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

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
22 June 2017 (22.06.2017)

WIPO | PCT

(10) International Publication Number
WO 2017/106636 A1

(51) International Patent Classification:
A61M 16/10 (2006.01)

(21) International Application Number:
PCT/US2016/067157

(22) International Filing Date:
16 December 2016 (16.12.2016)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
62/269,266 18 December 2015 (18.12.2015) US

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(81) Designated States *(unless otherwise indicated, for every kind of national protection available)*: AE, AG, AL, AM, AO, AT, AU, AZ, BA, BB, BG, BH, BN, BR, BW, BY, BZ, CA, CH, CL, CN, CO, CR, CU, CZ, DE, DJ, DK, DM, DO, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN, HR, HU, ID, IL, IN, IR, IS, JP, KE, KG, KH, KN, KP, KR, KW, KZ, LA, LC, LK, LR, LS, LU, LY, MA, MD, ME, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM, PA, PE, PG, PH, PL, PT, QA, RO, RS, RU, RW, SA, SC, SD, SE, SG, SK, SL, SM, ST, SV, SY, TH, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, ZA, ZM, ZW.

(84) Designated States *(unless otherwise indicated, for every kind of regional protection available)*: ARIPO (BW, GH, GM, KE, LR, LS, MW, MZ, NA, RW, SD, SL, ST, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, RU, TJ, TM), European (AL, AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HR, HU, IE, IS, IT, LT, LU, LV, MC, MK, MT, NL, NO, PL, PT, RO, RS, SE, SI, SK, SM, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, KM, ML, MR, NE, SN, TD, TG).

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(54) Title: USE OF AN OXYGEN CONCENTRATOR FOR CPAP THERAPY

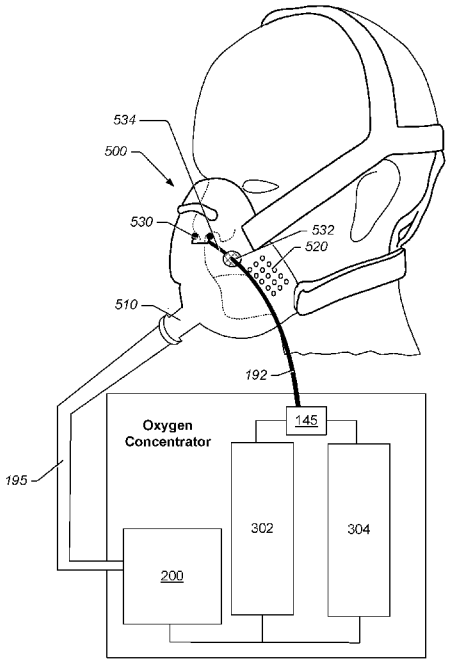


FIG. 5

(57) Abstract: Oxygen concentrator apparatus and method of use are described herein. The oxygen concentration may include at least one canister; gas separation adsorbent disposed in at least one canister, and a compression system. The compression system may include at least one compressor coupled to the at least one canister. The compressor may include a first rotor comprising at least two projections and a second rotor comprising at least two recesses. During rotation of the first and second rotors, gas moves through the compressor to at least one of the canisters. In the canisters, gas separation adsorbent may separate at least some nitrogen from air produce oxygen enriched gas.

WO 2017/106636 A1

Published:

— *with international search report (Art. 21(3))*

— *before the expiration of the time limit for amending the claims and to be republished in the event of receipt of amendments (Rule 48.2(h))*

TITLE: USE OF AN OXYGEN CONCENTRATOR FOR CPAP THERAPY

BACKGROUND OF THE INVENTION

1. Field of the Invention

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

2. Description of the Related Art

Many patients 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 could 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.

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.

SUMMARY

Systems and methods of providing an oxygen enriched gas to a user of an oxygen concentrator are described herein.

In some embodiments, 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; a

compression system, wherein the compressor compresses air during operation; an accumulator coupled to one or more of the canisters, wherein oxygen enriched gas produced in one or more of the canisters is passed into the accumulation chamber during use; a first conduit coupling the compression system to a mask coupleable to a face of the user of the oxygen concentrator apparatus; and a second conduit coupling the accumulator to the mask.

In some embodiments, a method of providing positive pressure therapy to a user through a mask using an oxygen concentrator apparatus includes: coupling a compression system of the oxygen concentrator apparatus to the mask via a first conduit; coupling an accumulator of the oxygen concentrator to the mask via a second conduit; supplying pressurized air from the compression system through the first conduit to the mask after the mask is coupled to a user's face; assessing an onset of inhalation of the user; supplying oxygen enriched gas from the oxygen concentrator to the mask through the second conduit when the onset of inhalation of the user is detected; and increasing the pressure of air provided from the compression system to the user when a sleep apnea episode is detected, wherein the increased pressure is sufficient to force an airway of the user to open.

BRIEF DESCRIPTION OF THE DRAWINGS

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 an embodiment of the components of an oxygen concentrator;

FIG. 2 depicts a schematic diagram of an embodiment of the outlet components of an oxygen concentrator;

FIG. 3 depicts a schematic diagram of an embodiment of an outlet conduit for an oxygen concentrator;

FIG. 4 depicts various profiles of embodiments for providing oxygen enriched gas from an oxygen concentrator; and

FIG. 5 depicts a schematic diagram of an oxygen concentrator system that provides positive pressure therapy.

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

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."

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.

Oxygen concentrators take advantage of pressure swing adsorption (PSA). Pressure swing adsorption involves using a compressor to increase gas pressure inside a canister that contains particles of a gas separation adsorbent. As the pressure increases, certain molecules in the gas may become adsorbed onto the gas separation adsorbent. Removal of a portion of the gas in the canister under the pressurized conditions allows separation of the non-adsorbed molecules from the adsorbed molecules. The gas separation adsorbent may be regenerated by reducing the pressure, which reverses the adsorption of molecules from the adsorbent. Further details regarding oxygen concentrators may be found, for example, in U.S. Published Patent Application No. 2009-0065007, published March 12, 2009, and entitled "Oxygen Concentrator Apparatus and Method", which is incorporated herein by reference.

Ambient air usually includes approximately 78% nitrogen and 21% oxygen with the balance comprised of argon, carbon dioxide, water vapor and other trace elements. If a gas mixture such as air, for example, is passed under pressure through a vessel containing a gas separation adsorbent bed that attracts nitrogen more strongly than it does oxygen, part or all of the nitrogen will stay in the bed, and the gas coming out of the vessel will be enriched in oxygen. When the bed reaches the end of its capacity to adsorb nitrogen, it can be regenerated by reducing the pressure, thereby releasing the adsorbed nitrogen. It is then ready for another cycle

of producing oxygen enriched air. By alternating canisters in a two-canister system, one canister can be collecting oxygen while the other canister is being purged (resulting in a continuous separation of the oxygen from the nitrogen). In this manner, oxygen can be accumulated out of the air for a variety of uses including providing supplemental oxygen to patients.

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**

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. In some embodiments, compression system may include one, two, three, four, or more compressors. Compression system **200** may include a compressor coupled to a motor. The motor provides an operating force to the compressor to operate the compression mechanism. 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.

In some embodiments, the compressor may be a piston compressor or a diaphragm compressor. The pressuring device may be a piston compressor that has multiple pistons. During operation, the pistons may be selectively turned on or off. In some embodiments, a motor may be coupled to multiple compressors. Each compressor may be selectively turned on or off. For example, controller **400** may determine which compressors or pistons should be operated based on predetermined operating conditions.

Referring back to FIG. 1, coupled to each canister **302/304** are inlet valves **122/124** and outlet valves **132/134**. 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 some embodiments, a two-step valve actuation voltage may be used to control inlet valves **122/124** and outlet valves **132/134**. For example, a high voltage (e.g., 24 V) may be applied to an inlet valve to open the inlet valve. The voltage may then be reduced (e.g., to 7 V) to keep the inlet valve open. Using less voltage to keep a valve open may use less power (Power = Voltage * Current). This reduction in voltage minimizes heat buildup and power consumption to extend run time from the battery. When the power is cut off to the valve, it closes by spring

action. In some embodiments, the voltage may be applied as a function of time that is not necessarily a stepped response (e.g., a curved downward voltage between an initial 24 V and a final 7 V).

In some embodiments, air may be pulled into the oxygen concentrator through two compressors. In some embodiments, air may flow from at least two compressors to canisters **302**, **304.** In some embodiments, one of valves **122** or **124** may be closed (e.g., as signaled by controller **400**) resulting in the combined output of both compressors lowing through the other respective valve **122** or **124** into a respective canister **302**, **304**. For example, if valve **124** is closed, the air from both compressors may flow through valve **122**. If valve **122** is closed, the air from both compressors may flow through valve **124**. In some embodiments, valve **122** and valve **124** may alternate to alternately direct the air from the two compressors into respective canisters **302** or **304**.

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 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.

The term “check valve”, as used herein, refers to a valve that allows flow of a fluid (gas or liquid) in one direction and inhibits back flow of the fluid. Examples of check valves that are

suitable for use include, but are not limited to: a ball check valve; a diaphragm check valve; a butterfly check valve; a swing check valve; a duckbill valve; and a lift check valve. Under pressure, nitrogen molecules in the pressurized ambient air are adsorbed by the gas separation adsorbent in the pressurized canister. As the pressure increases, more nitrogen is adsorbed until the gas in the canister is enriched in oxygen. The nonadsorbed gas molecules (mainly oxygen) flow out of the pressurized canister when the pressure reaches a point sufficient to overcome the resistance of the check valve coupled to the canister. In one embodiment, the pressure drop of the check valve in the forward direction is less than 1 psi. The break pressure in the reverse direction is greater than 100 psi. It should be understood, however, that modification of one or more components would alter the operating parameters of these valves. If the forward flow pressure is increased, there is, generally, a reduction in oxygen enriched gas production. If the break pressure for reverse flow is reduced or set too low, there is, generally, a reduction in oxygen enriched gas pressure.

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 **145**.

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**, pressure in the canister drops. The drop in pressure may allow 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.

During venting of the canisters, it is advantageous that at least a majority of the nitrogen is removed. In an embodiment, at least about 50%, at least about 60%, at least about 70%, at least about 80%, at least about 90%, at least about 95%, at least about 98%, or substantially all of the nitrogen in a canister is removed before the canister is re-used to separate oxygen from air. In some embodiments, a canister may be further purged of nitrogen using an oxygen enriched stream that is introduced into the canister from the other canister.

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. 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 of 0.009 inches which is less than the diameter of the tube it is inside). Flow restrictors **153** and **155** may be 0.013D flow restrictors. Other flow restrictor types and sizes are also contemplated and may be used depending on the specific configuration and tubing used to couple the canisters. In some embodiments, the flow restrictors may be press fit flow restrictors that restrict air flow by introducing a narrower diameter in their respective tube. In some embodiments, the press fit flow restrictors may be made of sapphire, metal or plastic (other materials are also contemplated).

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 shut down 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.

In an embodiment, outside air may be inhibited from entering canisters after the oxygen concentrator is shut down by pressurizing both canisters prior to shut down. 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.

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 **145** through check valves **142** and

144, respectively, as depicted schematically in FIG. 1. The oxygen enriched gas leaving the canisters may be collected in oxygen accumulator **145** prior to being provided to a user. In some embodiments, a tube may be coupled to accumulator **145** 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. 2, a schematic diagram of an embodiment of an outlet system for an oxygen concentrator is shown. Supply valve **160** may be coupled to outlet tube to control the release of the oxygen enriched gas from accumulator **145** 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.

Oxygen enriched gas in accumulator **145** passes through supply valve **160** into expansion chamber **170** as depicted in FIG. 2. 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 small orifice flow restrictor **175** to 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. It has been found, in our specific system, that the total volume of the bolus required for prescriptions is equal

to 11 mL for each LPM, i.e., 11 mL for a prescription of 1 LPM; 22 mL for a prescription of 2 LPM; 33 mL for a prescription of 3 LPM; 44 mL for a prescription of 4 LPM; 55 mL for a prescription of 5 LPM; etc. This is generally referred to as the LPM equivalent. It should be understood that the LPM equivalent may vary between apparatus due to differences in construction design, tubing size, chamber size, etc.

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 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 ultrasonic emitter **166** and 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).

In use, an ultrasonic sound wave (from emitter **166**) may be directed through oxygen enriched gas disposed in chamber **170** to receiver **168**. Ultrasonic sensor assembly may be based on detecting the speed of sound through the gas mixture to determine the composition of the gas mixture (e.g., the speed of sound is different in nitrogen and oxygen). In a mixture of the two gases, the speed of sound through the mixture may be an intermediate value proportional to the relative amounts of each gas in the mixture. In use, the sound at the receiver **168** is slightly out of phase with the sound sent from emitter **166**. This phase shift is due to the relatively slow velocity of sound through a gas medium as compared with the relatively fast speed of the electronic pulse through wire. The phase shift, then, is proportional to the distance between the emitter and the receiver and the speed of sound through the expansion chamber. The density of the gas in the chamber affects the speed of sound through the chamber and the density is proportional to the ratio of oxygen to nitrogen in the chamber. Therefore, the phase shift can be used to measure the concentration of oxygen in the expansion chamber. In this manner the relative concentration of oxygen in the accumulation chamber may be assessed as a function of one or more properties of a detected sound wave traveling through the accumulation chamber.

In some embodiments, multiple emitters **166** and receivers **168** may be used. The readings from the emitters **166** and receivers **168** may be averaged to cancel errors that may be

inherent in turbulent flow systems. In some embodiments, the presence of other gases may also be detected by measuring the transit time and comparing the measured transit time to predetermined transit times for other gases and/or mixtures of gases.

The sensitivity of the ultrasonic sensor system may be increased by increasing the distance between emitter **166** and receiver **168**, for example to allow several sound wave cycles to occur between emitter **166** and the receiver **168**. In some embodiments, if at least two sound cycles are present, the influence of structural changes of the transducer may be reduced by measuring the phase shift relative to a fixed reference at two points in time. If the earlier phase shift is subtracted from the later phase shift, the shift caused by thermal expansion of expansion chamber **170** may be reduced or cancelled. The shift caused by a change of the distance between emitter **166** and receiver **168** may be the approximately the same at the measuring intervals, whereas a change owing to a change in oxygen concentration may be cumulative. In some embodiments, the shift measured at a later time may be multiplied by the number of intervening cycles and compared to the shift between two adjacent cycles. 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, which is incorporated herein by reference.

Flow rate sensor **185** may be used to determine the flow rate of gas flowing through the outlet system. Flow rate sensors that may be used include, but are not limited to: diaphragm/bellows flow meters; rotary flow meters (e.g. 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 **196**, as depicted in FIG. 3. Airway coupling member **196** 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. 3. During use, oxygen enriched gas from oxygen concentrator system **100** is provided to the user through conduit **192** and airway coupling member **196**. Airway coupling member **196** 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.

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**. A non-transitory memory medium may include any of various types of memory devices or storage devices. The term "memory medium" is intended to include an installation medium, e.g., a Compact Disc Read Only Memory (CD-ROM), floppy disks, or tape device; a computer system memory or random access memory such as Dynamic Random Access Memory (DRAM), Double Data Rate Random Access Memory (DDR RAM), Static Random Access Memory (SRAM), Extended Data Out Random Access Memory (EDO RAM), Rambus Random Access Memory (RAM), etc.; or a non-volatile memory such as a magnetic media, e.g., a hard drive, or optical storage. The memory medium may comprise other types of memory as well, or combinations thereof. In addition, the memory medium may be located in a first computer in which the programs are executed, or may

be located in a second different computer that connects to the first computer over a network, such as the Internet. In the latter instance, the second computer may provide program instructions to the first computer for execution. The term "memory medium" may include two or more memory mediums that may reside in different locations, e.g., in different computers that are connected over a network.

In some embodiments, controller **400** includes processor **410** that includes, for example, one or more field programmable gate arrays (FPGAs), microcontrollers, etc. included on a circuit board disposed in oxygen concentrator system **100**. Processor **410** is capable of executing programming instructions stored in memory **420**. In some embodiments, programming instructions may be built into processor **410** such that a memory external to the processor may not be separately accessed (i.e., the memory **420** may be internal to the processor **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**, or combinations thereof), 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.

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. Adjustments made by the oxygen concentrator system in response to activating active mode or sleep mode are described in more detail herein.

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 **145** 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 the prescription requirements of a user, 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 a 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 **145**.

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.

In some embodiments, the sensitivity of the pressure sensor **194** may be affected by the physical distance of the pressure sensor **194** from the user, especially if the pressure sensor is located in oxygen concentrator system **100** and the pressure difference is detected through the tubing coupling the oxygen concentrator system to the user. In some embodiments, the pressure sensor may be placed in the airway delivery device used to provide the oxygen enriched gas to the user. A signal from the pressure sensor may be provided to controller **400** in the oxygen concentrator **100** electronically via a wire or through telemetry such as through BLUETOOTH® (Bluetooth, SIG, Inc. Kirkland, Washington) or other wireless technology.

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 **145**.

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 the control panel of the oxygen concentrator. Alternatively, a user may operate controller **400** from a remote electronic device. For example, a user may operate the controller using a smart phone or tablet device.

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, controller **400** may operate the oxygen concentrator based on the change in the inspiration breath pressure threshold. The frequency and/or duration of the provided oxygen enriched gas to the user relative to the current frequency and/or duration may be adjusted based on the change in the inspiration breath pressure threshold. Upon determining that the inspiration breath pressure threshold has been lowered, the controller **400** may switch the oxygen concentrator to a sedentary mode. Controller **400** may switch the oxygen concentrator to an active mode, when the inspiration breath pressure threshold has been raised.

In some embodiments, as seen in FIG. 4, 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 **556** at approximately 7 cubic centimeters and a

second pulse **558** 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 **556** 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 **556** is shown to be approximately twice the second pulse **558**, in some embodiments, the second pulse **558** may be larger than the first pulse **556**. 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.

In some embodiments, in active mode, the sensitivity of the pressure sensor **194** may be mechanically, electronically, or programmatically attenuated. For example, during active mode, controller **400** may look for a greater pressure difference to indicate the start of a user breath (e.g., an elevated threshold may be compared to the detected pressure difference to determine if the bolus of oxygen should be released). In some embodiments, the pressure sensor **194** may be mechanically altered to be less sensitive to pressure differences. In some embodiments, an electronic signal from the pressure sensor may be electronically altered to ignore small pressure

differences. This can be useful when in active mode. In some embodiments, during the inactive mode the sensitivity of the pressure sensor may be increased. For example, the controller **400** may look for a smaller pressure difference to indicate the start of a user breath (e.g., a smaller threshold may be compared to the detected pressure difference to determine if the bolus of oxygen should be released). In some embodiments, with increased sensitivity, the response time for providing the bolus of oxygen during the user's inhalation may be reduced. The increased sensitivity and smaller response time may reduce the size of the bolus necessary for a given flow rate equivalence. The reduced bolus size may also reduce the size and power consumption of the oxygen concentrator **100.**

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. In FIG. 5, a positive pressure therapy mask **500** is depicted. Positive pressure therapy mask **500** includes a first conduit port **510** for coupling to a compressed air source and a venting port **520** 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 two conduits. Conduit **195** couples compression system **200** directly to mask **500**. Conduit **192** couples accumulator **145** to mask **500**. Conduit **192** may pass through the mask through second conduit port **532** and rest near an air passage of the user. For example, a nasal cannula **530** 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. In such embodiments, nasal cannula **530** may be coupled to the second conduit port **532** via conduit **534**. A pressure sensor **194** may be coupled to conduit **192** as depicted in FIG. 2.

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. While the positive therapy mask **500** 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.

During use compression system **200** of the oxygen concentrator produces a compressed air stream which is directed through conduit **195** to mask **500**. Controller **200** (not shown in this figure) operates compression system **200** 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 **200** is further coupled to an inhalation sensor **194**. Inhalation sensor **194** is coupled to mask **500** 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 **200** may active a mechanism of the oxygen concentrator to release a bolus of oxygen directed directly to the user's airway via conduits **192** and **534**. Thus, oxygen is only provided when needed, minimizing the volume requirements of oxygen needed and allowing the patient to receive the prescribed oxygen.

When mask **500** is coupled to the user, and compressed air is received by the mask from compression system **200**, 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 **200** 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 **200** 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 **200** 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 **200** 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 **200** 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 **200** (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 **500**. In one embodiment, the correction pressure is the difference between the pressure inside of mask **500** 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.

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 **520** 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.

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.

In this patent, certain U.S. patents, U.S. patent applications, and other materials (e.g., articles) have been incorporated by reference. The text of such U.S. patents, U.S. patent applications, and other materials is, however, only incorporated by reference to the extent that no conflict exists between such text and the other statements and drawings set forth herein. In the event of such conflict, then any such conflicting text in such incorporated by reference U.S. patents, U.S. patent applications, and other materials is specifically not incorporated by reference in this patent.

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.

WHAT IS CLAIMED IS:

1. A method of providing positive pressure therapy to a user through a mask using an oxygen concentrator apparatus, the method comprising:

coupling a compression system of the oxygen concentrator apparatus to the mask via a first conduit;

coupling an accumulator of the oxygen concentrator to the mask via a second conduit;

supplying pressurized air from the compression system through the first conduit to the mask after the mask is coupled to a user's face;

assessing an onset of inhalation of the user;

supplying oxygen enriched gas from the oxygen concentrator to the mask through the second conduit when the onset of inhalation of the user is detected; and

increasing the pressure of air provided from the compression system to the user when a sleep apnea episode is detected, wherein the increased pressure is sufficient to force an airway of the user to open.

2. The method of claim 1, wherein the oxygen concentrator apparatus further comprises a pressure sensor couplable to the mask, wherein the method further comprises:

automatically assessing a pressure inside the mask when pressurized air is being supplied to the mask when the mask is coupled to the user;

assessing a change in the pressure inside the mask;

assessing an onset of inhalation of the user is based on a pressure detected by the pressure sensor;

supplying oxygen enriched gas from the oxygen concentrator to the mask if the detected

change in the pressure indicates a decrease in the pressure inside of the mask.

3. The method of claim 2, wherein oxygen enriched gas is supplied from the oxygen concentrator to the mask when the pressure detected by the pressure sensor is below a predetermined pressure.

4. The method of any one of claims 1-3, wherein the oxygen enriched gas supplied by the oxygen concentrator is supplied at a volume sufficient to meet a prescription requirement of the user.

5. The method of any one of claims 1-4, further comprising reducing the pressure of the pressurized air produced by the compression system when the detected change in pressure indicates an increase in the pressure inside the mask.

6. The method of any one of claims 1-5, further comprising producing an alarm or other signal in response to a stoppage of inhalation for a predetermined amount of time.

7. The method of any one of claims 1-6, further comprising:

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;

determining a correction pressure, wherein the correction pressure is an average mask pressure measured over one or more breathing cycles;

continuously and repetitively reassessing a pressure inside the mask, after determining a correction pressure, while additional pressurized air is supplied to the mask coupled to the user's face;

determining an adjusted assessed pressure inside the mask after the pressure inside the mask is reassessed, wherein the adjusted assessed pressure is the difference between the measured reassessed pressure inside the mask 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; and

increasing the pressure of air provided from the compression system to the user when a sleep apnea episode is detected, wherein the increased pressure is sufficient to force an airway of the user to open.

8. The method of claim 7, wherein the oxygen enriched gas is supplied when the adjusted assessed pressure is less than zero.

9. An oxygen concentrator apparatus comprising:

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;

a compression system, wherein the compressor compresses air during operation;

an accumulator coupled to one or more of the canisters, wherein oxygen enriched gas produced in one or more of the canisters is passed into the accumulation chamber during use;

a first conduit coupling the compression system to a mask coupleable to a face of the user of the oxygen concentrator apparatus; and

a second conduit coupling the accumulator to the mask.

10. The apparatus of claim 9, further comprising an oxygen sensor coupled to the accumulation chamber, wherein the oxygen sensor is capable of detecting oxygen in a gas during use.

11. The apparatus of claim 9 or 10, further comprising a pressure sensor coupled to the first and/or second conduit; wherein the pressure sensor is operable to detect a change in pressure at the first or second conduit.

12. The apparatus of any one of claims 9-11, further comprising a valve positioned between one or more of the conduits and the airway delivery device, wherein the valve controls release of oxygen enriched gas from one or more of the canisters such that a pulse of oxygen enriched gas passes through the airway delivery device.

13. The apparatus of any one of claims 9-12, further comprising:

a plurality of valves coupled to the compression system and the accumulator, wherein the valves control the flow of air and oxygen enriched as through the oxygen concentrator apparatus; and

a processor coupled to the compressions system and the valves, wherein the processor is operable to execute program instructions, wherein the program instructions are operable to perform the method comprising:

supplying pressurized air from the compression system through the first conduit to the mask after the mask is coupled to a user's face;

assessing an onset of inhalation of the user;

supplying oxygen enriched gas from the oxygen concentrator to the mask through the second conduit when the onset of inhalation of the user is detected; and

increasing the pressure of air provided from the compression system to the user when a sleep apnea episode is detected, wherein the increased pressure is sufficient to force an airway of the user to open

14. The apparatus of claim 13, further comprising a pressure sensor coupled to the first and/or second conduit; wherein the pressure sensor is operable to detect a change in pressure at the first or second conduit; and wherein the program instructions are operable to direct oxygen enriched

gas from one or more of the canisters through one or more of the conduits to the airway delivery device in response to detecting a drop in pressure in one or more of the conduits.

15. The apparatus of claim 13 or 14, wherein the program instructions are further operable to produce an alarm or other signal in response to an absence of a drop in pressure for a predetermined amount of time.

16. The apparatus of any one of claims 13-15, further comprising a valve positioned between one or more of the conduits and the airway delivery device, wherein the valve controls release of oxygen enriched gas from one or more of the canisters such that a pulse of oxygen enriched gas passes through the airway delivery device, wherein the program instructions are operable to control the operation of the valve to provide two or more pulses of oxygen enriched gas to the airway delivery device during each breathing cycle.

17. The apparatus of any one of claims 9-16, wherein the oxygen concentrator apparatus has a weight of less than about 5 lbs.

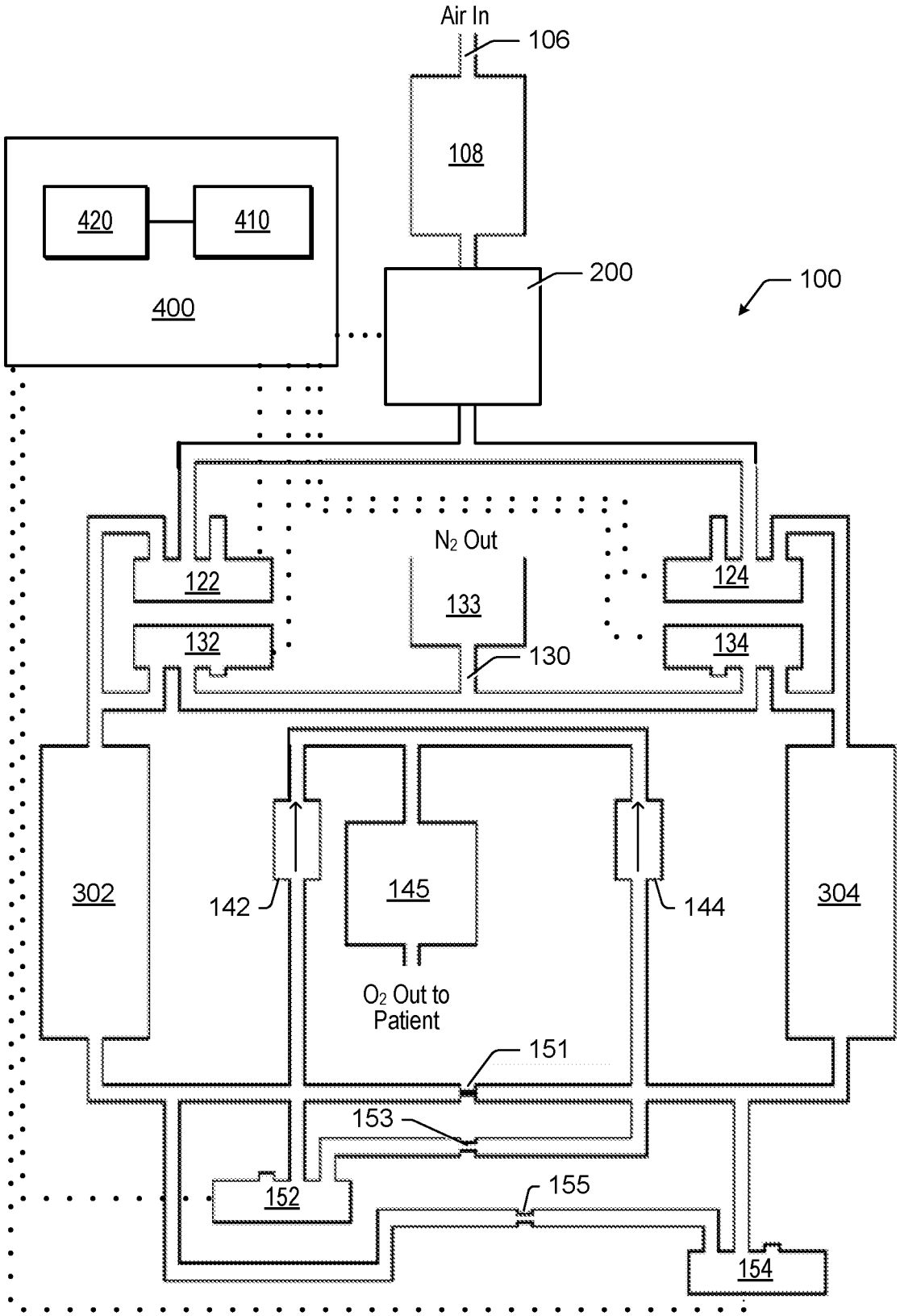

Air In
106
108
420
410
400
200
100
N_2 Out
122
124
133
132
134
130
302
142
145
144
304
O_2 Out to Patient
151
153
152
155
154

FIG. 1

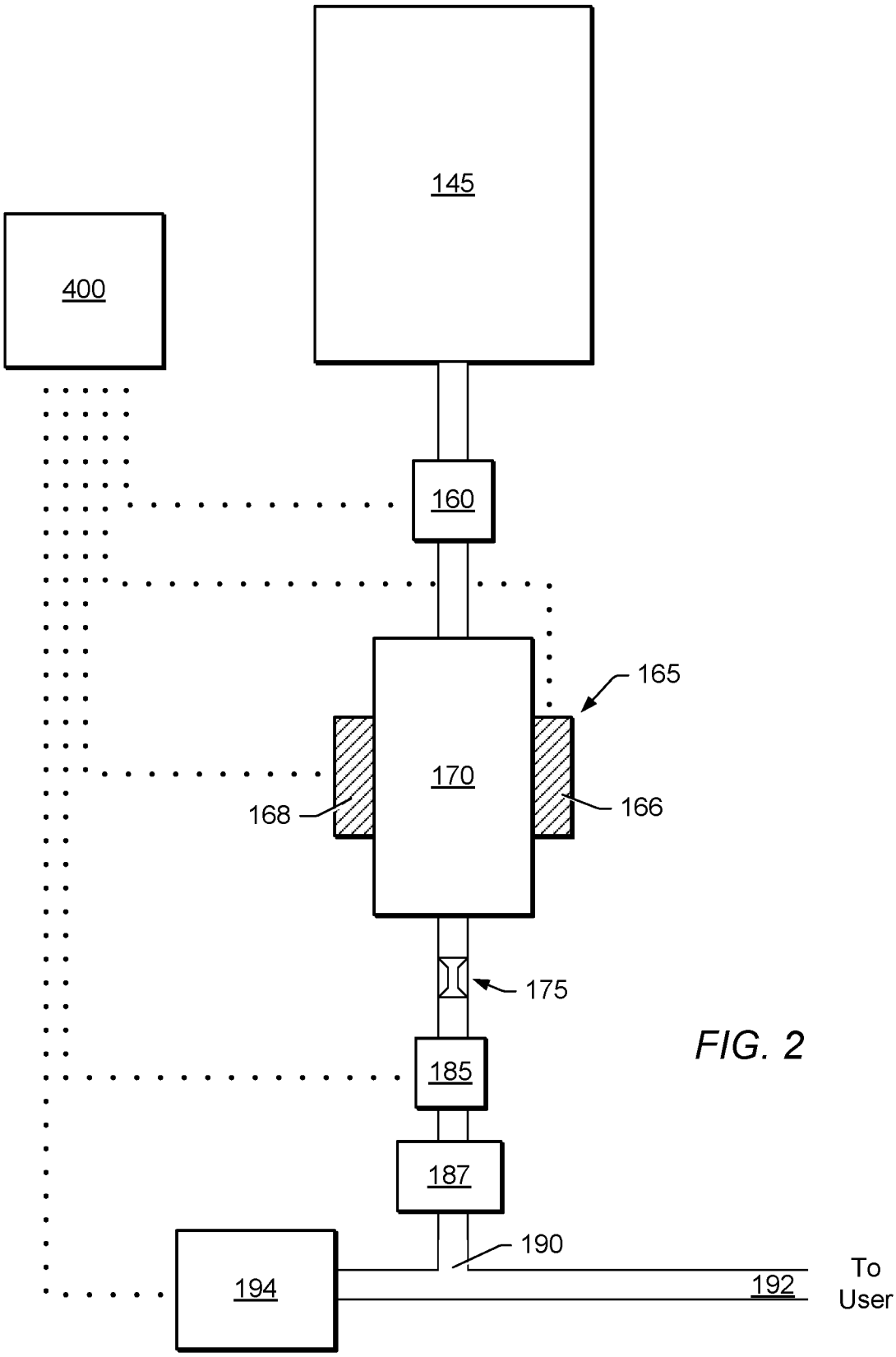


FIG. 2

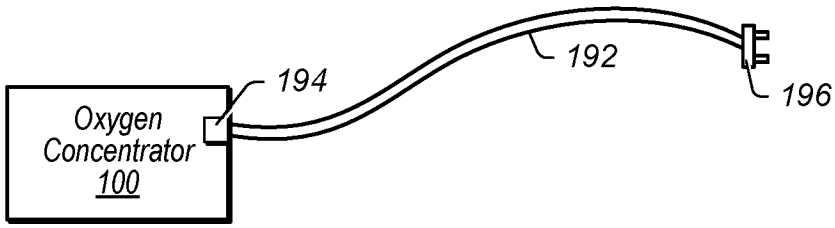


FIG. 3

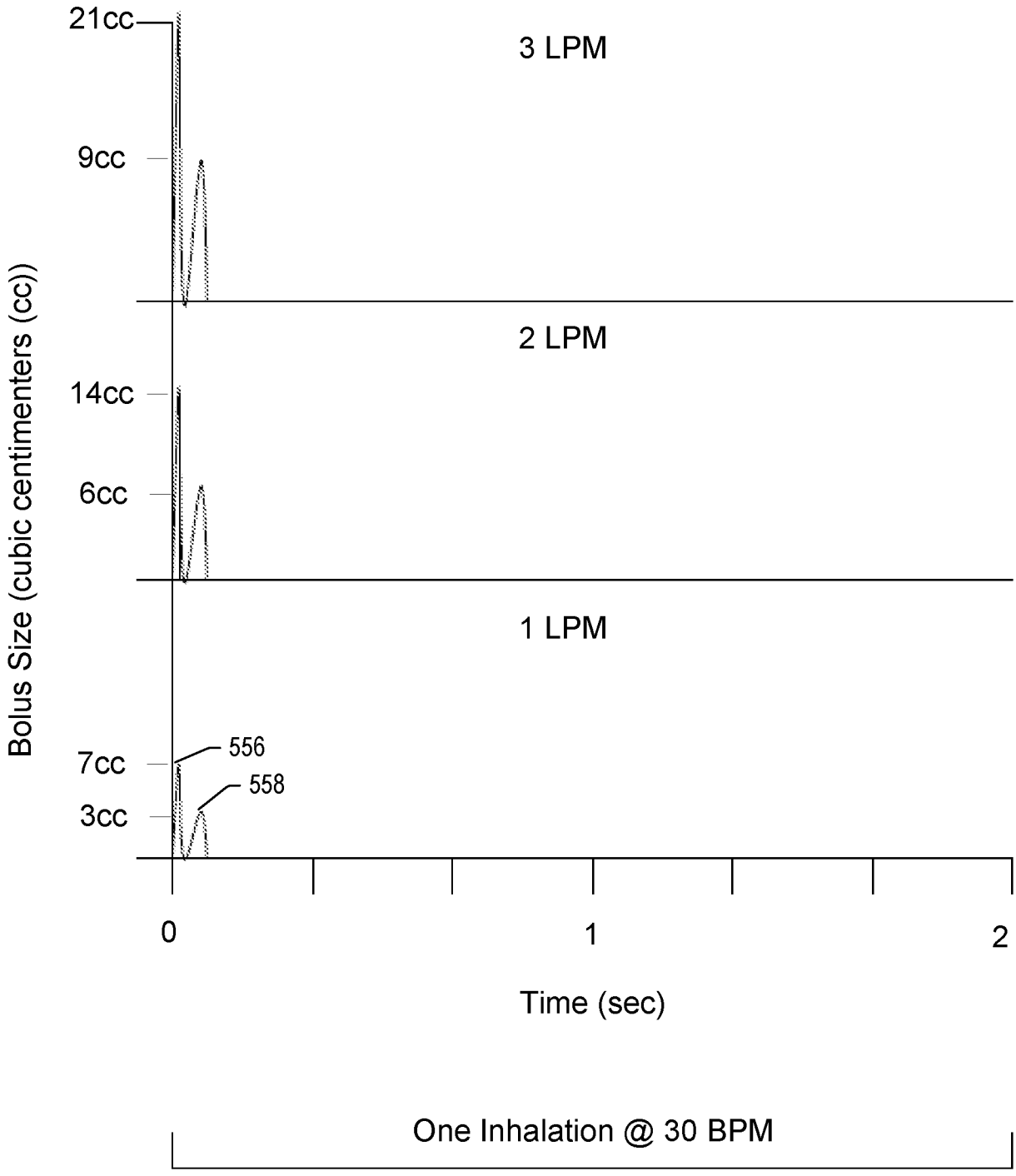

21cc
3 LPM
9cc
2 LPM
14cc
6cc
1 LPM
7cc
556
558
3cc
Bolus Size (cubic centimenters (cc))
0
1
2
Time (sec)
One Inhalation @ 30 BPM

FIG. 4

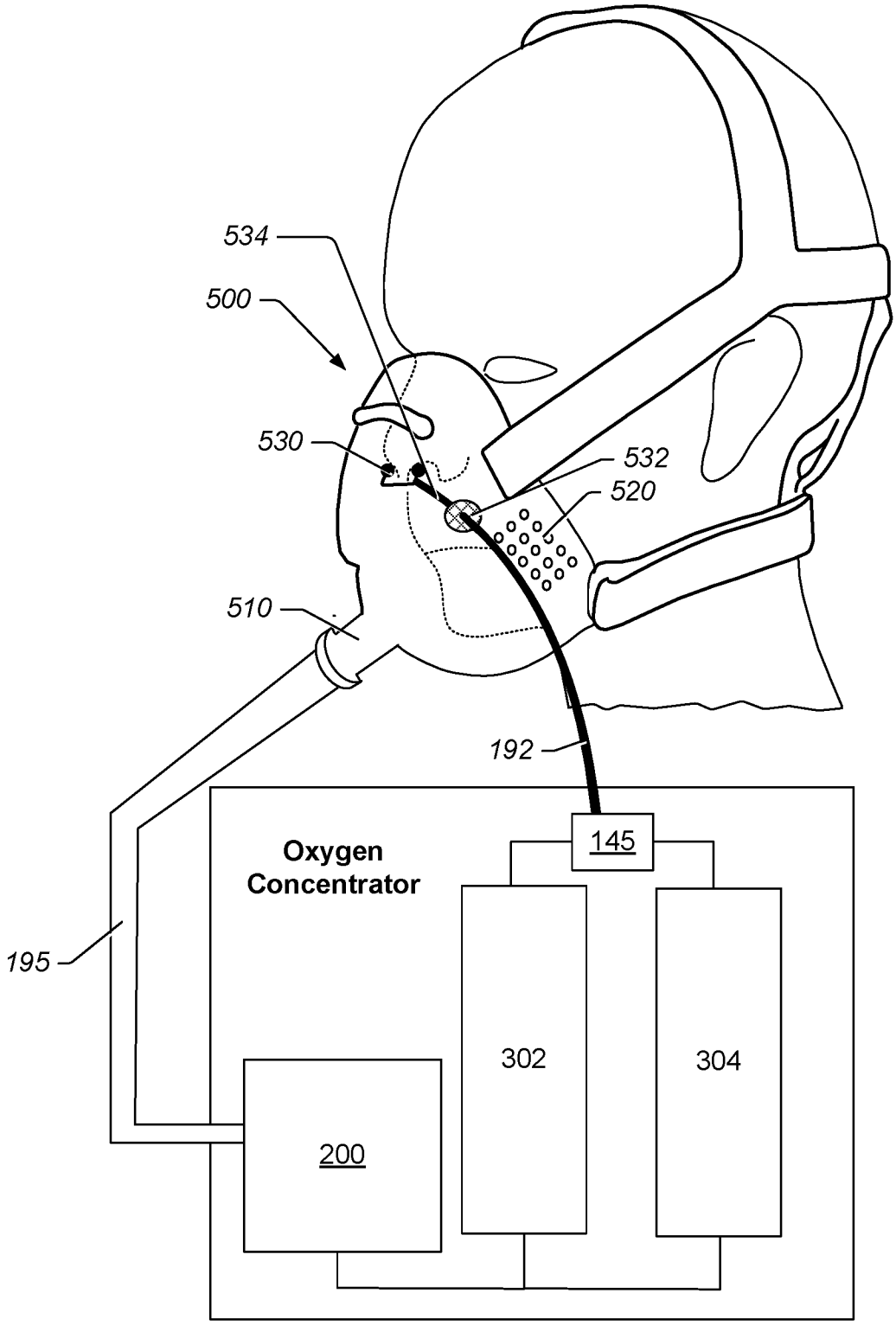

534
500
530
532
520
510
192
145
Oxygen
Concentrator
195
302
304
200

FIG. 5

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US 16/67157

A. CLASSIFICATION OF SUBJECT MATTER
IPC(8) - A61M 16/10 (2017.01)
CPC - A61M 16/101, A61B 5/4818, A61M 2016/1025, A61M 16/12, A61M 16/105, A61M 2016/0015, A61M 16/20

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

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
See Search History Document

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

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

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2012/0055478 A1 (WILKINSON) 08 March 2012 (08.03.2012) Entire document, especially Abstract, para[0061], par[a0066]- para[0069], para[00189]- para[0191] and FIGS. 1, 16.	1-4, 9-11
A	US 2015/0128941 A1 (HOLLEY et al.) 14 May 2015 (14.05.2015) Entire document.	1-4, 9-11
A	US 2013/0312752 A2 (KAPUST et al.) 28 November 2013 (28.11.2013) Entire document.	1-4, 9-11
A	US 8,069,852 B2 (BURTON et al.) 06 December 2011 (06.12.2011) Entire document.	1-4, 9-11
A	US 7,331,343 B2 (SCHMIDT et al.) 19 February 2003 (19.02.2003) Entire document.	1-4, 9-11
A	US 4,823,788 A (SMITH et al.) 25 April 1989 (25.04.1989) Entire document.	1-4, 9-11

☐ Further documents are listed in the continuation of Box C. ☐

* Special categories of cited documents:
"A" document defining the general state of the art which is not considered to be of particular relevance
"E" earlier application or patent but published on or after the international filing date
"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
"O" document referring to an oral disclosure, use, exhibition or other means
"P" document published prior to the international filing date but later than the priority date claimed
"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
24 March 2017	22 MAY 2017
Name and mailing address of the ISA/US Mail Stop PCT, Attn: ISA/US, Commissioner for Patents P.O. Box 1450, Alexandria, Virginia 22313-1450 Facsimile No. 571-273-8300	Authorized officer: Lee W. Young PCT Helpdesk: 571-272-4300 PCT OSP: 571-272-7774

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

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US 16/67157

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

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

1. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:

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

3. ☒ Claims Nos.: 5-8, 12-17
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

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

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

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.

2. ☐ As all searchable claims could be searched without effort justifying additional fees, this Authority did not invite payment of additional fees.

3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:

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

Remark on Protest

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

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

☐ No protest accompanied the payment of additional search fees.