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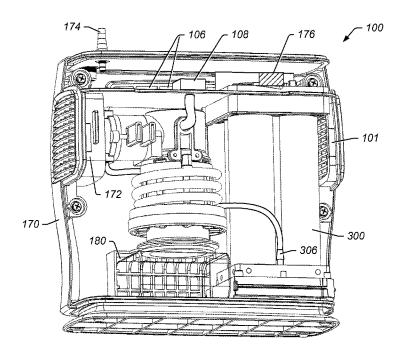
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(54) Title: OXYGEN CONCENTRATOR HEAT MANAGEMENT SYSTEM AND METHOD



(57) Abrégé/Abstract:

Described herein are various embodiments of an oxygen concentrator system. In some embodiments, oxygen concentrator system includes one or more components that improve dissipation of heat formed during operation of the oxygen concentrator system.



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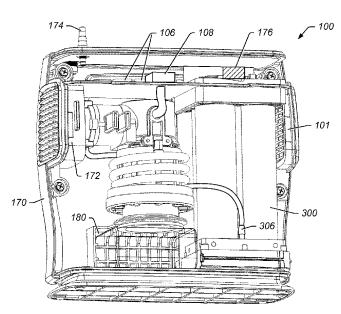
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(54) Title: OXYGEN CONCENTRATOR HEAT MANAGEMENT SYSTEM AND METHOD



(57) Abstract: Described herein are various embodiments of an oxygen concentrator system. In some embodiments, oxygen concentrator system includes one or more components that improve dissipation of heat formed during operation of the oxygen concentrator system.

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FIG. 2

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BACKGROUND OF THE INVENTION

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1. <u>Field of the Invention</u>

The present invention relates generally to health equipment and, more specifically, to oxygen concentrators.

10 2. <u>Description of the Related Art</u>

There are many patients that require supplemental oxygen as part of Long Term Oxygen Therapy, LTOT. Currently, the vast majority of patients that are receiving LTOT, are diagnosed under the general category of Chronic Obstructive Pulmonary Disease, COPD. This general diagnosis includes such common diseases as Chronic Asthma, Emphysema, Congestive Heart Failure and several other cardio-pulmonary conditions. Other people (e.g., obese individuals) may also require supplemental oxygen, for example, to maintain elevated activity levels.

Doctors may prescribe oxygen concentrators or portable tanks of medical oxygen for these patients. Usually a specific oxygen flow rate is prescribed (e.g., 1 liter per minute (LPM), 2 LPM, 3 LPM, etc.). Experts in this field have also recognized that exercise for these patients provide long term benefits that slow the progression of the disease, improve quality of life and extend patient longevity. Most stationary forms of exercise like tread mills and stationary bicycles, however, are too strenuous for these patients. As a result, the need for mobility has long been recognized. Until recently, this mobility has been facilitated by the use of small compressed oxygen tanks. The disadvantage of these tanks is that they have a finite amount of oxygen and they are heavy, weighing about 50 pounds, when mounted on a cart with dolly wheels.

Oxygen concentrators have been in use for about 50 years to supply patients suffering from respiratory insufficiency with supplemental oxygen. Traditional oxygen concentrators used to provide these flow rates have been bulky and heavy making ordinary ambulatory activities with them difficult and impractical. Recently, companies that manufacture large stationary home oxygen concentrators began developing portable oxygen concentrators, POCs. The advantage of POCs concentrators was that they can produce a theoretically endless supply of oxygen. In order to make these devices small for mobility, the various systems necessary for the production of oxygen enriched gas are condensed.

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SUMMARY

In an embodiment., an oxygen concentrator apparatus, includes at least two canisters; gas separation adsorbent disposed in at least two canisters, wherein the gas separation adsorbent separates at least some nitrogen from air in the canister to produce oxygen enriched gas; and a compression system. The compression system includes a compressor coupled to at least one canister, wherein the compressor compresses air during operation; and a motor coupled to the compressor, wherein the motor comprises an external rotating armature that drives the operation of the compressor.

In an embodiment, an oxygen concentrator apparatus, includes at least two canisters; gas separation adsorbent disposed in at least two canisters, wherein the gas separation adsorbent separates at least some nitrogen from air in the canister to produce oxygen enriched gas; and a compression system. The compression system includes a compressor coupled to at least one canister, wherein the compressor compresses air during operation; and a motor coupled to the compressor that drives the operation of the compressor. The compression system further includes an air transfer device coupled to the motor, wherein the air transfer device creates an air flow when the motor is operated, wherein the created airflow passes over at least a portion of the motor.

In an embodiment, an oxygen concentrator apparatus includes at least two canisters; gas separation adsorbent disposed in at least two canisters, wherein the gas separation adsorbent separates at least some nitrogen from air in the canister to produce oxygen enriched gas; and a compression system coupled to at least one canister. The compression system includes a compressor outlet conduit coupling the compressor to at least one canister, wherein compressed air is transferred from the compressor to at least one canister through the compressor outlet conduit. The oxygen concentrator appartus also includes at least one air transfer device, wherein the air transfer device creates an air flow during use, and wherein the air transfer device is positioned such that the created airflow passes over at least a portion of the compressor outlet conduit.

In an embodiment, an oxygen concentrator apparatus includes at least two canisters; gas separation adsorbent disposed in at least two canisters, wherein the gas separation adsorbent separates at least some nitrogen from air in the canister to produce oxygen enriched gas; and a compression system. The compression system includes a compressor coupled to at least one canister, wherein the compressor compresses air during operation; and a motor coupled to the compressor, wherein the motor drives the operation of the compressor. The oxygen concentrator apparatus also includes a compressor outlet conduit coupling the compressor to at least one canister, wherein compressed air is transferred from the compressor to at least one canister

through the compressor outlet conduit. An outlet of one or more canisters is positioned such that gas exiting one or more canisters during a venting process is directed toward: at least a portion of the motor; at least a portion of the compressor; at least a portion of the compressor outlet conduit; or combinations thereof, during use.

In an embodiment, an oxygen concentrator apparatus includes at least two canisters; gas separation adsorbent disposed in at least two canisters, wherein the gas separation adsorbent separates at least some nitrogen from air in the canister to produce oxygen enriched gas; and a compression system. The compression system includes a compressor coupled to at least one canister, wherein the compressor compresses air during operation; and a motor coupled to the compressor, wherein the motor drives the operation of the compressor. The oxygen concentrator apparatus also includes a compressor outlet conduit coupling the compressor to at least one canister, wherein compressed air is transferred from the compressor to at least one canister through the compressor outlet conduit. At least a portion of the compressor outlet conduit is positioned proximate to at least a portion of the motor; and an outlet of one or more canisters is positioned such that gas exiting one or more canisters during a venting process is directed toward at least the portion of the compressor outlet conduit positioned proximate to the motor, and gas exiting one or more canisters during a venting process is directed toward at least a portion of the motor proximate to the compressor outlet conduit, during use.

In an embodiment, an oxygen concentrator apparatus includes at least two canisters; gas separation adsorbent disposed in at least two canisters, wherein the gas separation adsorbent separates at least some nitrogen from air in the canister to produce oxygen enriched gas; and a compression system. The compression system includes a compressor coupled to at least one canister, wherein the compressor compresses air during operation; and a motor coupled to the compressor, wherein the motor drives the operation of the compressor. The oxygen concentrator apparatus also includes a compressor outlet conduit coupling the compressor to at least one canister, wherein compressed air is transferred from the compressor to at least one canister through the compressor outlet conduit. An air transfer device is coupled to the motor, wherein the air transfer device creates an air flow when the motor is operated. At least a portion of the compressor outlet conduit is positioned proximate to at least a portion of the motor. An outlet of one or more canisters is positioned such that gas exiting one or more canisters during a venting process is directed toward at least the portion of the compressor outlet conduit positioned proximate to the motor, and gas exiting one or more canisters during a venting process is directed toward at least a portion of the motor proximate to the compressor outlet conduit, during use. The air transfer device facilitates flow of gas exiting the canister during the venting process.

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In an embodiment, a method of providing an oxygen enriched gas to a user of an oxygen concentrator includes automatically assessing at least a portion of an inhalation profile of the user during use of the oxygen concentrator; providing oxygen enriched gas produced by the oxygen concentrator to the user, wherein the frequency and/or duration of the delivery of the oxygen enriched gas is at least partially based on the assessed inhalation profile; and adjusting the frequency and/or duration of the provided oxygen enriched gas based on one or more changes in the assessed inhalation profile.

In an embodiment, a method of providing an oxygen enriched gas to a user of an oxygen concentrator includes: automatically detecting user inhalations during use of the oxygen concentrator; automatically assessing a current breathing rate of the user based on detected user inhalations; providing oxygen enriched gas produced by the oxygen concentrator to the user from the oxygen concentrator, wherein the frequency and/or duration of the provided oxygen enriched gas is at least partially based on the automatically assessed breathing rate; and adjusting the frequency and/or duration of the provided oxygen enriched gas based on changes in the automatically assessed current breathing rate.

In an embodiment, a method of providing an oxygen enriched gas to a user of an oxygen concentrator includes: automatically assessing an inhalation air flow rate of the user based on detected inhalations of the user; providing oxygen enriched gas produced by the oxygen concentrator to the user from the oxygen concentrator, wherein the frequency and/or duration of the provided oxygen enriched gas is at least partially based on the automatically assessed inhalation flow rate; and adjusting the frequency and/or duration of the provided oxygen enriched gas based on changes in the automatically assessed inhalation flow rate.

In an embodiment, an oxygen concentrator includes at least two canisters; gas separation adsorbent disposed in at least two canisters, wherein the gas separation adsorbent separates at least some nitrogen from air in the canister to produce oxygen enriched gas; and a compression system coupled to at least one canister, wherein the compression system compresses air during operation. The oxygen concentrator also includes a pressure sensor capable of detecting an ambient pressure of the apparatus during use, wherein operation of the compression system is based, at least in part, on the pressure detected by the pressure sensor.

In an embodiment, a method of providing an oxygen enriched gas to a user of an oxygen concentrator includes: assessing an ambient pressure with the pressure sensor; operating the compression system to compress air, wherein the operation of the compression system is based, at least in part, on the assessed ambient pressure; directing the compressed air into one or more of the canisters, wherein nitrogen is separated from oxygen in one or more of the canisters to produce an oxygen enriched gas; and providing the oxygen enriched gas to the user.

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In an embodiment, an oxygen concentrator system includes: at least two canisters; gas separation adsorbent disposed in at least two canisters, wherein the gas separation adsorbent separates at least some nitrogen from air in the canister to produce an oxygen enriched gas; a compression system coupled to at least one canister, wherein the compression system compresses air during operation. An internal power supply isi coupled to the compression system, the internal power supply providing power to operate the compression system during use, the internal power supply including an internal power supply input port. An auxiliary power supply is removably connectable to the internal power supply input port. The auxiliary power supply includes one or more battery cells, an auxiliary power supply input port, and an auxiliary power supply output connector used to removably connect the auxiliary power supply to the internal power supply input port during use. The auxiliary power supply output connector is also removably connectable to the auxiliary power supply input port. An external charger is removable connectable to the internal power supply and the auxiliary power supply. The external charger includes an external charger output connector used to removably connect the external charger to the internal power supply input port and removable connect the external charger to the auxiliary power supply input port.

In an embodiment, an oxygen concentrator system includes: at least two canisters; gas separation adsorbent disposed in at least two canisters, wherein the gas separation adsorbent separates at least some nitrogen from air in the canister to produce an oxygen enriched gas; a compression system coupled to at least one canister, wherein the compression system compresses air during operation. An internal power supply is coupled to the compression system, the internal power supply providing power to operate at least the compression system during use, the internal power supply including an internal power supply input port. An auxiliary power supply includes: one or more battery cells; a control circuit coupled to one or more of the battery cells; an auxiliary power supply input port coupled to the control circuit; and an auxiliary power supply output connector coupled to the control circuit; wherein the auxiliary power supply output connector is used to removably couple the auxiliary power supply to the internal power supply input port during use. The control circuit directs flow of current through the auxiliary power supply during use.

In an embodiment, a method of providing continuous positive airway pressure to a user includes: supplying pressurized air from the compression system to a mask that has been coupled to a user's face; assessing an onset of inhalation of the user; and supplying oxygen enriched gas from the oxygen concentrator to the mask when the onset of inhalation of the user is detected.

In an embodiment, a method of providing continuous positive airway pressure to a user includes: supplying pressurized air from the compression system to a mask that has been coupled to a user's face; assessing an ambient pressure; assessing a pressure inside the mask while the pressurized air is supplied to the mask coupled to the user's face; assessing a correction pressure, wherein the correction pressure is a function of the ambient pressure and the assessed pressure inside the mask; automatically assessing a pressure inside the mask while the pressurized air is supplied to the mask coupled to the user's face; assessing an adjusted assessed pressure inside the mask as a function of the automatically assessed pressure and the correction pressure; supplying oxygen enriched gas from the oxygen concentrator to the mask if the adjusted assessed pressure inside the mask is less than a predetermined pressure.

In an embodiment, a method of providing continuous positive airway pressure to a user includes: supplying pressurized air from the compression system to a mask that has been coupled to a user's face, the mask comprising a venting port that allows gas to exit the mask; automatically assessing a flow rate of gas exiting the mask through the venting port; assessing a change in the flow rate of gas exiting the mask through the venting port; supplying oxygen enriched gas from the oxygen concentrator to the mask if the detected change in the flow rate indicates a decrease in the flow rate of gas exiting the mask.

In an embodiment, a method of providing continuous positive airway pressure to a user includes: coupling the oxygen concentrator to one or more of the conduits; supplying pressurized air from the compression system to a mask that has been coupled to a user's face; supplying oxygen enriched gas from the oxygen concentrator to one or more conduits.

In an embodiment, a method of positive pressure ventilation to a user includes: supplying pulses of pressurized breathing gas from the compressed gas system to a mask that has been coupled to a user's face; and supplying oxygen enriched gas from the oxygen concentrator to the mask.

In an embodiment, a mask for use in a continuous positive airway pressure system, includes a body, the body having a shape to substantially conform to a breathing orifice of a user; a first conduit port for receiving a conduit from a compression system that produces pressurized air during use, the compression system being couplable to the mask via one or more conduits through the first conduit port; a second conduit port for receiving a conduit from an oxygen generator that produces oxygen enriched gas from air, the oxygen generator being couplable to the mask via one or more conduits through the second conduit port; and a venting port, wherein gas exits through the venting port of a mask during use.

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In an embodiment, an oxygen concentrator system includes: at least two canisters; gas separation adsorbent disposed in at least two canisters, wherein the gas separation adsorbent separates at least some nitrogen from air in the canister to produce an oxygen enriched gas; and a compression system coupled to at least one canister, wherein the compression system compresses air during operation; at least one conduit coupled to at least one canister, the conduit receiving an oxygen enriched gas from at least one canister during use; and a mouthpiece, removably couplable to one or more teeth in a user's mouth, wherein the mouthpiece is coupled to at least one conduit, wherein an oxygen enriched gas is directed to the mouth of the user via the mouthpiece during use.

In an embodiment, a method of operating an oxygen concentrator apparatus includes: automatically pressurizing one or more canisters with oxygen enriched gas during a shut-down sequence of the oxygen concentrator such that the pressure inside one or more canisters is above ambient pressure.

BRIEF DESCRIPTION OF THE DRAWINGS

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Advantages of the present invention will become apparent to those skilled in the art with the benefit of the following detailed description of embodiments and upon reference to the accompanying drawings in which:

- FIG. 1 depicts a schematic diagram of the components of an oxygen concentrator;
- FIG. 2 depicts a side view of the main components of an oxygen concentrator;
 - FIG 3A depicts a perspective side view of a compression system;
- FIG. 3B depicts a side view of a compression system that includes a heat exchange conduit;
- FIG. 4A depicts a schematic diagram of the outlet components of an oxygen concentrator;
- FIG. 4B depicts an outlet conduit for an oxygen concentrator;
 - FIG. 4C depicts an alternate outlet conduit for an oxygen concentrator;
 - FIG. 5 depicts a perspective view of a dissembled canister system;
 - FIG. 6A depicts a perspective view of an end of a canister system;
 - FIG. 6B depicts the assembled end of the canister system end depicted in FIG. 6A;
- FIG. 7A depicts a perspective view of an opposing end of the canister system depicted in FIG. 5 and 6A;
 - FIG. 7B depicts the assembled opposing end of the canister system end depicted in FIG. 7A;
 - FIG. 8 depicts an external charger coupled to an oxygen concentrator system;

- FIG. 9 depicts an auxiliary power supply coupled to an oxygen concentrator system;
- FIG. 10 depicts a schematic diagram of an auxiliary power supply control circuit;
- FIG. 11A depicts an auxiliary power supply coupled to an oxygen concentrator system, and an external charger coupled to the auxiliary power supply;
- FIG. 11B depicts an output connector of an auxiliary power supply coupled to the input port of the auxiliary power supply;
 - FIG. 12 depicts various profiles for providing oxygen enriched gas from an oxygen concentrator;
 - FIG. 13 depicts an outer housing for an oxygen concentrator;
- FIG. 14 depicts a control panel for an oxygen concentrator;
 - FIG. 15 depicts an embodiment of a mask for use with positive pressure therapy;
 - FIG. 16 depicts a schematic diagram of a positive pressure therapy system;
 - FIG. 17 depicts a schematic diagram of an alternate embodiment of a positive pressure therapy system;
- FIG. 18 depicts a schematic diagram of a ventilator system; and

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FIG. 19 depicts a schematic diagram of an alternate embodiment of a ventilator system.

While the invention is susceptible to various modifications and alternative forms, specific embodiments thereof are shown by way of example in the drawings and will herein be described in detail. It should be understood, however, that the drawings and detailed description thereto are not intended to limit the invention to the particular form disclosed, but on the contrary, the intention is to cover all modifications, equivalents, and alternatives falling within the spirit and scope of the present invention as defined by the appended claims.

DETAILED DESCRIPTION OF THE EMBODIMENTS

It is to be understood the present invention is not limited to particular devices or methods, which may, of course, vary. It is also to be understood that the terminology used herein is for the purpose of describing particular embodiments only, and is not intended to be limiting. Headings are for organizational purposes only and are not meant to be used to limit or interpret the description or claims. As used in this specification and the appended claims, the singular forms "a", "an", and "the" include singular and plural referents unless the content clearly dictates otherwise. Furthermore, the word "may" is used throughout this application in a permissive sense (i.e., having the potential to, being able to), not in a mandatory sense (i.e., must). The term "include," and derivations thereof, mean "including, but not limited to."

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The term "coupled" as used herein means either a direct connection or an indirect connection (e.g., one or more intervening connections) between one or more objects or components. The phrase "connected" means a direct connection between objects or components such that the objects or components are connected directly to each other. As used herein the phrase "obtaining" a device means that the device is either purchased or constructed.

FIG. 1 illustrates a schematic diagram of an oxygen concentrator 100, according to an embodiment. Oxygen concentrator 100 may concentrate oxygen out of an air stream to provide oxygen enriched gas to a user. As used herein, "oxygen enriched gas" is composed of at least about 50% oxygen, at least about 60% oxygen, at least about 70% oxygen, at least about 80% oxygen, at least about 90% oxygen, at least about 95% oxygen, at least about 98% oxygen, or at least about 99% oxygen.

Oxygen concentrator 100 may be a portable oxygen concentrator. For example, oxygen concentrator 100 may have a weight and size that allows the oxygen concentrator to be carried by hand and/or in a carrying case. In one embodiment, oxygen concentrator 100 has a weight of less than about 20 lbs., less than about 15 lbs., less than about 10 lbs, or less than about 5 lbs. In an embodiment, oxygen concentrator 100 has a volume of less than about 1000 cubic inches, less than about 750 cubic inches; less than about 500 cubic inches, less than about 250 cubic inches, or less than about 200 cubic inches.

Oxygen may be collected from ambient air by pressurizing ambient air in canisters 302 and 304, which include a gas separation adsorbent. Gas separation adsorbents useful in an oxygen concentrator are capable of separating at least nitrogen from an air stream to produce oxygen enriched gas. Examples of gas separation adsorbents include molecular sieves that are capable of separation of nitrogen from an air stream. Examples of adsorbents that may be used in an oxygen concentrator include, but are not limited to, zeolites (natural) or synthetic crystalline aluminosilicates that separate nitrogen from oxygen in an air stream under elevated pressure. Examples of synthetic crystalline aluminosilicates that may be used include, but are not limited to: OXYSIV adsorbents available from UOP LLC, Des Plaines, IW; SYLOBEAD adsorbents available from W. R. Grace & Co, Columbia, MD; SILIPORITE adsorbents available from CECA S.A. of Paris, France; ZEOCHEM adsorbents available from Zeochem AG, Uetikon, Switzerland; and AgLiLSX adsorbent available from Air Products and Chemicals, Inc., Allentown, PA.

As shown in FIG. 1, air may enter the oxygen concentrator through air inlet 106. Air may be drawn into air inlet 106 by compression system 200. Compression system 200 may draw in air from the surroundings of the oxygen concentrator and compress the air, forcing the compressed air into one or both canisters 302 and 304. In an embodiment, an inlet muffler 108

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may be coupled to air inlet 106 to reduce sound produced by air being pulled into the oxygen generator by compression system 200. In an embodiment, inlet muffler 108 may be a moisture and sound absorbing muffler. For example, a water absorbent material (such as a polymer water absorbent material or a zeolite material) may be used to both absorb water from the incoming air and to reduce the sound of the air passing into the air inlet 106.

Compression system 200 may include one or more compressors capable of compressing air. Pressurized air, produced by compression system 200, may be forced into one or both of the canisters 302 and 304. In some embodiments, the ambient air may be pressurized in the canisters to a pressure approximately in a range of 13-20 pounds per square inch (psi). Other pressures may also be used, depending on the type of gas separation adsorbent disposed in the canisters.

Coupled to each canister 302/304 are inlet valves 122/124 and outlet valves 132/134. As shown in FIG. 1, inlet valve 122 is coupled to canister 302 and inlet valve 124 is coupled to canister 304. Outlet valve 132 is coupled to canister 302 and outlet valve 134 is coupled to canister 304. Inlet valves 122/124 are used to control the passage of air from compression system 200 to the respective canisters. Outlet valves 132/134 are used to release gas from the respective canisters during a venting process. In some embodiments, inlet valves 122/124 and outlet valves 132/134 may be silicon plunger solenoid valves. Other types of valves, however, may be used. Plunger valves offer advantages over other kinds of valves by being quiet and having low slippage.

In an embodiment, pressurized air is sent into one of canisters 302 or 304 while the other canister is being vented. For example, during use, inlet valve 122 is opened while inlet valve 124 is closed. Pressurized air from compression system 200 is forced into canister 302, while being inhibited from entering canister 304 by inlet valve 124. In an embodiment, a controller 400 is electrically coupled to valves 122, 124, 132, and 134. Controller 400 includes one or more processors 410 operable to execute program instructions stored in memory 420. The program instructions are operable to perform various predefined methods that are used to operate the oxygen concentrator. Controller 400 may include program instructions for operating inlet valves 122 and 124 out of phase with each other, i.e., when one of inlet valves 122 or 124 is opened, the other valve is closed. During pressurization of canister 302, outlet valve 132 is closed and outlet valve 134 is opened. Similar to the inlet valves, outlet valves 132 and 134 are operated out of phase with each other. In some embodiments, the voltages and the duration of the voltages used to open the input and output valves may be controlled by controller 400.

Check valves 142 and 144 are coupled to canisters 302 and 304, respectively. Check valves 142 and 144 are one way valves that are passively operated by the pressure differentials that occur as the canisters are pressurized and vented. Check valves 142 and 144 are coupled to

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canisters to allow oxygen produced during pressurization of the canister to flow out of the canister, and to inhibit back flow of oxygen or any other gases into the canister. In this manner, check valves 142 and 144 act as one way valves allowing oxygen enriched gas to exit the

respective canister during pressurization.

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In an exemplary embodiment, canister 302 is pressurized by compressed air produced in compression system 200 and passed into canister 302. During pressurization of canister 302 inlet valve 122 is open, outlet valve 132 is closed, inlet valve 124 is closed and outlet valve 134 is open. Outlet valve 134 is opened when outlet valve 132 is closed to allow substantially simultaneous venting of canister 304 while canister 302 is pressurized. Canister 302 is pressurized until the pressure in canister is sufficient to open check valve 142. Oxygen enriched gas produced in canister 302 exits through check valve and, in one embodiment, is collected in accumulator 106.

After some time the gas separation adsorbent will become saturated with nitrogen and will be unable to separate significant amounts of nitrogen from incoming air. This point is usually reached after a predetermined time of oxygen enriched gas production. In the embodiment described above, when the gas separation adsorbent in canister 302 reaches this saturation point, the inflow of compressed air is stopped and canister 302 is vented to remove nitrogen. During venting, inlet valve 122 is closed, and outlet valve 132 is opened. While canister 302 is being vented, canister 304 is pressurized to produce oxygen enriched gas in the same manner described above. Pressurization of canister 304 is achieved by closing outlet valve 134 and opening inlet valve 124. The oxygen enriched gas exits canister 304 through check valve 144.

During venting of canister 302, outlet valve 132 is opened allowing pressurized gas (mainly nitrogen) to exit the canister through concentrator outlet 130. In an embodiment, the vented gases may be directed through muffler 133 to reduce the noise produced by releasing the pressurized gas from the canister. As gas is released from canister 302, the pressure in the canister drops, allowing the nitrogen to become desorbed from the gas separation adsorbent. The released nitrogen exits the canister through outlet 130, resetting the canister to a state that allows renewed separation of oxygen from an air stream. Muffler 133 may include open cell foam (or another material) to muffle the sound of the gas leaving the oxygen concentrator. In some embodiments, the combined muffling components/techniques for the input of air and the output of gas, may provide for oxygen concentrator operation at a sound level below 50 decibels.

In an embodiment, a portion of the oxygen enriched gas may be transferred from canister 302 to canister 304 when canister 304 is being vented of nitrogen. Transfer of oxygen enriched gas from canister 302 to 304, during venting of canister 304, helps to further purge nitrogen (and

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other gases) from the canister. In an embodiment, oxygen enriched gas may travel through flow restrictors 151, 153, and 155 between the two canisters. Flow restrictor 151 may be a trickle flow restrictor. Flow restrictor 151, for example, may be a 0.009D flow restrictor (e.g., the flow restrictor has a radius 0.009" which is less than the diameter of the tube it is inside). Flow restrictors 153 and 155 may be 0.013D flow restrictors.

Flow of oxygen enriched gas is also controlled by use of valve 152 and valve 154. Valves 152 and 154 may be opened for a short duration during the venting process (and may be closed otherwise) to prevent excessive oxygen loss out of the purging canister. Other durations are also contemplated. In an exemplary embodiment, canister 302 is being vented and it is desirable to purge canister 302 by passing a portion of the oxygen enriched gas being produced in canister 304 into canister 302. A portion of oxygen enriched gas, upon pressurization of canister 304, will pass through flow restrictor 151 into canister 302 during venting of canister 302. Additional oxygen enriched air is passed into canister 302, from canister 304, through valve 154 and flow restrictor 155. Valve 152 may remain closed during the transfer process, or may be opened if additional oxygen enriched gas is needed. The selection of appropriate flow restrictors 151 and 155, coupled with controlled opening of valve 154 allows a controlled amount of oxygen enriched gas to be sent from canister 304 to 302. In an embodiment, the controlled amount of oxygen enriched gas is an amount sufficient to purge canister 302 and minimize the loss of oxygen enriched gas through venting valve 132 of canister 302. While this embodiment describes venting of canister 302, it should be understood that the same process can be used to vent canister 304 using flow restrictor 151, valve 152 and flow restrictor 153.

The pair of equalization/vent valves 152/154 work with flow restrictors 153 and 155 to optimize the air flow balance between the two canisters. This may allow for better flow control for venting the canisters with oxygen enriched gas from the other of the canisters. It may also provide better flow direction between the two canisters. It has been found that, while flow valves 152/154 may be operated as bi-directional valves, the flow rate through such valves varies depending on the direction of fluid flowing through the valve. For example, oxygen enriched gas flowing from canister 304 toward canister 302 has a flow rate faster through valve 152 than the flow rate of oxygen enriched gas flowing from canister 302 toward canister 304 through valve 152. If a single valve was to be used, eventually either too much or too little oxygen enriched gas would be sent between the canisters and the canisters would, over time, begin to produce different amounts of oxygen enriched gas. Use of opposing valves and flow restrictors on parallel air pathways may equalize the flow pattern of the oxygen between the two canisters. Equalizing the flow may allow for a steady amount of oxygen available to the user over multiple cycles and also may allow a predictable volume of oxygen to purge the other of the canisters. In

some embodiments, the air pathway may not have restrictors but may instead have a valve with a built in resistance or the air pathway itself may have a narrow radius to provide resistance.

At times, oxygen concentrator may be shutdown for a period of time. When an oxygen concentrator is shut down, the temperature inside the canisters may drop as a result of the loss of adiabatic heat from the compression system. As the temperature drops, the volume occupied by the gases inside the canisters will drop. Cooling of the canisters may lead to a negative pressure in the canisters. Valves (e.g., valves 122, 124, 132, and 134) leading to and from the canisters are dynamically sealed rather than hermetically sealed. Thus, outside air may enter the canisters after shutdown to accommodate the pressure differential. When outside air enters the canisters, moisture from the outside air may condense inside the canister as the air cools. Condensation of water inside the canisters may lead to gradual degradation of the gas separation adsorbents, steadily reducing ability of the gas separation adsorbents to produce oxygen enriched gas.

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In an embodiment, outside air may be inhibited from entering canisters after the oxygen concentrator is shutdown by pressurizing both canisters prior to shutdown. By storing the canisters under a positive pressure, the valves may be forced into a hermetically closed position by the internal pressure of the air in the canisters. In an embodiment, the pressure in the canisters, at shutdown, should be at least greater than ambient pressure. As used herein the term "ambient pressure" refers to the pressure of the surroundings that the oxygen generator is located (e.g. the pressure inside a room, outside, in a plane, etc.). In an embodiment, the pressure in the canisters, at shutdown, is at least greater than standard atmospheric pressure (i.e., greater than 760 mmHg (Torr), 1 atm, 101,325 Pa). In an embodiment, the pressure in the canisters, at shutdown, is at least about 1.1 times greater than ambient pressure; is at least about 1.5 times greater than ambient pressure; or is at least about 2 times greater than ambient pressure.

In an embodiment, pressurization of the canisters may be achieved by directing pressurized air into each canister from the compression system and closing all valves to trap the pressurized air in the canisters. In an exemplary embodiment, when a shutdown sequence is initiated, inlet valves 122 and 124 are opened and outlet valves 132 and 134 are closed. Because inlet valves 122 and 124 are joined together by a common conduit, both canisters 302 and 304 may become pressurized as air and or oxygen enriched gas from one canister may be transferred to the other canister. This situation may occur when the pathway between the compression system and the two inlet valves allows such transfer. Because the oxygen generator operates in an alternating pressurize/venting mode, at least one of the canisters should be in a pressurized state at any given time. In an alternate embodiment, the pressure may be increased in each canister by operation of compression system 200. When inlet valves 122 and 124 are opened, pressure between canisters 302 and 304 will equalize, however, the equalized pressure in either

canister may not be sufficient to inhibit air from entering the canisters during shutdown. In order to ensure that air is inhibited from entering the canisters, compression system 200 may be operated for a time sufficient to increase the pressure inside both canisters to a level at least greater than ambient pressure. Regardless of the method of pressurization of the canisters, once the canisters are pressurized, inlet valves 122 and 124 are closed, trapping the pressurized air inside the canisters, which inhibits air from entering the canisters during the shutdown period.

Referring to FIG. 2, an embodiment of an oxygen concentrator 100 is depicted. Oxygen concentrator 100 includes a compression system 200, a canister assembly 300, and a power supply 180 disposed within an outer housing 170. Inlets 101 are located in outer housing 170 to allow air from the environment to enter oxygen concentrator 100. Inlets 101 may allow air to flow into the compartment to assist with cooling of the components in the compartment. Power supply 180 provides a source of power for the oxygen concentrator 100. Compression system 200 draws air in through the inlet 106 and muffler 108. Muffler 108 may reduce noise of air being drawn in by the compression system and also may include a desiccant material to remove water from the incoming air. Oxygen concentrator 100 may further include fan 172 used to vent air and other gases from the oxygen concentrator.

Compression System

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In some embodiments, compression system 200 includes one or more compressors. In another embodiment, compression system 200 includes a single compressor, coupled to all of the canisters of canister system 300. Turning to FIGS. 3A and 3B, a compression system 200 is depicted that includes compressor 210 and motor 220. Motor 220 is coupled to compressor 210 and provides an operating force to the compressor to operate the compression mechanism. For example, motor 220 may be a motor providing a rotating component that causes cyclical motion of a component of the compressor that compresses air. When compressor 210 is a piston type compressor, motor 220 provides an operating force which causes the piston of compressor 210 to be reciprocated. Reciprocation of the piston causes compressed air to be produced by compressor 210. The pressure of the compressed air is, in part, assessed by the speed that the compressor is operated at, (e.g., how fast the piston is reciprocated). Motor 220, therefore, may be a variable speed motor that is operable at various speeds to dynamically control the pressure of air produced by compressor 210.

In one embodiment, compressor 210 includes a single head wobble type compressor having a piston. Other types of compressors may be used such as diaphragm compressors and other types of piston compressors. Motor 220 may be a DC or AC motor and provides the operating power to the compressing component of compressor 210. Motor 220, in an

WO 2012/033839 PCT/US2011/050700 embodiment, may be a brushless DC motor. Motor 220 may be a variable speed motor capable

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of operating the compressing component of compressor 210 at variable speeds. Motor 220 may be coupled to controller 400, as depicted in FIG. 1, which sends operating signals to the motor to control the operation of the motor.

Compression system 200 inherently creates substantial heat. Heat is caused by the consumption of power by motor 220 and the conversion of power into mechanical motion. Compressor 210 generates heat due to the increased resistance to movement of the compressor components by the air being compressed. Heat is also inherently generated due to adiabatic compression of the air by compressor 210. Thus the continual pressurization of air produces heat in the enclosure. Additionally, power supply 180 may produce heat as power is supplied to compression system 200. Furthermore, users of the oxygen concentrator may operate the device in unconditioned environments (e.g., outdoors) at potentially higher ambient temperatures than indoors, thus the incoming air will already be in a heated state.

Heat produced inside oxygen generator 100 can be problematic. Lithium ion batteries are generally employed as a power source for oxygen generators due to their long life and light weight. Lithium ion battery packs, however, are dangerous at elevated temperatures and safety controls are employed in oxygen concentrator 100 to shutdown the system if dangerously high power supply temperatures are detected. Additionally, as the internal temperature of oxygen concentrator 100 increases, the amount of oxygen generated by the concentrator may decrease. This is due, in part, to the decreasing amount of oxygen in a given volume of air at higher temperatures. If the amount of produced oxygen drops below a predetermined amount, the oxygen concentrator system may automatically shut down.

Because of the compact nature of oxygen concentrators, dissipation of heat can be difficult. Solutions typically involve the use of one or more fans to create a flow of cooling air through the enclosure. Such solutions, however, require additional power from the power supply and thus shorten the portable usage time of the oxygen concentrator. In an embodiment, a passive cooling system may be used that takes advantage of the mechanical power produced by motor 210. Referring to FIGS. 3A and 3B, compression system 200 includes motor 220 having an external rotating armature 230. Specifically, armature 230 of motor 220 (e.g. a DC motor) is wrapped around the stationary field that is driving the armature. Since motor 220 is a large contributor of heat to the overall system it is helpful to pull heat off of the motor and sweep it out of the enclosure. With the external high speed rotation, the relative velocity of the major component of the motor and the air in which it exists is very high. The surface area of the armature is larger if externally mounted than if it is internally mounted. Since the rate of heat exchange is proportional to the surface area and the square of the velocity, using a larger surface

area armature mounted externally increases the ability of heat to be dissipated from motor 220. The gain in cooling efficiency by mounting the armature externally, allows the elimination of one or more cooling fans, thus reducing the weight and power consumption while maintaining the interior of the oxygen concentrator within the appropriate temperature range. Additionally, the rotation of the externally mounted armature creates movement of air proximate to the motor to create additional cooling.

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Moreover, an external rotating armature may help the efficiency of the motor, allowing less heat to be generated. A motor having an external armature operates similar to the way a flywheel works in an internal combustion engine. When the motor is driving the compressor, the resistance to rotation is low at low pressures. When the pressure of the compressed air is higher, the resistance to rotation of the motor is higher. As a result, the motor does not maintain consistent ideal rotational stability, but instead surges and slows down depending on the pressure demands of the compressor. This tendency of the motor to surge and then slow down is inefficient and therefore generates heat. Use of an external armature adds greater angular momentum to the motor which helps to compensate for the variable resistance experienced by the motor. Since the motor does not have to work as hard, the heat produced by the motor may be reduced.

In an embodiment, cooling efficiency may be further increased by coupling an air transfer device 240 to external rotating armature 230. In an embodiment, air transfer device 240 is coupled to the external armature 230 such that rotation of the external armature causes the air transfer device to create an airflow that passes over at least a portion of the motor. In an embodiment, air transfer device includes one or more fan blades coupled to the armature. In an embodiment, a plurality of fan blades may be arranged in an annular ring such that the air transfer device acts as an impeller that is rotated by movement of the external rotating armature. As depicted in FIGS. 3A and 3B, air transfer device 240 may be mounted to an outer surface of the external armature 230, in alignment with the motor. The mounting of the air transfer device to the armature allows airflow to be directed toward the main portion of the external rotating armature, providing a cooling effect during use. In an embodiment, the air transfer device directs air flow such that a majority of the external rotating armature is in the air flow path.

Further, referring to FIGS. 3A and 3B, air pressurized by compressor 210 exits compressor 210 at compressor outlet 212. A compressor outlet conduit 250 is coupled to compressor outlet 212 to transfer the compressed air to canister system 300. As noted previously, compression of air causes an increase in the temperature of the air. This increase in temperature can be detrimental to the efficiency of the oxygen generator. In order to reduce the temperature of the pressurized air, compressor outlet conduit 250 is placed in the air flow path

produced by air transfer device 240. At least a portion of compressor outlet conduit 250 may be positioned proximate to motor 220. Thus, airflow, created by air transfer device, may contact both motor 220 and compressor outlet conduit 250. In one embodiment, a majority of compressor outlet conduit 250 is positioned proximate to motor 220. In an embodiment, the compressor outlet conduit 250 is coiled around motor 220, as depicted in FIG. 3B.

In an embodiment, the compressor outlet conduit 250 is composed of a heat exchange metal. Thus, compressor outlet conduit 250 can act as a heat exchanger to remove heat that is inherently caused by compression of the air. By removing heat from the compressed air, the number of oxygen molecules in a given volume is increased. As a result, the amount of oxygen that can be generated by each canister during each pressuring swing cycle may be increased.

The heat dissipation mechanisms described herein are either passive or make use of elements required for the oxygen concentrator system. Thus, for example, dissipation of heat may be increased without using systems that require additional power. By not requiring additional power, the run-time of the battery packs may be increased and the size and weight of the oxygen concentrator may be minimized. Likewise, use of an additional box fan or cooling unit may be eliminated. Eliminating such additional features reduces the weight and power consumption of the oxygen concentrator.

As discussed above, adiabatic compression of air causes the air temperature to increase. During venting of a canister in canister system 300, the pressure of the gas being released from the canisters decreases. The adiabatic decompression of the gas in the canister causes the temperature of the gas to drop as it is vented. In an embodiment, the cooled vented gases from canister system 300 are directed toward power supply 180 and toward compression system 200. In an embodiment, base 315 of compression system 300 receives the vented gases from the canisters. The vented gases 327 are directed through base 315 toward outlet 325 of the base and toward power supply 180. The vented gases, as noted, are cooled due to decompression of the gases and therefore passively provide cooling to the power supply. When the compression system is operated, the air transfer device will gather the cooled vented gases and direct the gases toward the motor of compression system 200. Fan 172 may also assist in directing the vented gas across compression system 200 and out of the enclosure 170. In this manner, additional cooling may be obtained without requiring any further power requirements from the battery.

Outlet System

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An outlet system, coupled to one or more of the canisters, includes one or more conduits for providing oxygen enriched gas to a user. In an embodiment, oxygen enriched gas produced in either of canisters 302 and 304 is collected in accumulator 106 through check valves 142 and

144, respectively, as depicted schematically in FIG. 1. The oxygen enriched gas leaving the canisters may be collected in an oxygen accumulator 106 prior to being provided to a user. In some embodiments, a tube may be coupled to the accumulator 106 to provide the oxygen enriched gas to the user. Oxygen enriched gas may be provided to the user through an airway delivery device that transfer the oxygen enriched gas to the user's mouth and/or nose. In an embodiment, an outlet may include a tube that directs the oxygen toward a user's nose and/or mouth that may not be directly coupled to the user's nose.

Turning to FIG. 4A, a schematic diagram of an embodiment of an outlet system for an oxygen concentrator is shown. A supply valve 160 may be coupled to outlet tube to control the release of the oxygen enriched gas from accumulator 106 to the user. In an embodiment, supply valve 160 is an electromagnetically actuated plunger valve. Supply valve 160 is actuated by controller 400 to control the delivery of oxygen enriched gas to a user. Actuation of supply valve 160 is not timed or synchronized to the pressure swing adsorption process. Instead, actuation is, in some embodiments, synchronized to the patient's breathing. Additionally, supply valve 160 may have multiple actuations to help establish a clinically effective flow profile for providing oxygen enriched gas.

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Oxygen enriched gas in accumulator 106 passes through supply valve 160 into expansion chamber 170 as depicted in FIG. 4A. In an embodiment, expansion chamber may include one or more devices capable of being used to determine an oxygen concentration of gas passing through the chamber. Oxygen enriched gas in expansion chamber 170 builds briefly, through release of gas from accumulator by supply valve 160, and then is bled through a small orifice flow restrictor 175 to a flow rate sensor 185 and then to particulate filter 187. Flow restrictor 175 may be a 0.025 D flow restrictor. Other flow restrictor types and sizes may be used. In some embodiments, the diameter of the air pathway in the housing may be restricted to create restricted air flow. Flow rate sensor 185 may be any sensor capable of assessing the rate of gas flowing through the conduit. Particulate filter 187 may be used to filter bacteria, dust, granule particles, etc prior to delivery of the oxygen enriched gas to the user. The oxygen enriched gas passes through filter 187 to connector 190 which sends the oxygen enriched gas to the user via conduit 192 and to pressure sensor 194. The fluid dynamics of the outlet pathway, coupled with the programmed actuations of supply valve 160, results in a bolus of oxygen being provided at the correct time and with a flow profile that assures rapid delivery into the patient's lungs without any excessive flow rates that would result in wasted retrograde flow out the nostrils and into the atmosphere.

Expansion chamber 170 may include one or more oxygen sensors capable of being used to determine an oxygen concentration of gas passing through the chamber. In an embodiment,

the oxygen concentration of gas passing through expansion chamber 170 is assessed using an oxygen sensor 165. An oxygen sensor is a device capable of detecting oxygen in a gas. Examples of oxygen sensors include, but are not limited to, ultrasonic oxygen sensors, electrical oxygen sensors, and optical oxygen sensors. In one embodiment, oxygen sensor 165 is an ultrasonic oxygen sensor that includes an ultrasonic emitter 166 and an ultrasonic receiver 168. In some embodiments, ultrasonic emitter 166 may include multiple ultrasonic emitters and ultrasonic receiver 168 may include multiple ultrasonic receivers. In embodiments having multiple emitters/receivers, the multiple ultrasonic emitters and multiple ultrasonic receivers may be axially aligned (e.g., across the gas mixture flow path which may be perpendicular to the axial alignment). Further details regarding sensing of oxygen in the expansion chamber may be found, for example, in U.S. Published Patent Application No. 2009-0065007, published March 12, 2009, and entitled "Oxygen Concentrator Apparatus and Method.

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Flow rate sensor 185 may be used to determine the flow rate of gas flowing through the outlet system. Flow rate sensor that may be used include, but are not limited to: diaphragm/bellows flow meters; rotary flow meters (e.g. a hall effect flow meters); turbine flow meters; orifice flow meters; and ultrasonic flow meters. Flow rate sensor 185 may be coupled to controller 400. The rate of gas flowing through the outlet system may be an indication of the breathing volume of the user. Changes in the flow rate of gas flowing through the outlet system may also be used to determine a breathing rate of the user. Controller 400 may control actuation of supply valve 160 based on the breathing rate and/or breathing volume of the user, as assessed by flow rate sensor 185

In some embodiments, ultrasonic sensor system 165 and, for example, flow rate sensor 185 may provide a measurement of an actual amount of oxygen being provided. For example, follow rate sensor 185 may measure a volume of gas (based on flow rate) provided and ultrasonic sensor system 165 may provide the concentration of oxygen of the gas provided. These two measurements together may be used by controller 400 to determine an approximation of the actual amount of oxygen provided to the user.

Oxygen enriched gas passes through flow meter 185 to filter 187. Filter 187 removes bacteria, dust, granule particles, etc prior to providing the oxygen enriched gas to the user. The filtered oxygen enriched gas passes through filter 187 to connector 190. Connector 190 may be a "Y" connector coupling the outlet of filter 187 to pressure sensor 194 and outlet conduit 192. Pressure sensor 194 may be used to monitor the pressure of the gas passing through conduit 192 to the user. Changes in pressure, sensed by pressure sensor 194, may be used to determine a breathing rate of a user, as well as the onset of inhalation. Controller 400 may control actuation of supply valve 160 based on the breathing rate and/or onset of inhalation of the user, as assessed

by pressure sensor 194. In an embodiment, controller 400 may control actuation of supply valve 160 based on information provided by flow rate sensor 185 and pressure sensor 194.

Oxygen enriched gas may be provided to a user through conduit 192. In an embodiment, conduit 192 may be a silicone tube. Conduit 192 may be coupled to a user using an airway coupling member 710, as depicted in FIGS. 4B and 4C. Airway delivery device 710 may be any device capable of providing the oxygen enriched gas to nasal cavities or oral cavities. Examples of airway coupling members include, but are not limited to: nasal masks, nasal pillows, nasal prongs, nasal cannulas, and mouthpieces. A nasal cannula airway delivery device is depicted in FIG. 4B. During use, oxygen enriched gas from oxygen concentrator system 100 is provided to the user through conduit 192 and airway coupling member 710. Airway delivery device 710 is positioned proximate to a user's airway (e.g., proximate to the user's mouth and or nose) to allow delivery of the oxygen enriched gas to the user while allowing the user to breath air from the surroundings.

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In an alternate embodiment, a mouthpiece may be used to provide oxygen enriched gas to the user. As shown in FIG. 4C, a mouthpiece 720 may be coupled to oxygen concentrator system 100. Mouthpiece 720 may be the only device used to provide oxygen enriched gas to the user, or a mouthpiece may be used in combination with a nasal delivery device (e.g., a nasal cannula). As depicted in FIG. 4C, oxygen enriched gas may be provided to a user through both a nasal coupling member 720 and a mouthpiece 720. During use, oxygen enriched gas is directed into the user's mouth via the mouthpiece. In an embodiment, at least a majority of the mouthpiece is positioned in a user's mouth during use.

During use, oxygen enriched gas may be directed to mouthpiece 720 when a change in pressure is detected proximate to the mouthpiece. In one embodiment, mouthpiece 720 may be coupled to a pressure sensor. When a user inhales air through the user's mouth, pressure sensor may detect a drop in pressure proximate to the mouthpiece. Controller 400 of oxygen concentrator system 100 may provide a bolus of oxygen enriched gas to the user at the onset of the detection of inhalation.

In an embodiment, a mouthpiece 720 is used in combination with an airway delivery device 710 (e.g., a nasal cannula) to provide oxygen enriched gas to a user, as depicted in FIG. 4C. Both mouthpiece 720 and airway delivery device 710 are coupled to an inhalation sensor. In one embodiment, mouthpiece 720 and airway delivery device 710 are coupled to the same inhalation sensor. In an alternate embodiment, mouthpiece 720 and airway delivery device 710 are coupled to different inhalation sensors. In either embodiment, inhalation sensor(s) may now detect the onset of inhalation from either the mouth or the nose. Oxygen concentrator system 100 may be configured to provide oxygen enriched gas to the device (i.e. mouthpiece 720 or

airway delivery device 710) that the onset of inhalation was detected. Alternatively, oxygen enriched gas may be provided to both mouthpiece 720 and the airway delivery device 710 if onset of inhalation is detected proximate either device. The use of a dual delivery system, such as depicted in FIG. 4C may be particularly useful for users when they are sleeping and may switch between nose breathing and mouth breathing without conscious effort.

Canister System

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Oxygen concentrator system 100 may include at least two canisters, each canister including a gas separation adsorbent. The canisters of oxygen concentrator system 100 may be disposed formed from a molded housing. In an embodiment, canister system 300 includes two housing components 310 and 510, as depicted in FIG. 5. The housing components 310 and 510 may be formed separately and then coupled together. In some embodiments, housing components 310 and 510 may be injection molded or compression molded.

As shown, valve seats 320, 322, 324, and 326 and air pathways 330 and 332 may be integrated into the housing component 310 to reduce the number of sealed connections needed throughout the air flow of the oxygen concentrator 100. In various embodiments, the housing components 310 and 410 of the oxygen concentrator 100 may form a two-part molded plastic frame that defines two canisters 302 and 304 and accumulation chamber 106.

Air pathways/tubing between different sections in housing components 310 and 510 may take the form of molded conduits. Conduits in the form of molded channels for air pathways may occupy multiple planes in housing components 310 and 510. In some embodiments, apertures 337 leading to the exterior of housing components 310 and 410 may be used to insert devices such as flow restrictors.

In some embodiments, spring baffle 129 may be placed into respective canister receiving portions of housing component 310 and 510 with the spring side of the baffle 129 facing the exit of the canister. Spring baffle 129 may apply force to gas separation adsorbent 139 in the canister while also assisting in preventing gas separation adsorbent 139 from entering the exit apertures. Use of a spring baffle 129 may keep the gas separation adsorbent compact while also allowing for expansion (e.g., thermal expansion). Keeping the gas separation adsorbent 139 compact may prevent the gas separation adsorbent from breaking during movement of the oxygen concentrator system 100).

In some embodiments, pressurized air from the compression system 200 may enter air inlet 306 as depicted in FIG. 2. Air inlet 306 is coupled to inlet conduit 330. Air entering housing component 310 through inlet 306, travels through conduit 330 to valve seats 320 and 328. FIG. 6A and FIG. 6B depict an end view of housing 310. FIG. 6A, depicts an end view of

housing 310 prior to fitting valves to housing 310; FIG. 6B depicts an end view of housing 310 with the valves fitted to the housing 310. Valve seats 322 and 324 are configured to receive inlet valves 122 and 124 respectively. Inlet valve 122 is coupled to canister 302 and inlet valve 124 is coupled to canister 304. Housing 310 also includes valve seats 332 and 334 configured to receive outlet valves 132 and 134 respectively. Outlet valve 132 is coupled to canister 302 and outlet valve 134 is coupled to canister 304. Inlet valves 122/124 are used to control the passage of air from conduit 330 to the respective canisters.

In an embodiment, pressurized air is sent into one of canisters 302 or 304 while the other canister is being vented. For example, during use, inlet valve 122 is opened while inlet valve 124 is closed. Pressurized air from compression system 200 is forced into canister 302, while being inhibited from entering canister 304 by inlet valve 124. During pressurization of canister 302, outlet valve 132 is closed and outlet valve 134 is opened. Similar to the inlet valves, outlet valves 132 and 134 are operated out of phase with each other. Each inlet valve seat 322 includes an opening 375 that passes through housing 310 into canister 302. Similarly valve seat 324 includes an opening 325 that passes through housing 310 into canister 302. Air from conduit 330 passes through openings 323 or 325 if the respective valve (322 or 324) is open and enters a canister.

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Check valves 142 and 144 are coupled to canisters 302 and 304, respectively. Check valves 142 and 144 are one way valves that are passively operated by the pressure differentials that occur as the canisters are pressurized and vented. Oxygen enriched gas, produced in canisters 302 and 304 pass from the canister into openings 542 and 544 of housing 410. A passage, not shown, links openings 542 and 544 to conduits 342 and 344, respectively. Oxygen enriched gas produced in canister 302 passes from the canister though opening 542 and into conduit 342 when the pressure in the canister is sufficient to open check valve 142. When check valve 142 is open, oxygen enriched gas flows through conduit 342 toward the end of housing 310. Similarly, oxygen enriched gas produced in canister 304 passes from the canister though opening 544 and into conduit 344 when the pressure in the canister is sufficient to open check valve 144. When check valve 144 is open, oxygen enriched gas flows through conduit 344 toward the end of housing 310.

Oxygen enriched gas from either canister, travels through conduit 342 or 344 and enters conduit 346 formed in housing 310. Conduit 346 includes openings that couple the conduit to conduit 342, conduit 344 and accumulator 106. Thus oxygen enriched gas, produced in canister 302 or 304, travels to conduit 346 and passes into accumulator 106.

After some time the gas separation adsorbent will become saturated with nitrogen and will be unable to separate significant amounts of nitrogen from incoming air. When the gas separation adsorbent in a canister reaches this saturation point, the inflow of compressed air is stopped and the canister is vented to remove nitrogen. Canister 302 is vented by closing inlet valve 122 and opening outlet valve 132. Outlet valve 132 releases the vented gas from canister 302 into the volume defined by the end of housing 310. Foam material may cover the end of housing 310 to reduce the sound made by release of gases from the canisters. Similarly, canister 304 is vented by closing inlet valve 124 and opening outlet valve 134. Outlet valve 134 releases the vented gas from canister 304 into the volume defined by the end of housing 310.

While canister 302 is being vented, canister 304 is pressurized to produce oxygen enriched gas in the same manner described above. Pressurization of canister 304 is achieved by closing outlet valve 134 and opening inlet valve 124. The oxygen enriched gas exits canister 304 through check valve 144.

In an exemplary embodiment, a portion of the oxygen enriched gas may be transferred from canister 302 to canister 304 when canister 304 is being vented of nitrogen. Transfer of oxygen enriched gas from canister 302 to 304, during venting of canister 304, helps to further purge nitrogen (and other gases) from the canister. Flow of oxygen enriched gas between the canisters is controlled using flow restrictors and valves, as depicted in FIG. 1. Three conduits are formed in housing 510 for use in transferring oxygen enriched gas between canisters. Referring to FIG. 7A, conduit 530 couples canister 302 to 304. Flow restrictor 151 (not shown) is disposed in conduit 530, between canister 302 and 304 to restrict flow of oxygen enriched gas during use. Conduit 532 also couples canister 302 to 304. Conduit 532 is coupled to valve seat 552 which receives valve 152, as shown in FIG. 7B. Flow restrictor 153 (not shown) is disposed in conduit 532, between canister 302 and 304. Conduit 534 also couples canister 302 to 304. Conduit 534 is coupled to valve seat 554 which receives valve 154, as shown in FIG. 7B. Flow restrictor 155 (not shown) is disposed in conduit 434, between canister 302 and 304. The pair of equalization/vent valves 152/154 work with flow restrictors 153 and 155 to optimize the air flow balance between the two canisters.

Oxygen enriched gas in accumulator 106 passes through supply valve 160 into expansion chamber 170 which is formed in housing 510. An opening (not shown) in housing 510 couples accumulator 106 to supply valve 160. In an embodiment, expansion chamber may include one or more devices capable of being used to determine an oxygen concentration of gas passing through the chamber.

Power Management

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Power for operation of oxygen concentrator system is provided by an internal power supply 180. Having an internal power supply allows portable use of the oxygen concentrator system. In one embodiment, internal power supply 180 includes a lithium ion battery. Lithium ion batteries offer advantages over other rechargeable batteries by being able to provide more power by weight than many other batteries.

In one embodiment, the compression system, valves, cooling fans and controller may all be powered but an internal power supply. Controller **400** (depicted schematically in FIG. 1) measures the actual output voltage of the internal power supply and adjusts the voltage to the various subsystems to the appropriate level though dedicated circuits on a printed circuit board positioned inside the oxygen concentrator.

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To recharge internal power supply 180, an external charger 820 may be used as depicted in FIG. 8. As used herein, the phrase "external charger" refers to a device capable of coupling to a power source and providing power at sufficient voltage and current to at least charge the internal power supply. In an embodiment, an external charger is capable of providing power at sufficient voltage and current to charge the internal power supply and to run the oxygen concentrator system during charging. The need for an external charger restricts the long term mobility of the oxygen concentrator, since, during recharging, the oxygen concentrator system is restricted to the area where the power source is provided. In order to extend the portable run time of the oxygen concentrator system, an auxiliary power supply may be coupled to the internal power supply to extend the run time of the device and expand the mobility options for the user. In theory, a user of the oxygen concentrator may have limitless portable use of the oxygen concentrator by bringing a sufficient number of auxiliary power supplies.

FIG. 9 depicts an oxygen concentrator system 100 coupled to an auxiliary power supply 810. Auxiliary power supply 810 may be attachable to oxygen concentrator system 100 using various fasteners 812 (e.g., hook-loop fasters). Alternatively, the auxiliary power supply may be attachable to the patient so as to have the weight of the auxiliary power supply carried by a different portion of the patient's body (e.g., a belt worn around the waist) rather than on a shoulder strap. Physically attaching auxiliary power supply 810 to oxygen concentrator system 100 may improve the portability and ease of use of the oxygen concentrator system. By providing options for attachment, the patient can optimize the carrying mode for their individual circumstance and thereby increase the potential for extending their mobility. Auxiliary power supply 810 may include an external output connector 815 which electrically couples the auxiliary power supply to input port 805 of oxygen concentrator system 100. When electrically coupled to

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input port 805 of oxygen concentrator system 100, auxiliary power supply 810 may provi

input port 805 of oxygen concentrator system 100, auxiliary power supply 810 may provide power to operate the oxygen concentrator system.

Oxygen concentrator system 100 includes a controller 400 (depicted in FIG. 1) configured to manage the power supplied to various components of the oxygen concentrator system. When no external power supplies (e.g., external charger 820 or auxiliary power supply 810) are coupled to oxygen concentrator system 100, controller 400 operates the system using internal power supply 180. Internal power supply 180 provides sufficient power to operate all components. During operation, controller 400 monitors the voltage produced by each of the cells of internal power supply 180. Since internal power supply 180 is capable of producing voltages in excess of the voltage required, controller 400 manages the internal power supply by monitoring the charge level of each cell to maintain consistent discharge from the cells so as not to overload any one cell and cause a runaway discharge.

Lithium batteries are also potentially explosive if the temperature of the battery becomes too high (e.g., above about 140 C). In an embodiment, controller 400 monitors the temperature of internal power supply 180 and shuts down oxygen concentrator system 100 if the temperature of the internal power supply exceeds a predetermined temperature.

When the stored power of internal power supply 180 is depleted, it is necessary to recharge the internal power supply in order to portably operate oxygen concentrator system 100. Alternatively, an auxiliary power supply 810 may be coupled to oxygen concentrator system 100. When auxiliary power supply 810 is coupled to oxygen concentrator system 100, as depicted in FIG. 9, controller 400 detects this condition and applies power from the auxiliary power supply to the components of the oxygen concentrator system. Internal power supply 180 is electrically decoupled while running oxygen concentrator system 100 using the auxiliary power supply. Once auxiliary power supply 810 is depleted of power, controller 400 will switch the oxygen concentrator system back to operation using internal power supply 180. If internal power supply 180 does not have sufficient power to operate the oxygen concentrator system, controller 400 places the system in a shutdown state.

If internal power supply 180 of the oxygen concentrator system 100 is depleted, an external charger 820 may be coupled to the oxygen concentrator system to provide power to recharge the internal power supply, as depicted in FIG. 8. External charger 820 is also capable of supplying power to operate oxygen concentrator system 100. Thus, power supplied by external charger 820 would need to be significantly greater than power supplied by auxiliary power supply 810 in order to both charge internal power supply 180 and operate oxygen concentrator system 100.

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In one embodiment, two charging input ports may be disposed on oxygen concentrator system 100 (not shown). A first input port may be used for coupling an auxiliary power supply to the oxygen concentrator system. The second input port may be used for coupling an external charger to the oxygen concentrator to supply charging power to the internal power supply and operating power to the oxygen concentrator system components. Internal circuitry may be coupled to each port and the internal power supply to provide the appropriate routing of the power when the appropriate power source is coupled to the appropriate charging input port.

In order to provide power to both the internal power supply and the oxygen concentrator system components, the external charger operates at a much higher current than the auxiliary power supply, which is only used to run the oxygen concentrator system components. If the external charger is accidentally coupled to the first input port (the auxiliary power supply input port), there exists the possibility that that one or more system components and/or the power supply may be damaged due to the excessive current. In one embodiment, inhibiting coupling of the wrong power supply to the wrong port may be accomplished by providing different physical dimensions to the first input port and second input port (and the corresponding auxiliary power supply connector and external charger connector). Thus, it may be physically difficult or impossible to couple the external charger to the first input port (i.e., the port for the auxiliary power supply), thus preventing accidental overpowering of the oxygen concentrator system.

Once the auxiliary power supply is depleted, it may be recharged by coupling the auxiliary power supply to an external charger. The external charger used to recharge the auxiliary battery system would have different output current requirements compared to an external power charger used to recharge the internal power supply and run the oxygen concentrator system. Thus, in an embodiment, an oxygen concentrator system includes: an internal power supply, an auxiliary power supply which can be coupled to the oxygen concentrator system to operate the oxygen concentrator system, a first external charger used to operate the oxygen concentrator system and recharge the internal power supply, and a second external charger used to charge the auxiliary battery. While this solution is effective, a traveling user may need to carry multiple external chargers in order to operate the system portably for prolonged periods.

In order to solve the problems created by differing power requirements of an auxiliary power supply and eternal chargers, control circuitry may be provided in both the oxygen concentrator system and the auxiliary power supply. In one embodiment, the oxygen concentrator system 100 includes a single input port 805 which is electrically coupled to the internal power source and the electrical components of the oxygen concentrator system through an internal power control circuit. The internal power control circuit is capable of directing

current to the appropriate components based on the power source that is electrically coupled to input port 805. For example, if an auxiliary power supply is coupled to input port 805, as depicted in FIG. 9, the internal power control circuit routes the current to the components of the oxygen concentrator system until the auxiliary power supply is depleted. If an external charger is coupled to the same input port 805, as depicted in FIG. 8, the internal power control circuit routes the current to the components of the oxygen concentrator system and to the internal power supply to charge the internal power supply. Because the internal power supply control circuit is capable of detecting these changes and making the appropriate routing, there is no need to have multiple input ports, and thus the external connectors from the auxiliary power supply and the external chargers may be the same.

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Use of a single port for coupling external charger 820 or auxiliary power supply 810 to input port 805 of oxygen concentrator system 100, allows output connector 815 for the auxiliary power supply to be identical to output connector 824 of the external charger. To reduce the number of chargers required, auxiliary power supply is designed to accept the external charger used for the oxygen concentrator system. Thus, in an embodiment, a single external charger is used to charge the internal power supply of the oxygen concentrator system and the auxiliary power supply. In order to facilitate the dual use of the external charger in this manner, input port 805 for the oxygen concentrator system, is identical to the input port 814 for the auxiliary battery pack. This mechanical compatibility simplifies the operation of the power system for the patient. External charger 820 can charge either oxygen concentrator system 100 or auxiliary power supply 810. This allows a traveling user to need only a single external charger to operate and charge the oxygen concentrator system and auxiliary power supply(s). In this mechanical arrangement, it is possible that auxiliary power supply 810 can be connected to oxygen concentrator system 100 and, simultaneously, external charger 820 can be connected to auxiliary power supply 810 in a daisy chain fashion, as depicted in FIG. 11A.

For this mechanical versatility, it is necessary to provide circuitry and software in both the oxygen concentrator system and the auxiliary power supply that establishes a hierarchy for the current flow. External charger 820 should be able to provide sufficient current to: charge the auxiliary power supply; provide enough current to charge the internal power source of the oxygen concentrator system; and simultaneously provide sufficient current to operate the oxygen concentrator system. Added together this amount of current could charge the batteries of the auxiliary power supply of the internal power supply too rapidly, causing overheating and even a fire in or explosion of the batteries.

In an embodiment, auxiliary power supply 810 may also have a control circuit 1100 coupled to an input 814 and an output 815. An embodiment of the auxiliary power supply control circuit is depicted in FIG. 10. The auxiliary power supply control circuit includes 3 connectors, one internal connector connecting the internal battery pack 1115 to the control circuit, and two external connectors, output 815 and input 814, to be used by the user. It should be noted that output connector 815 can plug into input port 814 by virtue of the input port for the auxiliary battery pack being substantially identical to input port 805 for the oxygen concentrator system. In order to prevent possible overheating and damage to the auxiliary power supply if output connector 815 is plugged into input port 814, the auxiliary power supply control circuit is designed to place the auxiliary power supply in standby mode, reducing internal current drain.

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The auxiliary power supply control circuit may direct flow of current through the auxiliary power supply. The auxiliary power supply control circuit comprises four main blocks: the charger block 1110; the boost block 1120; the power path controller 1130; and the current limit protection circuit 1140.

Charger block 1110 includes a DC/DC buck converter stepping down the input voltage to control the charging cycle of the internal battery. The maximum charging current allowed for a typical lithium ion battery setup is about 2A. Other current limits would be set depending on the specific configuration and types of battery used. A current limit is generally needed in the case of charging lithium ion battery cells and to size power from the external charger. The external charger requires a voltage on its input greater than the internal voltage of the battery, thus additional circuitry can be implemented to detect the voltage difference between input voltage and internal battery voltage before enabling the charging process. In FIG. 10 a blocking diode is placed at the input of the DC/DC buck converter to block any reverse voltage coming of the internal battery.

Boost block 1120 includes a basic boost converter with a switching device, a diode and an output capacitor. An enable pin is provided to enable/disable the control signal which would save power. The enable pin is activated by a logic low signal, this pin is assumed to be internally pulled low when it has no connection therefore enabling the controller. In an alternate embodiment, a synchronous boost converter could be used instead to improve efficiency.

Power path controller 1130 includes a MOSFET driver controlled by a voltage comparator. The power path controller emulates an approximate ideal OR'ing diode configured to switch between power supplies with minimum power losses, such that the power supply with the highest voltage is assigned to the output.

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The current limit protection circuit will cut off power when current exceeds a fixed current limit. The protection circuit can include a manual reset button or a timed reset signal. The purpose of this protection is to protect the boost converter from overload conditions and to determine the maximum power of the external charger.

Control circuit 1100 is capable of automatically detecting various power conditions and directing the current appropriately through the auxiliary power supply. For example, when the internal battery of auxiliary power supply 810 is charged and output connector 815 is not connected to any load, boost converter 1110 is activated and the stepped up regulated voltage is available at output connector 815 for the user. Thus the auxiliary power supply 810 is ready, upon connection with the oxygen concentrator system, to supply power to run the oxygen concentrator system.

When control circuit 1100 detects that the battery is discharged, the internal protection circuit cuts off power from the battery, and no voltage is available to output connector 815.

Control circuit 1100 permits auxiliary power supply 810 to recognize when it is put into service. When output connector 815 is not connected to a load, control circuit 1100 is always active, and requires a significant amount of power to stay active. Thus, auxiliary power supply 810 is in a continual state of discharging itself, even when not being used to run the oxygen concentrator system. As a result, auxiliary power supply 810 can become fully discharged and be useless to the use when needed.

To inhibit unintentional discharge, a standby mode is embedded in control circuit 1100. Standby mode can be initiated by the user connecting output connector 815 into input port 814, as depicted in FIG. 11B. Upon detection of this situation, control circuit 1100 uses the available output voltage to disable boost block 1120 through the enable line connection therefore reducing the operational quiescent currents needed to power the control and switching devices of the boost block. Once boost block 1120 is disabled, the output voltage drops to less than the internal voltage of battery 1115, because of the internal diode of the boost block, which provides a continuous path for battery 1115 to output connector 815. Maintaining this voltage on the output continuously will disable boost block 1120 through the same enable line. At the same time, the buck block 1110 is disabled, because a buck converter cannot step up the voltage, since the voltage at the input of the buck converter is the voltage of battery 1115 minus the forward voltage of the two series diodes shown in FIG. 10, when the connection between output connector 815 and input port 814 is established. Additional circuitry is designed inside buck block 1110 to completely disable the control when the input voltage is lower or equal to the voltage of battery 1115.

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Thus a user, upon completion of charging of auxiliary power supply 810, can place the auxiliary power supply into a standby mode by connecting output connector 815 to input port 814. In standby mode the boost converter and the buck converter are disabled to reduce the darin on the battery cells. This extends the power storage time of auxiliary power supply 820, and avoids potentially dangerous self charging of the auxiliary power supply.

When battery 1115 of auxiliary power supply 810 is discharged, control circuit 1110 of will disconnect power from the battery. Connection of output connector 815 to input port 814 will have no effect.

When external charger 820, with an output voltage higher than the output voltage of battery 1115, is plugged into input port 814, boost block 1120 is disabled and buck block 1110 is enabled. Enabling buck block 1110 allows battery 1115 to be charged by current from external charger 820. In addition, power path controller 1130 will enable a channel connected directly to input port 814 thus providing voltage to output connector 815 from external charger 820. Thus external charger 820 may be coupled to auxiliary power supply 810 while the auxiliary power supply is coupled to oxygen concentrator system 100, as depicted in FIG. 11, such that external charger can: charge the auxiliary power supply; provide enough current to charge the internal power source of the oxygen concentrator system; and simultaneously provide sufficient current to operate the oxygen concentrator system.

20 Controller System

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Operation of oxygen concentrator system 100 may be performed automatically using an internal controller 400 coupled to various components of the oxygen concentrator system, as described herein. Controller 400 includes one or more processors 410 and internal memory 420, as depicted in FIG. 1. Methods used to operate and monitor oxygen concentrator system 100 may be implemented by program instructions stored in memory 420 or a carrier medium coupled to controller 400, and executed by one or more processors 410.

Processor 410 may be coupled to various components of oxygen concentrator system 100, including, but not limited to compression system 200, one or more of the valves used to control fluid flow through the system (e.g., valves 122, 124, 132, 134, 152, 154, 160), oxygen sensor 165, pressure sensor 194, flow rate monitor 180, temperature sensors, fans, and any other component that may be electrically controlled. In some embodiments, a separate processor (and/or memory) may be coupled to one or more of the components.

Controller 400 is programmed to operate oxygen concentrator system 100 and is further programmed to monitor the oxygen concentrator system for malfunction states. For example, in one embodiment, controller 400 is programmed to trigger an alarm if the system is operating and

no breathing is detected by the user for a predetermined amount of time. For example, if controller 400 does not detect a breath for a period of 75 seconds, an alarm LED may be lit and/or an audible alarm may be sounded. If the user has truly stopped breathing, for example, during a sleep apnea episode, the alarm may be sufficient to awaken the user, causing the user to resume breathing. The action of breathing may be sufficient for controller 400 to reset this alarm function. Alternatively, if the system is accidently left on when output conduit 192 is removed from the user, the alarm may serve as a reminder for the user to turn oxygen concentrator system 100 off.

Controller 400 is further coupled to oxygen sensor 165, and may be programmed for continuous or periodic monitoring of the oxygen concentration of the oxygen enriched gas passing through expansion chamber 170. A minimum oxygen concentration threshold may be programmed into controller 400, such that the controller lights an LED visual alarm and/or an audible alarm to warn the patient of the low concentration of oxygen.

Controller 400 is also coupled to internal power supply 180 and is capable of monitoring the level of charge of the internal power supply. A minimum voltage and/or current threshold may be programmed into controller 400, such that the controller lights an LED visual alarm and/or an audible alarm to warn the patient of low power condition. The alarms may be activated intermittently and at an increasing frequency as the battery approaches zero usable charge.

Further functions of controller 400 are described in detail in other sections of this disclosure.

Outer Housing – Control Panel

FIG. 13 depicts an embodiment of an outer housing 170 of an oxygen concentrator system 100. In some embodiments, outer housing 170 may be comprised of a light-weight plastic. Outer housing includes compression system inlets 106, cooling system passive inlet 101 and outlet 172 at each end of outer housing 170, outlet port 174, and control panel 600. Inlet 101 and outlet 172 allow cooling air to enter ousing, flow through the housing, and exit the interior of housing 170 to aid in cooling of the oxygen concentrator system. Compression system inlets 101 allow air to enter the compression system. Outlet port 174 is used to attach a conduit to provide oxygen enriched gas produced by the oxygen concentrator system to a user.

Control panel 600 serves as an interface between a user and controller 400 to allow the user to initiate predetermined operation modes of the oxygen concentrator system and to monitor the status of the system. Charging input port 805 may be disposed in control panel 600. FIG. 14 depicts an embodiment of control panel 600.

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In some embodiments, control panel 600 may include buttons to activate various operation modes for the oxygen concentrator system. For example, control panel may include power button 610, dosage buttons (e.g., 1 LPM button 620, 2 LPM button 622, and 3 LPM button 624, and 4 LPM button 626), active mode button 630, sleep mode button 635, and a battery check button 650. In some embodiments, one or more of the buttons may have a respective LED that may illuminate when the respective button is pressed (and may power off when the respective button is pressed again). Power button 610 may power the system on or off. If the power button is activated to turn the system off, controller 400 may initiate a shutdown sequence to place the system in a shutdown state (e.g., a state in which both canisters are pressurized). Dosage buttons 620, 622, 624, and 626 allows the proper prescription level to be selected. Altitude button 640 may be selected when a user is going to be in a location at a higher elevation than the oxygen concentrator is regularly used by the user. The adjustments made by the oxygen concentrator system in response to activating altitude mode are described in more detail herein. Battery check button 650 initiates a battery check routine in the oxygen concentrator system which results in a relative battery power remaining LED 655 being illuminated on control panel 600.

A user may have a low breathing rate or depth if relatively inactive (e.g., asleep, sitting, etc.) as assessed by comparing the detected breathing rate or depth to a threshold. The user may have a high breathing rate or depth if relatively active (e.g., walking, exercising, etc.). An active/sleep mode may be assessed automatically and/or the user may manually indicate a respective active or sleep mode by pressing button 630 for active mode and button 635 for sleep mode. The adjustments made by the oxygen concentrator system in response to activating active mode or sleep mode are described in more detail herein.

25 Methods of Delivery of Oxygen Enriched Gas

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The main use of an oxygen concentrator system is to provide supplemental oxygen to a user. Generally, the amount of supplemental oxygen to be provided is assessed by a physician. Typical prescribed amounts of supplemental oxygen may range from about 1 LPM to up to about 10 LPM. The most commonly prescribed amounts are 1 LPM, 2 LPM, 3 LPM, and 4 LPM. Generally, oxygen enriched gas is provided to the use during a breathing cycle to meet the prescription requirement of the user. As used herein the term "breathing cycle" refers to an inhalation followed by an exhalation of a person.

In order to minimize the amount of oxygen enriched gas that is needed to be produced to meet the prescribed amounts, controller 400 may be programmed to time delivery of the oxygen enriched gas with the user's inhalations. Releasing the oxygen enriched gas to the user as the

user inhales may prevent unnecessary oxygen generation (further reducing power requirements) by not releasing oxygen, for example, when the user is exhaling. Reducing the amount of oxygen required may effectively reduce the amount of air compressing needed for oxygen concentrator 100 (and subsequently may reduce the power demand from the compressors).

Oxygen enriched gas, produced by oxygen concentrator system 100 is stored in an oxygen accumulator 106 and released to the user as the user inhales. The amount of oxygen enriched gas provided by the oxygen concentrator system is controlled, in part, by supply valve 160. In an embodiment, supply valve 160 is opened for a sufficient amount of time to provide the appropriate amount of oxygen enriched gas, as assessed by controller 400, to the user. In order to minimize the amount of oxygen required to meet he prescription requirements of a use, the oxygen enriched gas may be provided in a bolus when a user's inhalation is first detected. For example, the bolus of oxygen enriched gas may be provided in the first few milliseconds of a user's inhalation.

In an embodiment, pressure sensor 194 and/or flow rate sensor 185 may be used to determine the onset of inhalation by the user. For example, the user's inhalation may be detected by using pressure sensor 194. In use, a conduit for providing oxygen enriched gas is coupled to a user's nose and/or mouth (e.g., using a nasal cannula or face mask). At the onset of an inhalation, the user begins to draw air into their body through the nose and/or mouth. As the air is drawn in, a negative pressure is generated at the end of the conduit, due, in part, to the venturi action of the air being drawn across the end of the delivery conduit. Pressure sensor 194 may be operable to create a signal when a drop in pressure is detected, to signal the onset of inhalation. Upon detection of the onset of inhalation, supply valve 160 is controlled to release a bolus of oxygen enriched gas from the accumulator 106.

In some embodiments, pressure sensor 194 may provide a signal that is proportional to the amount of positive or negative pressure applied to a sensing surface. The amount of the pressure change detected by pressure sensor 194 may be used to refine the amount of oxygen enriched gas being provided to the user. For example, if a large negative pressure change is detected by pressure sensor 194, the volume of oxygen enriched gas provided to the user may be increased to take into account the increased volume of gas being inhaled by the user. If a smaller negative pressure is detected, the volume of oxygen enriched gas provided to the user may be decreased to take into account the decreased volume of gas being inhaled by the user. A positive change in the pressure indicates an exhalation by the user and is generally a time that release of oxygen enriched gas is discontinued. Generally while a positive pressure change is sensed, valve 160 remains closed until the next onset of inhalation.

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In an embodiment, the user's inhalation may be detected by using flow rate sensor 185. In use, a conduit for providing oxygen enriched gas is coupled to a user's nose and/or mouth (e.g., using a nasal cannula or face mask). At the onset of an inhalation, the user begins to draw air into their body through the nose and/or mouth. As the air is drawn in, an increase in flow of gas passing through conduit is created. Flow rate sensor 185 may be operable to create a signal when an increase in flow rate is detected, to signal the onset of inhalation. Upon detection of the onset of inhalation, supply valve 160 is controlled to release a bolus of oxygen enriched gas from the accumulator 106.

A user breathing at a rate of 30 breaths per minute (BPM) during an active state (e.g., walking, exercising, etc.) may consume two and one-half times as much oxygen as a user who is breathing at 12 BPM during a sedentary state (e.g., asleep, sitting, etc.). Pressure sensor 194 and/or flow rate sensor 185 may be used to determine the breathing rate of the user. Controller 400 may process information received from pressure sensor 194 and/or flow rate sensor 185 and determine a breathing rate based on the frequency of the onset of inhalation. The detected breathing rate of the user may be used to adjust the bolus of oxygen enriched gas. The volume of the bolus of oxygen enriched gas may be increased as the users breathing rate increase, and may be decreased as the users breathing rate decreases. Controller 400 may automatically adjust the bolus based on the detected activity state of the user. Alternatively, the user may manually indicate a respective active or sedentary mode by selecting the appropriate option on control panel 600.

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In some embodiments, if the user's current activity level as assessed using the detected user's breathing rate exceeds a predetermined threshold, controller **400** may implement an alarm (e.g., visual and/or audio) to warn the user that the current breathing rate is exceeding the delivery capacity of the oxygen concentrator system. For example, the threshold may be set at 20 breaths per minute.

In some embodiments, as seen in FIG. 12, the bolus of provided oxygen enriched gas may include two or more pulses. For example, with a one liter per minute (LPM) delivery rate, the bolus may include two pulses: a first pulse 1210 at approximately 7 cubic centimeters and a second pulse 1220 at approximately 3 cubic centimeters. Other delivery rates, pulse sizes, and number of pulses are also contemplated. For example, at 2 LPMs, the first pulse may be approximately 14 cubic centimeters and a second pulse may be approximately 6 cubic centimeters and at 3 LPMs, the first pulse may be approximately 21 cubic centimeters and a second pulse may be approximately 9 cubic centimeters. In some embodiments, the larger pulse 1210 may be provided when the onset of inhalation is detected (e.g., detected by pressure sensor 194). In some embodiments, the pulses may be provided when the onset of inhalation is detected

and/or may be spread time-wise evenly through the breath. In some embodiments, the pulses may be stair-stepped through the duration of the breath. In some embodiments, the pulses may be distributed in a different pattern. Additional pulses may also be used (e.g., 3, 4, 5, etc. pulses per breath). While the first pulse 1210 is shown to be approximately twice the second pulse 1220, in some embodiments, the second pulse 1220 may be larger than the first pulse 1210. In some embodiments, pulse size and length may be controlled by, for example, supply valve 160 which may open and close in a timed sequence to provide the pulses. A bolus with multiple pulses may have a smaller impact on a user than a bolus with a single pulse. The multiple pulses may also result in less drying of a user's nasal passages and less blood oxygen desaturation. The multiple pulses may also result in less oxygen waste.

In some embodiments, the sensitivity of the oxygen concentrator 100 may be selectively attenuated to reduce false inhalation detections due to movement of air from a different source (e.g., movement of ambient air). For example, the oxygen concentrator 100 may have two selectable modes — an active mode and an inactive mode. In some embodiments, the user may manually select a mode (e.g., through a switch or user interface). In some embodiments, the mode may be automatically selected by the oxygen concentrator 100 based on a detected breathing rate. For example, the oxygen concentrator 100 may use the pressure sensor 194 to detect a breathing rate of the user. If the breathing rate is above a threshold, the oxygen concentrator 100 may operate in an active mode (otherwise, the oxygen concentrator may operate in an inactive mode). Other modes and thresholds are also contemplated. Further details regarding modes of operation of an oxygen concentrator may be found, for example, in U.S. Published Patent Application No. 2009-0065007, published March 12, 2009, and entitled "Oxygen Concentrator Apparatus and Method.

25 Providing a Bolus Based on Inhalation Profile

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In an embodiment, the bolus profile can be designed to match the profile of a particular user. To do so, an inhalation profile may be generated based on information gathered from pressure sensor 194 and flow rate sensor 185. An inhalation profile is assessed based on, one or more of the following parameters: the breathing rate of the user; the inhalation volume of the user; the exhalation volume of the user; the inhalation flow rate of the user; and the exhalation flow rate of the user. The breathing rate of the user may be assessed by detecting the onset of inhalation using pressure sensor 194 or flow rate sensor 185 as previously discussed. Inhalation volume may be assessed by measuring the change in pressure during inhalation and calculating or empirically assessing the inhalation volume based on the change in pressure. Alternatively, inhalation volume may be assessed by measuring the flow rate during inhalation and calculating

or empirically assessing the inhalation volume based on the flow rate and the length of the inhalation. Exhalation volume may be assessed in a similar manner using either positive pressure changes during exhalation, or flow rate and exhalation time. Inhalation flow rate of the user is measured from shortly after the onset of inhalation. Detection of the end of inhalation may be from the pressure sensor or the flow rate sensor. When onset of inhalation is detected by the pressure sensor, the onset is characterized by a drop in pressure. When the pressure begins to increase, the inhalation is considered complete. When onset of inhalation is detected by the flow rate sensor, the onset is characterized by an increase in the flow rate. When the flow rate begins to decrease, the inhalation is considered complete.

There is a minimum amount of oxygen necessary for a person to remain conscious. A person who is breathing rapidly is bringing in a lower volume of air in each breath, and thus, requires less oxygen enriched gas per inhalation. While there is some variation from patient to patient, this relationship can be used to establish the mean flow rate for each breath mathematically. By measuring a large population of patients, the profile of the relative flow from onset of inhalation to the onset of exhalation may be established. Using this flow profile as a template, the calculated actual flow based on breathing rate can be adjusted mathematically to a calculated actual flow profile. This profile can be used to adjust the opening and closing of the delivery valve to create an idealized profile for the patient based on their breathing rate. Inhalaiton profile data gathered from a population of users may be used to create an algorithm that makes the appropriate adjustments based on the detected inhalation profile. Alternatively, a look up table may be used to control valve actuation durations and pulse quantities based on a detected inhalation profile.

Measuring the inhalation profile of the patient provides a more accurate basis for control of the bolus of oxygen enriched gas being provided to the patient. For example, basing the delivery of oxygen enriched gas on the onset of inhalation may not take into account differences between individual users. For example, people having a similar breathing rate can have different inhalation/exhalation volume, inhalation/exhalation flow rates and, thus, different bolus requirements necessary to produce the prescribed amount of oxygen. In one embodiment, an inhalation profile is created based on the flow rate of air during inhalation and the duration of inhalation. The inhalation profile can then be used as a predictor of the volume of air taken in by a specific user during inhalation. Thus, inhalation profile information can be used to modify the amount of oxygen enriched air provided to the user to ensure that the prescribed level of oxygen is received. The amount of oxygen provided to a user may be adjusted by modifying the frequency and or duration of release of oxygen enriched gas from the accumulator with supply valve 160. By tracking the inhalation profile of the patient controller adjusts the delivery supply

valve actuation to idealize the bolus profile to provide the oxygen at the maximum rate without causing wasteful retrograde flow.

Altitude Compensation

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An oxygen concentrator system uses a pressure swing adsorption process to separate oxygen from nitrogen in air. In order to have an effective separation of the oxygen from the nitrogen, the compressed air in the canisters should reach a minimum absolute pressure. Generally, the compressors move a fixed amount of ambient air with each revolution of the drive motor. Based on the speed that the motors are being operated, the time required to reach the minimum pressure can be predicted and programmed into the controller. Thus, the timing of the actuation of inlet and outlet valves for pressurization and venting can be based on the motor speed and is generally assumed to be constant. At higher altitudes, air pressure drops and less air is available for each revolution of the drive. Consequently, the time it takes for a compressor to pressurize the canister to the minimum pressure at higher altitudes is longer than the time it would take for the compression system to reach the minimum pressure at sea level.

In an embodiment, controller 400 includes a mode of operation that is capable of compensating for use at elevations significantly above sea level. Controller 400 can compensate for the thinner air at higher elevations by adjusting the motor speed and or valve timing to ensure that the proper pressure is reached inside the canisters. In one embodiment, a compression system includes a motor 220 coupled to a compressor 210, as depicted in FIGS. 3A and 3B. A default motor speed may be set by controller 400 which is based on an air pressure at or proximate to the pressure of air at sea level. At high altitudes, controller may alter the motor to run at a speed greater than the default speed. Running the motor at a faster speed ensures that a canister reaches the appropriate pressure for oxygen enriched gas production, before being vented in preparation of the next cycle. Using a motor control scheme, the timing of the inlet and outlet valves would not be modified.

Alternatively, the valve timing sequence may be altered to ensure the appropriate pressure is reached at higher elevations A default timing sequence for opening and closing inlet valves and outlet valves may be set by controller 400 which is based on an air pressure at or proximate to the pressure of air at sea level. At high altitudes, controller may alter the delay opening and closing of the valves to allow the compression system more time to collect and compress air. Delaying the timing sequence of the valves ensures that a canister reaches the appropriate pressure for oxygen enriched gas production, before being vented in preparation of the next cycle. Using a valve timing control scheme, the timing of the compression system would not be modified.

In an alternate embodiment, a combination of changing the motor speed and altering the timing of opening the valves can be used to ensure proper pressurization of the canisters. Oxygen concentrator may include a pressure sensor 176 disposed in the oxygen concentrator and coupled to controller 400 to determine an ambient pressure. Based on the ambient air pressure detected by pressure sensor 176, the controller may automatically modify the motor speed and/or the timing of the actuation of the valves to compensate for the reduced air pressure. The automatic adjustment of the operating conditions based on air pressure may be controlled by the user.

The altitude adjustment mode may be entered manually by the user, or automatically by the controller. For example, a user operated switch may be coupled to a controller. In an embodiment, the user operated switch allows the user to switch operation of the oxygen concentrator between a first mode of operation and a second mode of operation. In the first mode of operation, the program instructions are further operable to operate the compression system using default operating conditions, wherein the default operating conditions are not altered based on the ambient pressure sensed by the pressure sensor. In the second mode of operation, the program instructions are further operable to operate the compression system using modified operating conditions, wherein the modified operating conditions are altered based on the ambient pressure sensed by the pressure sensor. The user operated switch may be an "altitude" switch 640 on control panel 600.

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When the oxygen concentrator system is in the second mode of operation, a signal (e.g., a light or an alarm) may be presented to the user. Alternatively, the oxygen concentrator system may display a light or produce an alarm when the ambient pressure is less than the ambient pressure at an elevation of 1000 meters, or 1500 meters, or 2000 meters. When an ambient pressure is detected that is less than the ambient pressure at an elevation of 1000 meters, or 1500 meters, or 2000 meters, a controller may: increase the rate of compression; increase the amount of compression; increase the compression cycle time; or perform combinations thereof, to compensate for the reduced air pressure.

The delivery of a bolus of oxygen enriched air to a user is based, in part on the air resistance of the environment. For example, in order to provide the bolus of oxygen enriched air to the user, the bolus must be released at a pressure sufficient to overcome the ambient pressure against the conduit leading to the user. At sea level the ambient pressure is significantly greater than at higher elevations. Thus, if no compensation is made for the higher elevation, the outward flow of the bolus will be too large and take too long. In one embodiment, the controller may modify the actuation of the supply valve to adjust the bolus delivery based on the detected

ambient pressure. For example, the supply valve actuation may be adjusted to ensure that the oxygen and ambient air proportion provided to the patient is substantially identical to the ratios that would occur at sea level and result in a delivery that conforms to the patient's prescribed level of supplemental oxygen.

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Positive Pressure Therapy Systems

Sleep apnea is a sleep disorder characterized by having one or more pauses in breathing or shallow breaths during sleep. Each pause in breathing, called an apnea, can last from a few seconds to minutes, and may occur 5 to 30 times or more an hour. For moderate to severe sleep apnea, the most common treatment is the use of a positive airway pressure, which helps to maintain an open airway during sleep by means of a flow of pressurized air into the patient's mouth and/or nose. The patient typically wears a mask that covers the nose and/or mouth and which is connected by a flexible tube to a small bedside compressor.

Positive pressure therapy relies on the use of pressurized air to assist in maintaining an open airway for the user while sleeping. There are various techniques that are used to accomplish this. One technique is known as continuous positive airway pressure (CPAP). In CPAP air is pushed from a flow generator through the tubing to a mask. The air then passes through the nose and/or mouth and into the throat, where the slight pressure keeps the upper airway open. During treatment by CPAP the pressure remains constant during use of the device. Automatic positive airway pressure (APAP) is an alternate method of applying pressurized air to a user's airway. In APAP, the positive air pressure applied to the user is continuously adjusted based on the breathing pattern of the patient. For example, if a sleep apnea episode is detected the pressure applied to the user may be increased to force the airway open. If the user is having difficulty exhaling or appears to be breathing normally, the pressure may be reduced to make the system more comfortable. Bi-level devices work by providing two different pressures of air to the user. During inhalation, a maximum pressure is provided to the user to ensure that the airway passages remain opened. The pressure is dropped during exhalation to make exhalation more comfortable for the user.

If a person suffering from sleep apneas is also in need of oxygen therapy significant amounts of oxygen may be required. As discussed above, positive pressure therapy of sleep apnea requires a constant pressure to be applied to the patient, while allowing release of pressurized air during exhalation. This is typically accomplished by use of a ventilated mask on the patient that allows some of the gas to flow out of the mask. This requires high flow rate (from 20 - 60 liters per minute) in order to achieve the required positive pressure. Since most oxygen concentrators can only produce up to about 10 LPM at most, it has been generally

thought that oxygen concentrators could not be used in conjunction with positive pressure therapy.

In one embodiment, an inhalation detection sensor (e.g., a pressure sensor or a flow rate sensor) may be coupled to a mask used for positive pressure therapy, and a pulse of oxygen enriched gas may be provided through a structure in the mask such that the bolus is sent directly into the air passages of the user (e.g., the nose or mouth) in spite of the continuous outflow of air from the mask that is an inherent feature of positive pressure treatment. One embodiment of a positive pressure therapy mask is depicted in FIG. 15. In FIG. 15, a positive pressure therapy mask 1500 is depicted. Positive pressure therapy mask 1500 includes a first conduit port 1510 for coupling to a compressed air source and a venting port 1520 for allowing a portion of the pressurized air entering the mask to exit. An oxygen concentrator, similar to the oxygen concentrators described herein, may be coupled to the mask via conduit 192. Conduit 192 may pass through the mask through second conduit port 1532 and rest near an air passage of the user. For example, a nasal cannula 1530 coupled to conduit 192 may be positioned proximate to the nose of the user to allow delivery of pulses of oxygen directly to the nose during use. Alternatively, a second conduit port 1532 may include a coupling that allows a conduit from an oxygen concentrator to be attaché to the mask. A seprate conduit may extend from the mask to the user's nose to deliver ocygen enriched gas to the user. In such emdoiments, a nasal cannula may be coupled to the second conduit port 1532 via conduit 1534. A pressure sensor 194 may be coupled to conduit 192 and conduit 190 may couple conduit 192 to an oxygen concentrator system. While the positive therapy mask 1500 is depicted as a full face mask (i.e., a mask that covers both nose and mouth) it should be understood that a similar configuration may be used on other kinds of masks including nasal masks, oral masks and total face masks.

A schematic diagram of a positive pressure therapy system is depicted in FIG. 16. Positive therapy system 1600 includes compression system 1610, oxygen concentrator 1620, a mask 1500 and an inhalation sensor 1640. Mask 1500 is coupled to oxygen concentrator 1620 via conduits 1622 and 1624 through inhalation sensor 1640. Mask 1500 is also coupled to compression system 1610 via conduit 1612. The term "mask" as used herein refers to any device capable of providing a gas to nasal cavities or oral cavities. Examples of masks include, but are not limited to: nasal masks, nasal pillows, nasal prongs, oral masks, full face masks (e.g., masks that cover both the nose and the mouth), total face masks (e.g., masks that cover the mouth, nose, and eyes). The term "mask" also includes invasive gas delivery devices such as an endotracheal tube, an oropharyngeal airway, or laryngeal mask. Operation of compression system 1610 and oxygen concentrator 1620 is controlled by controller 1650.

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During use compression system 1610 produces a compressed air stream which is directed through conduit 1612 to mask 1500. Controller 1650 operates compression system 1610 to produce a stream of compressed air that is sufficient to meet the positive pressure therapy requirements of the user, typically producing compressed air having a flow rate of between about 20 LPM to 60 LPM. Controller 1650 is further coupled to inhalation sensor 1640. Inhalation sensor 1640 is coupled to mask 1500 and determines the onset of inhalation for the user by sensing a change in the air flow or pressure inside the mask. For example inhalation sensor may be a flow rate meter or a pressure sensor. Methods for detecting changes in pressure include methods discussed herein based on pressure changes and/or flow rate changes. At the onset of inhalation, controller 1650 may active a mechanism of the oxygen concentrator to release a bolus of oxygen directed directly to the user's airway via conduits 1622 and 1624. Thus, oxygen is only provided when needed, minimizing the volume requirements of oxygen needed and allowing the patient to receive the prescribed oxygen.

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When mask 1500 is coupled to the user, and compressed air is received by the mask from compression system 1610, a positive pressure (i.e. a pressure greater than the ambient pressure, builds up in the mask, due, in part to the restrictive venting of the mask. The positive pressure creates a condition such that the pressure measured by a pressure sensor coupled to the mask may never become negative. In such an embodiment, the onset of inhalation may be assessed by a significant drop in pressure, even if the drop in pressure still indicates a pressure in the mask that is above ambient pressure. Controller 1650 may therefore be configured to sense this condition and provide the bolus of oxygen enriched gas to user at the onset of inhalation.

For positive therapy systems that are based on APAP or bi-level control, controller 1650 may already be programmed to determine the breathing status of the patient, and make adjustments to the pressure in the mask. In an embodiment, controller 1650 may be configured to release a bolus of oxygen enriched gas from the oxygen concentrator system in synchronization with the pressure changing algorithm. For example, in an APAP device, the positive air pressure applied to the user is continuously adjusted based on the breathing pattern of the patient. Thus, an APAP device controller is already programmed to recognize when an increase in positive pressure is required to overcome resistance to breathing. Controller 1650 may include an APAP algorithm that is modified to also coordinate the release of an oxygen enriched gas from oxygen concentrator system when pressure is adjusted to stimulate breathing during a sleep apnea episode. In a bi-level system device the controller is already programmed to recognize when to increase the positive pressure during inhalation and when to decrease the pressure during exhalation. Controller 1650 may include a bi-level algorithm that is modified to

also coordinate the release of an oxygen enriched gas from oxygen concentrator system when pressure is adjusted during inhalation.

During positive pressure therapy, a positive pressure is created inside the mask that is greater than ambient pressure. In one embodiment, a correction pressure is assessed by measuring ambient pressure and comparing ambient pressure to the pressure measured inside the mask. An ambient pressure sensor may be coupled to controller 1650 (e.g., ambient pressure sensor 176 in oxygen concentrator) and the ambient pressure measured. A correction pressure may be assessed as a function of the ambient pressure and the pressure inside of mask 1630. In one embodiment, the correction pressure is the difference between the pressure inside of mask 1630 and the ambient pressure. The pressure in the mask may be measured using a mask pressure sensor. During use, the pressure inside the mask may vary due to inhalation and exhalation of the user. In one embodiment, a correction pressure may be based on an average mask pressure measured over one or more breathing cycles. In another embodiment, a correction pressure may be based on a maximum mask pressure assessed over one or more breathing cycles. In another embodiment, a correction pressure may be based on a pressure in the mask when no breathing events (i.e., inhalation or exhalation) are occurring.

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Once a correction pressure is assessed, operation of the oxygen generation system may be keyed to changes in pressure in the mask. During use the pressure in the mask is continuously or automatically measured. After each measurement, an adjusted mask pressure is assessed as a function of the measured mask pressure and the correction pressure. In one embodiment, the adjusted pressure is the difference between the measured pressure inside the mask and the correction pressure. In this embodiment, the onset of inhalation may be signaled by a drop in the adjusted pressure. If the adjusted pressure is less than a predetermined pressure, the system recognizes the onset of inhalation and provides a bolus of oxygen enriched gas to the user. Alternatively, since the adjusted pressure is corrected for ambient pressure, the onset of inhalation may be recognized when the adjusted pressure is less than ambient pressure. The correction pressure may be used by the system to automatically account for different mask pressures. Additionally, many oxygen concentrator systems are programmed to provide oxygen enriched air to the user when a pressure sensor detects a pressure below ambient pressure at the conduit used to provide oxygen enriched gas to the user. By using an adjusted pressure to signal the onset of inhalation, the oxygen concentrator system may need little if any adjustment.

During positive pressure therapy, a positive pressure is created inside the mask that is greater than ambient pressure. To prevent a continual increase of pressure inside the mask, masks used for positive pressure therapy have one or more venting ports built into the mask. This allows excess air to continuously exit the mask and also provides an outlet for exhalation.

In one embodiment, a flow rate of air exiting the mask through one or more venting ports is assessed. During a breathing cycle the flow rate of the gasses exiting the mask will vary. When no breathing event occurs (i.e., when the patient is neither inhaling nor exhaling) the flow rate of gas exiting the mask is substantially constant and represents a baseline flow rate. During exhalation, the flow rate of gas exiting the mask will increase; during inhalation the flow rate of gas exiting the mask will decrease. During use the flow rate of gas exiting the mask is continuously or automatically measured. If the flow rate drops and is less than a baseline flow rate, the system recognizes the onset of inhalation and provides a bolus of oxygen enriched gas to the user. In an alternate embodiment, the onset of inhalation is recognized when the flow rate exiting the mask drops by a predetermined amount.

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In another embodiment, a system for positive pressure therapy includes an independent compression system for providing a substantially continuous flow of air to a mask (e.g., a CPAP, APAP, or Bi-level sleep apnea device) and an independent oxygen concentrator system. An oxygen concentrator system may be independently coupled to the mask and/or coupled to a continuous air flow delivery conduit. A schematic diagram of a positive pressure therapy system is depicted in FIG. 17. Positive therapy system 1700 includes compression system 1710, an oxygen concentrator system 1720, and a mask 1500. System 1700 also includes an inhalation sensor 1740 coupled to oxygen concentrator system 1720. Inhalation sensor may be separate from or an integral component of oxygen concentrator system 1720. Mask 1500 is coupled to oxygen concentrator system 1720 via conduits 1722 and 1724. Mask 1500 is also coupled to compression system 1710 via conduit 1712. Since both compression system 1710 and oxygen concentrator system 1720 are designed for independent use, each system includes a controller that directs operation of the system. Compression system 1710 include controller 1715 for directing the delivery of compressed air to the patient. Oxygen concentrator system 1720 includes controller 1725 for directing the production and delivery of oxygen enriched gas to the user. Compression system 1710 and oxygen concentrator system 1720 are removably couplable to mask 1500, such that the system can be used independently from each other.

During use compression system 1710 produces a compressed air stream which is directed through conduit 1712 to mask 1500. Controller 1715 operates compression system 1710 to produce a stream of compressed air that is sufficient to meet the positive pressure therapy requirements of the user, typically producing compressed air having a flow rate of between about 20 LPM to 60 LPM. Inhalation sensor 1740, coupled to mask 1500 and oxygen concentrator system 1720, determines the onset of inhalation for the user by sensing a change in the air flow or pressure inside the mask. For example inhalation sensor may be a flow rate meter or a pressure sensor. Methods for detecting changes in pressure include methods discussed herein

based on pressure changes and/or flow rate changes. At the onset of inhalation, oxygen concentrator system controller 1725 may active a mechanism of the oxygen concentrator to release a bolus of oxygen directed directly to the user's airway via conduits 1722 and 1724. Thus, oxygen is only provided when needed, minimizing the volume requirements of oxygen needed and allowing the patient to receive the prescribed oxygen.

The detection of the onset of inhalation, as well as other information regarding the inhalation profile of the user, is useful for the operation of both compression system 1710 and oxygen concentrator system 1720. In one embodiment, to facilitate the coordination of the operation of compression system 1710 and oxygen concentrator system 1720, controller 1715 is couplable to controller 1725 via connection link 1730. Connection link 1730 may be embodied by a wired connection between controllers or may be a wireless connection. At least one of controllers 1715 and 1725 may be programmed to recognize the presence of the other controller along the connection link. Upon detection of another controller, one or both controllers operate to synchronize delivery of oxygen enriched gas with the delivery of pressurized air by the compression system. For example, in an APAP or bi-level device, the pressure of the air produced by the compression system various according to the breathing pattern of the user. The changes in pressure produced by the compression system may be used to control the delivery of oxygen enriched gas to the user, such that the delivery is synchronized with the pressure change. For example, when compression system initiates an increase in pressure to assist with inhalation, oxygen concentrator system may initiate delivery of oxygen enriched gas to the user.

Since the mask or other delivery device is under elevated pressure, the delivery flow rate of the oxygen concentrator is reduced. In one embodiment of the invention, the delivery valve of the oxygen concentrator is adjusted based on the pressure transducer reading of the internal mask pressure. This assures the system is delivering the correct bolus size that would otherwise be reduced by the resisting pressure in the mask.

Ventilator Systems

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A positive pressure ventilator includes a compressed air source and a controller for providing the compressed air to the patient. Positive pressure ventilation works by forcing a breathing gas into the lungs, thereby increasing the pressure inside the airway and causing the lung to expand. When the pressurized air is discontinued, the patient will exhale passively due to the lungs' elasticity, the exhaled gas being released usually through a one-way valve within the conduits and mask coupled to the patient. As used herein the term "breathing gas" refers to a gas that is used by a user for respiration. Examples of breathing gases include, air, air/oxygen

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mixtures, nitrogen/oxygen mixtures, and pure oxygen. Air/oxygen and nitrogen/oxygen mixtures
may vary in oxygen content from about 21% up to about 100% oxygen by volume.

In some instances, the person under ventilation may need more oxygen than is present in air. As discussed above, ventilation uses pulses of pressurized breathing gas that are applied to the patient to create inhalation for the patient, while allowing release of pressurized breathing gas during exhalation. This is typically accomplished by use of a ventilated mask on the patient that allows the gas to flow out of the mask when the pressurized air delivery is discontinued. In order to provide oxygen enriched gas to the patient, most ventilators rely on upstream mixing of oxygen from a compressed oxygen storage system (e.g., a compressed oxygen tank) with air or nitrogen to establish the proper oxygen level in the breathing gases provided to the patient.

In one embodiment, an inhalation detection sensor (e.g., a pressure sensor or a flow rate sensor) may be coupled to a mask used for ventilation, and a pulse of oxygen enriched gas may be provided through a structure in the mask such that the bolus is sent directly into the air passages of the user (e.g., the nose or mouth) during the pulsed delivery of pressurized breathing gas. The release of oxygen enriched gas may be at or near a time when a pulse of pressurized breathing gas is supplied to the mask.

A schematic diagram of a ventilation system is depicted in FIG. 18. Ventilation system 1800 includes compression system 1810, oxygen concentrator 1820, a mask 1860 and an inhalation sensor 1840. Mask 1860 is coupled to oxygen concentrator 1820 via conduits 1822 and 1824 through inhalation sensor 1840. Mask 1860 is also coupled to compression system 1810 via conduit 1812. Operation of compression system 1810 and oxygen concentrator 1820 is controlled by controller 1850.

During use compression system 1810 produces a pulse of compressed breathing gas which is directed through conduit 1812 to mask 1860. Controller 1850 operates compression system 1810 to produce a pulse of pressurized breathing gas that is sufficient to expand the patient's lungs, creating an inhalation for the patient. Controller 1850 is further coupled to inhalation sensor 1840. Inhalation sensor 1840 is coupled to mask 1860 and determines the onset of inhalation for the user. In one embodiment, inhalation sensor 1840 is a pressure sensor that can detect a change in the pressure inside the mask. Methods for detecting changes in pressure include methods discussed herein based on pressure changes. At the onset of inhalation, controller 1850 may active a mechanism of the oxygen concentrator to release a bolus of oxygen directed directly to the user's airway via conduits 1822 and 1824. Thus, oxygen is only provided when needed, minimizing the volume requirements of oxygen needed and allowing the patient to receive the prescribed oxygen.

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When mask 1860 is coupled to the user, and compressed breathing gas is received by the mask from compression system 1810, a positive pressure (i.e. a pressure greater than the ambient pressure, builds up in the mask. The positive pressure created in the mask initiates the inhalation portion of the breathing cycle for the patient. The onset of inhalation, therefore, may be assessed by a significant increase in pressure. Controller 1850 may therefore be configured to sense an increase in pressure in the mask and provide the bolus of oxygen enriched gas to user at the onset of inhalation.

Alternatively, controller 1850 may be programmed to provide pulses of compressed breathing gas to the patient at predetermined intervals. Thus, the onset of inhalation occurs at predetermined times and is known by controller. In one embodiment, controller 1650 may coordinate the release of oxygen enriched gas from oxygen concentrator 1820 with the delivery of the pressurized breathing gas from compression system 1810. Controller 1850 may be programmed to substantially simultaneously send signals to compression system 1810 and oxygen concentrator 1820 to initiate release of their respective gases to the patient.

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In another embodiment, a ventilation system includes an independent compression system for providing pulses of breathing gas to a mask and an independent oxygen concentrator system. An oxygen concentrator system may be independently coupled to the mask and/or coupled to a breathing gas delivery conduit. A schematic diagram of a ventilation system is depicted in FIG. 19. Positive therapy system 1900 includes compression system 1910, an oxygen concentrator system 1920, and a mask 1960. System 1900 also includes an inhalation sensor 1940 coupled to oxygen concentrator system 1920. Inhalation sensor may be separate from or an integral component of oxygen concentrator system 1920. Mask 1960 is coupled to oxygen concentrator system 1920 via conduits 1922 and 1924. Mask 1960 is also coupled to compression system 1910 via conduit 1912. Since both compression system 1910 and oxygen concentrator system 1920 are designed for independent use, each of system includes a controller that directs operation of the system. Compression system 1910 include controller 1915 for directing the delivery of compressed air to the patient. Oxygen concentrator system 1920 includes controller 1925 for directing the production and delivery of oxygen enriched as to the user. Compression system 1910 and oxygen concentrator system 1920 are removably couplable to mask 1960, such that the system can be used independently from each other.

During use compression system 1920 produces a pulse of compressed breathing gas which is directed through conduit 1912 to mask 1960. Controller 1915 operates compression system 1910 to produce a pulse of compressed breathing gas that is sufficient induce or create inhalation in the patient. Inhalation sensor 1940, coupled to mask 1960 and oxygen concentrator system 1920, determines the onset of inhalation for the patient by sensing a change in the

pressure inside the mask. For example, an onset of inhalation by the patient is indicated when the pressure inside the mask increases due to the delivery of a pulse of compressed breathing gas to the mask. At the onset of inhalation, oxygen concentrator system controller 1925 may active a mechanism of the oxygen concentrator to release a bolus of oxygen directed directly to the user's airway via conduits 1922 and 1924. Thus, oxygen is only provided when needed, minimizing the volume requirements of oxygen needed and allowing the patient to receive the prescribed oxygen.

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In one embodiment, to facilitate the coordination of the operation of compression system 1910 and oxygen concentrator system 1920, controller 1915 is couplable to controller 1925 via connection link 1930. Connection link 1930 may be embodied by a wired connection between controllers or may be a wireless connection. At least one of controllers 1915 and 1925 may be programmed to recognize the presence of the other controller along the connection link. Upon detection of another controller, one or both controllers operate to synchronize delivery of oxygen enriched gas with the delivery a pulse of compressed breathing gas by the compression system. For example, when compression system initiates delivery of a pulse of compressed breathing gas, oxygen concentrator system may initiate delivery of oxygen enriched gas to the user.

As with the other positive airway adjustments above, the delivery valve of the oxygen concentrator is adjusted based on the resisting pressure in the mask or other delivery device of the ventilator so that the same size bolus of oxygen is delivered into the airstream being delivered to the patient.

Further modifications and alternative embodiments of various aspects of the invention may be apparent to those skilled in the art in view of this description. Accordingly, this description is to be construed as illustrative only and is for the purpose of teaching those skilled in the art the general manner of carrying out the invention. It is to be understood that the forms of the invention shown and described herein are to be taken as embodiments. Elements and materials may be substituted for those illustrated and described herein, parts and processes may be reversed, and certain features of the invention may be utilized independently, all as would be apparent to one skilled in the art after having the benefit of this description of the invention. Changes may be made in the elements described herein without departing from the spirit and scope of the invention as described in the following claims.

CLAIMS

1. An oxygen concentrator apparatus comprising:

a canister system configured for a gas separation adsorbent that separates at least some nitrogen from air in the canister system to produce oxygen enriched gas;

a compression system comprising at least one compressor coupled to the canister system, wherein the at least one compressor compresses air for the canister system during operation;

an accumulator coupled to canister system to collect oxygen enriched gas produced in the canister system during use;

a sensor responsive to user inhalation and configured to generate a proportional sensing signal; and

a controller coupled to the sensor, the controller including one or more processors and a set of valves, the controller configured to control operation of the set of valves to (a) produce oxygen enriched gas into the accumulator and (b) release a plurality of boluses of the produced oxygen enriched gas from the accumulator, the controller further configured to:

receive the proportional sensing signal,

adjust a volume of at least one bolus of the plurality of boluses according to an amount of the proportional sensing signal; and

control a release of each bolus of the plurality of boluses in association with a detection of inhalation by a user.

- 2. The oxygen concentrator apparatus of claim 1 wherein the controller is configured to control release of a first bolus of the plurality of boluses and second bolus of the plurality of boluses, wherein the first bolus comprises a first volume and the second bolus comprises a second volume, wherein the first volume is less than the second volume when an increase in the proportional sensing signal is detected.
- 3. The oxygen concentrator apparatus of claim 2 wherein the controller is configured to control release of a third bolus of the plurality of boluses and fourth bolus of the plurality of boluses, wherein the third bolus comprises a third volume and the fourth bolus comprises a fourth volume, wherein the third volume is greater than the fourth volume when a decrease in the proportional sensing signal is detected.
- 4. The oxygen concentrator apparatus of claim 1 wherein the controller is configured to control release of a first bolus of the plurality of boluses and second bolus of the plurality of boluses, wherein the first bolus comprises a first volume and the second bolus comprises a second

volume, wherein the first volume is greater than the second volume when a decrease in the proportional sensing signal is detected.

- 5. The oxygen concentrator apparatus of claim 4 wherein the controller is configured to control release of a third bolus of the plurality of boluses and fourth bolus of the plurality of boluses, wherein the third bolus comprises a third volume and the fourth bolus comprises a fourth volume, wherein the third volume is less than the fourth volume when an increase in the proportional sensing signal is detected.
- 6. The oxygen concentrator apparatus of any one of claims 1 to 5 wherein the sensor comprises a pressure sensor.
- 7. The oxygen concentrator apparatus of claim 6 wherein the proportional sensing signal is a pressure signal.
- 8. The oxygen concentrator apparatus of claim 7 wherein the controller is configured to detect a negative pressure change of a first amount with the pressure sensor, and in a case of such a detection, control release of a bolus of a first volume.
- 9. The oxygen concentrator apparatus of claim 8 wherein the controller is configured to detect a negative pressure change of a second amount smaller than the first amount, and in a case of such a detection, control release of a bolus of a second volume smaller than the first volume to account for a decreased volume of gas being inhaled by the user.
- 10. The oxygen concentrator apparatus of any one of claims 7 to 9 wherein the controller is configured to detect a positive change in pressure, and in a case of such a detection, discontinue release of oxygen enriched gas to the user.
- 11. The oxygen concentrator apparatus of any one of claims 1 to 10 wherein the controller is configured to detect user inhalation by detection of a drop in a signal from the sensor.
- 12. The oxygen concentrator apparatus of claim 11 wherein upon release of a bolus, the controller is configured to prevent the release of a further bolus until a next onset of inhalation is detected.
- 13. The oxygen concentrator apparatus of any one of claims 1 to 12 wherein the controller is further configured to:

determine a breathing rate of the user, and

adjust a volume of a bolus of another plurality of boluses according to the determined breathing rate.

14. A control method of a controller for operation of an oxygen concentrator apparatus, the control method comprising:

controlling a set of valves to (a) produce oxygen enriched gas into an accumulator, and (b) release a plurality of boluses of the produced oxygen enriched gas from the accumulator; the set of valves being coupled to a gas separation adsorbent canister system and a compression system;

receiving, from a sensor responsive to user inhalation, a proportional sensing signal generated by the sensor;

adjusting a volume of at least one bolus of the plurality of boluses according to an amount of the proportional sensing signal; and

generating signals to control a release of each bolus of the plurality of boluses in association with a detection of inhalation by a user.

- 15. The method of claim 14 wherein the controller generates a signal to control release of a first bolus of the plurality of boluses and second bolus of the plurality of boluses, wherein the first bolus comprises a first volume and the second bolus comprises a second volume, wherein the first volume is less than the second volume when an increase in the proportional sensing signal is detected.
- 16. The method of claim 15 wherein the controller generates signals to control release of a third bolus of the plurality of boluses and fourth bolus of the plurality of boluses, wherein the third bolus comprises a third volume and the fourth bolus comprises a fourth volume, wherein the third volume is greater than the fourth volume when a decrease in the proportional sensing signal is detected.
- 17. The method of claim 14 wherein the controller controls release of a first bolus of the plurality of boluses and second bolus of the plurality of boluses, wherein the first bolus comprises a first volume and the second bolus comprises a second volume, wherein the first volume is greater than the second volume when a decrease in the proportional sensing signal is detected.
- 18. The method of claim 17 wherein the controller generates signals to control release of a third bolus of the plurality of boluses and fourth bolus of the plurality of boluses, wherein the third bolus comprises a third volume and the fourth bolus comprises a fourth volume, wherein the third volume is less than the fourth volume when an increase in the proportional sensing signal is detected.

- 19. The method of any one of claims 14 to 18 wherein the sensor senses pressure.
- 20. The method of claim 19 wherein the proportional sensing signal is a pressure signal.
- 21. The method of claim 20 wherein when the controller detects a negative pressure change of a first amount with the pressure sensor, the controller generates a signal for release of a bolus of a first volume of oxygen enriched gas to the user.
- 22. The method of claim 21 wherein when the controller detects a negative pressure change of a second amount smaller than the first amount, the controller generates a signal to control release of a bolus of a second volume smaller than the first volume to the user to account for a decreased volume of gas being inhaled by the user.
- 23. The method of any one of claims 20 to 22 wherein when the controller detects a positive change in pressure, the controller discontinues control of release of oxygen enriched gas to the user.
- 24. The method of any one of claims 14 to 23 wherein the controller detects user inhalation by detection of a drop in a signal from the sensor.
- 25. The method of claim 24 wherein upon release of a bolus, the controller prevents release of a further bolus until a next onset of inhalation is detected.
- 26. The method of any one of claims 14 to 25 wherein the controller determines a breathing rate of the user and adjusts a volume of a bolus of another plurality of boluses according to the determined breathing rate.



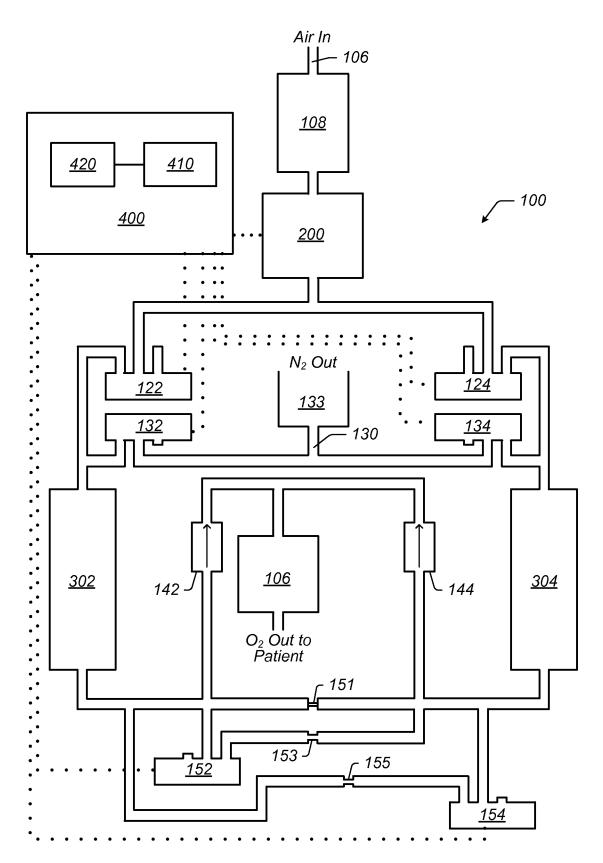


FIG. 1

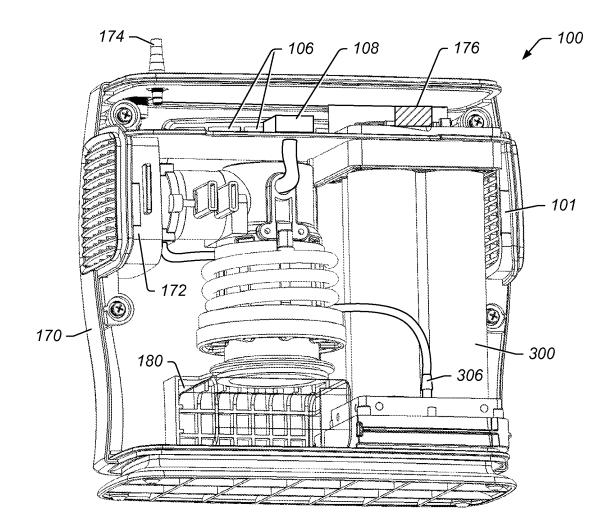


FIG. 2



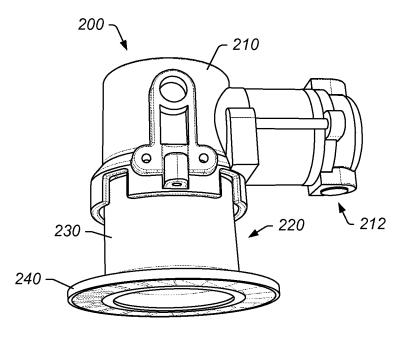
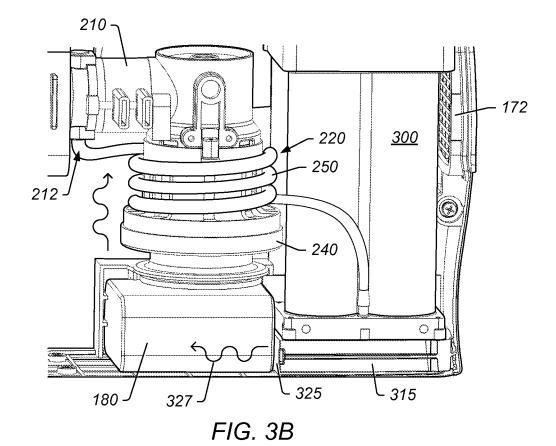
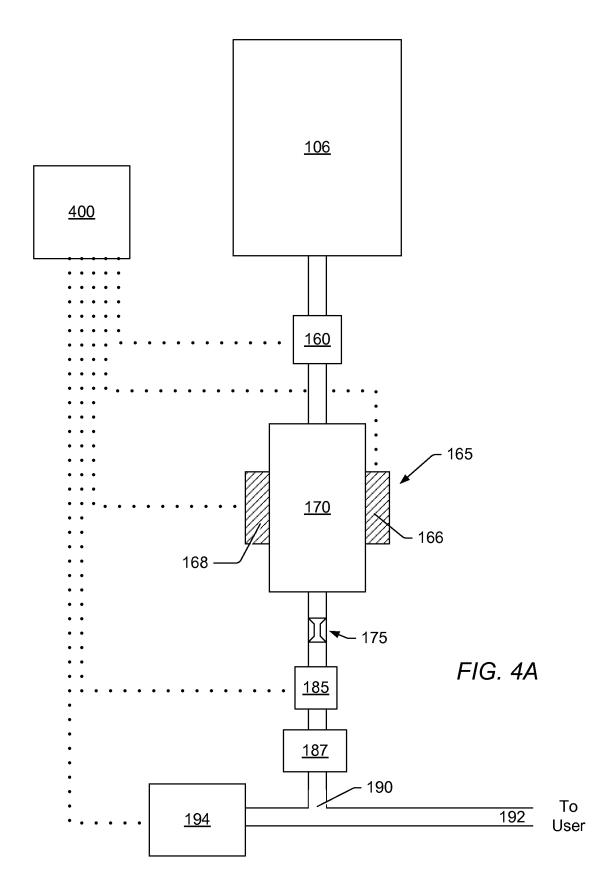
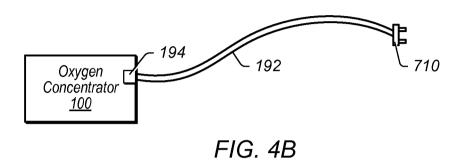


FIG. 3A

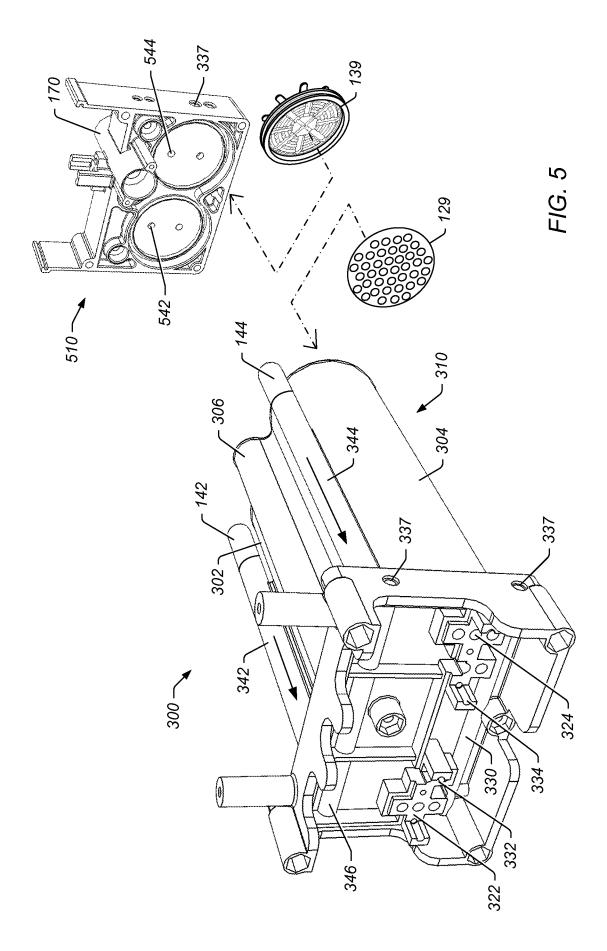


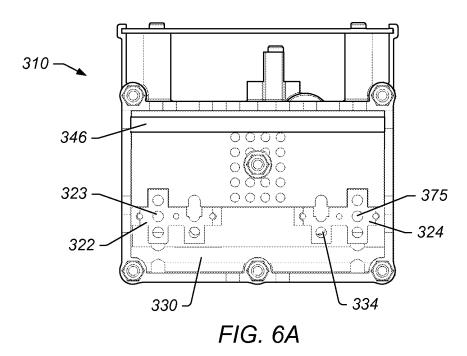


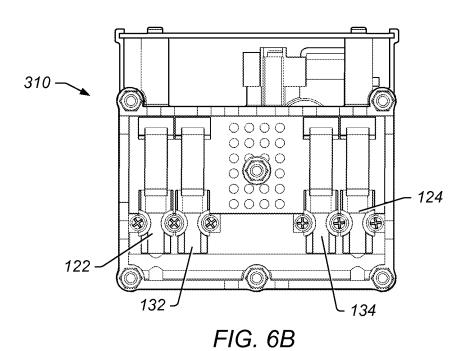


Oxygen Concentrator 100 710

FIG. 4C







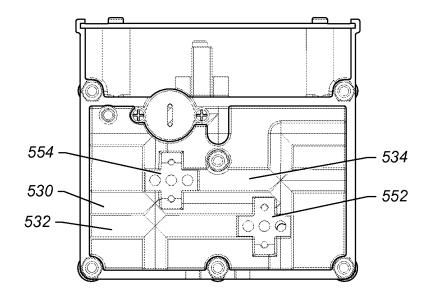


FIG. 7A

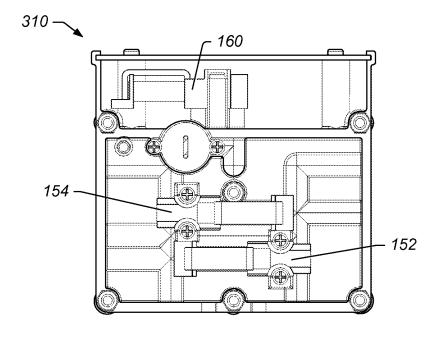
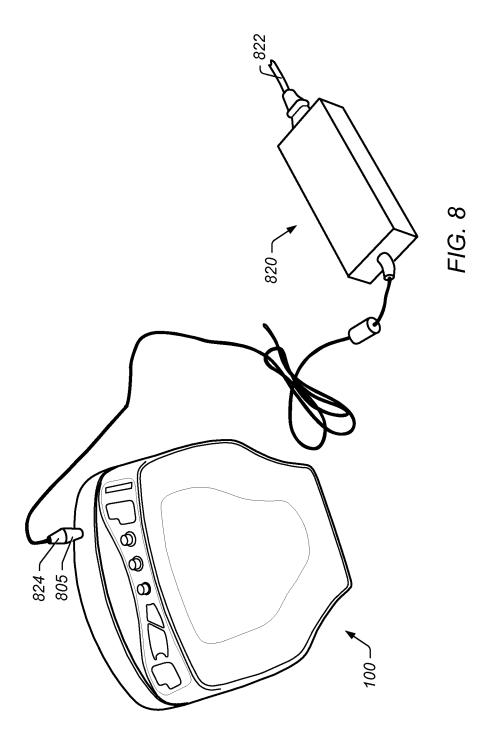
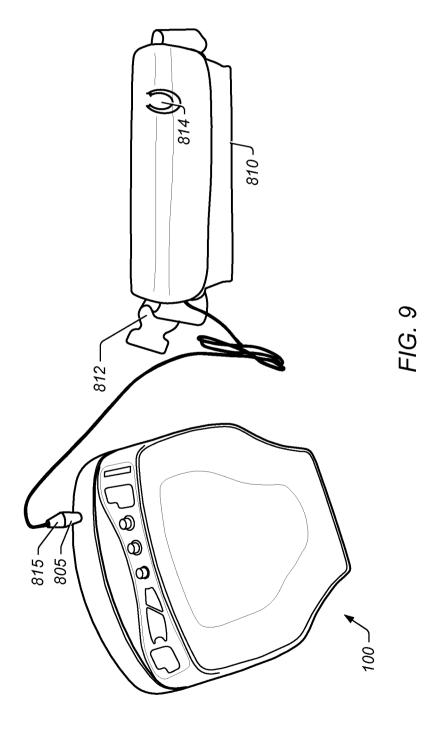
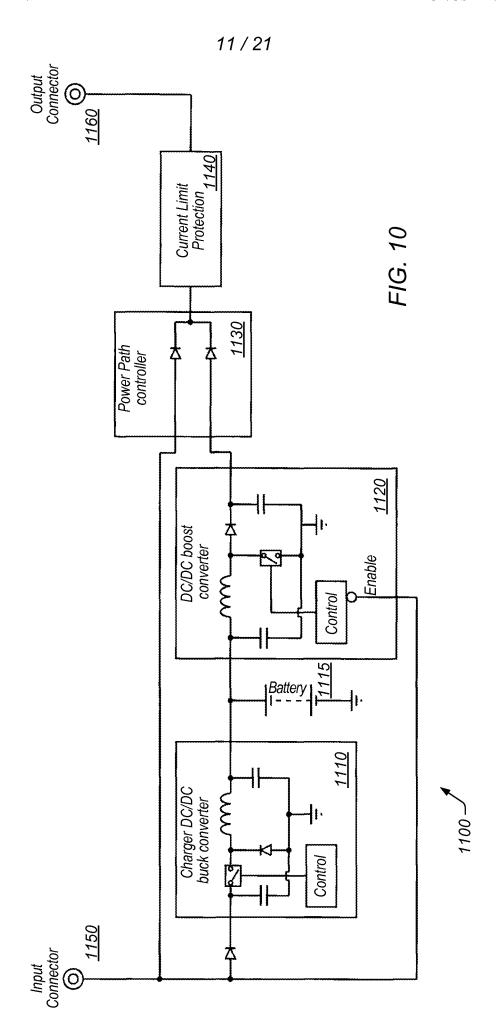


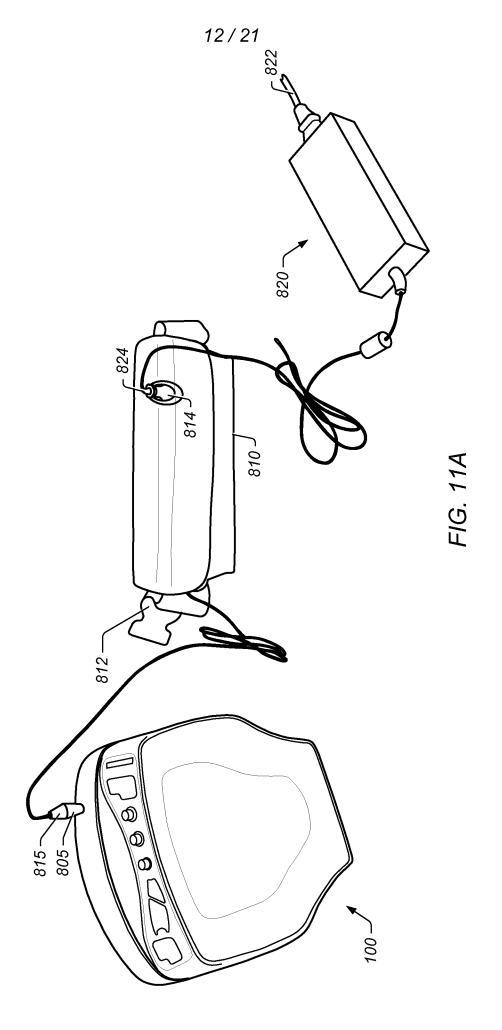
FIG. 7B



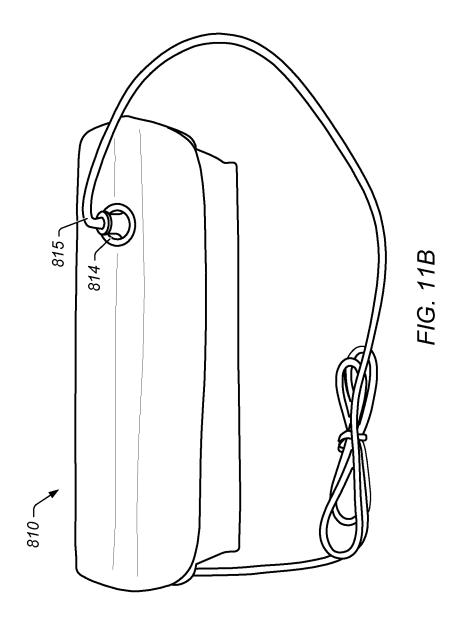




SUBSTITUTE SHEET (RULE 26)



SUBSTITUTE SHEET (RULE 26)



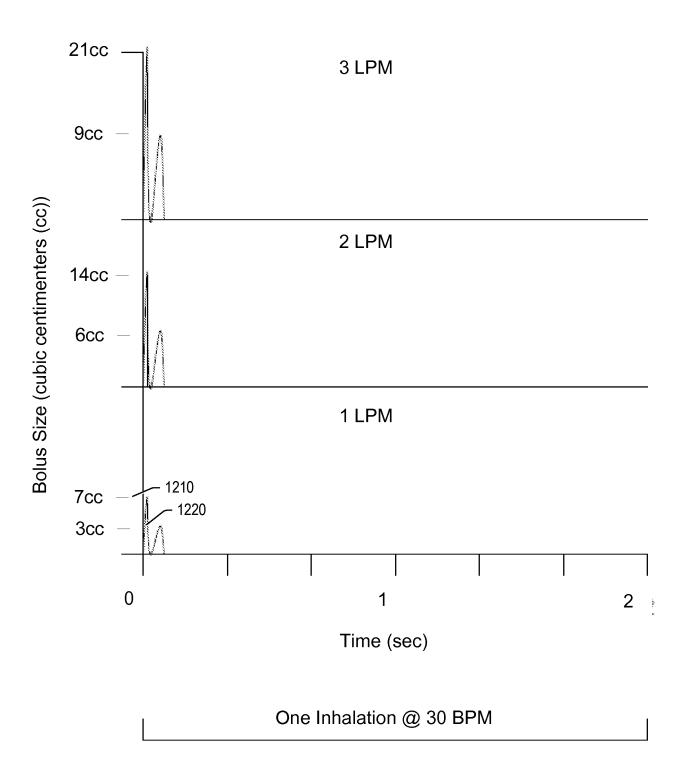


FIG. 12

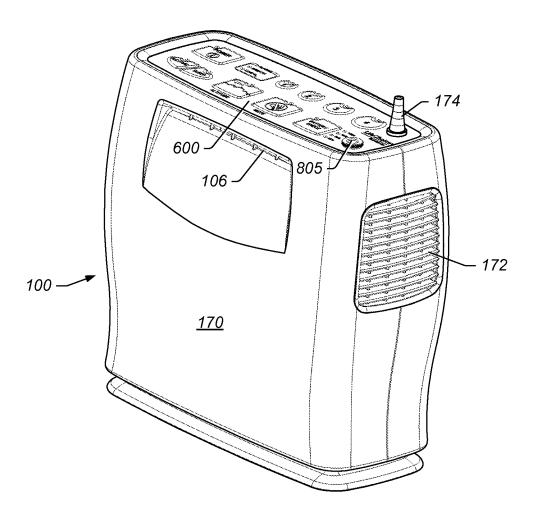


FIG. 13

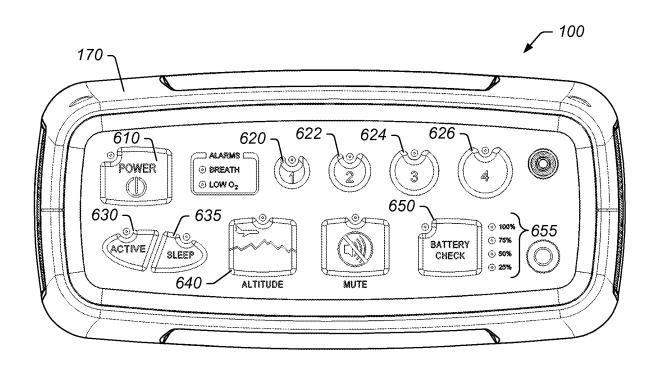


FIG. 14

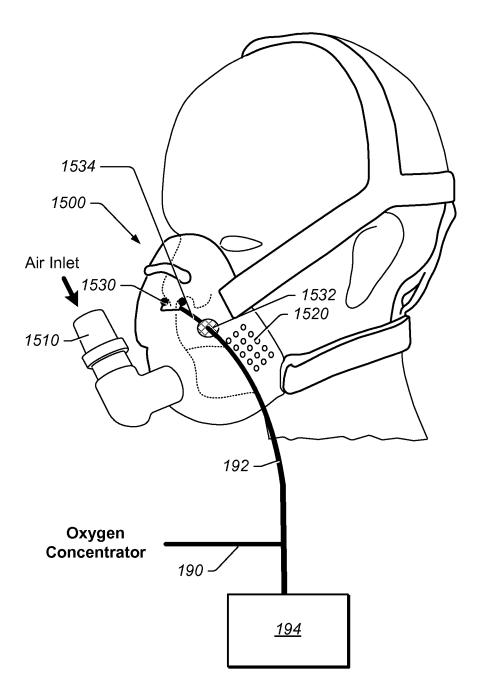


FIG. 15

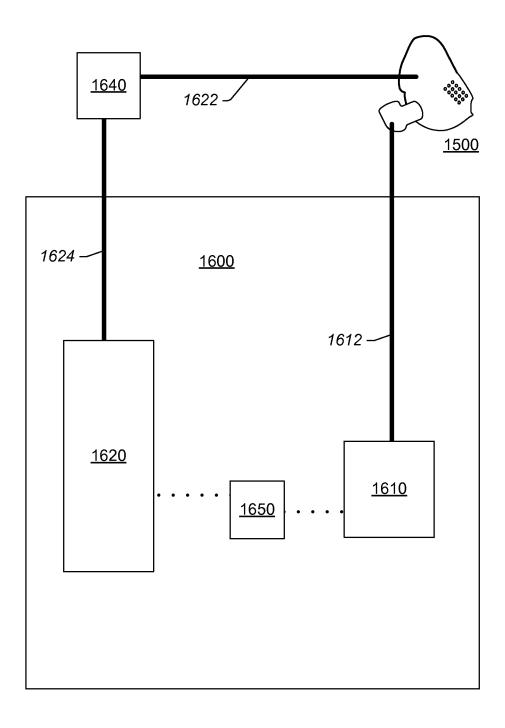


FIG. 16

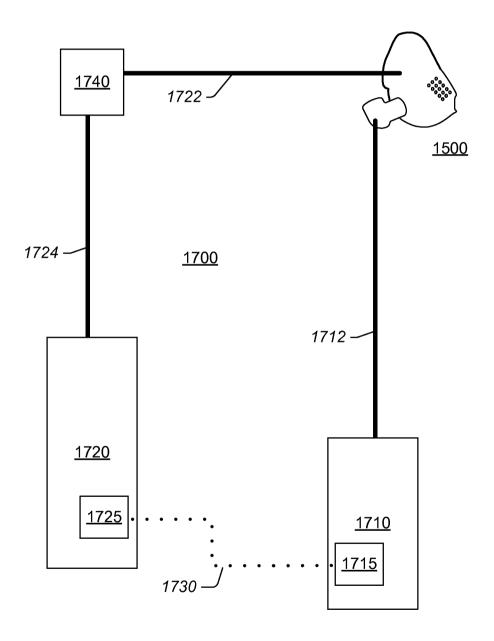


FIG. 17

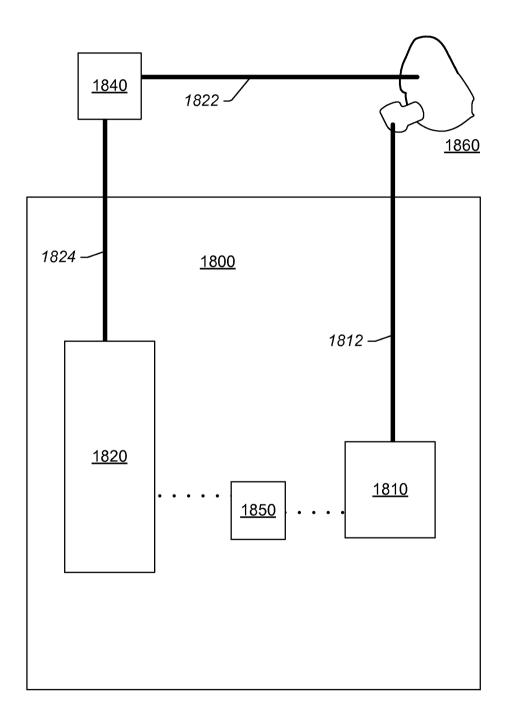


FIG. 18

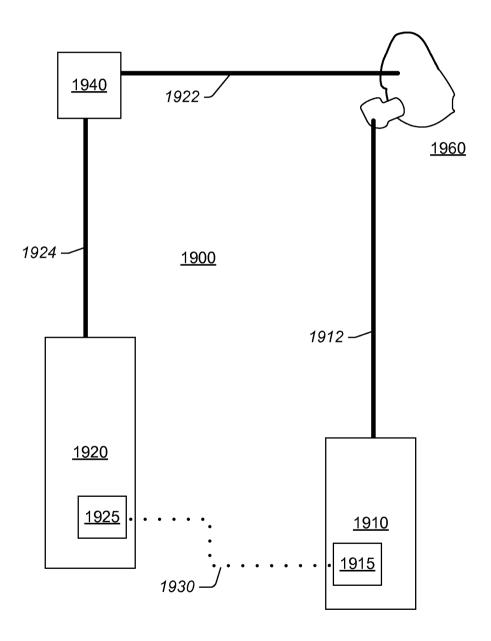


FIG. 19

