantage is that as conventional devices deliver a fixed dose or low flow of nitrogen, the total fraction of inspired oxygen (FiO_2) would change as the inspiratory flow rate changes, and would depend on the user's inspiratory tidal volume, meaning that a change in breath rate or volume would alter the composition being delivered. This could make targeting a specific FiO_2 or SpO_2 very challenging. In contrast, systems and methods as disclosed herein can deliver flow rates in excess of the user's inspiratory demand, which can advantageously provide a more consistent and controlled hypoxic composition regardless of changes in the user's breathing. At least two parameters can be used to determine oxygen delivery to the user, FiO_2 and FdO_2 . FiO_2 is

the fraction of inspired oxygen, which is the oxygen concentration of the gas that the user is actually breathing in. FdO_2 is the fraction of delivered oxygen, which is the oxygen concentration of the gas flowing out of the cannula. FdO_2 can be directly measured by the flow therapy system, such as by measuring the oxygen concentration of the gas flowing through the system. FiO_2 is dependent on FdO_2 as well as the proportion of ambient air, if any, that is entrained when the user breathes in. While FiO_2 can be a preferred parameter in some cases in assessing the effect of the gas on the user, control of FdO_2 can allow the target FiO_2 be achieved, for example, due to the assumption that those two parameters have the same or substantially the same value in a high flow therapy system. During a high flow therapy session, the oxygen concentration measured in the system, FdO_2 , can be substantially the same as the oxygen concentration the user is breathing, FiO_2 , when the flow rate of gas delivered meets or exceeds the peak inspiratory demand of the user. That is, the volume of gas delivered by the system to the user during inspiration meets, or is in excess of, the volume of gas inspired by the user during inspiration. In that situation, no ambient air is entrained (e.g., around a non-sealed nasal cannula) and hence the value of FdO_2 is equal to the value of FiO_2 . Accordingly, high flow therapies can help to prevent entrainment of ambient air when the user breathes in, as well as to flush the user's airways of expired gas. Further, systems and methods as disclosed herein can also provide a closed loop control to provide hypoxic composition, such as based on monitoring of the user's oxygen saturation, SpO_2 , when the flow rate is not meeting the user's inspiratory demand such that FdO_2 is not equal to FiO_2 due to entrainment of ambient air.

[0308] While nitrogen is a common hypoxic gas that can be utilized in creating a hypoxic gas mixture, the use of other hypoxic gases are possible in addition to, or instead of nitrogen. In some examples, the hypoxic gas composition can include, or consist entirely of or substantially entirely of physiologically inert gases. Some examples include, but are not limited to nitrogen, heliox, nitric oxide, carbon dioxide, argon, helium, methane, sulfur hexafluoride, and combinations thereof.

[0309] In some cases, systems and methods as disclosed herein can advantageously not require or perform any detection of when the user breathes in, as a fixed flow rate of gas can be delivered at all times. Systems and methods can also provide a safe, predictable, precise, hypoxic gas composition that avoids the risk of pooling large quantities

of nitrogen, such as in situations where the user temporarily breathes through their mouth or the breath synchronization is not used.

[0310] Conventional systems can also suffer from the disadvantage of at best only being able to control the composition of gas up to the user's face. The actual composition of gas in the airways of the user would vary based on respiratory volume, respiratory rate, gas exchange rates of the lung, among other factors. Due to the high flow of gas being delivered by some examples as disclosed herein, the user's airways can be constantly flushed of old expired gas, so when the user inspires, the gas in user's upper airways would match that being delivered from the device or system, regardless of the aforementioned factors. Nasal high-flow gas delivery systems have been disclosed to enhance oxygen delivery to patients, but not to provide the opposite effect of delivering a hypoxic gas composition for various indications.

[0311] In some configurations, the use of a nasal system (with or without high flow delivery) to deliver warm and/or humidified hypoxic gas compositions could be beneficial in recovery from physical activity. One current criticism of altitude training is that the hypoxic conditions lead to lower intensity during training and poorer recovery after training, and that these factors have the potential to counteract out the benefits of the body's acclimatization to altitude. By combining the hot and/or humidified gas delivery of the nasal high flow system with an altitude training program, a user could potentially gain the benefits of natural acclimatization with reduced negative side effects that would otherwise impede performance and reduce overall benefits. In some cases, heated and/or humidified air can prevent or treat infections by various pathogens as discussed elsewhere herein, including via raising the temperature, or creating enough heat energy in the nasal passage, to kill some or all of the pathogens.

[0312] A schematic representation of a respiratory system or flow therapy apparatus 10 is provided in Figure 1. The apparatus 10 can include a main housing 100. The main housing 100 can contain a flow generator 11 that can be in the form of a motor/impeller arrangement, an optional humidifier or humidification chamber 12, a controller 13, and a user interface 14. The apparatus 10 can include any suitable gas flow generation element. The gas flow generation element can be used to generate a flow of gas and can include one or more flow generators and/or sources of pressurized gas. Examples of flow generators can include a

blower or a compressor. Examples of sources of pressurized gas can include a pressurized tank or a gas source in the wall. The user interface 14 can include a display and input device(s) such as button(s), a touch screen, a combination of a touch screen and button(s), or the like. The controller 13 can include a hardware processor and can be configured or programmed to control the components of the apparatus, including but not limited to operating the flow generator 11 to create a flow of gases (e.g., hypoxic gases) for delivery to a user, operating the humidifier 12 (if present) to humidify and/or heat the gases flow, receiving user input from the user interface 14 for reconfiguration and/or user-defined operation of the apparatus 10, and outputting information (for example on the display) to the user or healthcare professional or anyone else viewing the apparatus.

[0313] With continued reference to Figure 1, a user breathing conduit 16 can be coupled to a gases flow outlet 21 in the housing 100 of the flow therapy apparatus 10, and be coupled to a user interface 17, which can be a non-sealing interface such as a nasal cannula with a manifold 19 and nasal prongs 18. The term “non-sealing interface” as used herein can refer to an interface providing a pneumatic link between an airway of a user and a gases flow source (such as from flow generator 11) that does not completely occlude the airway of the user. A non-sealed pneumatic link can comprise an occlusion of less than about 95% of the airway of the user. The non-sealed pneumatic link can comprise an occlusion of less than about 90% of the airway of the user. The non-sealed pneumatic link can comprise an occlusion of between about 40% and about 80% of the airway of the user. The airway can include one or more of a nare or mouth of the user. Additionally, or alternatively, the user breathing conduit 16 can be coupled to a face mask, or a tracheostomy interface. The gases flow that is generated by the flow therapy apparatus 10, and which may be humidified, is delivered to the user via the inspiratory conduit 16 through the cannula 17. The inspiratory conduit 16 can have a heater wire 16a to heat gases flow passing through to the user. The heater wire 16a can be under the control of the controller 13. In some embodiments, the device could include a gas heating mode in which the heater wire 16a or another heating element can be utilized to heat the hypoxic gases above the temperature of gases in the user’s airway, and/or provide heat energy sufficient to kill or otherwise inactivate pathogens (e.g. viruses, including human rhinoviruses, influenza, and the like; fungi; and/or bacteria) from the gases flow, and/or pathogens already in the airways or elsewhere within the user. In some

embodiments, a heating element can be present within or otherwise associated with a humidifier to raise the actual temperature and/or dew point temperature of the humidified gases stream to create a heated, humidified hypoxic gas composition, as discussed further below. Killing pathogens as both a therapeutic and/or preventative measure could be beneficial especially to athletes, where illness could severely undermine any training regime or competition performance. In some configurations, the gas heating mode can raise the temperature in the user's nasal passage high enough to provide heat energy for killing some or all of the pathogens, but not to the extent that the gases are too hot and cause other discomfort, airway damage, and other adverse effects. The hypoxic gases delivered could, in some configurations, be heated to at least about 30°C, but not more than about 50°C, 49°C, 48°C, 47°C, 46°C, 45°C, 44°C, or 43°C, such as about 31°C, 32°C, 33°C, 34°C, 35°C, 36°C, 37°C, 38°C, 39°C, 40°C, 41°C, 42°C, 43°C, or ranges incorporating any two of the aforementioned values. In some configurations, the gases can be heated to between about 31°C and about 50°C, between about 33°C and about 48°C, between about 35°C and about 46°C, between about 37°C and about 44°C, between about 39°C and about 42°C, between about 40°C and about 41°C, or about 41°C. In some configurations, the hypoxic gases are delivered at room temperature, such as between about 20°C and about 25°C, or other higher or lower temperatures, such as between about 15°C and about 30°C. The gases can also be humidified in some embodiments to prevent evaporation of moisture in the user's nasal passage and subsequently cool down too much to be effective. Humidified gases, for example, in the temperature ranges specified can in some embodiments carry enough latent heat to not only kill infections and reduce sickness times, but also act as a preventative measure, something which can be advantageous to athletes, among others. The hypoxic gases delivered could, in some configurations, have a dew point temperature of at least about 30°C, but not more than about 50°C, 49°C, 48°C, 47°C, 46°C, 45°C, 44°C, or 43°C, such as about 31°C, 32°C, 33°C, 34°C, 35°C, 36°C, 37°C, 38°C, 39°C, 40°C, 41°C, 42°C, 43°C, or ranges incorporating any two of the aforementioned values. In some configurations, the gases can have a dew point temperature of between about 31°C and about 50°C, between about 33°C and about 48°C, between about 35°C and about 46°C, between about 37°C and about 44°C, between about 39°C and about 42°C, between about 40°C and about 41°C, or about 41°C. In some configurations, the hypoxic gases can have a dew point temperature at room

temperature, such as between about 20°C and about 25°C, or other higher or lower temperatures, such as between about 15°C and about 30°C. In some embodiments, the relative humidity of the hypoxic gas flow can be, for example, about or at least about 50%, 55%, 60%, 65%, 70%, 75%, 80%, 85%, 90%, 91%, 92%, 93%, 94%, 95%, 96%, 97%, 98%, 99%, or more, such as 100% or ranges incorporating any two of the aforementioned values. In some embodiments, the heating and/or humidification is not in an open room setup or configuration, and as such the heating and/or humidification is delivered through the discrete breathing conduit 16 directly connected to the user's nose and/or mouth.

[0314] The inspiratory conduit 16 and/or user interface 17 can be considered part of the flow therapy apparatus 10, or alternatively peripheral to it. The flow therapy apparatus 10, breathing conduit 16, and user interface 17 together can form a flow therapy system.

[0315] General operation of a flow therapy breathing apparatus 10 will now be described. The controller 13 can control the flow generator 11 to generate a gases flow of a desired flow rate, one or more valves to control mixing (e.g., hypoxic mixing) of air and nitrogen or other breathable gas, and/or the humidifier 12, if present, to humidify the gases flow to an appropriate temperature and/or humidity. In some embodiments, humidification can advantageously prevent the user's airways from drying out, which can be particularly advantageous during concomitant exercise due to fluid loss from sweating. The flow delivered could be at any desired flow rate. In some embodiments, the flow rate is about or at least about 10 liters/minute. In some embodiments, the flow rate is about, or less than about 10 liters/minute, such as 9, 8, 7, 6, 5, 4, 3, 2, or 1 liter/minute, or ranges incorporating any two of the aforementioned values.

[0316] As will be described in greater detail below, the apparatus 10 can use ultrasonic or other types of sensing to monitor characteristics of the gases in the flow. For example, the characteristics of the gases flow can include gases concentration, flow rate, or the like. The apparatus 10 can include additional sensors that can be in communication with the hardware processor. These sensors can include a flow rate sensor, a temperature sensor, a humidity sensor, a pressure sensor, or the like. Output of the additional sensors can be used for determining the characteristics of the gases flow, such as temperature, pressure, humidity, and the like. Output of the additional sensors can be used for correcting measurement of the characteristics of the gases flow by ultrasonic sensing. The gases flow can be directed out

through the inspiratory conduit 16 and cannula 17 to the user. The cannula 17 may instead be any other user interface, such as a full face mask, nasal mask, nasal pillows mask, tracheostomy interface, or endotracheal tube. The controller 13 can also control a heating element in the humidifier 12 and/or the heating element 16a in the inspiratory conduit 16 to heat the gas to a desired temperature that achieves a desired level of therapy and/or level of comfort for the user. The controller 13 can be programmed with or can determine a suitable target temperature of the gases flow using one or more temperature sensors.

[0317] Additional sensors 3a, 3b, 3c, 20, 25, such as flow, temperature, humidity, and/or pressure sensors, can be placed in various locations in the flow therapy apparatus 10 and/or the inspiratory conduit 16 and/or cannula 17. The controller 13 can receive output from the sensors to assist it in operating the flow therapy apparatus 10 in a manner that provides suitable therapy. Providing suitable therapy can include meeting a user's peak inspiratory demand in some cases. The apparatus 10 can include a wireless data transmitter and/or receiver, or a transceiver 15 to enable the controller 13 to receive data signals 8 in a wireless manner from the operation sensors and/or to control the various components of the flow therapy apparatus 10. Additionally, or alternatively, the data transmitter and/or receiver 15 may deliver data to a remote server or enable remote control of the apparatus 10. The apparatus 10 can include a wired connection, for example, using cables or wires, to enable the controller 13 to receive data signals 8 from the operation sensors and/or to control the various components of the flow therapy apparatus 10. The transmitter can connect with a mobile device, such as a phone. The display, such as a graphic user interface (GUI) can be replicated on the mobile device's screen. Once connected to the apparatus 10, the mobile device can be used to control the device. The apparatus 10 can connect to the mobile device via a wireless connection, such as Bluetooth, WiFi, near field communication (NFC), 2G/3G/4G/5G, or other suitable wireless communications networks. The apparatus 10 can additionally or alternatively connect via a wired connection, such as USB, Ethernet, FireWire, serial port interface, or other suitable data transmission wires.

[0318] In some embodiments, one or more sensors (e.g., ultrasonic transducers as described herein) can be utilized to measure/verify the hypoxic gas composition (e.g., oxygen concentration) after, for example, nitrogen and ambient air have finished mixing. In some embodiments, at least one sensor on at least two of the ambient air inlet conduit, the nitrogen

inlet conduit, and the final delivery conduit can be utilized to determine the flow rate of at least two gases. By inputting the flow rate of both inlet gases or one inlet gas and one total flow rate, along with the assumed oxygen concentrations of the inlet gases (e.g., 20.9% for ambient air, 0% for 100% pure enriched nitrogen), the oxygen concentration of the final gas composition can be calculated. As such, the hypoxic gas composition could include, for example, nitrogen enriched with between about 2% and about 18% oxygen (e.g., FdO_2), between about 2% and about 15% of oxygen, between about 10% and about 15% of oxygen, about 2%, 3%, 4%, 5%, 6%, 7%, 8%, 9%, 10%, 11%, 12%, 13%, 14%, 15%, 16%, 17%, 18%, 19%, 20% of oxygen, or ranges incorporating any of the aforementioned values. If inspiratory demand is met by the flow rate delivered to the user, FiO_2 can also be any of the aforementioned values. If inspiratory demand is not met, FiO_2 may be somewhat closer to the oxygen concentration in ambient air, as ambient air would be entrained around the cannula, which may reduce the nitrogen concentration in the gases inspired by the user.

[0319] In some embodiments, the hypoxic gas source itself could be made of a hypoxic gas of less than 100% purity. For example, the hypoxic gas source (e.g., enriched nitrogen and/or other hypoxic gases) could be at a purity of, for example, between about 82% and about 100%, such as between about 85% and about 90%, or about 82%, 83%, 84%, 85%, 86%, 87%, 88%, 89%, 90%, 91%, 92%, 93%, 94%, 95%, 96%, 97%, 89%, 99%, 100%, or ranges incorporating any of the aforementioned values. The oxygen concentration of the hypoxic gas source could be in some cases between about 2% and about 18% oxygen, between about 2% and about 15% of oxygen, between about 10% and about 15% of oxygen, about 2%, 3%, 4%, 5%, 6%, 7%, 8%, 9%, 10%, 11%, 12%, 13%, 14%, 15%, 16%, 17%, 18%, 19%, 20% of oxygen, or ranges incorporating any of the aforementioned values. Enriched nitrogen or another hypoxic gas at less than about 100% purity, such as 90% purity (with 10% oxygen), for example, can be advantageous from a safety perspective in preventing the FiO_2 from dipping below 10% (or another desired floor percentage), even in the event of a malfunction when mixing the nitrogen-enriched gas with ambient air.

[0320] In some embodiments, flow rate sensors can be placed at each location to allow for redundancy and testing that each sensor is working correctly by checking for consistency of readings. Any combination of the above methods, for example, could be implemented together to further allow for checking of consistency of results, along with

failsafes if one or more sensors are not working correctly. Further sensors could be included (such as temperature and ambient pressure sensors) as disclosed herein to allow for correction of flow rate and/or gas concentration readings based on other factors.

[0321] Still referring to Figure 1, one, two, or more physiological sensors 99 can communicate with the data transmitter and/or receiver 15 to communicate data regarding physiological information of the user. The sensors 99 could be, for example, a pulse oximeter for measuring the oxygen saturation of a user's arterial blood, a heart rate sensor, blood pressure sensor, respiratory rate sensor, tidal volume sensor, ECG, heart rate variability sensor, and the like. Data received from the sensors 99 can also communicate with the controller 13 to be displayed on the user interface 14. Data from the sensors 99 can also be used by the controller 13 to provide closed loop feedback to modify various parameters of the device including oxygen concentration of the hypoxic gas concentration, flow rate, humidity, temperature, and the like as described in detail elsewhere herein.

Overview of Example Flow Therapy Apparatus

[0322] The flow therapy apparatus may be any suitable type of apparatus, but in some configurations may deliver a high gases flow or high flow therapy (of e.g., air, nitrogen, a hypoxic gas mixture, or some combination thereof) to a user for altitude training, enhanced athletic performance, or other indications such as those discussed elsewhere herein. The gas can be or comprise nitrogen. The gas can comprise ambient air. The gas can comprise a blend of nitrogen and ambient air to create hypoxic gas compositions as noted elsewhere herein. The gas source could be a less than 100% pure enriched hypoxic gas such as a hypoxic mix of nitrogen and oxygen that is mixed with ambient air in the system that can be advantageous from a safety perspective in some cases as mentioned elsewhere herein. "High flow therapy" as used in this disclosure may refer to delivery of gases to a user at a flow rate of greater than or equal to about 10 liters/minute (10 LPM). In some configurations, "high flow" therapy refers to administration of gas to the airways of a patient at a relatively high flow rate. In some configurations, the relatively high flow rate meets or exceeds the peak inspiratory demand of the user. In other configurations, the high flow rate may not meet or exceed the peak inspiratory demand of the user. The flow rates used to achieve "high flow" may be any of the flow rates listed below. For example, in some configurations, for an

adult patient “high flow therapy” may refer to the delivery of gases to a user at a flow rate of greater than or equal to about 10 litres per minute (10 LPM), such as between about 10 LPM and about 100 LPM, or between about 15 LPM and about 95 LPM, or between about 20 LPM and about 90 LPM, or between about 25 LPM and about 85 LPM, or between about 30 LPM and about 80 LPM, or between about 35 LPM and about 75 LPM, or between about 40 LPM and about 70 LPM, or between about 45 LPM and about 65 LPM, or between about 50 LPM and about 60 LPM. Gases delivered may comprise a percentage of nitrogen and oxygen. In some configurations, such as when the system is implementing a closed loop control algorithm as disclosed herein, delivery of hypoxic gases may not be limited to a high flow therapy and/or the inspiratory demand of the user may or may not be met by the flow rate.

[0323] In some embodiments, the device or system can allow for the user to change the flow rate during use, such as through interaction with a control, e.g., a user interface on the device. The flow rate may be varied, for example, by the controller varying the speed of the blower. This could be beneficial as the device could be used in different scenarios that require different flow rates. In some cases, flow rate could also oscillate in synchrony with breathing as long as a peak inspiratory demand of the user is being met. For example, if the user was to use the device while exercising then they could have an increased minute ventilation by way of an increased respiratory rate and/or increased tidal volume, so the flow rate could optionally be raised compared with when using the device at rest in order to meet increased peak inspiratory demand. In some embodiments, the device can allow for the user to change the oxygen concentration of the gases delivered via a control that modulates the flow of a hypoxic gas other than air, such as enriched nitrogen, from a hypoxic gas source into a conduit directly connected to the user, such as the nasal cannula.

[0324] The percentage of oxygen in the gases delivered may be, in embodiments where hypoxia is desired, such that the percentage of oxygen in the gas composition delivered to the user is less than that of typical room air (e.g., less than about 21%). In some embodiments, the percentage of oxygen in the gas composition is between about 10% and about 20.9%, or between about 11.9% and about 17.4%, or between about 13.8% and about 17.4%, or between about 15.7% and about 16.7%, or between about 15% and about 20%, or between about 13% and about 18%, or about or no more than about 10%, 10.5%, 11%,

11.5%, 12%, 12.5%, 13%, 13.5%, 14%, 14.5%, 15%, 15.5%, 16%, 16.5%, 17%, 17.5%, 18%, 18.5%, 19%, 19.5%, 20%, or 20.5%, or any ranges incorporating two of the aforementioned values. The percentage of oxygen in the inspired gas would be the same or greater than the aforementioned values, depending on whether inspiratory demand is met. In some embodiments, the percentage of nitrogen in the hypoxic gas composition is about or at least about 78.2%, 78.5%, 79%, 79.5%, 80%, 80.5%, 81%, 81.5%, 82%, 82.5%, 83%, 83.5%, 84%, 84.5%, 85%, 85.5%, 86%, 86.5%, 87%, 87.5%, 88%, 88.5%, 89%, 89.5%, 90%, or more, or any ranges incorporating two of the aforementioned values. The percentage of nitrogen in the inspired gas would be the same or less than the aforementioned values, depending on whether inspiratory demand is met. In some embodiments, the percentage of inspired or delivered nitrogen, oxygen, and/or other gases could be any of the preceding values or ranges, or others as disclosed elsewhere herein.

[0325] High flow hypoxic gas therapy can be effective in meeting or exceeding the user's peak inspiratory demand, delivering nitrogen enriched air (and therefore O₂ diminished air) and using a nasal high flow system configured for a variety of medical and non-medical applications, including but not limited to simulated altitude training, enhanced athletic performance, or other indications. Not to be limited by theory, in some embodiments systems and methods as disclosed herein could be used to treat or prevent hypertension, obesity, hyperlipidemia, prediabetes or impaired glucose tolerance, diabetes mellitus type I or type II, metabolic syndrome, mitochondrial regeneration, aging, fatigue, inflammatory diseases, anemia, or other conditions. Additionally, high flow therapy may generate a flushing effect in the nasopharynx such that the anatomical dead space of the upper airways is flushed completely or substantially completely by the high incoming gases flow. This can create a reservoir of fresh gas available of each and every breath of the exact desired composition (e.g., hypoxic composition), and prevent entrainment of ambient air that would alter the composition of the gas as well as minimizing re-breathing of carbon dioxide. These aforementioned features can work together to give increased consistency and control of the hypoxic solution that the user breathes, regardless of factors such as breath rate and volume.

[0326] The user interface may be in some embodiments a non-sealing interface, which advantageously prevents barotrauma (e.g. tissue damage to the lungs or other organs of the respiratory system due to difference in pressure relative to the atmosphere). The user

interface may be a nasal cannula with a manifold and nasal prongs, and/or a face mask, and/or a nasal pillows mask, and/or a nasal mask, and/or a tracheostomy interface, or any other suitable type of user interface.

[0327] Some examples of the flow therapy apparatus are described herein. Figures 2 to 17B show an example flow therapy apparatus 10 having a main housing 100. The main housing 100 has a main housing upper chassis 102 and a main housing lower chassis 202.

[0328] The main housing upper chassis 102 has a peripheral wall arrangement 106 (see Figure 15). The peripheral wall arrangement defines a humidifier or humidification chamber bay 108 for receipt of a removable humidification chamber 300. The removable humidification chamber 300 contains a suitable liquid such as water for humidifying gases that can be delivered to a user.

[0329] In the form shown, the peripheral wall arrangement 106 of the main housing upper chassis 102 can include a substantially vertical left side outer wall 110 that is oriented in a front-to-rear direction of the main housing 100, a substantially vertical left side inner wall 112 that is oriented in a front-to-rear direction of the main housing 100, and an interconnecting wall 114 that extends between and interconnects the upper ends of the left side inner and outer walls 110, 112. The main housing upper chassis 102 can further include a substantially vertical right side outer wall 116 that is oriented in a front-to-rear direction of the main housing 100, a substantially vertical right side inner wall 118 that is oriented in a front-to-rear direction of the main housing 100, and an interconnecting wall 120 that extends between and interconnects the upper ends of the right side inner and outer walls 116, 118. The interconnecting walls 114, 120 are angled towards respective outer edges of the main housing 100, but can alternatively be substantially horizontal or inwardly angled.

[0330] The main housing upper chassis 102 can further include a substantially vertical rear outer wall 122. An upper part of the main housing upper chassis 102 can include a forwardly angled surface 124. The surface 124 can have a recess 126 for receipt of a display and user interface module 14. The display can be configured to display characteristics of sensed gas(es) in real time, such as the oxygen concentration, temperature, humidity, and/or other characteristics. In some embodiments, the oxygen concentration could be displayed as an altitude above sea level (e.g., in meters or feet) that would result in an

equivalent partial pressure of oxygen. Conversions between FiO_2 and equivalent altitude could be done by the device by assuming an ambient oxygen concentration of, for example, about 20.9%. An interconnecting wall 128 can extend between and interconnect the upper end of the rear outer wall 122 and the rear edge of the surface 124.

[0331] A substantially vertical wall portion 130 can extend downwardly from a front end of the surface 124. A substantially horizontal wall portion 132 can extend forwardly from a lower end of the wall portion 130 to form a ledge. A substantially vertical wall portion 134 can extend downwardly from a front end of the wall portion 132 and terminate at a substantially horizontal floor portion 136 of the humidification chamber bay 108. The left side inner wall 112, right side inner wall 118, wall portion 134, and floor portion 136 together can define the humidification chamber bay 108. The floor portion 136 of the humidification chamber bay 108 can have a recess 138 to receive a heater arrangement such as a heater plate 140 or other suitable heating element(s) for heating liquid in the humidification chamber 300 for use during a humidification process.

[0332] The main housing lower chassis 202 can be attachable to the upper chassis 102, either by suitable fasteners or integrated attachment features such as clips for example. The main housing lower chassis 202 can include a substantially vertical left side outer wall 210 that is oriented in a front-to-rear direction of the main housing 100 and is contiguous with the left side outer wall 110 of the upper chassis 102, and a substantially vertical right side outer wall 216 that is oriented in a front-to-rear direction of the main housing 100 and is contiguous with the right side outer wall 116 of the upper chassis 102. The main housing lower chassis 202 can further include a substantially vertical rear outer wall 222 that is contiguous with the rear outer wall 122 of the upper chassis 102.

[0333] The lower housing chassis 202 can have a lip 242 that is contiguous with the lip 142 of the upper housing chassis 102, and also forms part of the recess for receiving the handle portion 506 of the lever 500. The lower lip 242 can include a forwardly directed protrusion 243 that acts as a retainer for the handle portion 506 of the lever 500.

[0334] An underside of the lower housing chassis 202 can include a bottom wall 230. Respective interconnecting walls 214, 220, 228 can extend between and interconnect the substantially vertical walls 210, 216, 222 and the bottom wall 230. The bottom wall 230 can include a grill 232 comprising a plurality of apertures to enable drainage of liquid in case of

leakage from the humidification chamber 300 (e.g. from spills). The bottom wall 230 additionally can include elongated forward-rearward oriented slots 234. The slots 234 can additionally enable drainage of liquid in case of leakage from the humidification chamber 300, without the liquid entering the electronics housing. In the illustrated configuration, the slots 234 can be wide and elongate relative to the apertures of the grill 232 to maximize the drainage of liquid.

[0335] As shown in Figure 17A to 17B, the lower chassis 202 can have a motor recess 250 for receipt of a motor/sensor module. The motor/sensor module may be non-removable from the main housing 100. The motor/sensor module may be removable from the main housing 100, as illustrated in Figures 17A-17B. A recess opening 251 can be provided in the bottom wall 230 adjacent a rear edge thereof, for receipt of a removable motor/sensor module. A continuous, gas impermeable, unbroken peripheral wall 252 can be integrally formed with the bottom wall 230 of the lower chassis 202 and extend upwardly from the periphery of the opening 251. A rearward portion 254 of the peripheral wall 252 has a first height, and a forward portion 256 of the peripheral wall 252 has a second height that is greater than the first height. The rearward portion 254 of the peripheral wall 252 terminates at a substantially horizontal step 258, which in turn terminates at an upper auxiliary rearward portion 260 of the peripheral wall 252. The forward portion 256 and upper auxiliary rearward portion 260 of the peripheral wall 252 terminate at a ceiling 262. All of the walls and the ceiling 262 can be continuous, gas impermeable, and unbroken other than the gases flow passage. Therefore, the entire motor recess 250 can be gas impermeable and unbroken, other than the gases flow passage.

[0336] The motor/sensor module may be insertable into the recess 250 and attachable to the lower chassis 202. Upon insertion of the motor/sensor module into the lower chassis 202, the gases flow passage tube 264 can extend through the downward extension tube 133 and be sealed by the soft seal.

[0337] The humidification chamber 300 can be fluidly coupled to the apparatus 10 in a linear slide-on motion in a rearward direction of the humidification chamber 300 into the chamber bay 108, from a position at the front of the housing 100 in a direction toward the rear of the housing 100. A gases outlet port 322 can be in fluid communication with the motor.

[0338] A gases inlet port 340 (humidified gases return) as shown in Figure 8 can include a removable L-shaped elbow. The removable elbow can further include a user outlet port 344 for coupling to the inspiratory conduit 16 to deliver gases to the user interface 17. The gases outlet port 322, gases inlet port 340, and user outlet port 344 each can have soft seals such as O-ring seals or T-seals to provide a sealed gases passageway between the apparatus 10, the humidification chamber 300, and the inspiratory conduit 16.

[0339] The humidification chamber gases inlet port 306 can be complementary with the gases outlet port 322, and the humidification chamber gases outlet port 308 can be complementary with the gases inlet port 340. The axes of those ports can be parallel to each other to enable the humidification chamber 300 to be inserted into the chamber bay 108 in a linear movement.

[0340] The apparatus 10 can have air and nitrogen (or alternative auxiliary gas) inlets in fluid communication with the motor to enable the motor to deliver air, nitrogen-enhanced air to form a hypoxic mixture, or a suitable mixture thereof to the humidification chamber 300 and thereby to the user. As shown in Figure 10, the apparatus 10 may have a combined air/nitrogen (or alternative auxiliary gas) inlet arrangement 350. This arrangement can include a combined air/nitrogen port 352 into the housing 100, a filter 354, and a cover 356 with a hinge 358. In other embodiments, a gases tube can extend laterally or in another appropriate direction and be in fluid communication with a nitrogen source. The port 352 can be fluidly coupled with the motor 402. For example, the port 352 may be coupled with the motor/sensor module 400 via a gases flow passage between the port 352 and an inlet aperture or port in the motor/sensor module 400, which in turn would lead to the motor.

[0341] The apparatus 10 may have the arrangement shown in Figures 11 to 14 to enable the motor to deliver air, nitrogen (or alternative auxiliary gas), or a suitable mixture thereof to the humidification chamber 300 and thereby to the user. This arrangement can include an air inlet 356' in the rear wall 222 of the lower chassis 202 of the housing 100. The air inlet 356' comprises a rigid plate with a suitable grill arrangement of apertures and/or slots. Sound dampening foam may be provided adjacent the plate on the interior side of the plate. An air filter box 354' can be positioned adjacent the air inlet 356' internally in the main housing 100, and include an air outlet port 360 to deliver filtered air to the motor via an air inlet port 404 in the motor/sensor module 400. The air filter box 354' may include a filter

configured to remove particulates (e.g. dust) and/or pathogens (e.g. viruses, fungi, or bacteria) from the gases flow. A soft seal such as an O-ring seal can be provided between the air outlet port 360 and air inlet port 404 to seal between the components. The apparatus 10 can include a separate nitrogen inlet port 358' positioned adjacent one side of the housing 100 at a rear end thereof, the nitrogen port 358' for receipt of nitrogen from a nitrogen source such as a tank or source of piped nitrogen. The nitrogen inlet port 358' can optionally be in fluid communication with a valve 362. The valve 362 can suitably be a solenoid valve that enables the control of the amount of nitrogen that is added to the gases flow that is delivered to the humidification chamber 300. The nitrogen port 358' and valve 362 may be used with other (e.g., other than nitrogen) auxiliary gases to control the addition of other auxiliary gases to the gases flow. The other auxiliary gases may include any one or more of a number of gases useful for gas therapy, including but not limited to heliox, oxygen, nitrogen, nitric oxide, carbon dioxide, argon, helium, methane, sulfur hexafluoride, and combinations thereof. In some embodiments a valve need not be present, and nitrogen flow can be manually controlled at the nitrogen source. The oxygen concentration of the hypoxic gases flow can be read from the user interface, and the amount of nitrogen titrated at the nitrogen source accordingly depending on the desired result.

[0342] As shown in Figures 13 to 16, the lower housing chassis 202 can include suitable electronics boards 272, such as sensing circuit boards. The electronics boards can be positioned adjacent respective outer side walls 210, 216 of the lower housing chassis 202. The electronics boards 272 can contain, or can be in electrical communication with, suitable electrical or electronics components, such as but not limited to microprocessors, capacitors, resistors, diodes, operational amplifiers, comparators, and switches. Sensors may be used with the electronic boards 272. Components of the electronics boards 272 (such as but not limited to one or more microprocessors) can act as the controller 13 of the apparatus.

[0343] One or both of the electronics boards 272 can be in electrical communication with the electrical components of the apparatus 10, including the display unit and user interface 14, motor, valve 362, and the heater plate 140 to operate the motor to provide the desired flow rate of gases, operate the humidifier 12 to humidify and heat the gases flow to an appropriate level, and supply appropriate quantities of nitrogen (or quantities of an alternative auxiliary gas) to the gases flow.

[0344] The electronics boards 272 can be in electrical communication with a connector arrangement 274 projecting from the rear wall 122 of the upper housing chassis 102. The connector arrangement 274 may be coupled to an audible, visual, tactile, or other alarm, pulse oximetry port, and/or other suitable accessories. The electronics boards 272 can also be in electrical communication with an electrical connector 276 that can also be provided in the rear wall 122 of the upper housing chassis 102 to provide mains or battery power to the components of the apparatus 10.

[0345] As mentioned above, operation sensors, such as flow, temperature, humidity, and/or pressure sensors can be placed in various locations in the flow therapy apparatus 10 and/or the inspiratory conduit 16 and/or cannula 17. The electronics boards 272 can be in electrical communication with those sensors. Output from the sensors can be received by the controller 13, to assist the controller 13 to operate the flow therapy apparatus 10 in a manner that provides optimal therapy, including optionally meeting peak inspiratory demand.

[0346] As outlined above, the electronics boards 272 and other electrical and electronic components can be pneumatically isolated from the gases flow path to improve safety. The sealing also prevents water ingress.

[0347] Figures 18A-E illustrate another flow therapy apparatus 3010 including a main housing having a main housing upper chassis 3102 and a main housing lower chassis 3202. The flow therapy apparatus 3010 can further include a humidification chamber bay 3108 for receipt of a removable humidification chamber. The flow therapy apparatus 3010 may have any of the features and/or functionality described herein in relation to the flow therapy apparatus 10, but those features are not repeated here for simplicity. Similarly, the features and/or functionality of the flow therapy apparatus 3010 may be used in the other apparatus described herein.

[0348] The flow therapy apparatus 3010 can have a single-sided handle/lever 4500. That is, only one side of the handle/lever 4500 is movably connected relative to the main housing of the flow therapy apparatus 3010, whereas there is no pivot connection of the other side of the handle/lever 4500 to the main housing. As shown in Figure 18D, a left side of the handle/lever 4500 is pivotally connected relative to the main housing. However, it is possible to have only the right side pivotally connected to the main housing. The handle/lever

4500 is pivotally and translationally connected to the main housing, so that the handle/lever 4500 moves on a path having a varying radius relative to the main housing.

[0349] A terminal part of the handle/lever 4500 can have a cross-member handle portion 4506 that interconnects forward ends of a left side arm 4502 and a right side member 4504 and forms an engagement region for grasping by a user's fingers. When the handle 4500 is in the raised position as shown in Figure 18D for example, the cross-member 4506 can act as a carrying handle for the flow therapy apparatus 3010. When the handle is in the fully raised position, the cross member 4506 can be positioned generally above and generally in line with the centre of gravity of the flow therapy apparatus 3010 (including the liquid chamber). The liquid chamber can be inserted into or removed from the humidification chamber bay 3108 when the handle/lever 4500 is raised. When the handle/lever 4500 is in the lowered position, it can inhibit or prevent removal of the liquid chamber from the humidification chamber bay 108.

[0350] Figure 18E illustrates the flow therapy apparatus 3010 without the handle/lever. As shown in Figure 18E, a removable gases flow tube in the form of a removable elbow 1342 can be used in the flow therapy apparatus 3010. The elbow 1342 can receive humidified gases from the liquid chamber at an inlet port 1340 and direct the humidified gases to an outlet port 1344 toward the user interface through the user breathing conduit.

[0351] Similar to the flow therapy apparatus 10, the lower chassis 3202 of the flow therapy apparatus 3010 can have a motor recess for receiving a motor/sensor module. The motor/sensor module can include a blower, which entrains room air to deliver to a user. The gases can be mixed prior to entering the sensor module. The blower can be a mixer for mixing the gases before the gases enter a sensing chamber of the sensor module. The apparatus can include an integrated or separate gas mixer in some cases. The separate gas mixer can be positioned before or after the blower. Nitrogen can be entrained after the blower and the separate gas mixer can be used to mix the nitrogen and air following entrainment. The controller can increase or decrease a flow rate of the gases flowing through the flow therapy apparatus by controlling a motor speed of the blower.

Control System

[0352] FIG. 19A illustrates a block diagram 900 of an example control system 920 that can detect user conditions and control operation of the flow therapy apparatus including the gas source. The control system 920 can manage a flow rate of the gas flowing through the flow therapy apparatus as it is delivered to a user. For example, the control system 920 can increase or decrease the flow rate by controlling an output of a motor speed of the blower (hereinafter also referred to as a “blower motor”) 930 or an output of a valve 932 in a blender. The control system 920 can automatically determine a set value or a personalized value of the flow rate for a particular user as discussed below. The flow rate can be optimized by the control system 920 to improve user comfort and therapy.

[0353] The control system 920 can also generate audio and/or display/visual outputs 938, 939. For example, the flow therapy apparatus can include a display and/or a speaker. The display can indicate to the user, physician, trainer, or other party any warnings or alarms generated by the control system 920. The display can also indicate control parameters that can be adjusted by the user or other individual. For example, the control system 920 can automatically recommend a flow rate for a particular user. The control system 920 can also determine a respiratory state of the user, including but not limited to generating a respiratory rate of the user, and send it to the display.

[0354] In some embodiments, a physiological parameter, such as SpO_2 of a user for example, could additionally or alternatively be fed into an alarm system. The alarm system could monitor the user's SpO_2 , and have set responses if it were to fall below a certain level. The device could additionally or alternatively have alarms for FiO_2 values, assuming that the user's inspiratory demand is met, and that FdO_2 is equal to FiO_2 . As described above, if the user's inspiratory demand is not met, the actual FiO_2 value would be higher than the assumed value. The alarms would be on the basis of the measured oxygen concentration in the unit, which is FdO_2 . The device would alarm on the basis of FdO_2 and assume that the parameter being measured is FiO_2 . This could affect therapy, but not affect safety. Responses from the system could include visual and/or audible alarms, reducing the nitrogen being supplied, setting the nitrogen flow to a predetermined value, setting the nitrogen flow to achieve a specific FiO_2 or SpO_2 , completely shutting off the nitrogen supply, shutting off all flow completely or any combination of these responses.

[0355] The system could have multiple thresholds, where different responses or sets of responses are triggered at different SpO₂ and/or FiO₂ readings. As subsequent thresholds are crossed, different responses could occur in place of the previous responses, in addition to the previous responses, and/or act as a variation of a previous response (e.g. an audible alarm changes in volume or tone).

[0356] In some embodiments, the device could alarm for at least the FiO₂ when controlling SpO₂, and vice versa, as this could mean the user is prevented from reaching dangerous levels of both SpO₂ and FiO₂, as one is bound by the control limits of the device and the other is bound by alarm limits. It would also have added safety through redundancy in the event of a faulty reading of one of the SpO₂ or FiO₂ sensors.

[0357] Alarm thresholds could include time factors. These would allow for the device to not be triggered by brief false readings, such as requiring a threshold to be about or at least about 5, 10, 15, 20, 25, 30, or more seconds for example. They could also allow for escalation in response of the device based on length of time at a certain value (for example, going from a visual to audible alarm, or a louder or more prominent alarm). They could also allow for alarms to be set off after a set amount of time (for example, alarming at SpO₂ readings that are safe for a short exposure but become dangerous after a longer duration of exposure, such as, for example, at about or at least about 30, 45, 60, 75, 90, 120, 150, 180, 240, 300 seconds, or more).

[0358] Some non-limiting examples of values at which an SpO₂ reading could trigger an alarm could include below about 94% (as this is the lower limit of what is considered a healthy SpO₂ reading at sea level), and/or below about 85% (as this is typically the value below which negative side effects begin to occur), and/or below about 80% (as this is the value that is typically regarded as the point where altitude training becomes dangerous), and/or below about 75% (as this is the point where therapy should be stopped immediately), and/or below about 65% (as this is the point where the user would likely have impaired mental function and judgement), and/or below about 55% (as this is the point where the user would likely lose consciousness).

[0359] Some values at which FiO₂/equivalent altitude readings could trigger a response from the system could include about 15.7% (that is, about 2500m) as this is typically the upper altitude limit of an extended exposure therapy program, and/or about

13.8% (that is, about 3500m) as this is typically the upper altitude limit of any therapy program, and/or about 11.9% (that is, about 4800m) as this is the limit of what is typically considered safe without medical supervision, and/or about 10.2% (that is, about 5950m) as this represents the highest recorded permanently tolerable altitude, and/or about 7.7% (that is, about 8000m) as this is commonly referred to as the “death zone” where the oxygen concentration is insufficient to sustain human life.

[0360] The device could additionally or alternatively have one or more alarm limits for SpO₂ and/or FiO₂ that change in response to one or more inputs. The one or more inputs could include an FiO₂ reading, an SpO₂ reading, a heart rate measurement, a respiratory rate measurement, an input by the user of their desired therapy program, a sensed or user input indication that the user is exercising, an amount of time the user has been using the device, and/or one or more user characteristics (this could include age, height, weight, gender, activity/fitness level, experience with altitude training). The indication of user exercise in particular could come from one or a combination of the other inputs listed, and could be transmitted as qualitative signal (e.g., either exercising or not exercising) or as a quantitative signal (e.g., exercise intensity level).

[0361] The relationship between one or more alarm limits and one or more inputs could be one that changes dynamically (e.g., as age increases the alarm trigger threshold for FiO₂ steadily increases). Additionally, or alternatively, one or more alarm limits could change by a set amount in response to one or more inputs. The change in one or more limits could occur at one or more thresholds of a quantitative signal (e.g., the alarm threshold for SpO₂ increases by a certain amount after a specific amount of time that user has been using the device) and/or in response to a qualitative signal (e.g., the FiO₂ alarm threshold jumps to a higher value when the user indicates that they are beginning exercise).

[0362] Having alarm limits that vary on a range of conditions can allow the user to safely employ a training regime that allows them to reach their maximum potential. While alarm limits can be applied in a blanket “one fit all” approach in some embodiments, this may not be desirable in some implementations because in order for the system to be safe for all or most users in all or most scenarios the device may become overly safe (or not challenging enough) for others, to the point where certain users are not able to gain maximum benefit from the device. The system would also be able to provide alarms for

readings, particularly SpO₂ readings, that while potentially safe are abnormal given the current parameters provided. For example, if a user had an SpO₂ reading of less than 94% while at rest and breathing normoxic gas, then the device could alarm to tell the user that his or her resting SpO₂ is abnormally low, and the user should consult a medical professional before commencing with an altitude training program.

[0363] In some embodiments, any alarms that are capable of changing based off various inputs would be coupled with one or more fixed alarms (such as the ones listed above) that provide absolute limits regardless of any input.

[0364] A similar methodology to the above could be additionally or alternatively applied in a similar way to the ranges for FiO₂ and/or SpO₂ that the user can attempt to control to. As above, this could allow the user to use the device in a way that is individually tailored to be both optimally effective and safe based on the parameters provided. It could allow for access to a greater range of training levels while avoiding potentially dangerous misuse by the user. Optionally, a fixed upper limit for the device could be coupled with a variable lower limit, or vice versa. The device could have one or more variable limits paired with a fixed limit that the variable limit could not exceed.

[0365] Table 1 below lists various non-limiting flow rates of nitrogen to illustrate what would roughly be required to achieve various oxygen concentrations. Preferably a value for total flow would be selected, and this would remain constant regardless of changes to nitrogen flow rate and/or FiO₂, unless a new total flow rate is selected. If the total flow rate in the device is adjusted, a proportional change in the nitrogen flow rate would be required to maintain the same FiO₂.

TABLE 1

Total flow L/min	Nitrogen flowrate (L/min)	FiO ₂ (assuming inspiratory demand is met)
30	0	21.0%
30	1	20.2%
30	2	19.4%
30	3	18.7%
30	4	17.9%
30	5	17.1%
30	6	16.3%

30	7	15.6%
30	8	14.8%
30	9	14.0%
30	10	13.2%

[0366] The control system 920 can change heater control outputs to control one or more of the heating elements (for example, to maintain a temperature set point of the gas delivered to the user). The control system 920 can also change the operation or duty cycle of the heating elements. The heater control outputs can include heater plate control output(s) 934 and heated breathing tube control output(s) 936.

[0367] The control system 920 can determine the outputs 930-939 based on one or more received inputs 901-916. The inputs 901-916 can correspond to sensor measurements received automatically by the controller 600 (shown in FIG. 19B). The control system 920 can receive sensor inputs including but not limited to temperature sensor(s) inputs 901, flow rate sensor(s) inputs 902, motor speed inputs 903, pressure sensor(s) inputs 904, gas(s) fraction sensor(s) inputs 905, humidity sensor(s) inputs 906, pulse oximeter (for example, SpO₂) sensor(s) inputs 907, stored or user parameter(s) 908, duty cycle or pulse width modulation (PWM) inputs 909, voltage(s) inputs 910, current(s) inputs 911, acoustic sensor(s) inputs 912, power(s) inputs 913, resistance(s) inputs 914, CO₂ sensor(s) inputs 915, and/or spirometer inputs 916. The control system 920 can receive inputs from the user or stored parameter values in a memory 624 (shown in FIG. 19B). The control system 920 can dynamically adjust flow rate for a user over the time of their therapy. The control system 920 can continuously detect system parameters and user parameters. A person of ordinary skill in the art will appreciate based on the disclosure herein that any other suitable inputs and/or outputs can be used with the control system 920.

[0368] In some embodiments, a target oxygen concentration could be selected, and the difference between this and the measured oxygen concentration could be fed into a controller for the valve, which would open and close to alter the supply of nitrogen until the measured oxygen concentration matches the target oxygen concentration. In some embodiments, the target oxygen concentration and/or the measured oxygen concentration could be displayed on the device and/or an ancillary device, such as the user's smartphone, smartwatch, or the like. Alternatively, the device could control to the user's blood oxygen saturation (SpO₂) instead of inspired oxygen concentration (FiO₂). This could utilize at least

one sensor (such as a pulse oximeter) to measure SpO_2 at a point on the user's body (for example, their finger). This reading could then be displayed somewhere, potentially on the device or the sensor. The user, or the control system could then alter the FiO_2 being delivered using any of the above methods to reach a target SpO_2 . In some setups, the FiO_2 or equivalent altitude could be displayed. Additionally, the display could display the altitude equivalent of the current FiO_2 . The user may be able to change the target altitude via controls on the display or elsewhere. This target altitude would be converted to a target FiO_2 value by the device controller, which can be used to control the valve. The ability of allowing users to vary the altitude would be desirable for a user who wishes to simulate specific altitudes, instead of targeting specific FiO_2 values.

[0369] With reference to Figure 22, a schematic diagram of the closed loop control system is illustrated. The closed loop control system may utilize two control loops. The first control loop may be implemented by the SpO_2 controller. The SpO_2 controller can determine a target oxygen concentration, such as FdO_2 . Where the gases flow is being delivered as nasal high flow through a non-sealed cannula, assuming the user's inspiratory demand is met, FdO_2 would be substantially equivalent to FiO_2 . The determined target oxygen concentration is based at least in part on the target SpO_2 and/or the measured SpO_2 . The target SpO_2 value can be a single value or a range of acceptable values. The value(s) could be pre-set, chosen by a user, or determined automatically based on user characteristics. Generally, target SpO_2 values are received or determined before or at the beginning of a therapy session, though target SpO_2 values may be received at any time during the therapy session. During a therapy session, the SpO_2 controller can also receive as inputs: measured FdO_2 reading(s) from a gases composition sensor, and measured SpO_2 reading(s) and a signal quality reading(s) from the physiological sensor. In some configurations, the SpO_2 controller can receive target FdO_2 as an input. In such a case, the output of the SpO_2 controller may be provided directly back to the SpO_2 controller as the input. Based at least in part on the inputs, the SpO_2 controller can output a target FdO_2 to the second control loop.

[0370] The second control loop may be implemented by the FdO_2 controller. The FdO_2 controller can receive inputs of measured FdO_2 and target FdO_2 . The FdO_2 controller can then output a hypoxic gas inlet valve control signal to control the operation of the hypoxic gas valve based on a difference between these measured FdO_2 and target FdO_2

values. The FdO_2 controller may receive the target FdO_2 value that is output from the first control loop when the flow therapy apparatus is controlling to a target SpO_2 . In some configurations, the control signal of the FdO_2 controller may set the current of the hypoxic gas valve in order to control operation of the hypoxic gas valve. Additionally, or alternatively, the FdO_2 controller could detect changes to the measured FdO_2 and alter the position of the valve accordingly. In some configurations, the user manually sets a target SpO_2 or oxygen concentration, and the second control loop can operate independently without receiving the target FdO_2 from the first control loop. Rather, the target FdO_2 can be received from user input or a default value.

[0371] The FiO_2 could be controlled within a set of limits, such as pre-determined limits programmed into a memory of device that can be user-customizable in some cases. If the device allows for the supply of nitrogen to be suddenly blocked such that the device returns to delivery of normoxic gas, then such a function could be considered separate and unrestricted by any of the following limits. With each set of limits, an altitude e.g., in meters or feet, can be provided that roughly corresponds to an equivalent partial pressure of oxygen, as this could be displayed alternatively or in addition to the FiO_2 reading. The following FiO_2 limits serve as examples of possible ranges, but the FiO_2 range could be between any two values, including a lower limit from one range and an upper limit from another.

- **[0372]** FiO_2 could be limited between about 20.9% (i.e., about 0m) which represents sea level, and about 10.2% (i.e., about 5950m altitude) which represents the highest recorded permanently tolerable altitude.
- **[0373]** FiO_2 could be limited or between about 17.4% (i.e., about 1600m) which represents approximately the lowest simulated altitude at which the effects of high altitude begin to take effect, and about 11.9% (i.e., about 4800m altitude) as lower oxygen concentrations in some cases could require monitoring by a healthcare professional.
- **[0374]** FiO_2 could be limited between about 17.4% (i.e., about 1600m) for reasons given above, and about 13.8% (i.e., about 3500m altitude) as this is the limit of the “high altitude” region, and higher simulated altitudes may begin to have overly negative effects on training, recovery, sleep quality, appetite, etc. that result in loss of efficacy of the therapy.

- [0375] FiO_2 could be limited between about 16.7% (i.e., about 2000m) and about 15.7% (i.e., about 2500m altitude), which in some cases has been shown to have both benefit and safety advantages.
- [0376] FiO_2 could also be limited to other height/altitude equivalents, such as about 500m, about 750m, about 1,000m, about 1,250m, about 1,500m, about 1,750m, about 2,000m, about 2,250m, about 2,500m, about 2,750m, about 3,000m, about 3,250m, about 3,500m, about 3,750m, about 4,000m, or any ranges between the aforementioned values.

[0377] In some embodiments, the device could operate based upon a target SpO_2 measurement. One advantage of controlling the hypoxic gas delivery based on SpO_2 is that it allows the device to adjust the FiO_2 (and equivalent altitude) with the exercise intensity. For example, if the user begins exercising at a higher level of intensity, the user's SpO_2 may begin to drop. In response, the device would increase the FiO_2 in order to maintain the target SpO_2 . In this situation, the device would effectively be raising the FiO_2 in response to increased exercise intensity. The target SpO_2 could be a pre-set value, a selected value, a pre-set range, a selected range, or a value that changes over time based on a selected therapy program. The SpO_2 reading could be directly fed into the device, and the difference between the target SpO_2 and measured SpO_2 could be used to control a proportional valve on the nitrogen inlet, and therefore the oxygen content of the gas delivered (FiO_2), similar to the one discussed above. As described above, the device controls FiO_2 by changing FdO_2 , and assumes inspiratory demand is met, and therefore in such a scenario FiO_2 is equal to FdO_2 . If inspiratory demand is not met, the device can still control FdO_2 according to a target SpO_2 , as the controller would continue to change FdO_2 (and in turn assumed FiO_2) until the target SpO_2 is achieved. By constantly using feedback from the SpO_2 sensor to control the nitrogen inflow, the target SpO_2 can be reached by altering the oxygen content of the gas. In some embodiments, the measured SpO_2 , target SpO_2 , and/or FiO_2 can be displayed. The device could include limits on the amount of nitrogen that the valve can allow through and/or a valve position so that an overly dangerous hypoxic composition is not delivered. Additionally, the device could be configured to allow for control of SpO_2 when an SpO_2 sensor is used, but to then default back to one of the earlier FiO_2 control methods when the SpO_2 is not present. Additionally or alternatively, the system can use feedback from other

proxy measurements of exertion, such as heart rate, blood pressure, respiratory rate, or heart rate variability to adjust the FiO_2 (and equivalent altitude).

[0378] SpO_2 can in some embodiments be controlled between a set of pre-set or other limits. The following are a few non-limiting examples of possible limits, in practice SpO_2 could be limited between any two values, including any reasonable combination of a lower value from one range and an upper value from another.

- [0379] SpO_2 could be limited between about 80% (the absolute lower limit of what is considered a safe SpO_2 reading in some cases) and about 99% or about 100% (the upper limit of what is considered a safe SpO_2 reading in some cases).
- [0380] SpO_2 could be limited between about 80% and about 94% (the lower limit of a healthy SpO_2 reading at sea level, and therefore the upper limit of what can be considered altitude training in some cases).
- [0381] SpO_2 could be limited between about 85% (the lower limit of safe extended exposure without medical supervision in some cases) and about 92% (a typical SpO_2 reading at the lower range of high altitude, i.e. about 1600m), in some cases for extended use.
- [0382] SpO_2 could be limited between about 87% and about 90% (a more specific range of SpO_2 that can be both safe and effective in some cases), such as for extended use.
- [0383] SpO_2 could be limited between about 80% and about 85% (the lowest range that can be considered safe in some cases), such as for intermittent use.

[0384] The device could be for extended use, for example, all the time (e.g., 24 hours a day); using the device only when awake; using the device only when sleeping; using the device only when exercising; using the device only when not exercising; using the device for a set amount of time, e.g., about, at least about, or no more than about 30 minutes, 45 minutes, 1 hour, 2 hours, 3 hours, 4 hours, 5 hours, 6 hours, 7 hours, 8 hours, 9 hours, 10 hours, 11 hours, 12 hours, 16 hours, 20 hours, or 24 hours a day; or any logical combination of the above (e.g., only when awake and not exercising).

[0385] Intermittent use could entail using the device for a set amount of time, such as for example, shorter than about 4, 3, 2, or 1 hour, or using the device for short bursts of about or less than about 10, 9, 8, 7, 6, 5, 4, 3, 2, or 1 minute interspaced with similar short recovery periods of about or less than about 10, 9, 8, 7, 6, 5, 4, 3, 2, or 1 minute, or only using the device while exercising, or any logical combination of the above (e.g., short bursts with interspaced recovery only during exercise).

[0386] In some embodiments, the use can be done once a week, or for 2, 3, 4, 5, 6, or 7 days out of a week, 2 weeks, or month for example.

[0387] In some embodiments, the use can be continued for a total period of time depending on the desired clinical result. The device can be used over a time period of, for example, about, at least about, or no more than about 1 week, 2 weeks, 3 weeks, 1 month, 2 months, 3 months, 4 months, 5 months, 6 months, 9 months, 12 months, or more or less.

[0388] The device could be used in a therapy program that contains treatment periods that could be considered extended use as well as other periods that could be considered intermittent use, and could use different SpO₂ target ranges appropriate for both. For example, the device could be used in a lower SpO₂ target range while exercising, as well as a higher SpO₂ target range when not exercising for the rest of the day.

[0389] In some embodiments, personalized training methods and altitude equivalent oxygen concentrations for therapy can be determined by observing how different individuals acclimatize at different rates. In general, less than about 1250 meters above sea level is commonly described as “low altitude”, as noticeable effects generally begin to take place at about 1500 meters. From about 1500 meters to about 3500 meters is often referred to as the “high altitude” region, with regions over about 3500 meters being the “very high altitude”, and can be potentially dangerous to train at in some cases, especially if not given the proper time to acclimatize. High altitude training tends to occur in the region about 2000 meters to about 2500 meters, although this varies with training regimes, particularly the activity performed in the high altitude region and the length of time spent there. Some activity regimes include:

- [0390] Live high/train high: This is likely the simplest form of altitude training, as it simply consists of remaining at altitude (e.g., breathing an

altitude-equivalent oxygen concentration of the hypoxic gas composition) for the entire length of the therapy, including at training times.

- **[0391]** Live high/train low: This involves exposing oneself to altitude (e.g. >2000m meters) (e.g., breathing an altitude-equivalent oxygen concentration of the hypoxic gas composition) during non-training periods, but returning to a low altitude environment (i.e., less than about 1250 meters) (e.g., breathing an altitude-equivalent oxygen concentration of the hypoxic gas composition) for exercise. In some embodiments, the low altitude environment can be achieved by utilizing systems and methods as disclosed herein with supplemental oxygen during non-training periods (e.g., non-hypoxic gas compositions with oxygen concentrations of at least about 21%, 22%, 23%, 24%, 25%, 30%, 35%, 40%, 45%, 50%, or more, or ranges encompassing two or more of the aforementioned values). This is thought to allow for the benefits of acclimatization while still maintaining the same exercise intensity. A study using these altitude ranges showed improvements in speed, strength, endurance and recovery.
- **[0392]** Live low/train high: This involves athletes training at high altitude (e.g., breathing an altitude-equivalent oxygen concentration of the hypoxic gas composition) and spending the remaining non-training periods in a low oxygen environment. The idea is increase the strain on the user's cardiovascular system while allowing them to recover in a normoxic environment. This has the added benefit of reducing the time needed to be spent in hypoxia.
- **[0393]** Repeated sprints in hypoxia: This involves the athlete performing a high intensity exercise (e.g., sprinting) for a short period followed by a rest period, and then repeating the cycle, all in hypoxic conditions. In some embodiments, the high intensity exercise could be performed for, for example, between about 15 seconds and about 180 seconds, such as about 15, 30, 60, 75, 90, 105, 120, 150, or 180 seconds, or ranges incorporating any two of the aforementioned values. In some embodiments, the rest period can be, for example, about, at least about, or

no more than about 1x, 1.5x, 2x, 2.5x, 3x, 3.5x, 4x, 4.5x, 5x the exercise period or ranges incorporating any two of the aforementioned values. As one non-limiting example, high intensity exercise is performed for about 30 seconds, and then a rest period for about or no more than about 120 seconds, followed by additional cycles of high intensity exercise and rest. In some embodiments, the user can perform between about 2 cycles and about 20 cycles under this protocol, such as between about 2 cycles and about 12 cycles, between about 5 cycles and about 10 cycles, or about 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16, 17, 18, 19, or 20 cycles, or ranges incorporating any two of the aforementioned values. While this can be seen as a variation on live low/train high, the underlying mechanisms are theorized to achieve different results. This was tested on athletes who were able to complete 9-10 sprints before total exhaustion. The athletes were split into two groups that performed the above exercises, however one group did it in hypoxia and the other in normoxia. After 4 weeks the athletes who performed the sprints in hypoxia could manage 13 before total exhaustion, while the normoxic group had shown no improvement.

- **[0394]** In some configurations, an exercise program can include varying FiO_2 (or FdO_2) by increasing or decreasing FiO_2 (or FdO_2) during a training session based on a pre-set sequence. For example, the FiO_2 could start at or near 21% and slowly drop to a specific hypoxic value, and then slowly ramp back up to around 21% near the end of the session, or vice versa. The varying of FiO_2 (or FdO_2) can be performed gradually, in a series of step changes, and/or in one step change. The varying of FiO_2 (or FdO_2) can be repeated during the training session. This could be done to simulate rising from sea level to high altitude, followed by descending back to sea level. The FiO_2 could also be varied based on other determined exercise regimes. For example, an exercise session could involve high and low intensity phases, with the FiO_2 programmed to coordinate with these phases. This could involve lower FiO_2 values being set for periods of low exercise intensity, with the FiO_2 being raised for periods of high intensity.

The device could also assess exercise intensity level and automatically adjust the FiO_2 based on the determined exercise intensity level. Assessing intensity level could be done by monitoring one or more physiological parameters, such as heart rate, respiratory rate, blood pressure, heart rate variability, and/or the like. When performing the pre-set exercise programs, the user's SpO_2 could be monitored (e.g., by a pulse oximeter or otherwise) to ensure that the user's SpO_2 does not drop below a predetermined value. When the user's SpO_2 drops below a predetermined value, the device or system can manually override the target FiO_2 value or target altitude equivalent value.

Controller

[0395] Figure 19B illustrates a block diagram of an embodiment of a controller 600. The controller 600 can include programming instructions for detection of input conditions and control of output conditions. The programming instructions can be stored in a memory 624 of the controller 600. The programming instructions can correspond to the methods, processes and functions described herein. The programming instructions can be executed by one or more hardware processors 622 of the controller 600. The programming instructions can be implemented in C, C++, JAVA, or any other suitable programming languages. Some or all of the portions of the programming instructions can be implemented in application specific circuitry 628 such as ASICs and FPGAs.

[0396] The controller 600 can also include circuits 628 for receiving sensor signals. The controller 600 can further include a display 630 for transmitting status of the user and the respiratory assistance system. The display 630 can also show warnings. The display 630 can be configured to display characteristics of sensed gas(es) in real time. The controller 600 can also receive user inputs via the user interface such as display 630. The user interface may alternatively or additionally comprise buttons or a dial. The user interface may alternatively or additionally comprise a touch screen.

Motor/Sensor module

[0397] Any of the features of the flow therapy apparatus described herein, including but not limited to the humidifier, the flow generator, the user interface, the

controller, and the user breathing conduit configured to couple the gases flow outlet of the respiratory system to the user interface, can be combined with any of the sensor modules described herein.

[0398] Figure 20 illustrates a block diagram of the motor/sensor module 2000, which is received by the recess 250 in the flow therapy apparatus (shown in Figures 17A and 17B). The motor/sensor module can include a blower 2001, which entrains room air to deliver to a user. The blower 2001 can be a centrifugal blower.

[0399] Room air can enter an ambient/room air inlet 2002, which enters the blower 2001 through an inlet port 2003. The inlet port 2003 can include a valve 2004 through which a pressurized gas may enter the blower 2001. The valve 2004 can control a flow of nitrogen or other auxiliary gas into the blower 2001. The valve 2004 can be any type of valve, including a proportional valve or a binary valve. In some embodiments, the valve can be on the nitrogen supply line, e.g., a nitrogen source bottle or other reservoir, and manually or automatically adjusted to alter the amount of nitrogen being delivered. In some embodiments, the inlet port does not include a valve.

[0400] The blower 2001 can operate at a motor speed of greater than 1,000 RPM and less than 30,000 RPM, greater than 2,000 RPM and less than 21,000 RPM, or between any of the foregoing values. Operation of the blower 2001 mixes the gases entering the blower 2001 through the inlet port 2003. Using the blower 2001 as the mixer can decrease the pressure drop that would otherwise occur in a system with a separate mixer, such as a static mixer comprising baffles, because mixing requires energy.

[0401] The mixed air can exit the blower 2001 through a conduit 2005 and enters the flow path 2006 in the sensor chamber 2007. A sensing circuit board with sensors 2008 can be positioned in the sensor chamber 2007 such that the sensing circuit board is at least partially immersed in the gases flow. At least some of the sensors 2008 on the sensing circuit board can be positioned within the gases flow to measure gas properties within the flow. After passing through the flow path 2006 in the sensor chamber 2007, the gases can exit 2009 to the humidification chamber.

[0402] Positioning sensors 2008 downstream of the combined blower and mixer 2001 can increase accuracy of measurements, such as the measurement of gases fraction concentration, including nitrogen and/or oxygen concentration, over systems that position the

sensors upstream of the blower and/or the mixer. Such a positioning can give a repeatable flow profile. Further, positioning the sensors downstream of the combined blower and mixer avoids the pressure drop that would otherwise occur, as where sensing occurs prior to the blower, a separate mixer, such as a static mixer with baffles, is required between the inlet and the sensing system. The mixer can introduce a pressure drop across the mixer. Positioning the sensing after the blower can allow the blower to be a mixer, and while a static mixer would lower pressure, in contrast, a blower increases pressure. Also, immersing at least part of the sensing circuit board and sensors 2008 in the flow path can increase the accuracy of measurements because the sensors being immersed in the flow means they are more likely to be user to the same conditions, such as temperature and pressure, as the gases flow and therefore provide a better representation of the gas characteristics.

[0403] Turning to Figure 21, the gases exiting the blower can enter a flow path 402 in the sensor chamber 400, which can be positioned within the motor and/or sensor module. The flow path 402 can have a curved shape. The flow path 402 can be configured to have a curved shape with no sharp turns. The flow path 402 can have curved ends with a straighter section between the curved ends. A curved flow path shape can reduce pressure drop in a gases flow without reducing the sensitivity of flow measurements by partially coinciding a measuring region with the flow path to form a measurement portion of the flow path.

[0404] A sensing circuit board 404 with sensors, such as ultrasonic transmitters, receivers, humidity sensor, temperature sensor, flow rate sensor, and the like, can be positioned in the sensor chamber 400 such that the sensing circuit board 404 is at least partially immersed in the flow path 402. Immersing at least part of the sensing circuit board and sensors in the flow path can increase the accuracy of measurements because the sensors immersed in the flow are more likely to be user to the same conditions, such as temperature and pressure, as the gases flow, and therefore provide a better representation of the characteristics of the gases flow. After passing through the flow path 402 in the sensor chamber 400, the gases can exit to the humidification chamber.

[0405] With continued reference to Figure 21, openings 406 of the sensor chamber 400 can hold acoustic transmitters, such as ultrasonic transducers which form an acoustic axis along at least a portion of the flow path 402 to measure properties or

characteristics of the gases within the flow. The ultrasonic transducers can act as both transmitters and receivers.

Example 1

[0406] A human user performed a 3 km trial run on a gravel track and recorded a time of 10 minutes and 54 seconds. The user's best time over recent years has been 10 minutes and 38 seconds. 2 weeks later, the user commenced use of a high flow device, such as a high flow device coupled to a nasal cannula patient interface as disclosed herein with delivery of a hypoxic gas composition including enriched nitrogen at an altitude equivalent of about 2,000 m (about 16.7% oxygen concentration in the hypoxic gas composition) for 2-3 hours a night, 5 days a week, for a total of three weeks. During this time, the user typically maintained the hypoxic gas flow rate at between about 5 liters/minute and about 8 liters/minute, and occasionally raised the hypoxic gas flow rate to at least 15 liters/minute for a couple minutes to verify its effects on his blood saturation, and using a pulse oximeter was able to observe his blood oxygen saturation dropping below 90%. After three weeks of the therapy, the user took a week off with no therapy, and then ran a 3km trial run on a grass track (which typically produces much slower times than gravel) and recorded a much faster time of 10 minutes and 15 seconds. The user attributed the surprising and unexpected improvement in his run time to use of the high flow device disclosed herein.

[0407] Unless the context clearly requires otherwise, throughout the description and the claims, the words "comprise", "comprising", and the like, are to be construed in an inclusive sense as opposed to an exclusive or exhaustive sense, that is to say, in the sense of "including, but not limited to".

[0408] Although this disclosure has been described in the context of certain embodiments and examples, it will be understood by those skilled in the art that the disclosure extends beyond the specifically disclosed embodiments to other alternative embodiments and/or uses and obvious modifications and equivalents thereof. In addition, while several variations of the embodiments of the disclosure have been shown and described in detail, other modifications, which are within the scope of this disclosure, will be readily apparent to those of skill in the art. It is also contemplated that various combinations or sub-

combinations of the specific features and aspects of the embodiments may be made and still fall within the scope of the disclosure. For example, features described above in connection with one embodiment can be used with a different embodiment described herein and the combination still fall within the scope of the disclosure. It should be understood that various features and aspects of the disclosed embodiments can be combined with, or substituted for, one another in order to form varying modes of the embodiments of the disclosure. Thus, it is intended that the scope of the disclosure herein should not be limited by the particular embodiments described above. Accordingly, unless otherwise stated, or unless clearly incompatible, each embodiment of this invention may comprise, additional to its essential features described herein, one or more features as described herein from each other embodiment of the invention disclosed herein.

[0409] Features, materials, characteristics, or groups described in conjunction with a particular aspect, embodiment, or example are to be understood to be applicable to any other aspect, embodiment or example described in this section or elsewhere in this specification unless incompatible therewith. All of the features disclosed in this specification (including any accompanying claims, abstract and drawings), and/or all of the steps of any method or process so disclosed, may be combined in any combination, except combinations where at least some of such features and/or steps are mutually exclusive. The protection is not restricted to the details of any foregoing embodiments. The protection extends to any novel one, or any novel combination, of the features disclosed in this specification (including any accompanying claims, abstract and drawings), or to any novel one, or any novel combination, of the steps of any method or process so disclosed.

[0410] Furthermore, certain features that are described in this disclosure in the context of separate implementations can also be implemented in combination in a single implementation. Conversely, various features that are described in the context of a single implementation can also be implemented in multiple implementations separately or in any suitable subcombination. Moreover, although features may be described above as acting in certain combinations, one or more features from a claimed combination can, in some cases, be excised from the combination, and the combination may be claimed as a subcombination or variation of a subcombination.

[0411] Moreover, while operations may be depicted in the drawings or described in the specification in a particular order, such operations need not be performed in the particular order shown or in sequential order, or that all operations be performed, to achieve desirable results. Other operations that are not depicted or described can be incorporated in the example methods and processes. For example, one or more additional operations can be performed before, after, simultaneously, or between any of the described operations. Further, the operations may be rearranged or reordered in other implementations. Those skilled in the art will appreciate that in some embodiments, the actual steps taken in the processes illustrated and/or disclosed may differ from those shown in the figures. Depending on the embodiment, certain of the steps described above may be removed, others may be added. Furthermore, the features and attributes of the specific embodiments disclosed above may be combined in different ways to form additional embodiments, all of which fall within the scope of the present disclosure. Also, the separation of various system components in the implementations described above should not be understood as requiring such separation in all implementations, and it should be understood that the described components and systems can generally be integrated together in a single product or packaged into multiple products.

[0412] For purposes of this disclosure, certain aspects, advantages, and novel features are described herein. Not necessarily all such advantages may be achieved in accordance with any particular embodiment. Thus, for example, those skilled in the art will recognize that the disclosure may be embodied or carried out in a manner that achieves one advantage or a group of advantages as taught herein without necessarily achieving other advantages as may be taught or suggested herein.

[0413] Conditional language, such as “can,” “could,” “might,” or “may,” unless specifically stated otherwise, or otherwise understood within the context as used, is generally intended to convey that certain embodiments include, while other embodiments do not include, certain features, elements, and/or steps. Thus, such conditional language is not generally intended to imply that features, elements, and/or steps are in any way required for one or more embodiments or that one or more embodiments necessarily include logic for deciding, with or without user input or prompting, whether these features, elements, and/or steps are included or are to be performed in any particular embodiment.

[0414] Language of degree used herein, such as the terms “approximately,” “about,” “generally,” and “substantially” as used herein represent a value, amount, or characteristic close to the stated value, amount, or characteristic that still performs a desired function or achieves a desired result. For example, the terms “approximately”, “about”, “generally,” and “substantially” may refer to an amount that is within less than 10% of, within less than 5% of, within less than 1% of, within less than 0.1% of, and within less than 0.01% of the stated amount.

[0415] The scope of the present disclosure is not intended to be limited by the specific disclosures of embodiments in this section or elsewhere in this specification, and may be defined by claims as presented in this section or elsewhere in this specification or as presented in the future. The language of the claims is to be interpreted broadly based on the language employed in the claims and not limited to the examples described in the present specification or during the prosecution of the application, which examples are to be construed as non-exclusive.

WHAT IS CLAIMED IS:

1. A method of providing a hypoxic flow of gases to a user, comprising:
 - providing a hypoxic gas composition;
 - delivering the hypoxic gas composition to the nares of a user via a nasal cannula at a flow rate of at least about 10 liters/minute;
 - measuring at least one physiological parameter of the user; and
 - automatically controlling the delivery of the hypoxic gas composition based on the measured physiological parameter, wherein the measured physiological parameter is blood oxygen saturation.
2. The method of Claim 1, wherein the hypoxic gas composition comprises at least one physiologically inert gas.
3. The method of Claim 1 or 2, wherein the hypoxic gas composition comprises nitrogen.
4. The method of any of the preceding claims, comprising delivering the hypoxic gas composition continuously at a flow rate of at least about 10 liters/minute.
5. The method of any of the preceding claims, further comprising synchronizing delivering the hypoxic gas composition with an inspiratory phase of breathing of the user, wherein the delivering of the hypoxic gas composition is at a flow rate of at least about 10 liters/minute during inspiration.
6. The method of Claim 5, wherein synchronizing comprises increasing the flow rate on inspiration and reducing the flow rate on expiration.
7. The method of any of the preceding claims, wherein delivering the hypoxic gas is sufficient to meet peak inspiratory demand of the user.
8. The method of any of the preceding claims, further comprising heating the hypoxic gas composition prior to reaching the nares of the user.
9. The method of Claim 8, wherein heating the hypoxic gas composition is sufficient to inactivate a pathogen of interest.
10. The method of Claim 9, wherein the pathogen of interest is a human rhinovirus or influenza.
11. The method of Claims 8-10, wherein heating the hypoxic gas composition comprises heating the hypoxic gas composition to between about 30°C and about 43°C.

12. The method of Claims 8-10, wherein heating the hypoxic gas composition comprises heating the hypoxic gas composition to between about 37°C and about 43°C.

13. The method of Claims 8-10, wherein heating the hypoxic gas composition comprises heating the hypoxic gas composition to about 41°C.

14. The method of any of the preceding claims, further comprising humidifying the hypoxic gas composition prior to reaching the nares of the user.

15. The method of any of the preceding claims, comprising heating and humidifying the hypoxic gas composition to a dew point temperature between about 30°C and about 43°C.

16. The method of any of the preceding claims, comprising heating and humidifying the hypoxic gas composition to a dew point temperature between about 37°C and about 43°C.

17. The method of any of the preceding claims, comprising heating and humidifying the hypoxic gas composition to a dew point temperature about 41°C.

18. The method of Claims 14-17, wherein humidifying the hypoxic gas composition comprises humidifying the hypoxic gas composition to a relative humidity of at least about 80%.

19. The method of Claims 14-17, wherein humidifying the hypoxic gas composition comprises humidifying the hypoxic gas composition to a relative humidity of at least about 90%.

20. The method of Claims 14-17, wherein humidifying the hypoxic gas composition comprises humidifying the hypoxic gas composition to a relative humidity of at least about 95%.

21. The method of Claims 14-17, wherein humidifying the hypoxic gas composition comprises humidifying the hypoxic gas composition to a relative humidity of at least about 99%.

22. The method of Claims 14-17, wherein humidifying the hypoxic gas composition comprises humidifying the hypoxic gas composition to a relative humidity of at least about 100%.

23. The method of any of the preceding claims, further comprising mixing ambient air with a source of the hypoxic gas to create the hypoxic gas composition.

24. The method of any of the preceding claims, further comprising measuring inspiratory peak demand of the user; and adjusting the flow rate based upon the measured peak inspiratory demand.

25. The method of any of the preceding claims, wherein an oxygen concentration of the hypoxic gas composition is between about 10% and about 20%.

26. The method of Claims 1-25, wherein an oxygen concentration of the hypoxic gas composition is between about 15% and about 20%.

27. The method of Claims 1-25, wherein an oxygen concentration of the hypoxic gas composition is between about 10.2% and about 20.9%.

28. The method of Claims 1-25, wherein an oxygen concentration of the hypoxic gas composition is between about 11.9% and about 17.4%.

29. The method of Claims 1-25, wherein an oxygen concentration of the hypoxic gas composition is between about 13.8% and about 17.4%.

30. The method of Claims 1-25, wherein an oxygen concentration of the hypoxic gas composition is between about 15.7% and about 16.7%.

31. The method of any of the preceding claims, further comprising outputting the measured physiological parameter in real time to the display.

32. The method of Claims 1-31, wherein the measured physiological parameter further comprises at least one selected from the group consisting of: heart rate, respiratory rate, heart rate variability, and blood pressure.

33. The method of Claims 31-32, further comprising notifying the user when the physiological parameter deviates from a pre-selected range for at least a pre-determined period of time.

34. The method of Claim 33, further comprising altering the pre-selected range based upon individual characteristics of the user.

35. The method of Claims 33-34, wherein notifying the user comprises activating a visual, auditory, or tactile alarm.

36. The method of Claims 1-35-, wherein automatically controlling the delivery of the hypoxic gas comprises titrating the composition of the hypoxic gas composition to achieve a blood oxygen saturation of less than about 95%.

37. The method of Claims 1-35, wherein automatically controlling the delivery of the hypoxic gas comprises titrating the composition of the hypoxic gas composition to achieve a blood oxygen saturation of between about 80% and about 94%.

38. The method of Claims 1-35, wherein automatically controlling the delivery of the hypoxic gas comprises titrating the composition of the hypoxic gas composition to achieve a blood oxygen saturation of between about 85% and about 92%.

39. The method of Claims 1-35, wherein automatically controlling the delivery of the hypoxic gas comprises titrating the composition of the hypoxic gas composition to achieve a blood oxygen saturation of between about 87% and about 90%.

40. The method of Claims 1-35, wherein automatically controlling the delivery of the hypoxic gas comprises titrating the composition of the hypoxic gas composition to achieve a blood oxygen saturation of between about 80% and about 85%.

41. The method of Claims 1-40, wherein automatically controlling the delivery of the hypoxic gas composition comprises adjusting an amount of hypoxic gas mixed into the hypoxic gas composition.

42. The method of Claims 23-41, further comprising sensing the oxygen concentration of the hypoxic gas composition after mixing.

43. The method of Claim 42, further comprising outputting the sensed oxygen concentration in real time to a display.

44. The method of Claim 42-43, further comprising correlating the sensed oxygen concentration to an altitude equivalent using a processor, and outputting the altitude equivalent in real time to the display.

45. The method of Claim 42-43, further comprising obtaining a target oxygen concentration of the hypoxic gas composition based on the blood oxygen saturation.

46. The method of Claim 45, further comprising achieving the target oxygen concentration based on the sensed oxygen concentration after mixing.

47. The method of Claim 46, further comprising achieving the target oxygen concentration by controlling a hypoxic gas inlet valve.

48. The method of any preceding claims, wherein automatically controlling the delivery of the hypoxic gas comprises titrating the composition of the hypoxic gas composition to achieve a simulated altitude.

49. The method of Claim 48, wherein the simulated altitude is between about 0 m and about 5,950 m.

50. The method of Claim 48, wherein the simulated altitude is between about 1,000 m and about 5,000 m.

51. The method of Claim 48, wherein the simulated altitude is between about 1,250 m and about 4,800 m.

52. The method of Claim 48, wherein the simulated altitude is between about 1,500 m and about 3,500 m.

53. The method of Claim 48, wherein the simulated altitude is between about 1,600 m and about 3,000 m.

54. The method of Claim 48, wherein the simulated altitude is between about 2,000 m and about 2,500 m.

55. The method of Claims 36-54, wherein titrating the composition of the hypoxic gas composition comprises altering a flow rate of nitrogen into the hypoxic gas composition.

56. The method of Claims 1-55, wherein the hypoxic gas composition is delivered to the user at a flow rate of at least about 20 liters/minute.

57. The method of Claims 1-55, wherein the hypoxic gas composition is delivered to the user at a flow rate of at least about 30 liters/minute.

58. The method of Claims 1-55, wherein the hypoxic gas composition is delivered to the user at a flow rate of at least about 40 liters/minute.

59. The method of Claims 1-55, wherein the hypoxic gas composition is delivered to the user at a flow rate of at least about 50 liters/minute.

60. The method of Claims 1-55, wherein the hypoxic gas composition is delivered to the user at a flow rate of at least about 60 liters/minute.

61. The method of Claims 1-55, wherein the hypoxic gas composition is delivered to the user at a flow rate of at least about 70 liters/minute.

62. The method of any of the preceding claims, wherein the method is used for a time period sufficient to improve the user's conditioning at high altitude.

63. The method of any of the preceding claims, wherein the method is used for a time period sufficient to stimulate erythropoiesis such that the user's hemoglobin level increases by at least 5% compared to before starting the method.

64. The method of Claims 1-62, wherein the method is used for a time period sufficient to stimulate erythropoiesis such that the user's hemoglobin level increases by at least 10% compared to before starting the method.

65. The method of Claims 1-63, further comprising controlling the delivery of the hypoxic gas using a mobile device in electrical communication with the device.

66. A system configured for providing a hypoxic flow of gases to a user, comprising:

an apparatus comprising a gas flow path, an ambient air inlet, and a hypoxic gas source inlet configured to connect to a hypoxic gas source and configured to create a hypoxic gas composition upon mixing of ambient air and the hypoxic gas;

a user interface comprising a nasal cannula comprising nasal prongs;

a gas flow generation element configured to deliver the hypoxic gas composition to nares of the user at a predetermined flow rate of at least about 10 liters/minute;

a sensor configured to measure a physiological parameter of the user, wherein the physiological parameter is blood oxygen saturation; and

a controller configured to automatically control the delivery of the hypoxic gas composition based on the measured physiological parameter.

67. The system of Claim 66, wherein the gas flow generation element comprises one or more of a blower, a compressor, a pressurized tank, or a gas source in the wall.

68. The system of Claims 66-67, further comprising the hypoxic gas source.

69. The system of Claim 68, wherein the hypoxic gas source comprises a hypoxic gas reservoir.

70. The system of Claims 66-68, wherein the hypoxic gas comprises enriched nitrogen.

71. The system of Claims 66-69, wherein the gas flow generation element is configured to deliver the hypoxic gas composition sufficient to meet the peak inspiratory demand of the user.

72. The system of Claims 66-70, further comprising a heating element configured to heat the hypoxic gas composition prior to reaching the nares of the user.

73. The system of Claim 72, wherein the heating element is configured to heat the hypoxic gas composition to between about 30°C and about 43°C.

74. The system of Claim 72, wherein the heating element is configured to heat the hypoxic gas composition to between about 37°C and about 43°C.

75. The system of Claim 72, wherein the heating element is configured to heat the hypoxic gas composition to about 41°C.

76. The system of Claims 66-75, further comprising a humidification element configured to humidify the hypoxic gas composition prior to reaching the nares of the user.

77. The system of Claims 66-76, wherein the heating element and the humidification element are configured to heat and humidify the hypoxic gas composition to a dew point temperature between about 30°C and about 43°C.

78. The system of Claims 66-77, wherein the heating element and the humidification element are configured to heat and humidify the hypoxic gas composition to a dew point temperature between about 37°C and about 43°C.

79. The system of Claims 66-78, wherein the heating element and the humidification element are configured to heat and humidify the hypoxic gas composition to a dew point temperature about 41°C.

80. The system of Claim 76, wherein the humidification element is configured to humidify the hypoxic gas composition to a relative humidity of at least about 80%.

81. The system of Claim 76, wherein the humidification element is configured to humidify the hypoxic gas composition to a relative humidity of at least about 90%.

82. The system of Claim 76, wherein the humidification element is configured to humidify the hypoxic gas composition to a relative humidity of at least about 95%.

83. The system of Claim 76, wherein the humidification element is configured to humidify the hypoxic gas composition to a relative humidity of at least about 99%.

84. The system of Claim 76, wherein the humidification element is configured to humidify the hypoxic gas composition to a relative humidity of at least about 100%.

85. The system of Claims 66-84, wherein the system comprises a sensor configured to measure a peak inspiratory demand of the user; and the system is configured to adjust the flow rate based upon the measured peak inspiratory demand.

86. The system of Claims 66-85, wherein the system is configured to deliver the hypoxic gas in an oxygen concentration of between about 10% and about 20%.

87. The system of Claims 66-85, wherein the system is configured to deliver the hypoxic gas in an oxygen concentration of between about 15% and about 20%.

88. The system of Claims 66-85, wherein the system is configured to deliver the hypoxic gas in an oxygen concentration of between about 10.2% and about 20.9%.

89. The system of Claims 66-85, wherein the system is configured to deliver the hypoxic gas in an oxygen concentration of between about 11.9% and about 17.4%.

90. The system of Claims 66-85, wherein the system is configured to deliver the hypoxic gas in an oxygen concentration of between about 13.8% and about 17.4%.

91. The system of Claims 66-85, wherein the system is configured to deliver the hypoxic gas in an oxygen concentration of between about 15.7% and about 16.7%.

92. The system of Claims 66-91, wherein the physiological parameter further comprises at least one selected from the group consisting of: heart rate, respiratory rate, heart rate variability, and blood pressure.

93. The system of Claims 66-92, further comprising an alarm configured to notify the user when the physiological parameter deviates from a pre-selected range for at least a pre-determined period of time.

94. The system of Claim 93, wherein the alarm comprises one of a visual, auditory, or tactile alarm.

95. The system of Claims 66-94, wherein the controller is configured to titrate the composition of the hypoxic gas composition to achieve a blood oxygen saturation of the user of less than about 95%.

96. The system of Claims 66-94, wherein the controller is configured to titrate the composition of the hypoxic gas composition to achieve a blood oxygen saturation of the user of between about 80% and about 94%.

97. The system of Claims 66-94, wherein the controller is configured to titrate the composition of the hypoxic gas composition to achieve a blood oxygen saturation of the user of between about 85% and about 92%.

98. The system of Claims 66-94, wherein the controller is configured to titrate the composition of the hypoxic gas composition to achieve a blood oxygen saturation of the user of between about 87% and about 90%.

99. The system of Claims 66-94, wherein the controller is configured to titrate the composition of the hypoxic gas composition to achieve a blood oxygen saturation of the user of between about 80% and about 85%.

100. The system of Claims 66-99, wherein the controller is configured to automatically controlling the delivery of the hypoxic gas composition by adjusting an amount of hypoxic gas mixed into the hypoxic gas composition.

101. The system of Claims 66-100, further comprising a sensor configured to sense the oxygen concentration of the hypoxic gas composition.

102. The system of Claim 101, further comprising a display, wherein the system is configured to output the sensed oxygen concentration in real time to the display.

103. The system of Claims 101-102, wherein the system is further configured to correlate the sensed oxygen concentration to an altitude equivalent using a processor, and outputting the altitude equivalent in real time to the display.

104. The system of Claims 101-102, wherein the system is further configured to obtain a target oxygen concentration of the hypoxic gas composition based on the blood oxygen saturation.

105. The system of Claim 104, wherein the system is further configured to achieve the target oxygen concentration based on the sensed oxygen concentration.

106. The system of Claim 105, wherein the system is further configured to achieve the target oxygen concentration by controlling a hypoxic gas inlet valve.

107. The system of Claim 85-106, wherein the controller is configured to alter a flow rate of the hypoxic gas into the hypoxic gas composition.

108. The system of Claims 66-107, wherein the gas flow generation element is configured to deliver the hypoxic gas composition to the nares of the user at a predetermined flow rate of at least about 20 liters/minute.

109. The system of Claims 66-107, wherein the gas flow generation element is configured to deliver the hypoxic gas composition to the nares of the user at a predetermined flow rate of at least about 30 liters/minute.

110. The system of Claims 66-107, wherein the gas flow generation element is configured to deliver the hypoxic gas composition to nares of the user at a predetermined flow rate of at least about 40 liters/minute.

111. The system of Claims 66-107, wherein the gas flow generation element is configured to deliver the hypoxic gas composition to nares of the user at a predetermined flow rate of at least about 50 liters/minute.

112. The system of Claims 66-107, wherein the gas flow generation element is configured to deliver the hypoxic gas composition to nares of the user at a predetermined flow rate of at least about 60 liters/minute.

113. The system of Claims 66-107, wherein the gas flow generation element is configured to deliver the hypoxic gas composition to nares of the user at a predetermined flow rate of at least about 70 liters/minute.

114. The system of Claims 66-113, wherein the nasal cannula is non-sealed.

115. The system of Claims 66-114, wherein the system is a high flow device.

116. The system of Claim 115, wherein the high flow device is portable.

117. A method of providing a hypoxic flow of gases to a user, comprising:

providing a hypoxic gas composition;

humidifying and heating the hypoxic gas composition

to a dew point temperature of between about 30°C and about 45°C prior to reaching the airway of the user; and

delivering the heated, humidified hypoxic gas composition via a user interface in proximity to an airway of the user.

118. The method of Claim 117, comprising delivering the heated, humidified hypoxic gas composition via a nasal cannula to the user's nares.

119. The method of Claim 117, comprising delivering the heated, humidified hypoxic gas composition via a mask.

120. The method of Claims 117-119, wherein the hypoxic gas composition comprises at least one physiologically inert gas.

121. The method of Claim 120, wherein the hypoxic gas composition comprises nitrogen.

122. The method of Claims 117-121, comprising delivering the hypoxic gas composition continuously at a flow rate of at least about 10 liters/minute.

123. The method of Claims 117-121, comprising delivering the hypoxic gas composition continuously at a flow rate that meets the user's inspiratory demand.

124. The method of Claims 117-121, further comprising synchronizing delivering the hypoxic gas composition with an inspiratory phase of breathing of the user, wherein the delivering of the hypoxic gas composition is at a flow rate of at least about 10 liters/minute during inspiration.

125. The method of Claims 117-121, further comprising synchronizing delivering the hypoxic gas composition with an inspiratory phase of breathing of the user, wherein the delivering of the hypoxic gas composition is at a flow rate that meets the user's inspiratory demand.

126. The method of Claims 117-121, further comprising synchronizing delivering the hypoxic gas composition with a phase of breathing of the user, wherein the delivering of the hypoxic gas composition is at a flow rate of less than about 10 liters/minute during at least a portion of expiration.

127. The method of Claims 124-126, wherein synchronizing comprises increasing the flow rate on inspiration and reducing the flow rate on expiration.

128. The method of Claims 117-127, wherein heating the hypoxic gas composition is sufficient to inactivate a pathogen of interest.

129. The method of Claim 128, wherein the pathogen of interest is a human rhinovirus or influenza.

130. The method of Claims 117-129, wherein humidifying and heating the hypoxic gas composition comprises humidifying and heating the hypoxic gas composition to a dew point temperature between about 37°C and about 45°C.

131. The method of Claims 117-129, wherein humidifying and heating the hypoxic gas composition comprises humidifying and heating the hypoxic gas composition to a dew point temperature about 41°C.

132. The method of Claims 117-131, further comprising humidifying the hypoxic gas composition to a relative humidity of at least about 80%.

133. The method of Claims 117-131, further comprising humidifying the hypoxic gas composition to a relative humidity of at least about 90%.

134. The method of Claims 117-131, further comprising humidifying the hypoxic gas composition to a relative humidity of at least about 95%.

135. The method of Claims 117-131, further comprising humidifying the hypoxic gas composition to a relative humidity of at least about 99%.

136. The method of Claims 117-131, further comprising humidifying the hypoxic gas composition to a relative humidity of at least about 100%.

137. The method of Claims 117-136, further comprising mixing ambient air with a source of enriched nitrogen to create the hypoxic gas composition.

138. The method of Claims 117-137, further comprising measuring peak inspiratory demand of the user; and adjusting the flow rate based upon the measured peak inspiratory demand.

139. The method of Claims 117-138, wherein an oxygen concentration of the hypoxic gas composition is between about 10% and about 20%.

140. The method of Claims 117-138, wherein an oxygen concentration of the hypoxic gas composition is between about 15% and about 20%.

141. The method of Claims 117-138, wherein an oxygen concentration of the hypoxic gas composition is between about 10.2% and about 20.9%.

142. The method of Claims 117-138, wherein an oxygen concentration of the hypoxic gas composition is between about 11.9% and about 17.4%.

143. The method of Claims 117-138, wherein an oxygen concentration of the hypoxic gas composition is between about 13.8% and about 17.4%.

144. The method of Claims 117-138, wherein an oxygen concentration of the hypoxic gas composition is between about 15.7% and about 16.7%.

145. The method of Claims 117-144, further comprising measuring at least one physiological parameter of the user; and automatically controlling the delivery of the hypoxic gas composition based on the measured physiological parameter.

146. The method of Claim 145, further comprising outputting the measured physiological parameter in real time to the display.

147. The method of Claims 145-146, wherein the measured physiological parameter is blood oxygen saturation.

148. The method of Claim 147, wherein the measured physiological parameter further comprises at least one selected from the group consisting of: heart rate, respiratory rate, heart rate variability, and blood pressure.

149. The method of Claims 145-148, further comprising notifying the user when the physiological parameter deviates from a pre-selected range for at least a pre-determined period of time.

150. The method of Claim 149, further comprising altering the pre-selected range based upon individual characteristics of the user.

151. The method of Claims 149-150, wherein notifying the user comprises activating a visual, auditory, or tactile alarm.

152. The method of Claims 145-151, wherein automatically controlling the delivery of the hypoxic gas comprises titrating the composition of the hypoxic gas composition to achieve a blood oxygen saturation of less than about 95%.

153. The method of Claims 145-152, wherein automatically controlling the delivery of the hypoxic gas comprises titrating the composition of the hypoxic gas composition to achieve a blood oxygen saturation of between about 80% and about 94%.

154. The method of Claims 145-153, wherein automatically controlling the delivery of the hypoxic gas comprises titrating the composition of the hypoxic gas composition to achieve a blood oxygen saturation of between about 85% and about 92%.

155. The method of Claims 145-154, wherein automatically controlling the delivery of the hypoxic gas comprises titrating the composition of the hypoxic gas composition to achieve a blood oxygen saturation of between about 87% and about 90%.

156. The method of Claims 145-153, wherein automatically controlling the delivery of the hypoxic gas comprises titrating the composition of the hypoxic gas composition to achieve a blood oxygen saturation of between about 80% and about 85%.

157. The method of Claims 145-156, wherein automatically controlling the delivery of the hypoxic gas composition comprises adjusting an amount of hypoxic gas mixed into the hypoxic gas composition.

158. The method of Claim 157, further comprising sensing the oxygen concentration of the hypoxic gas composition after mixing.

159. The method of Claim 158, further comprising outputting the sensed oxygen concentration in real time to a display.

160. The method of Claim 158-159, further comprising correlating the sensed oxygen concentration to an altitude equivalent using a processor, and outputting the altitude equivalent in real time to the display.

161. The method of Claims 147-160, further comprising obtaining a target oxygen concentration of the hypoxic gas composition based on the blood oxygen saturation.

162. The method of Claim 161, further comprising achieving the target oxygen concentration based on the sensed oxygen concentration after mixing.

163. The method of Claim 162, further comprising achieving the target oxygen concentration by controlling a hypoxic gas inlet valve.

164. The method of Claims 117-163, wherein the hypoxic gas composition is delivered to the user at a flow rate of at least about 20 liters/minute.

165. The method of Claims 117-163, wherein the hypoxic gas composition is delivered to the user at a flow rate of at least about 30 liters/minute.

166. The method of Claims 117-163, wherein the hypoxic gas composition is delivered to the user at a flow rate of at least about 40 liters/minute.

167. The method of Claims 117-163, wherein the hypoxic gas composition is delivered to the user at a flow rate of at least about 50 liters/minute.

168. The method of Claims 117-163, wherein the hypoxic gas composition is delivered to the user at a flow rate of at least about 60 liters/minute.

169. The method of Claims 117-163, wherein the hypoxic gas composition is delivered to the user at a flow rate of at least about 70 liters/minute.

170. The method of Claims 117-169, wherein the method is used for a time period sufficient to improve the user's conditioning at high altitude.

171. The method of Claims 117-170, wherein the method is used for a time period sufficient to stimulate erythropoiesis such that the user's hemoglobin level increases by at least 5% compared to before starting the method.

172. The method of Claims 117-170, wherein the method is used for a time period sufficient to stimulate erythropoiesis such that the user's hemoglobin level increases by at least 10% compared to before starting the method.

173. The method of Claims 117-172, wherein the user interface comprises a nasal cannula.

174. The method of Claim 173, wherein the nasal cannula is non-sealed.

175. A system configured for providing a hypoxic flow of gases to a user, comprising:

an apparatus comprising a gas flow path, an ambient air inlet, and a hypoxic gas source inlet configured to connect to a hypoxic gas source and configured to create a hypoxic gas composition upon mixing of ambient air and the hypoxic gas;

a gas flow generation element configured to deliver the hypoxic gas composition;

a humidification element configured to humidify the hypoxic gas composition prior to reaching the nares of the user;

a heating element within the gas flow path,

wherein the humidification element and the heating element are configured to heat and humidify the hypoxic gas composition to a dew point temperature of between about 30°C and about 45°C; and

a user interface.

176. The system of Claim 175, wherein the humidification element comprises a humidification chamber.

177. The system of Claims 175 or 176, wherein the gas flow generation element comprises one or more of a blower, a compressor, a pressurized tank, or a gas source in the wall.

178. The system of Claims 175-177, wherein the heating element comprises a heater plate.

179. The system of Claims 175-178, wherein the heating element comprises a heater wire.

180. The system of Claims 175-179, wherein the user interface comprises nasal prongs.

181. The system of Claims 175-179, wherein the user interface comprises a mask.

182. The system of Claims 175-181, wherein the gas flow generation element is configured to deliver the hypoxic gas composition to the user at a predetermined flow rate of at least about 10 liters/minute.

183. The system of Claims 175-182, further comprising the hypoxic gas source.

184. The system of Claim 183, wherein the hypoxic gas source comprises a reservoir.

185. The system of Claims 175-184, wherein the hypoxic gas comprises a physiologically inert gas.

186. The system of Claims 175-185, wherein the hypoxic gas comprises enriched nitrogen.

187. The system of Claims 175-186, wherein the gas flow generation element is configured to deliver the hypoxic gas composition to the user at a predetermined flow rate that meets the user's inspiratory demand.

188. The system of Claim 187, wherein the gas flow generation element is configured to deliver the hypoxic gas composition sufficient to meet the peak inspiratory demand of the user.

189. The system of Claims 175-188, wherein the heating element and the humidification element are configured to heat and humidify the hypoxic gas composition to a dew point temperature between about 30°C and about 43°C.

190. The system of Claims 175-188, wherein the heating element and the humidification element are configured to heat and humidify the hypoxic gas composition to between a dew point temperature about 37°C and about 43°C.

191. The system of Claims 175-188, wherein the heating element and the humidification element are configured to heat and humidify the hypoxic gas composition to a dew point temperature about 41°C.

192. The system of Claims 175-191, wherein the humidification element is configured to humidify the hypoxic gas composition to a relative humidity of at least about 80%.

193. The system of Claims 175-191, wherein the humidification element is configured to humidify the hypoxic gas composition to a relative humidity of at least about 90%.

194. The system of Claims 175-191, wherein the humidification element is configured to humidify the hypoxic gas composition to a relative humidity of at least about 95%.

195. The system of Claims 175-191, wherein the humidification element is configured to humidify the hypoxic gas composition to a relative humidity of at least about 99%.

196. The system of Claims 175-191, wherein the humidification element is configured to humidify the hypoxic gas composition to a relative humidity of at least about 100%.

197. The system of Claims 175-196, wherein the system comprises a sensor configured to measure a peak inspiratory demand of the user; and the system is configured to adjust the flow rate based upon the measured peak inspiratory demand.

198. The system of Claims 175-197, wherein the system is configured to deliver the hypoxic gas in an oxygen concentration of between about 10% and about 20%.

199. The system of Claims 175-197, wherein the system is configured to deliver the hypoxic gas in an oxygen concentration of between about 15% and about 20%.

200. The system of Claims 175-197, wherein the system is configured to deliver the hypoxic gas in an oxygen concentration of between about 10.2% and about 20.9%.

201. The system of Claims 175-197, wherein the system is configured to deliver the hypoxic gas in an oxygen concentration of between about 11.9% and about 17.4%.

202. The system of Claims 175-197, wherein the system is configured to deliver the hypoxic gas in an oxygen concentration of between about 13.8% and about 17.4%.

203. The system of Claims 175-197, wherein the system is configured to deliver the hypoxic gas in an oxygen concentration of between about 15.7% and about 16.7%.

204. The system of Claims 175-203, further comprising a sensor configured to measure a physiological parameter of the user; and a controller configured to automatically control the delivery of the hypoxic gas composition based on the measured physiological parameter.

205. The system of Claim 204, wherein the physiological parameter is blood oxygen saturation.

206. The system of Claim 205, wherein the physiological parameter further comprises at least one selected from the group consisting of: heart rate, respiratory rate, heart rate variability, and blood pressure.

207. The system of Claims 204-206, further comprising an alarm configured to notify the user when the physiological parameter deviates from a pre-selected range for at least a pre-determined period of time.

208. The system of Claim 207, wherein the alarm comprises one of a visual, auditory, or tactile alarm.

209. The system of Claims 175-208, wherein the controller is configured to titrate the composition of the hypoxic gas composition to achieve a blood oxygen saturation of the user of less than about 95%.

210. The system of Claims 175-209, wherein the controller is configured to titrate the composition of the hypoxic gas composition to achieve a blood oxygen saturation of the user of between about 80% and about 94%.

211. The system of Claims 175-210, wherein the controller is configured to titrate the composition of the hypoxic gas composition to achieve a blood oxygen saturation of the user of between about 85% and about 92%.

212. The system of Claims 175-211, wherein the controller is configured to titrate the composition of the hypoxic gas composition to achieve a blood oxygen saturation of the user of between about 87% and about 90%.

213. The system of Claims 175-212, wherein the controller is configured to titrate the composition of the hypoxic gas composition to achieve a blood oxygen saturation of the user of between about 80% and about 85%.

214. The system of Claims 175-213, wherein the controller is configured to automatically control the delivery of the hypoxic gas composition by adjusting an amount of hypoxic gas mixed into the hypoxic gas composition.

215. The system of Claim 214, further comprising a sensor configured to sense the oxygen concentration of the hypoxic gas composition.

216. The system of Claim 215, further comprising a display, wherein the system is configured to output the sensed oxygen concentration in real time to the display.

217. The system of Claims 215-216, wherein the system is further configured to correlate the sensed oxygen concentration to an altitude equivalent using a processor, and outputting the altitude equivalent in real time to the display.

218. The system of Claims 205-517, wherein the system is further configured to obtain a target oxygen concentration of the hypoxic gas composition based on the blood oxygen saturation.

219. The system of Claim 218, wherein the system is further configured to achieve the target oxygen concentration based on the sensed oxygen concentration.

220. The system of Claim 219, wherein the system is further configured to achieve the target oxygen concentration by controlling a hypoxic gas inlet valve.

221. The system of Claims 214-220, wherein the controller is configured to alter a flow rate of the hypoxic gas into the hypoxic gas composition.

222. The system of Claims 175-221, wherein the gas flow generation element is configured to deliver the hypoxic gas composition at a predetermined flow rate of at least about 20 liters/minute.

223. The system of Claims 175-221, wherein the gas flow generation element is configured to deliver the hypoxic gas composition at a predetermined flow rate of at least about 30 liters/minute.

224. The system of Claims 175-221, wherein the gas flow generation element is configured to deliver the hypoxic gas composition at a predetermined flow rate of at least about 40 liters/minute.

225. The system of Claims 175-221, wherein the gas flow generation element is configured to deliver the hypoxic gas composition at a predetermined flow rate of at least about 50 liters/minute.

226. The system of Claims 175-221, wherein the gas flow generation element is configured to deliver the hypoxic gas composition at a predetermined flow rate of at least about 60 liters/minute.

227. The system of Claims 175-221, wherein the gas flow generation element is configured to deliver the hypoxic gas composition at a predetermined flow rate of at least about 70 liters/minute.

228. The system of Claims 175-227, wherein the user interface comprises a nasal cannula.

229. The system of Claim 228, wherein the nasal cannula is non-sealed.

230. The system of Claims 175-229, wherein the system is a high flow device.

231. The system of Claim 230, wherein the high flow device is portable.
232. A method of providing altitude or fitness training to a user, comprising:
simulating a higher altitude by providing a hypoxic gas composition;
humidifying the hypoxic gas composition; and
delivering the humidified, hypoxic gas composition via a user interface in proximity to an airway of a user.
233. A system configured for providing altitude or fitness training to a user, comprising:
an apparatus comprising a gas flow path, an ambient air inlet, and a hypoxic gas source inlet configured to connect to a hypoxic gas source and configured to create a hypoxic gas composition upon mixing of ambient air and the hypoxic gas;
a gas flow generation element configured to deliver the hypoxic gas composition to an airway of the user so as to simulate a higher altitude;
a humidification element within the gas flow path configured to humidify the hypoxic gas composition prior to reaching the airway of the user; and
a user interface.
234. The system of Claim 233, further comprising a screen configured to display an altitude equivalent of the altitude or fitness training.
235. The system of Claim 234, wherein the altitude equivalent is based on an oxygen concentration.
236. The system of Claim 235, wherein the oxygen concentration is an FdO_2 set point or a sensed oxygen concentration.
237. The system of Claim 233, further comprising a screen configured to display an SpO_2 of the user.
238. The system of Claims 234-237, wherein the screen comprises a touchscreen.
239. The system of Claims 233-238, further comprising user input devices for the user to select an altitude equivalent of the altitude or fitness training.
240. The system of Claim 239, wherein the user input devices comprise one or more buttons.
241. The system of Claim 239, wherein the user input devices comprise a touchscreen.

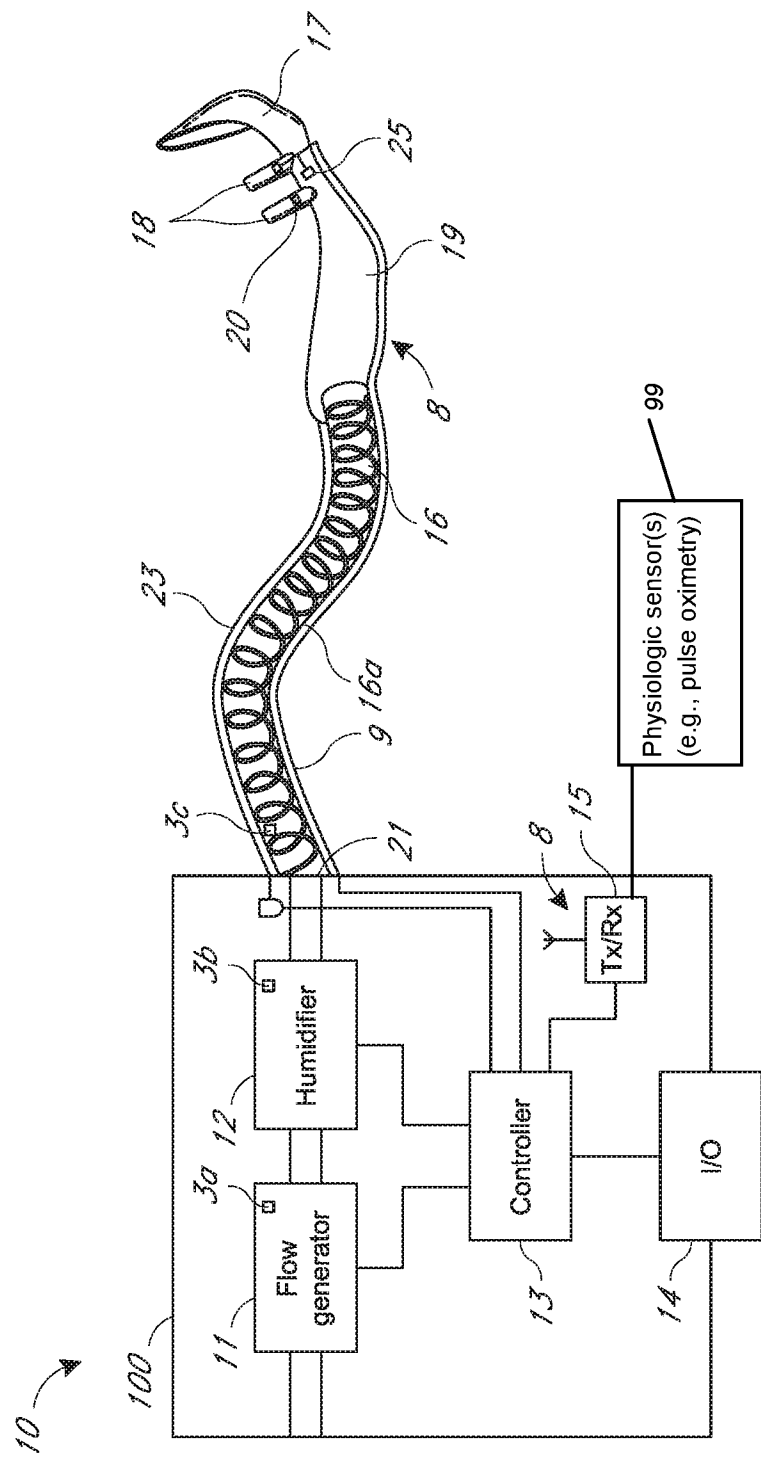


FIG. 1

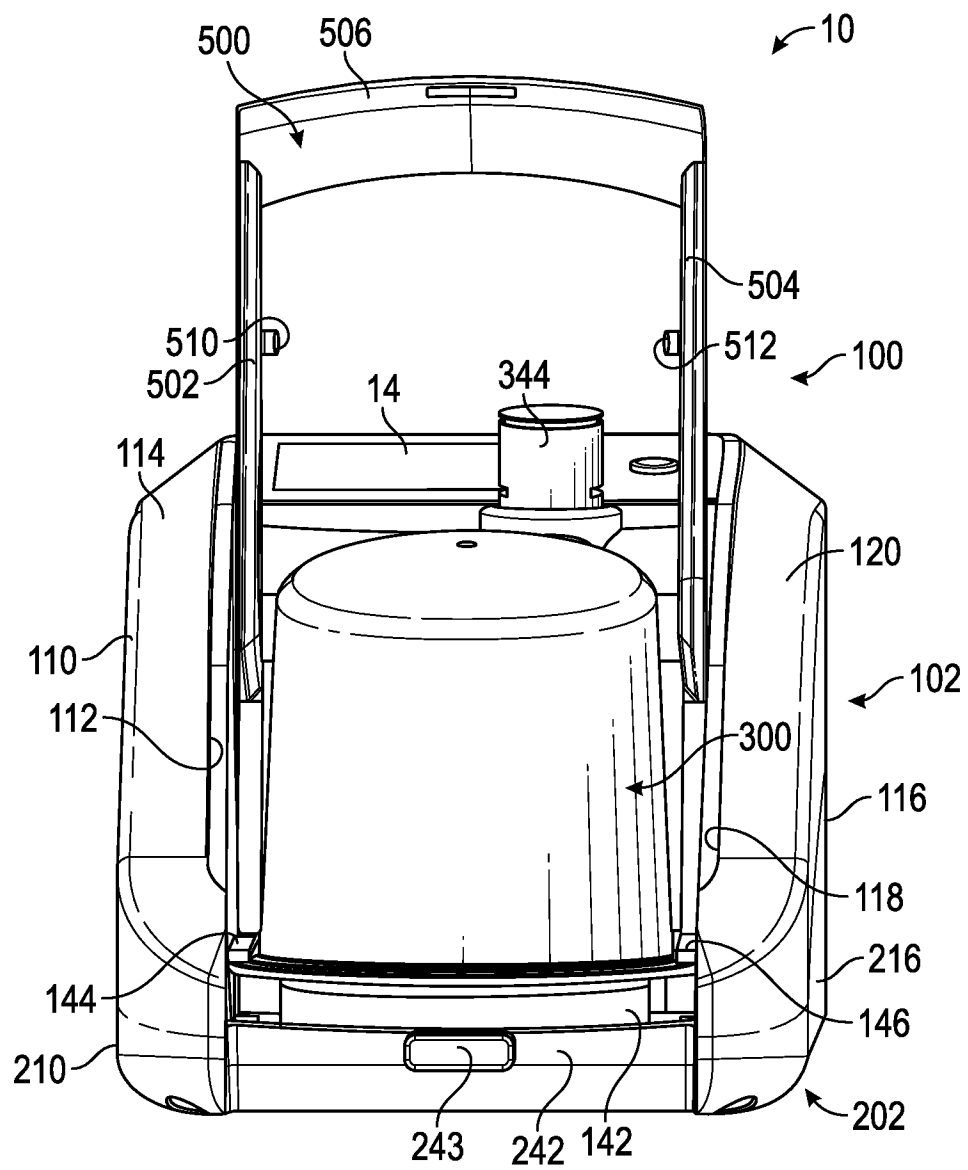


FIG. 2

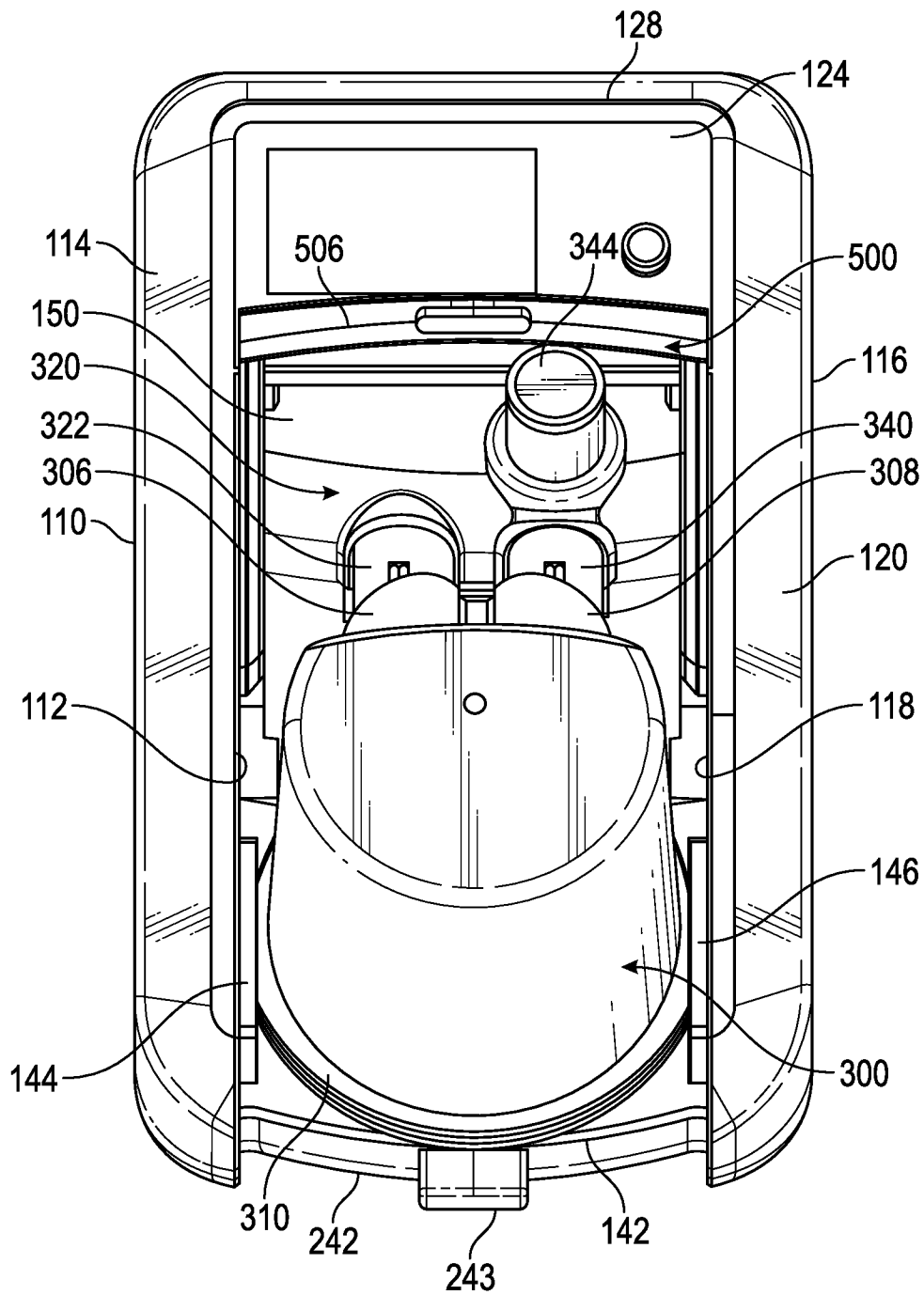
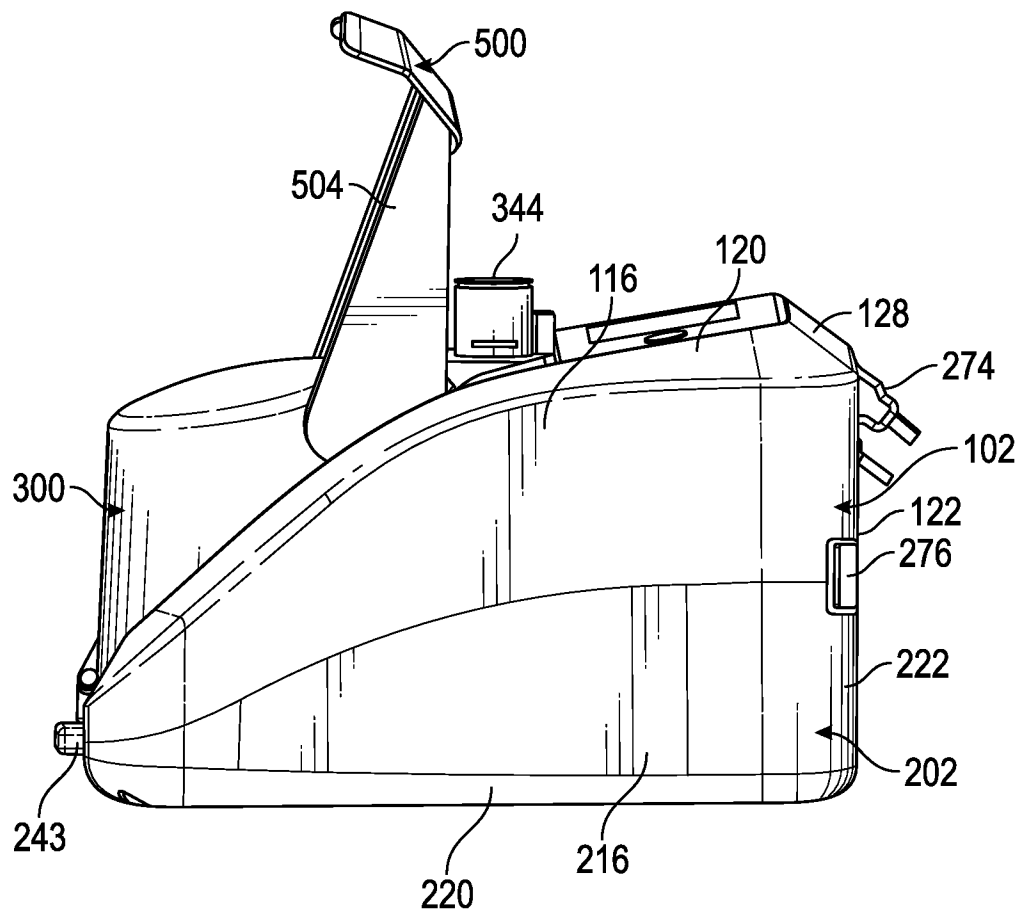
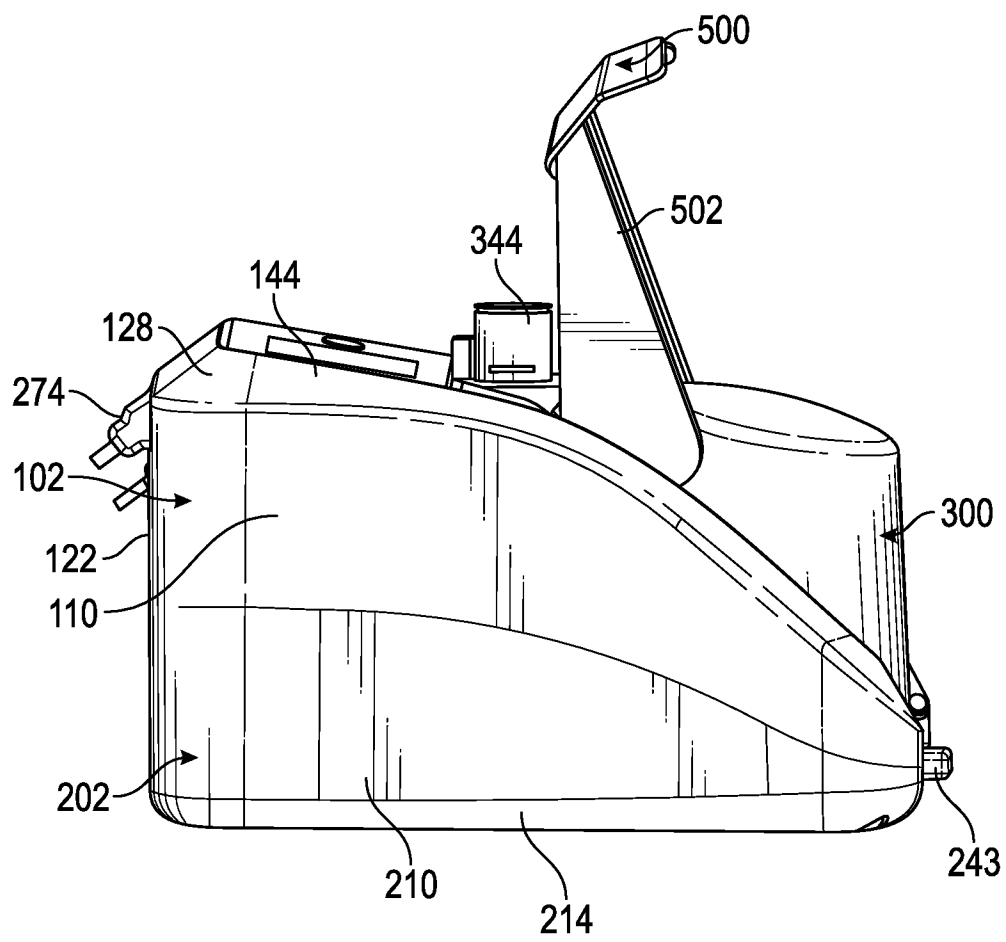


FIG. 3

*FIG. 4*

*FIG. 5*

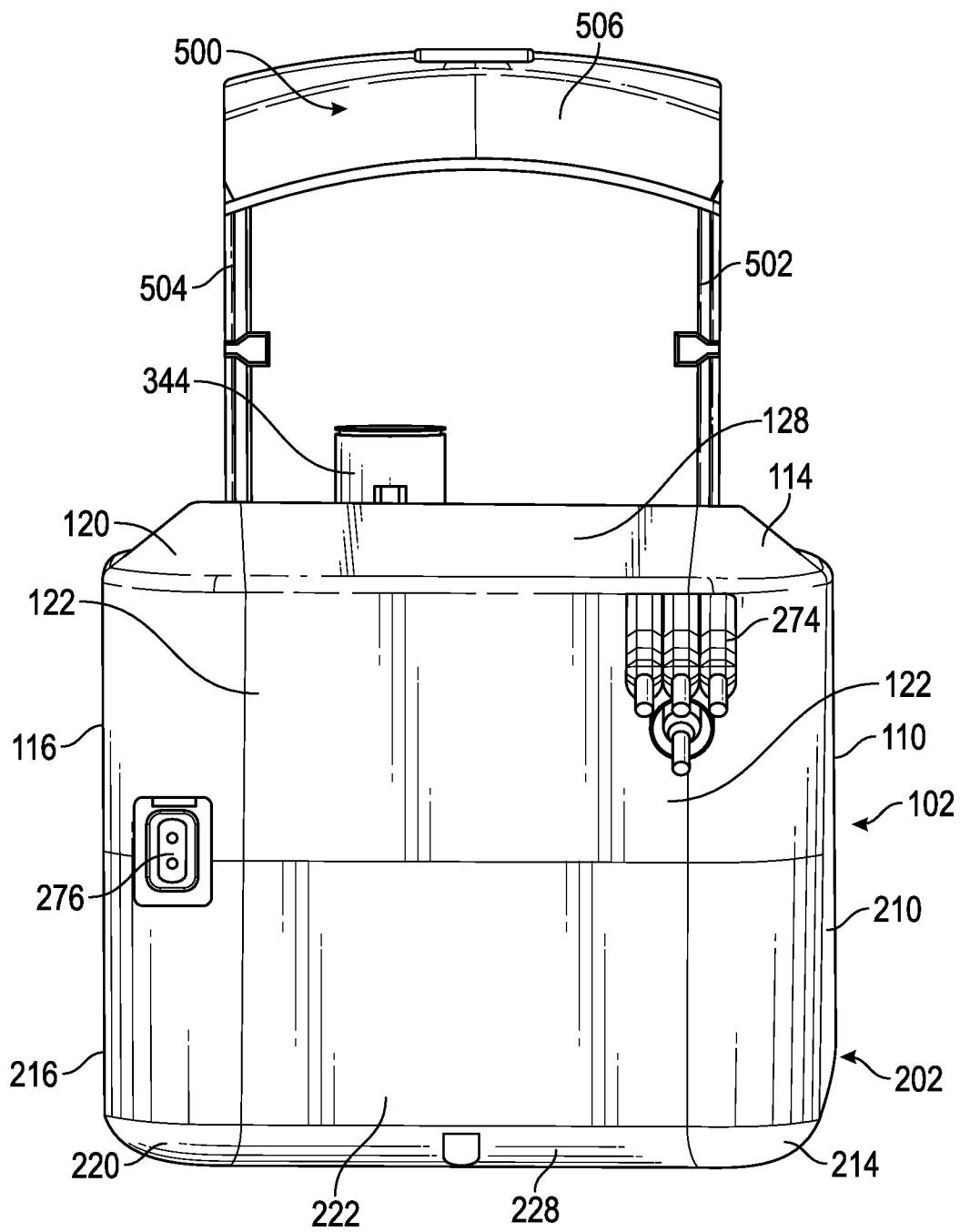


FIG. 6

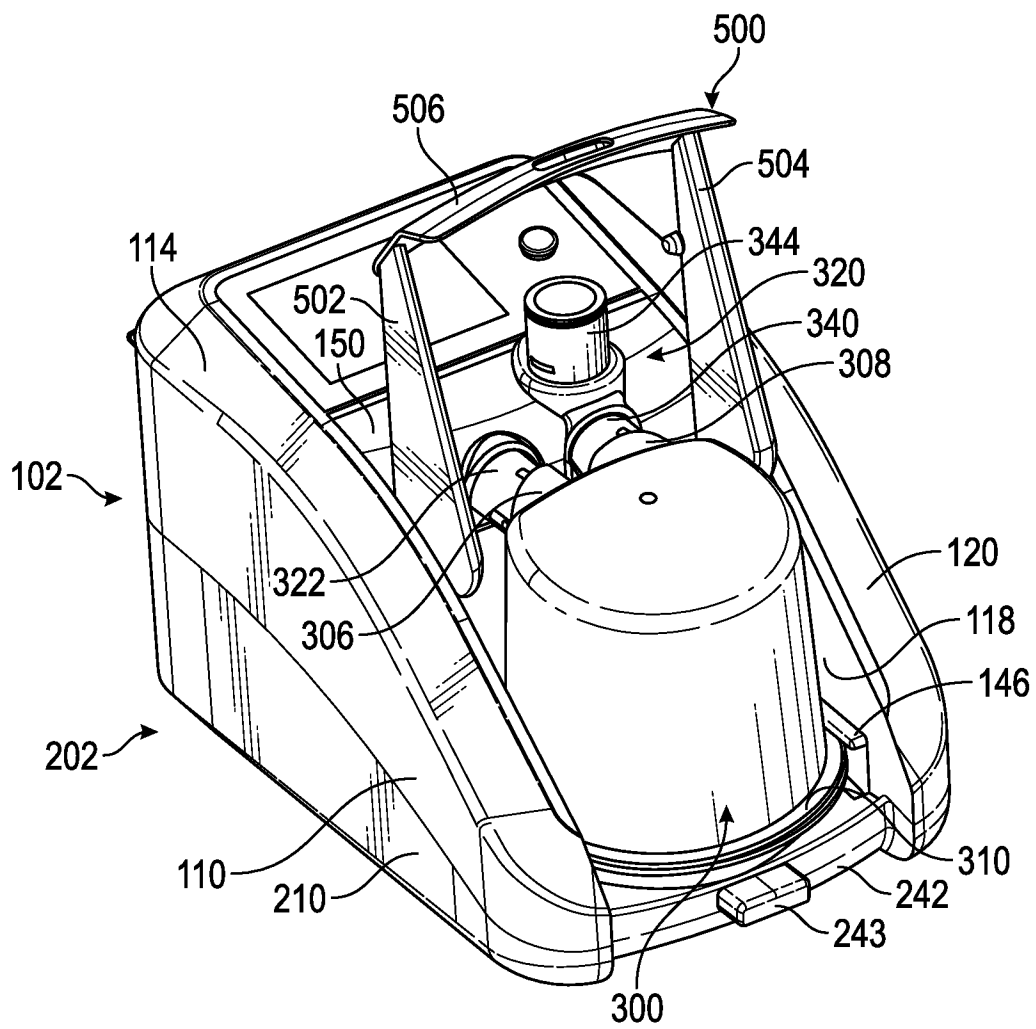


FIG. 7

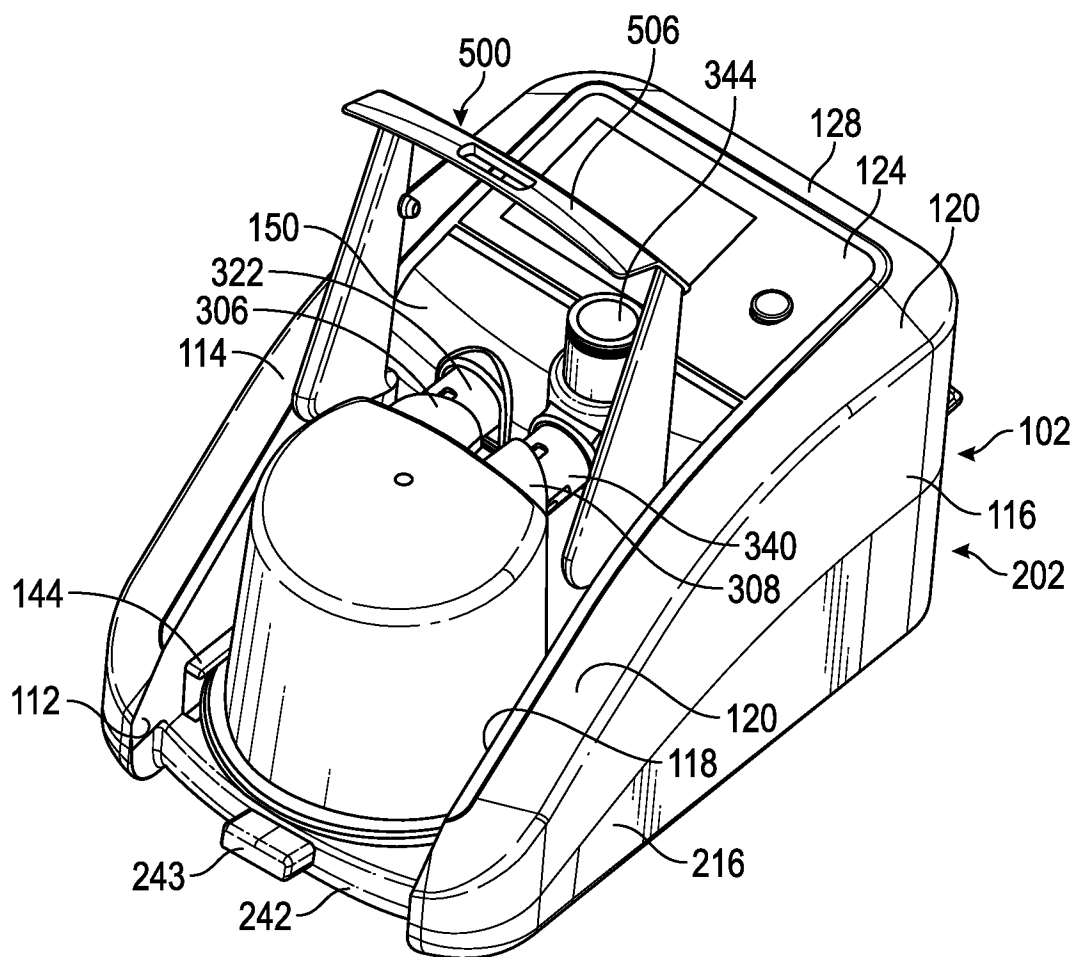


FIG. 8

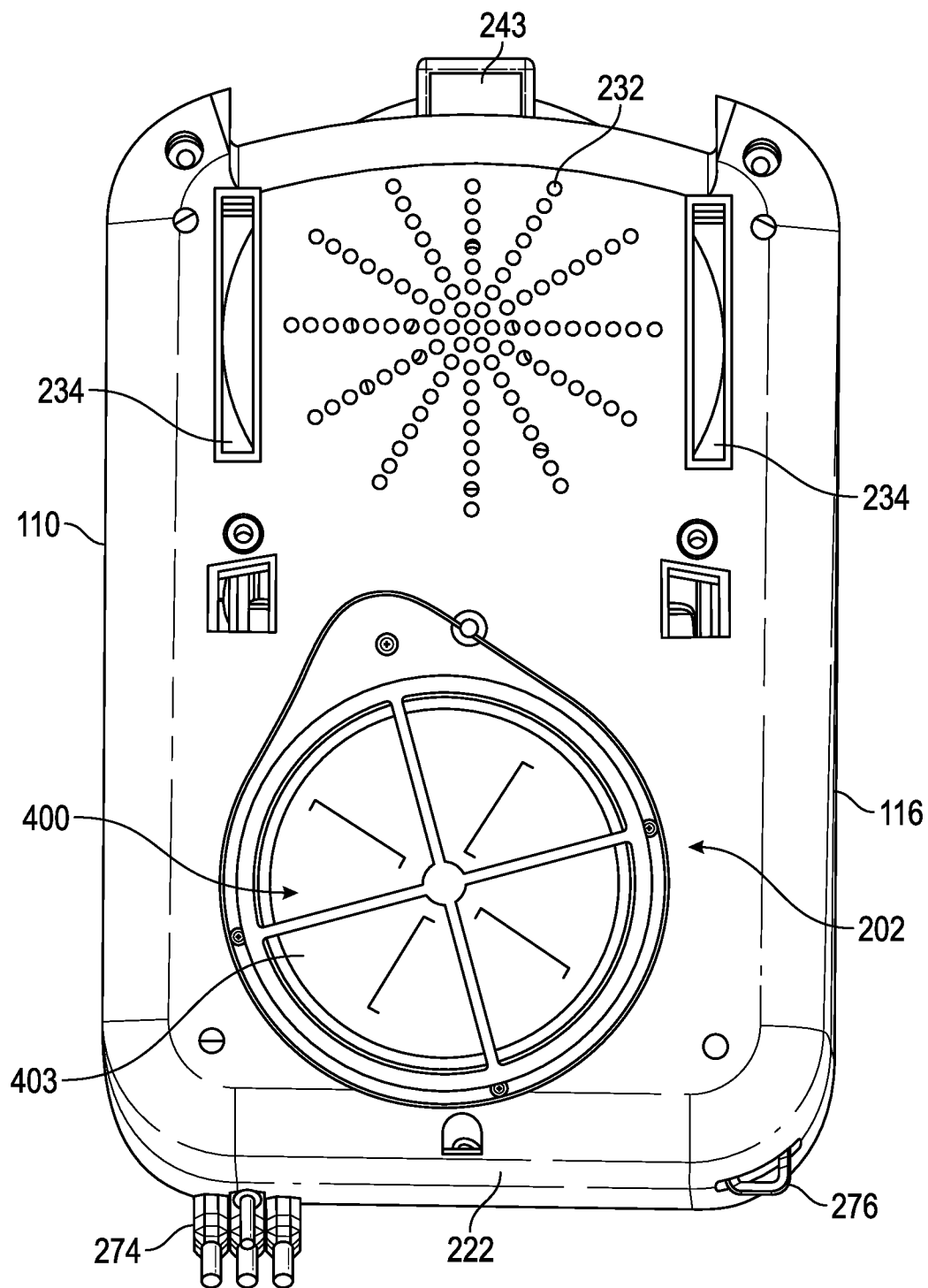
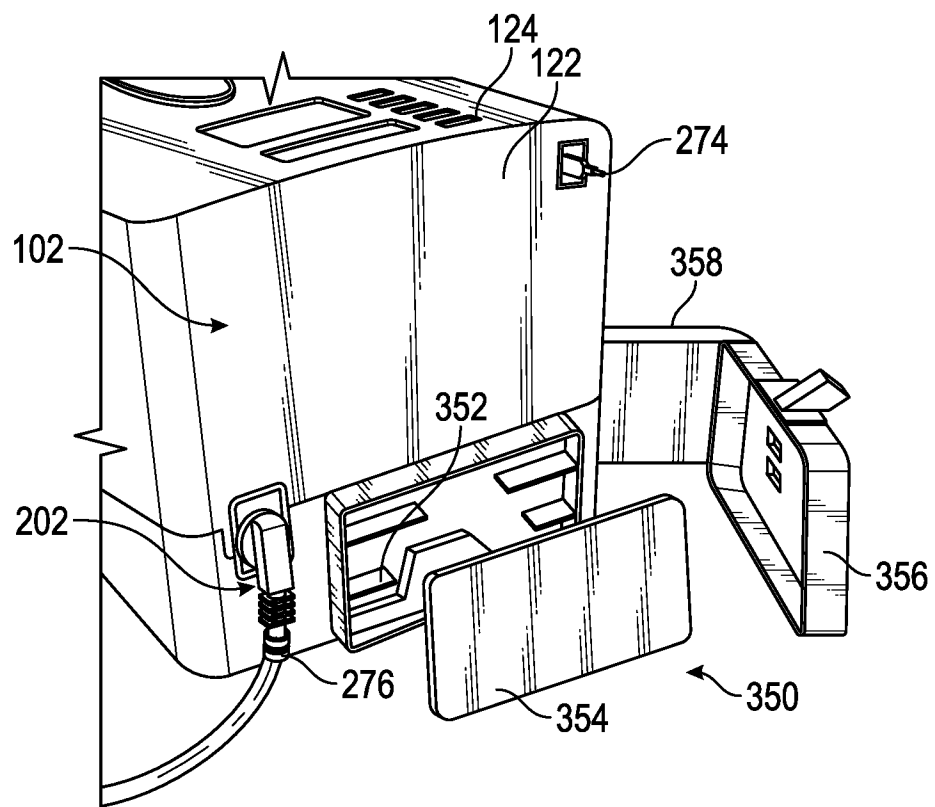


FIG. 9

*FIG. 10*

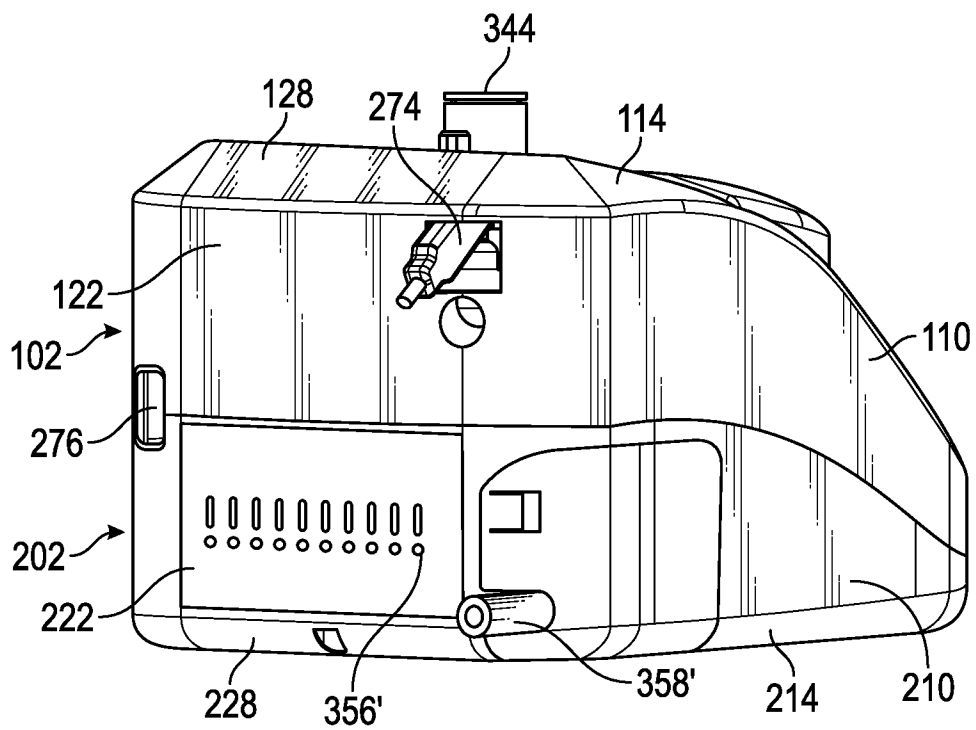


FIG. 11

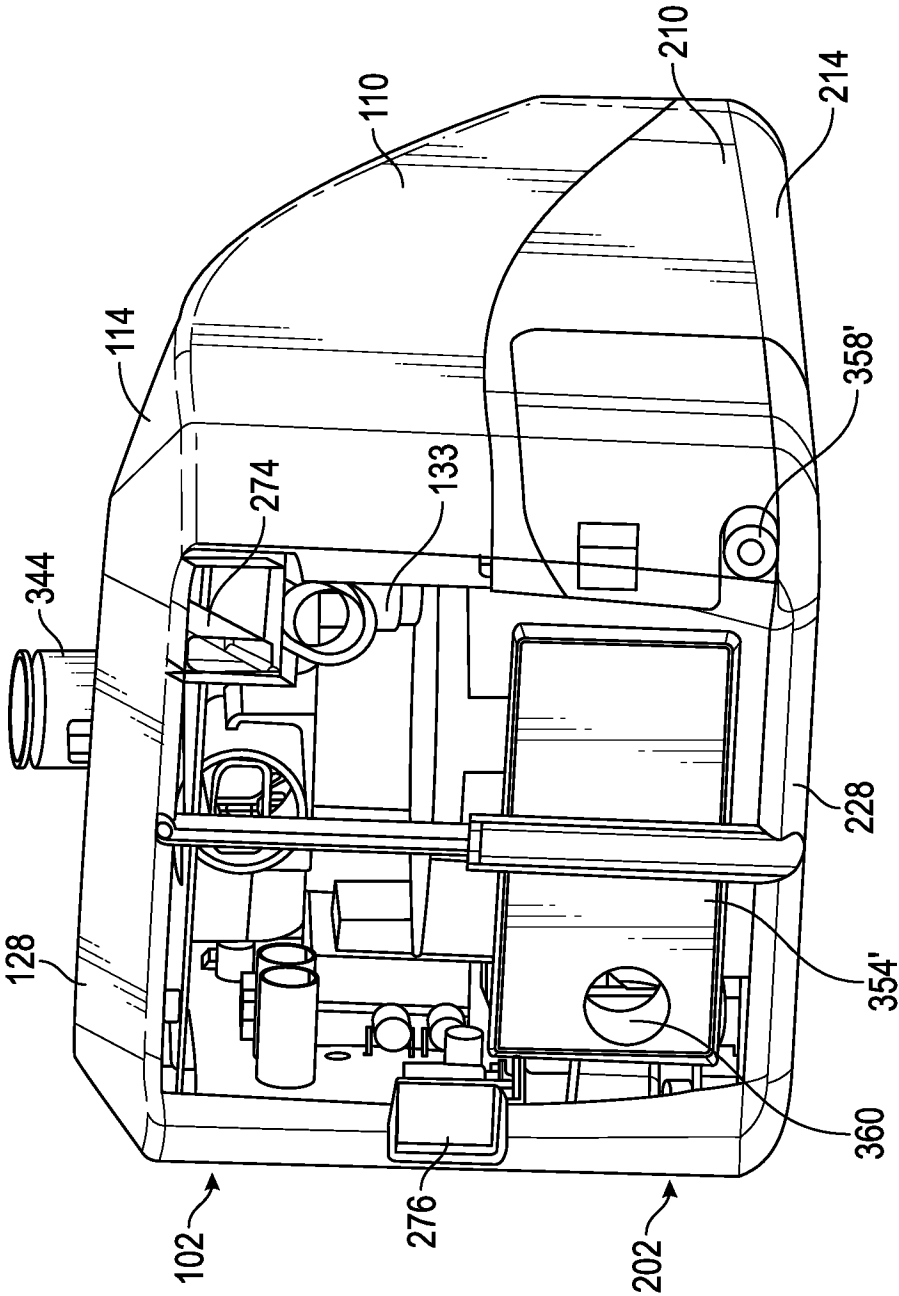


FIG. 12

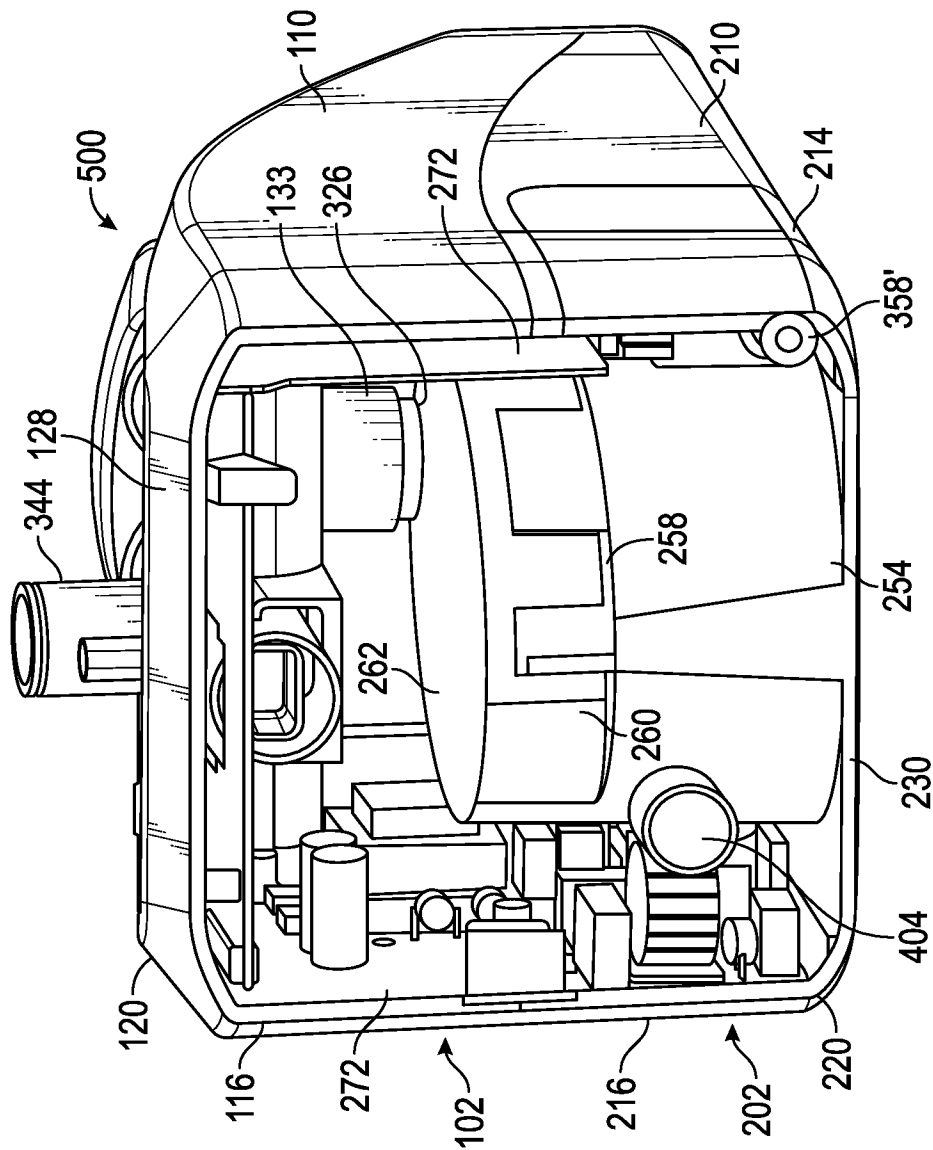


FIG. 13

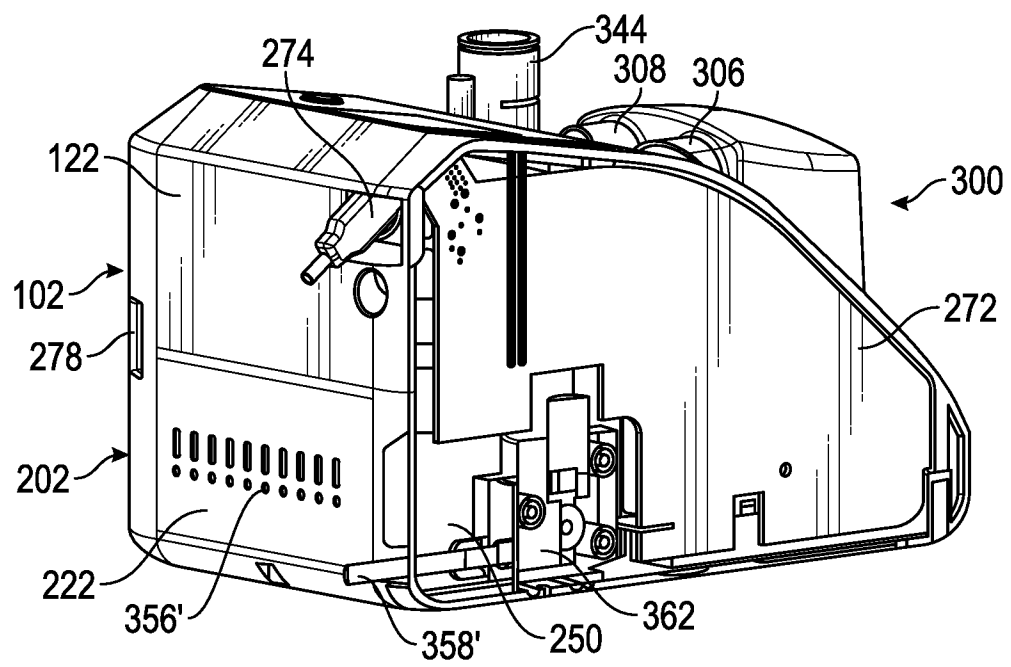
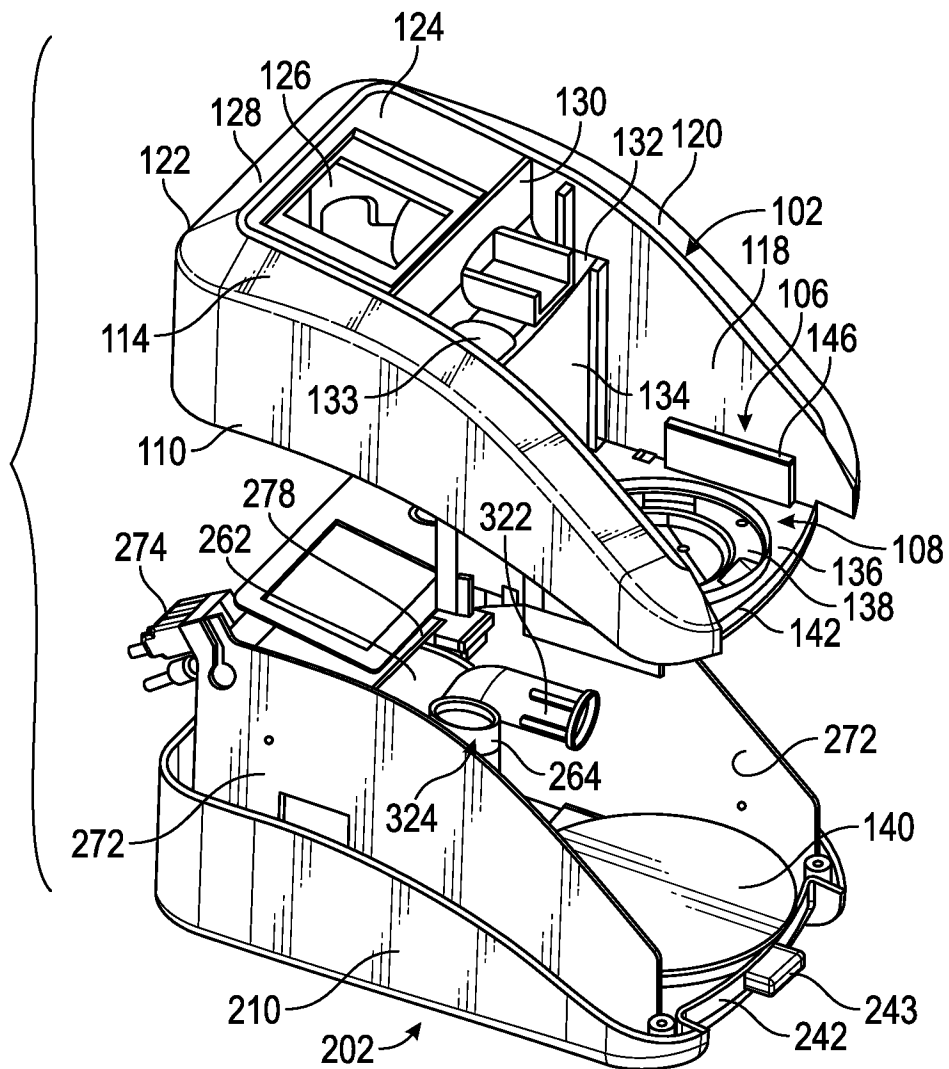
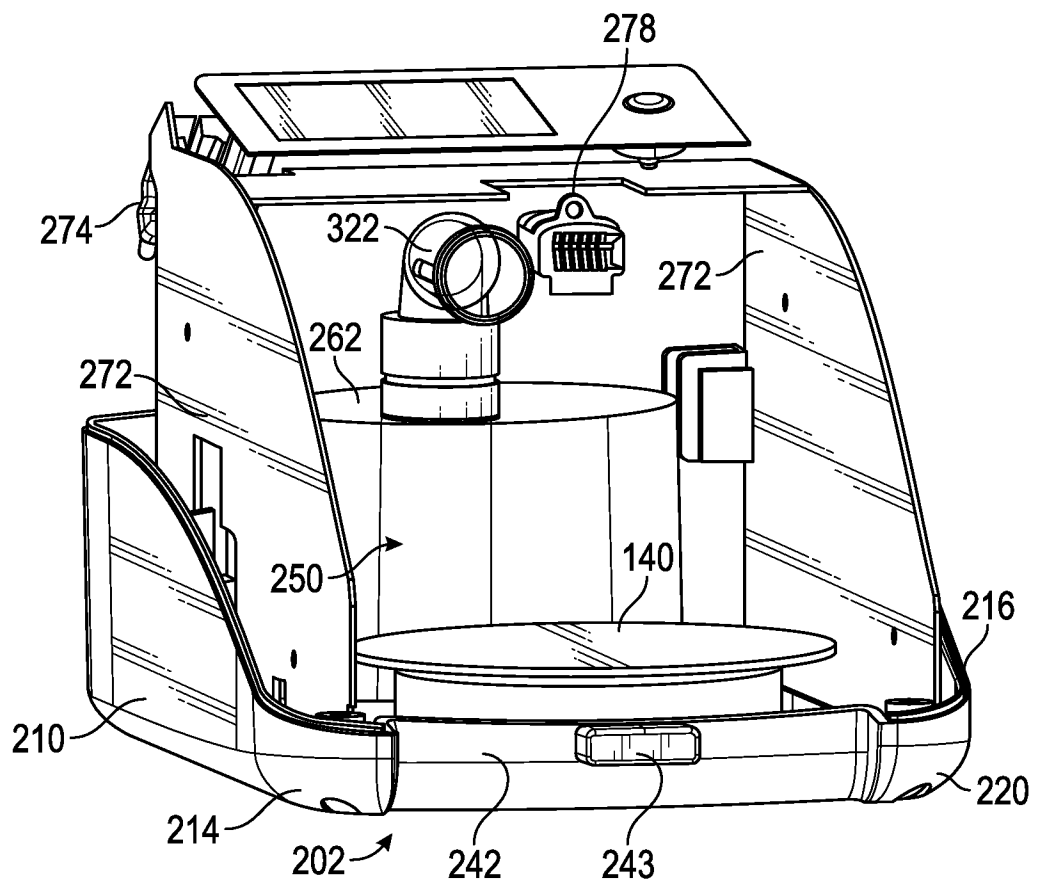


FIG. 14

*FIG. 15*

*FIG. 16*

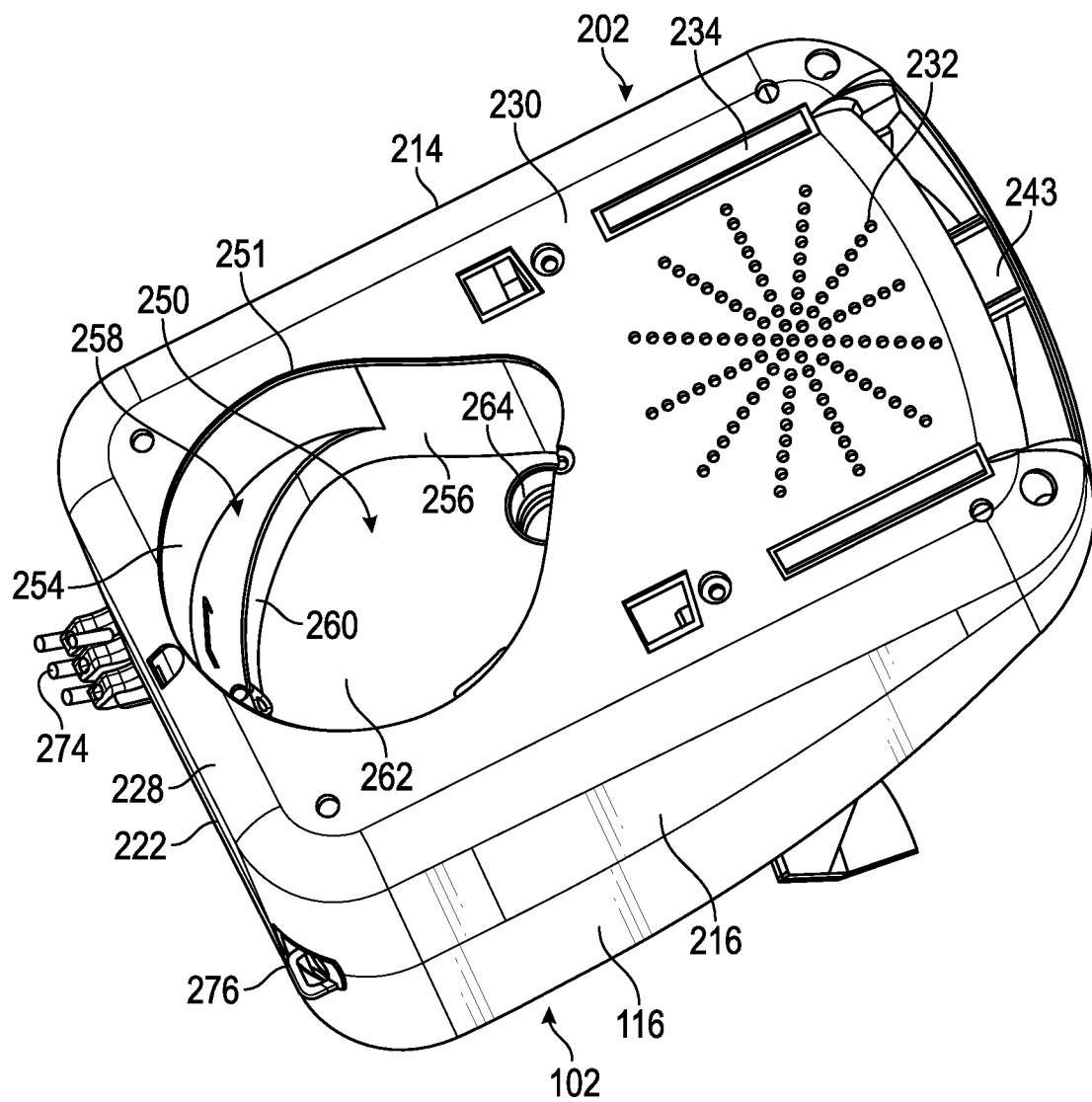


FIG. 17A

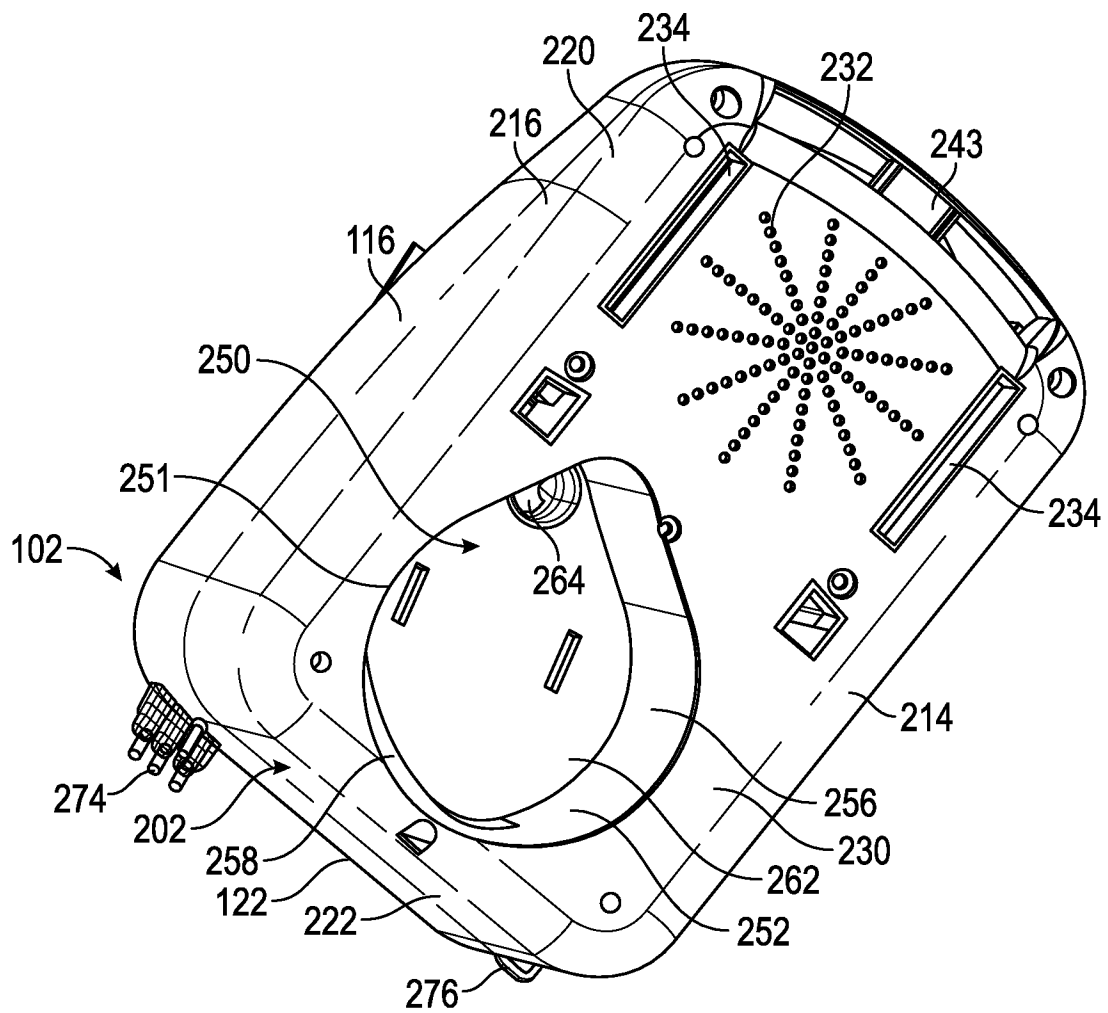


FIG. 17B

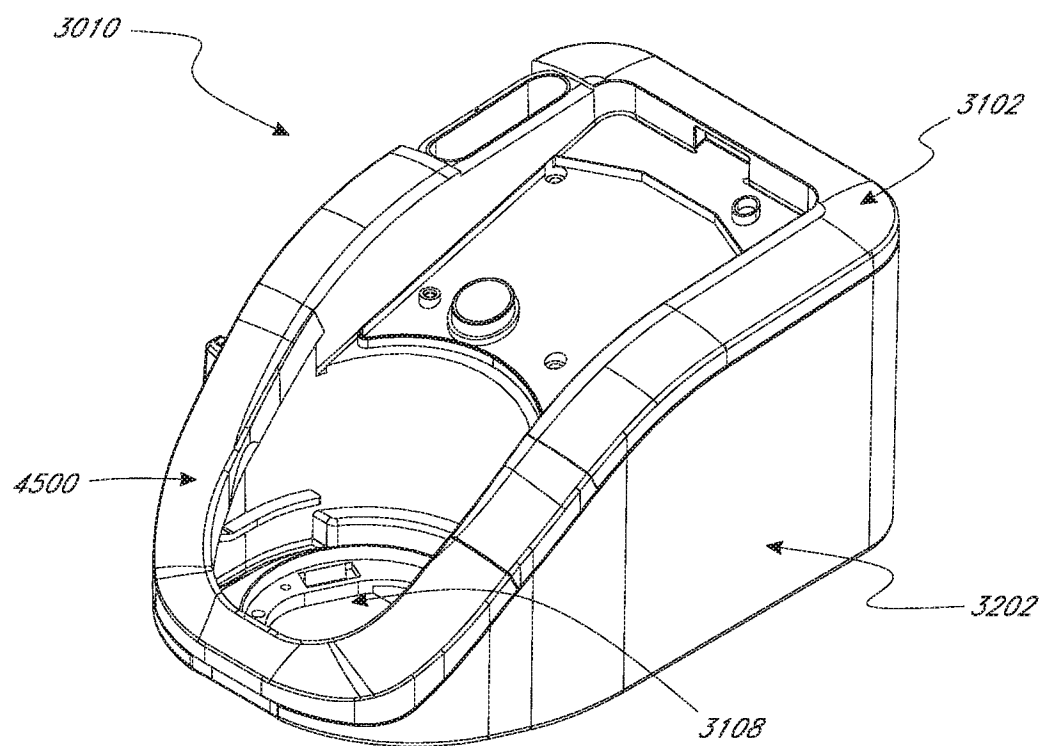


FIG. 18A

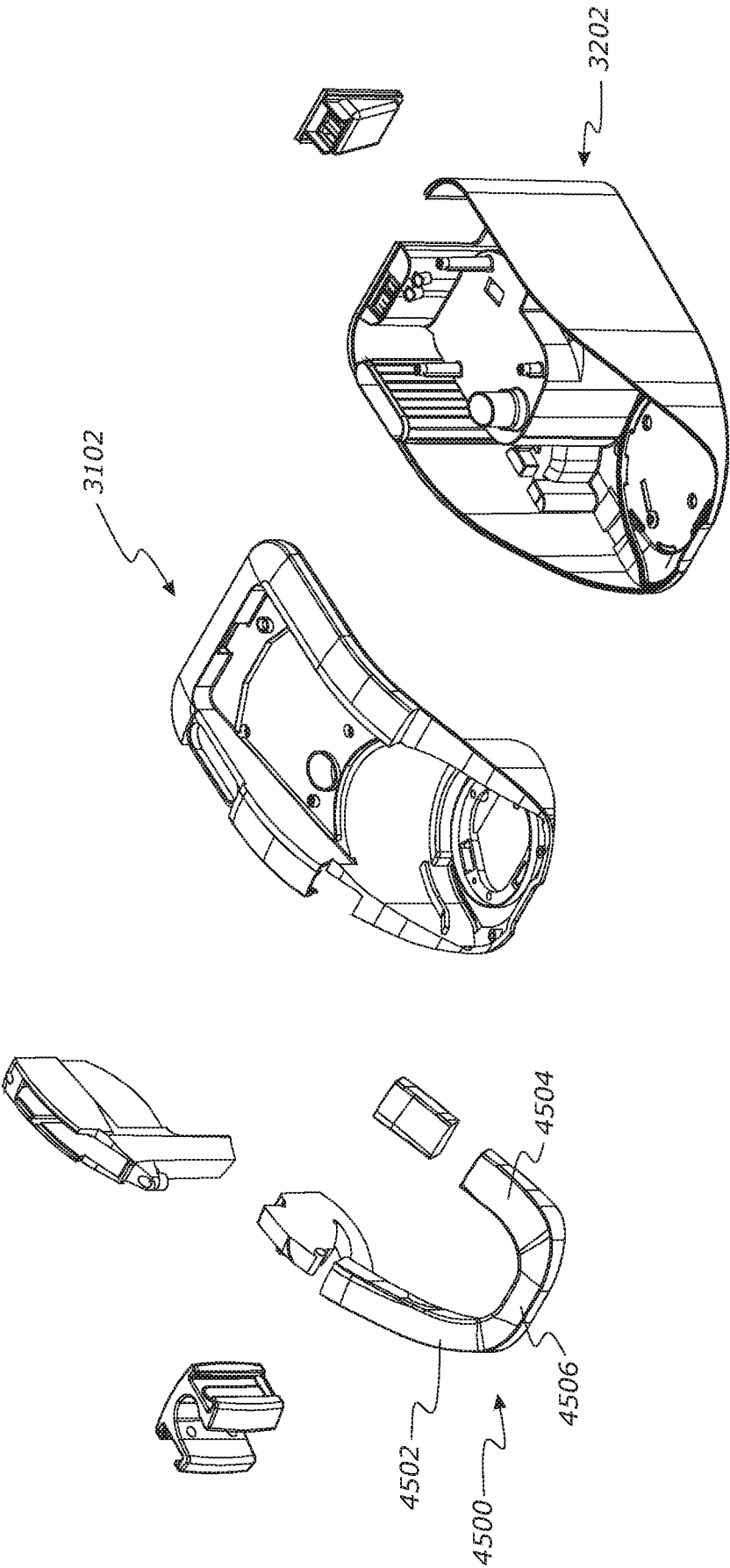


FIG. 18B

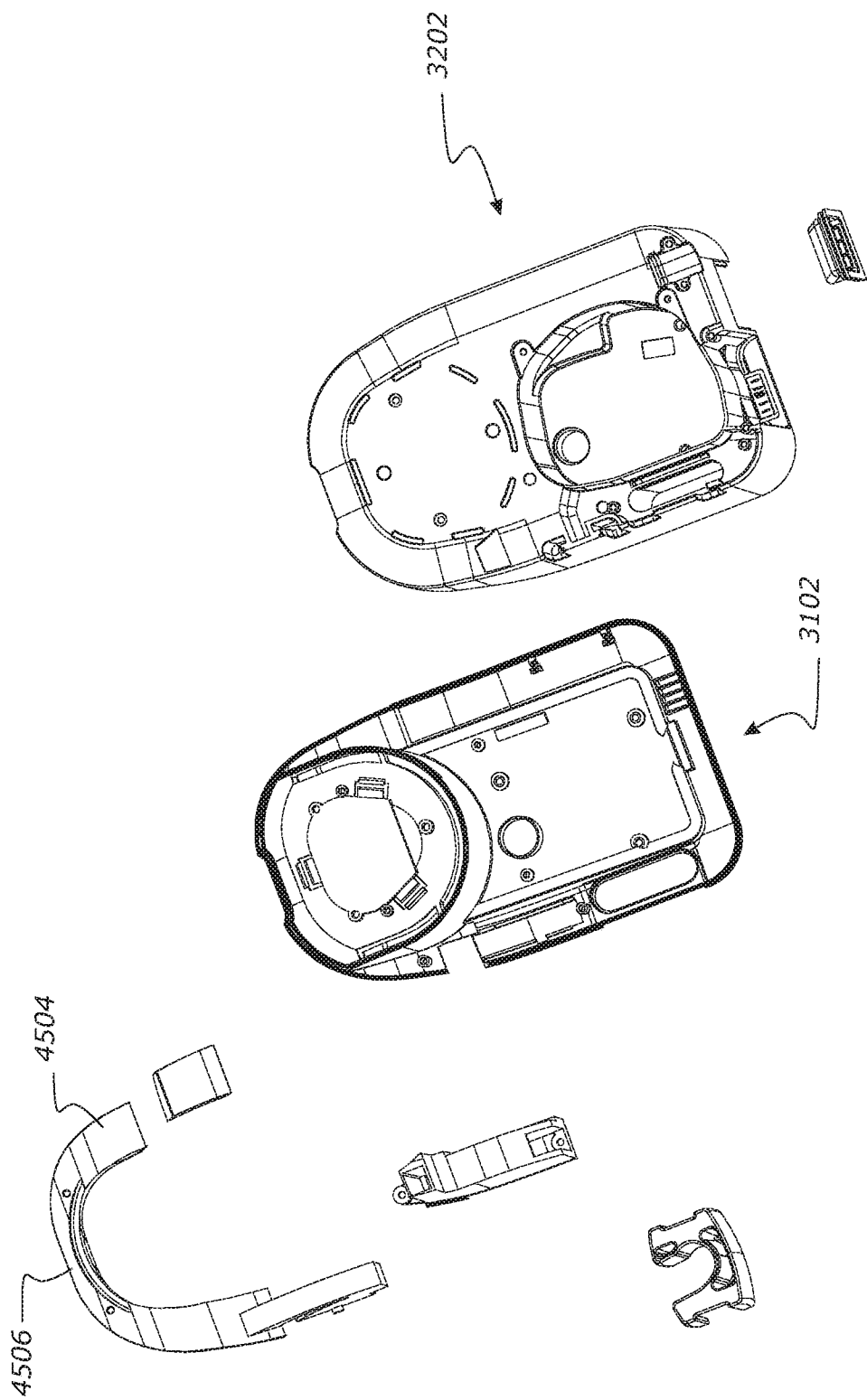
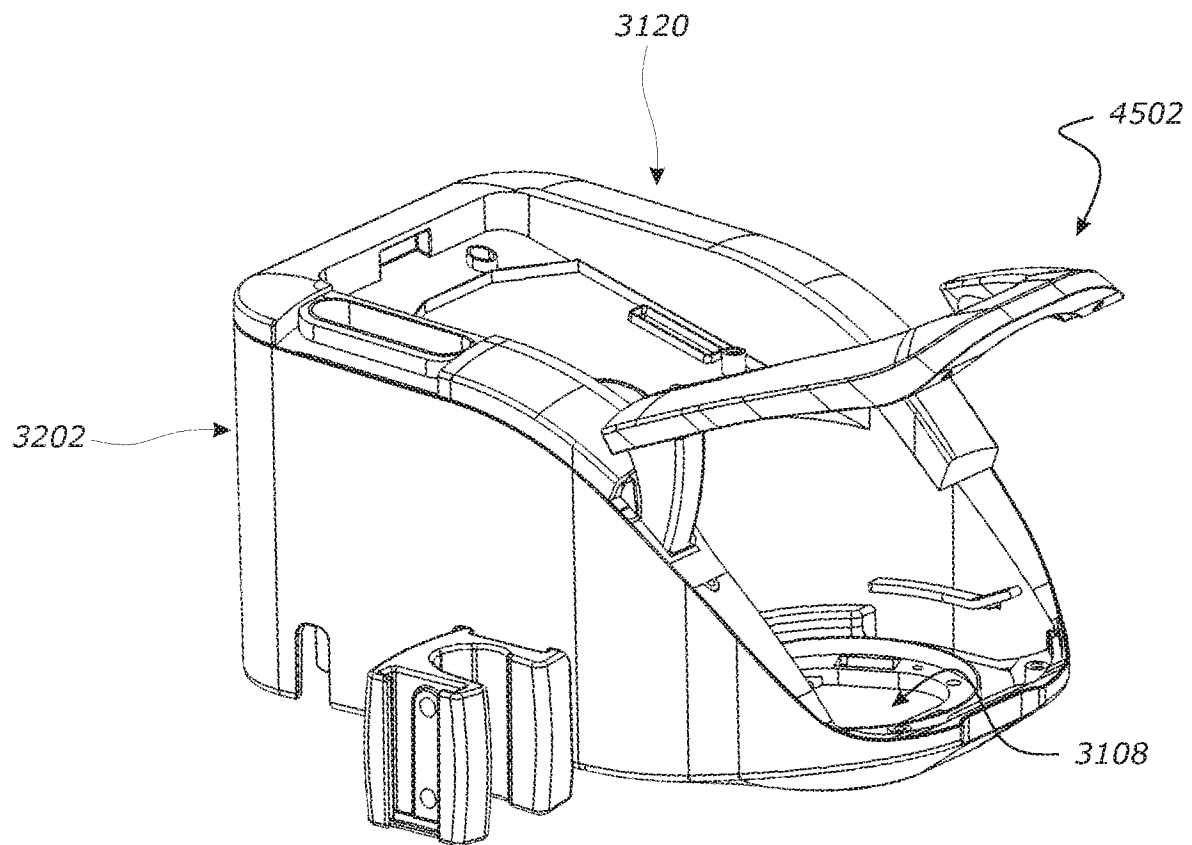
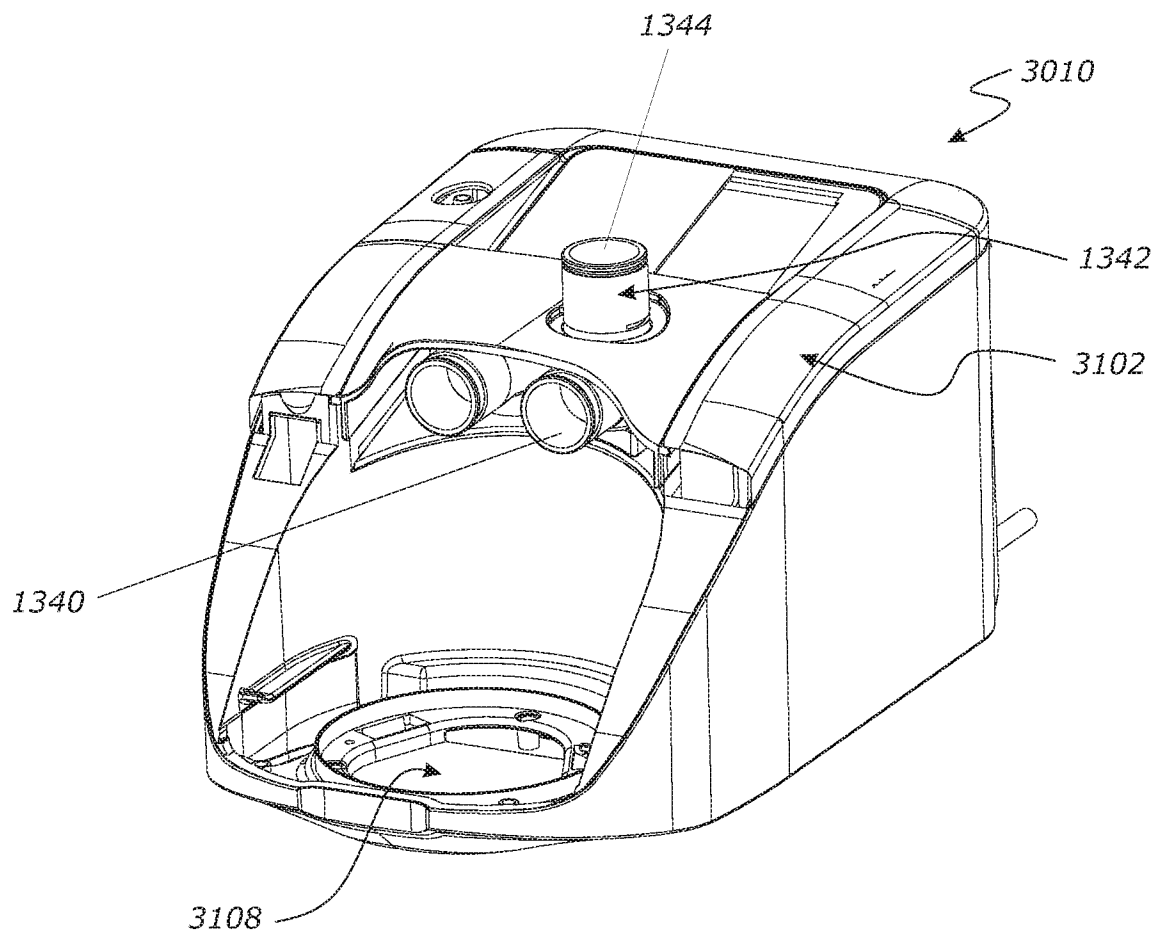


FIG. 18C

*FIG. 18D*

*FIG. 18E*

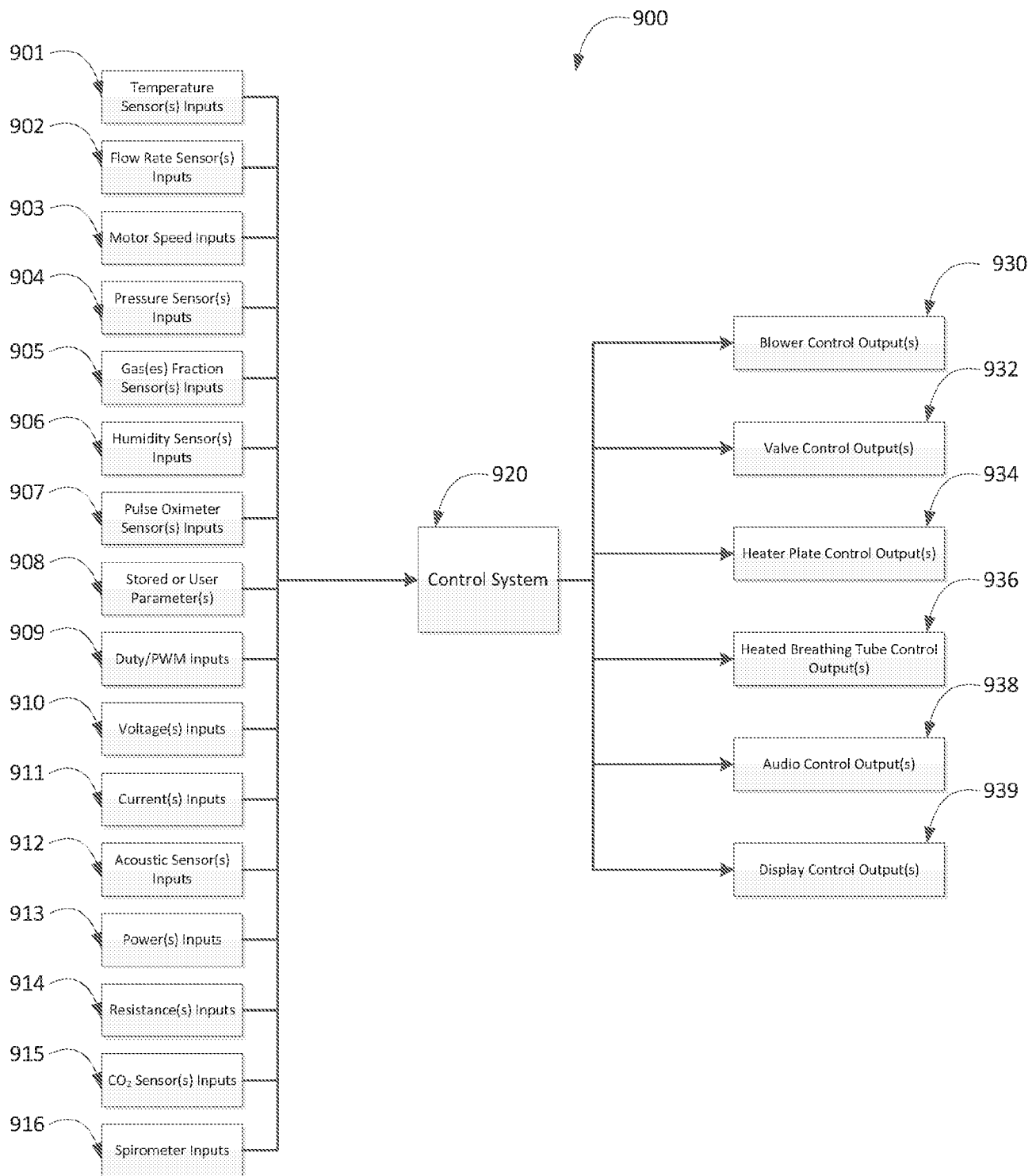
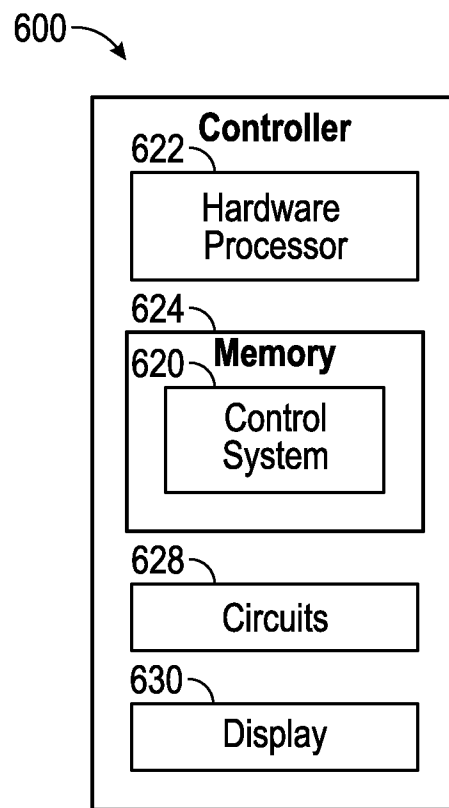
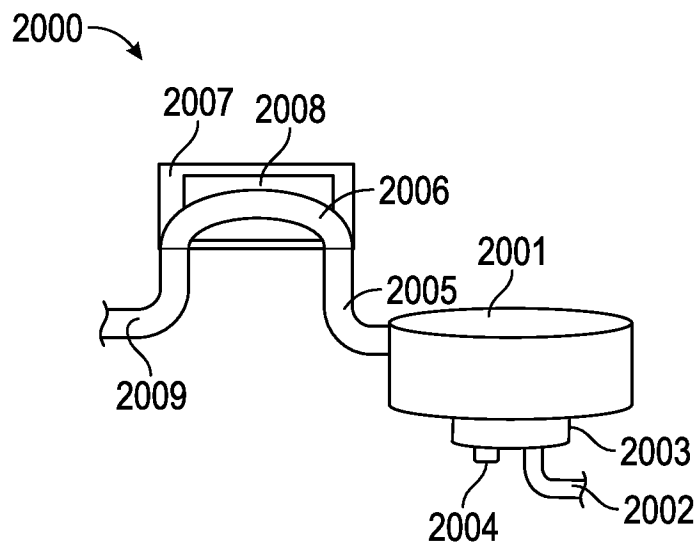
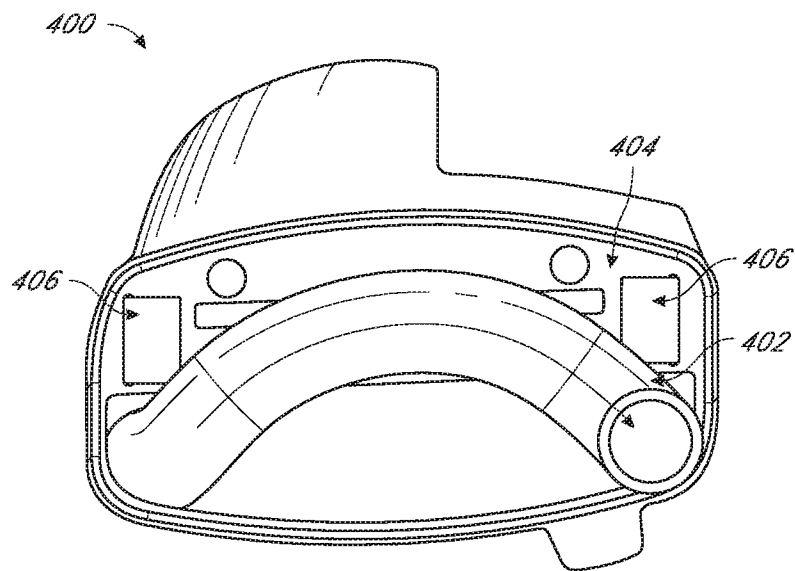


FIG. 19A

*FIG. 19B**FIG. 20*

*FIG. 21*

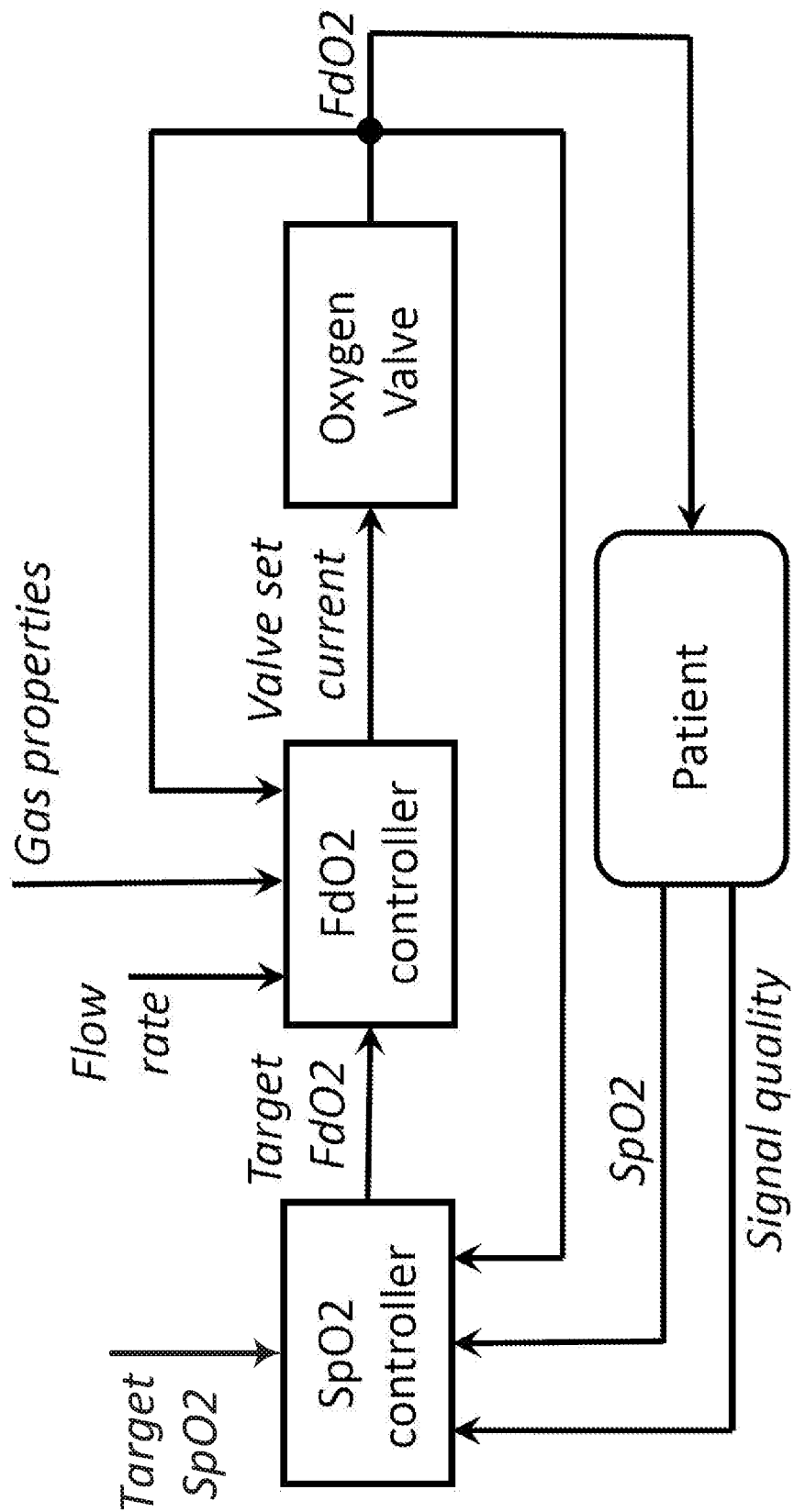


FIG. 22

INTERNATIONAL SEARCH REPORT

International application No.
PCT/NZ2018/050136

A. CLASSIFICATION OF SUBJECT MATTER		
A61M 16/10 (2006.01) A61M 16/12 (2006.01) A61M 16/16 (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) WPI, EPODOC: A61M16/--, A61M2205/--, A61M2230/-- and search terms (hypoxic, gas, heat, humid, nares and like terms). Applicant/Inventor name searched in internal databases provided by IP Australia Applicant/Inventor name searched in Espacenet Google Patent: Search Words 'Hypoxic, Gas, Heat, Humid' and like 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	
☒ Further documents are listed in the continuation of Box C ☒ See patent family annex		
* "A"	Special categories of cited documents: document defining the general state of the art which is not considered to be of particular relevance	"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
"E"	earlier application or patent but published on or after the international filing date	"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
"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)	"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
"O"	document referring to an oral disclosure, use, exhibition or other means	"&" document member of the same patent family
"P"	document published prior to the international filing date but later than the priority date claimed	
Date of the actual completion of the international search 29 January 2019		Date of mailing of the international search report 29 January 2019
Name and mailing address of the ISA/AU AUSTRALIAN PATENT OFFICE PO BOX 200, WODEN ACT 2606, AUSTRALIA Email address: pct@ipaustalia.gov.au		Authorised officer Timothy Williams AUSTRALIAN PATENT OFFICE (ISO 9001 Quality Certified Service) Telephone No. +61262832067

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.:

Remark on Protest

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

INTERNATIONAL SEARCH REPORT		International application No.
C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT		PCT/NZ2018/050136
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2005/0247311 A1 (VACCHIANO et al.) 10 November 2005 Abstract, Figure 1, Para 57-68, 123-138	1-241
X	US 2006/0196502 A1 (PILCHER et al.) 07 September 2006 Abstract, Figure 1, Para 13-27, 31-32, 58-59, 109-127, 137	1-241
X	US 2008/0078385 A1 (XIAO et al.) 03 April 2008 Abstract, Figure 1, Para 6-25, 45, 54, Claim 2	117-231
X	US 2007/0077200 A1 (BAKER) 05 April 2007 Abstract, Figure 1, Para 12-26,	1-116
X	US 2010/0282257 A1 (CHAPMAN et al.) 11 November 2010 Abstract, Figure 1, Para 34-104, 140-147, 177-189	1-116
X	US 2016/0095994 A1 (THIRD WIND, LLC.) 07 April 2016 Abstract, Figure 1, Para 14, 31-36,	1-116

Form PCT/ISA/210 (fifth sheet) (January 2015)

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 1-116 are directed to a method/system for providing a hypoxic flow of gases to a user. The feature of delivering a hypoxic gas composition to the nares of a user via a nasal cannula at a flow rate of at least about 10 liters/minute and automatically controlling the delivery based on a measured blood oxygen saturation of the user is specific to this group of claims.
- Claims 117-231 are directed to a method/system for providing a hypoxic flow of gases to a user. The feature of heating a hypoxic gas composition to a dew point temperature of between about 30°C and about 45°C prior to reaching the airway of a user is specific to this group of claims.
- Claims 232-241 are directed to a method/system for providing altitude or fitness training to a user. The feature of simulating a higher altitude by providing a hypoxic gas composition which is humidified and delivered to a user via a user interface 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. The only feature common to all of the claimed inventions and which provides a technical relationship among them is delivering a hypoxic gas composition to a user via a user interface

However this feature does not make a contribution over the prior art because it is disclosed in:

D1: US 2005/0247311 A1 (VACCHIANO et al.) 10 November 2005

Therefore in the light of this document this common feature cannot be a special technical feature. 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 posteriori*.

INTERNATIONAL SEARCH REPORT		International application No.	
Information on patent family members		PCT/NZ2018/050136	
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 2005/0247311 A1	10 November 2005	US 2005247311 A1	10 Nov 2005
		AU 2002341673 A1	01 Apr 2003
		US 2003070678 A1	17 Apr 2003
		US 6871645 B2	29 Mar 2005
		WO 03024505 A2	27 Mar 2003
US 2006/0196502 A1	07 September 2006	US 2006196502 A1	07 Sep 2006
		WO 2004071591 A1	26 Aug 2004
US 2008/0078385 A1	03 April 2008	US 2008078385 A1	03 Apr 2008
		US 2008078389 A1	03 Apr 2008
		WO 2008042734 A2	10 Apr 2008
		WO 2008042749 A2	10 Apr 2008
US 2007/0077200 A1	05 April 2007	US 2007077200 A1	05 Apr 2007
		TW 200724181 A	01 Jul 2007
		WO 2007041332 A1	12 Apr 2007
US 2010/0282257 A1	11 November 2010	US 2010282257 A1	11 Nov 2010
		EP 1981575 A1	22 Oct 2008
		NZ 544505 A	30 Oct 2009
		WO 2007086764 A1	02 Aug 2007
US 2016/0095994 A1	07 April 2016	US 2016095994 A1	07 Apr 2016
End of Annex			