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(71) Applicant: **COEO LABS PRIVATE LIMITED** [IN/IN]; 5th floor, Aanand towers. No. 4, Raja Rammohan Roy Road, Samangiramanagara, Karnataka, Bangalore 560025 (IN).

(72) Inventors: **DEVAL, Nachiket**; #4, 5th Floor, Aanand tower, Near Richmond circle, Raja ram mohan roy road, Bangalore 560025 (IN). **JANGIR, Nitesh Kumar**; #4, 5th Floor, Aanand tower, Near Richmond circle, Raja ram mohan roy road, Bangalore 560025 (IN). **CHATURVEDI, Jagdish**; #4, 5th Floor, Aanand tower, Near Richmond circle, Raja ram mohan roy road, Bangalore 560025 (IN). **M, Basava Kumar**; # 16/133, Near Basaveshwara Temple, Main Road, Kampli -583132, Bellary(Dt), Karnataka (IN). **A, Saravanan**; House Number 392, 3RD cross, 1st stage, kuvempunagar, jalahalli east, Bangalore 560014 (IN). **SHETTY, Sujay**; #104, pampa residency, 8th cross, 6th main, Vijaya bank layout, Billekahali, Bangalore 560076 (IN). **RAGHAVAN, Raksha**; #1412 South End, 'A' Main road, 9th Block, Jayanagar, Bangalore 560069 (IN). **KAKANI, Vimal Kishore**; c/o Sai Datta Ashramam, Near railway Station, Miriyalguda, Nalgonda, Telengana 508207 (IN). **OLSON, Kristian R.**; Massachusetts General Hospital-

(54) Title: CONTINUOUS POSITIVE AIRWAY PRESSURE DEVICE

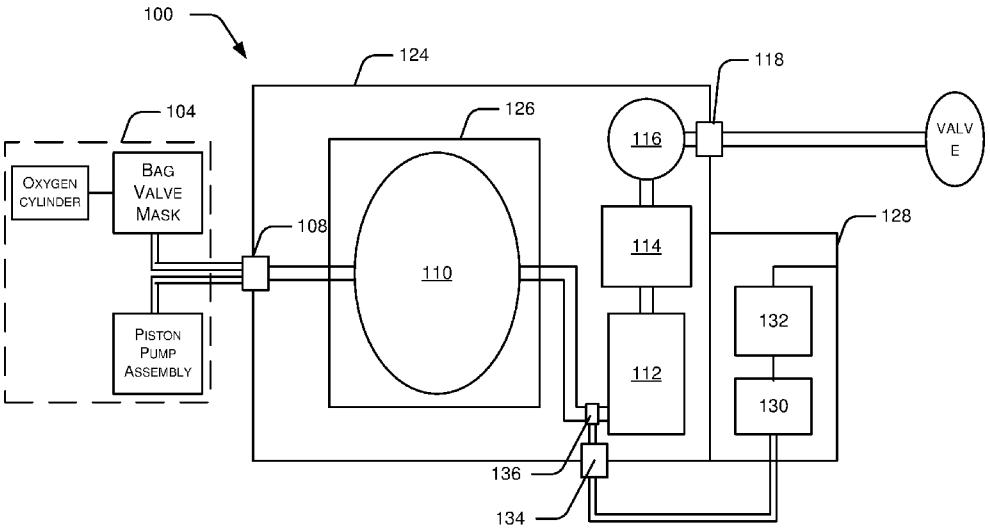

Fig. 1(c)

(57) Abstract: Continuous positive airway pressure (CPAP) devices (100) are provided. The device (100) comprises a stabilizing unit (102), a first gas source unit (104), and a patient interface unit (106). The first gas source unit (104) provides an input gas having a variable flow rate through an inlet port (108) of the stabilizing unit (102). Pressure stabilizer (110) of the stabilizing unit (102) receives the input airflow, expands and contracts to absorb variations in pressure and provides a continuous airflow at a controlled pressure. Flow meter (112) generates a regulated output airflow based on a preset flow rate. Output airflow is discharged through an outlet port (118) of the stabilizing unit (102) to the patient interface unit (106), which comprises a nasal cannula (120) to provide airflow to a patient and a valve (122) to maintain a positive pressure.

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CAMTech, 125 Nashua Street, Suite 7240, Boston, Massachusetts 02114 (US).

(74) **Agent: LAKSHMIKUMARAN, Malathi** et al.; B6/10, Safdarjung Enclave, New Delhi 110029 (IN).

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CONTINUOUS POSITIVE AIRWAY PRESSURE DEVICE

TECHNICAL FIELD

[0001] The present invention relates to a device for providing a constant pressure and airflow and, in particular, relates to a device for providing stabilized continuous positive airway pressure.

BACKGROUND

[0002] Respiratory Distress Syndrome (RDS) is a breathing disorder, which may cause the lungs to collapse and disable a patient from breathing. Treatment for such patients is provided by external respiratory support. For example, prematurely born infants having lungs with insufficient surfactant production and underdeveloped alveoli at birth may develop RDS. Typically, ventilators are used to provide external respiratory support in case of RDS.

[0003] Ventilator is a machine designed to mechanically move breathable air into and out of the lungs of a patient who is physically unable to breathe sufficiently. Ventilators are of different types and use different methods for providing respiratory support to sustain life. There are manual ventilators, such as bag valve masks and anesthesia bags that require the operator to hold the ventilator and maintain breaths with their hands. Some ventilators, such as mechanical ventilators are typically computer-controlled and have several components incorporated in them. In some cases, Bag Valve Masks (BVM) are used as a manual alternative to provide ventilation for a short duration when ventilator is not available.

BRIEF DESCRIPTION OF DRAWINGS

[0004] A detailed description is provided with reference to the accompanying figures. In the figures, the left-most digit(s) of a reference number identifies the

figure in which the reference number first appears. The same numbers are used throughout the drawings to reference like features and components.

[0005] Fig. 1(a) illustrates a schematic diagram of Continuous Positive Airway Pressure (CPAP) device, in accordance with an implementation of the present subject matter.

[0006] Fig. 1(b) illustrates a Continuous Positive Airway Pressure (CPAP) device, in accordance with an implementation of the present subject matter.

[0007] Fig. 1(c) illustrates a Continuous Positive Airway Pressure (CPAP) device, in accordance with an implementation of the present subject matter.

[0008] Fig 1(d) illustrates a perspective view of the Continuous Positive Airway Pressure (CPAP) device, in accordance with an implementation of the present subject matter.

[0009] Fig. 1(e) illustrates components of stabilizing unit arranged in the outer chamber, in accordance with an implementation of the present subject matter.

[0010] Fig. 1(f) illustrates a perspective view of the Continuous Positive Airway Pressure (CPAP) device, in accordance with an implementation of the present subject matter.

[0011] Fig. 2 illustrates a method for providing a continuous positive airway pressure, in accordance with an implementation of the present subject matter.

[0012] Fig. 3(a) illustrates a graph of pressure and flow rate of input airflow of CPAP device, in accordance with an implementation of the present subject matter.

[0013] Fig. 3(b) illustrates a graph of pressure and flow rate of output airflow of CPAP device, in accordance with an implementation of the present subject matter.

[0014] Fig. 3(c) illustrates a graph of pressure and flow rate of output airflow of CPAP device having a T-joint configuration of pressure stabilizer, in accordance with an implementation of the present subject matter.

[0015] Fig. 3(d) illustrates a graph of pressure and flow rate of output airflow of CPAP device without pressure stabilizer, in accordance with an implementation of the present subject matter.

[0016] Fig. 4 illustrates a waveform representing change in lung pressure during inhalation and exhalation with CPAP, in accordance with an implementation of the present subject matter.

[0017] Figs. 5a and 5b illustrate yet another embodiment of a CPAP device, in accordance with an implementation of the present subject matter.

DETAILED DESCRIPTION

[0018] The present subject matter, relates to a device for providing a constant pressure and airflow to maintain a continuous positive airway pressure, particularly in resource constrained settings. It will be understood that while the present invention disclosed hereinafter has been explained with neonates as an example, it can be used for providing continuous positive airway pressure to patients of different age groups as will be readily understood from the description.

[0019] Prematurely born infants, especially those born before 28 weeks of gestation period have underdeveloped alveoli at birth. The alveoli that are present tend not to be mature enough to function normally and the infant suffers from breathing complications like pulmonary hypoplasia, Respiratory Distress Syndrome (RDS), chronic lung diseases, etc. Respiratory Distress Syndrome (RDS) is a breathing disorder common in premature infants and begins shortly after birth. RDS is caused mainly due to insufficiency of surfactant production and structural immaturity of the lungs. Further, various factors like poor genetics, diabetic mother, multiple pregnancy, rapid labor, etc., increase the risk of RDS in neonates. The deficiency of surfactant causes the lungs to collapse at the end of exhalation and the infant experiences difficulty in breathing. The infant might not be able to breathe in enough oxygen to support the body's organs, which could be fatal.

[0020] A lack of oxygen can damage the infant's brain and other organs if proper treatment is not provided. Fast breathing, fast heart rate, chest wall retractions, expiratory grunting, nasal flaring, etc., are common early symptoms of RDS. As the symptoms worsen, breathing complications escalate, such as prolonged cessations of breathing or apnea, and collapsing of lungs. In such situations, a respiratory support is provided until sufficient surfactant is produced in the alveoli and the lungs can perform breathing independently.

[0021] The respiratory support is usually provided when spontaneous breathing or ventilation stops or when respiratory failure is a possibility. Ventilation refers to movement of air between the lungs via inhalation and exhalation and the ventilator is a machine designed to mechanically move breathable air in and out of the lungs. The ventilator is connected to a breathing tube that runs through the patient's mouth or nose into the windpipe to assist or replace spontaneous breathing.

[0022] Generally, ventilators are of many different types and have different methods of operation. Some of the common modes of ventilation include mechanical ventilation, Continuous Positive Airway Pressure (CPAP), Assist mode ventilation (Triggered ventilation), Pressure support ventilation (PSV), and the like. There are manual ventilators, such as bag valve masks and anesthesia bags that require the users to hold the ventilators to the face or to an artificial airway and maintain breathing with hands.

[0023] Further, ventilators have many different components, such as computing devices, displays, controllers, etc., that demand constant monitoring and assistance from an expert. In addition, such ventilators increase complexity, size, and cost associated with them.

[0024] As mentioned above, the ventilators used as respiratory support have large size, involve complex configuration, and are expensive. Therefore, these ventilators are not portable and limited to major health care settings in urban areas,

and not employed in remote geographical locations with poor infrastructure or when a patient is in transit.

[0025] In accordance with the present subject matter, a device and method for providing continuous positive airway pressure is described. The device and method may be used to provide a constant pressure and constant airflow from an input airflow having variable flow rate and pressure. The constant pressure and airflow is used to maintain a positive pressure in the airway of a patient suffering from Respiratory Distress Syndrome (RDS). The device can be used even without access to wall air and oxygen and can implement the lifesaving technique of CPAP using an oxygen canister or oxygen concentrator with added pressure to open the alveoli. The device disclosed thus provides a multi-powered low-cost version for implementing the continuous positive airway pressure (CPAP) technology.

[0026] The device described herein according to the present subject matter includes a stabilizing unit, a nasal cannula, and a valve. The stabilizing unit includes an inlet port, a pressure stabilizer, and a flow meter. The inlet port is connected to a first gas source unit for providing an input airflow at a variable flow rate. The first gas source unit may be a manually operated device, such as a bag valve mask, piston pump, or foot pump, to produce the input airflow.

[0027] The pressure stabilizer receives the input airflow through the inlet port of the stabilizing unit. The pressure stabilizer may be an elastic bag-like structure, such as a balloon or bellow, which has two openings: a first opening and a second opening. The first opening receives the input airflow while the second opening discharges a continuous airflow. The pressure stabilizer expands and contracts to absorb any variations in pressure of the input airflow and provides a continuous flow of air at a controlled pressure.

[0028] The flow meter is connected to the second opening of the pressure stabilizer to receive the continuous airflow. The flow meter provides an output airflow having a regulated flow rate based on a preset flow rate. The flow meter may

include a flow control valve and an actuator, for controlling the flow of air. For instance, the actuator may control the flow control valve based on the difference between the preset flow rate and the flow rate of the air and provide regulated output airflow. The output airflow at the output of the flow meter, has a constant flow rate and flows through an outlet port of the stabilizing unit.

[0029] In one implementation, the stabilizing unit includes a second inlet port for connecting a second gas source unit. The second gas source unit may be an air pump or an air compressor, powered by a battery. In another implementation, the third gas source unit may be a compressed gas source or an oxygen cylinder, to provide a continuous airflow through the second inlet port. The continuous airflow may be provided to the flow meter for producing regulated output airflow. In another implementation, the stabilizing unit may be enclosed in an outer chamber. The outer chamber is ergonomically designed to allow an operator to hold the device comfortably during operation.

[0030] Further, the outlet port of the stabilizing unit is connected to the nasal cannula and the valve. The nasal cannula is a lightweight tube which on one end is connected to the outlet port of the stabilizing unit and on the other is split into to two prongs placed in the nostrils. The tube receives the output airflow from the stabilizing unit and delivers the output airflow to the patient. Further, the valve may be a pressure control valve, which is attached in conjunction with the nasal cannula for maintaining a positive pressure in the lungs of the patient. The pressure control valve maintains the positive pressure by controlling flow of air exhaled from the lungs. In one implementation, a humidifier is coupled to the pressure control valve for humidifying the output gas provided to the patient.

[0031] In view of the above-mentioned, a device and method for providing a continuous positive airway pressure (CPAP) is provided that is simple, cost-effective, and easy to operate. The CPAP device is portable and may be used in resource constrained settings, such as outpatient clinics, and in emergency situations where

ventilators may not be available, such as in a vehicle. Further, the CPAP device is multi-powered device and can be used either manually or electrically. The CPAP device can also incorporate independent separate modules like temperature monitoring module, oxygen saturation module, pulse monitoring module, etc., such that each independent separate module has its own controller, sensor, display and battery source. In addition, the device does not require an expert assistance and may be used in remote geographical locations and in areas lacking medical infrastructure.

[0032] Fig. 1(a) illustrates a schematic diagram of Continuous Positive Airway Pressure (CPAP) device 100 and Fig. 1(b) illustrates a diagram of the same, according to an embodiment of the present subject matter. The CPAP device 100 includes a stabilizing unit 102, a first gas source unit 104, and a patient interface unit 106. The stabilizing unit 102 includes a first inlet port 108, a pressure stabilizer 110, and a flow meter 112. The first inlet port 108 is connected to the first gas source unit 104 for providing an input airflow at a variable flow rate. The first gas source unit 104 may be a manually operated device, such as a bag valve mask, piston pump, or foot pump, to produce the input airflow.

[0033] The pressure stabilizer 110 is connected to the first inlet port 108 to receive the input airflow. In one implementation, a one-way valve may be connected between the first gas source unit 104 and the pressure stabilizer 110. The pressure stabilizer 110 may be an elastic bag-like structure, such as a balloon or bellow, which has two openings: a first opening and a second opening. The first opening receives the input airflow while the second opening discharges a continuous airflow. The pressure stabilizer 110 expands and contracts to absorb any variations in pressure of the input airflow and provides a continuous flow of air at a controlled pressure. In one implementation, the first opening and the second opening may be coupled with collets to provide a secure connection with connecting pipes, which may be used for connecting the components of the stabilizing unit 102.

[0034] The flow meter 112 is connected to the second opening of the pressure stabilizer 110 to receive the continuous airflow. The flow meter 112 provides an output airflow having a regulated flow rate based on a preset flow rate. The flow meter 112 may include a flow control valve and an actuator, for controlling the flow of air.

[0035] In one implementation, a pressure relief valve 114 is connected to the second opening of pressure stabilizer 110. The pressure relief valve 114 ensures that a controlled pressure is maintained within the CPAP device 100. When the pressure in the device, particularly in the line after the pressure stabilizer 110, increases abnormally or an excess pressure develops in the line, a portion of the air is diverted through a bypass or released into atmosphere. This reduces excess pressure and the unreleased portion of the air flows towards the flow meter 112.

[0036] Further, the flow meter 112 may be connected to a pressure gauge 116 for measuring the pressure applied by the output airflow. The output airflow generated by the flow meter 112 has a substantially constant flow rate and flows through an outlet port 118 of the stabilizing unit 102. In one implementation, the pressure stabilizer 110, the flow meter 112, the pressure relief valve 114, and the pressure gauge 116 may be included in the stabilizing unit 102.

[0037] Further, the outlet port 118 of the stabilizing unit 102 is connected to the nasal cannula 120 and the valve 122. The nasal cannula 120 is a lightweight tube which on one end is connected to the outlet port 118 of the stabilizing unit 102 and on the other is split into to two prongs placed in the nostrils. The tube receives the output airflow from the stabilizing unit 102 and delivers the output airflow to the patient. Further, the valve 122 may be a pressure control valve, which is attached in conjunction with the nasal cannula 120 for maintaining a positive pressure in the lungs of the patient. The pressure control valve maintains the positive pressure by controlling flow of air exhaled from the lungs. In one implementation, a humidifier is

coupled to the pressure control valve for humidifying the output gas provided to the patient.

[0038] Fig. 1(c) illustrates a CPAP device 100, in accordance with an implementation of the present subject matter. The CPAP device 100 includes the stabilizing unit 102, the first gas source unit 104, and the patient interface unit 106. In one implementation, the first gas source unit 104 includes one or more of the bag valve mask, oxygen cylinder, and the piston pump assembly that provides the input airflow. In one example, the first gas source unit 104 includes a venture to receive gas from an oxygen cylinder and a piston pump assembly and provide the mixture of oxygen and air to the stabilizing unit 102. Thus, oxygen enriched air can also be supplied through the first gas source unit 104.

[0039] In one implementation, the stabilizing unit 102 may be enclosed in an outer chamber 124. The outer chamber 124 may be ergonomically designed to allow an operator to hold the CPAP device 100 comfortably during operation. The outer chamber 124 encloses the stabilizing unit 102, the pressure relief valve 114, and the pressure gauge 116, as shown. Further, in one implementation, the pressure stabilizer 110 may be enclosed in an inner chamber 126. The inner chamber may also include an input flow indicator (not shown in the figure), which can include a movable stopper plate, a plurality of labels, and a view window, as will be discussed later.

[0040] In one implementation, a E-module 128 may be connected to the outer chamber 124 using a detachable mechanism. The E-module 128 may include an air compressor 130 connected to a battery 132 and an electrical interface (not shown in figure). The air compressor 130 may be connected to a second inlet port 134 of the stabilizing unit 102 and provides a continuous flow of air with minimal variations in pressure. In one example, the flow of air may be directly provided to a flow meter 112 via a junction port 136. The junction port 136 may include a pair of one-way valves – one for providing connection between pressure stabilizer 110 and flow meter 112 and other for providing connection between second inlet port and flow meter

112. The one-way valves prevent the reverse flow of air provided by pressure stabilizer 110 and/or the second gas source unit 130.

[0041] The output airflow generated by the flow meter 112 has a substantially constant flow rate and flows through the outlet port 118 of the stabilizing unit 102. The outlet port 118 of the stabilizing unit 102 is connected to the patient interface unit for providing a positive pressure to the patient as explained earlier. The E-module 128 may be used either in conjunction with the first gas source unit 104 or independently.

[0042] Fig. 1(d) illustrates a perspective view of the CPAP device, in accordance with an embodiment of the present subject matter. As shown, the outer chamber 124 encloses the components of the stabilizing unit 102, which are compactly connected and enclosed, to provide an ergonomic design with an optimized size, shape, and weight. The outer chamber 124 provides a handle 138 at the top of the outer chamber 124 to carry the CPAP device 100. As the CPAP device 100 includes components, such as pressure stabilizer, flow meters, pressure gauge, etc., which are not heavy, the handle 138 enables the operator to carry the device with minimal effort.

[0043] Further, the outer chamber 124 provides a viewing window 140 for providing a clear view of the pressure stabilizer 110. In one implementation, the viewing window 140 may include a status indicator (not shown in figure). The status indicator may include a movable stopper plate and a plurality of labels for indicating a status of the pressure stabilizer 110. The pressure stabilizer 110 maybe placed beneath the movable stopper plate, which is connected to the plurality of labels. Each label may indicate the status of the pressure stabilizer.

[0044] For example, labels having different colors may be used to indicate volume of air inside the pressure stabilizer 110. A first red color label may be used for indicating that the air volume inside the pressure stabilizer 110 is less than a minimum threshold volume, a second red color label may be used for indicating that

the air volume inside the pressure stabilizer 110 is more than the maximum threshold volume, and a green label may be used to indicate that the air volume inside the pressure stabilizer 110 is within a desired working range, i.e., more than the minimum threshold volume and less than the maximum threshold volume.

[0045] In operation, depending on the input airflow, one of the pluralities of labels may be visible through the view window 140. For example, initially, the first red label indicating that the volume of air in the pressure stabilizer 110 is less than the minimum threshold may be visible. When the input airflow is received, as the pressure stabilizer 110 expands, the movable stopper plate is displaced and correspondingly the labels move so that the green label becomes visible after the volume of air has increased to more than the minimum threshold. As the pressure stabilizer 110 expands further, the labels may move further so that the second red label becomes visible indicating that the volume of air has increased beyond the maximum threshold.

[0046] As will be understood, the volume of air in the pressure stabilizer 110 depends on the pressure of the input airflow. Thus, when the labels indicate that the volume of air is outside the working range, the operator can vary the input airflow pressure to bring it within the working range. Thus, the input flow indicator having a simple and compact arrangement in a view window 140 can enable the operator to adjust the input airflow to be provided through the first gas source unit 104.

[0047] In another implementation, the status indicator may include a pair of stopper plates and a switch arrangement. The pressure stabilizer 110 may be placed between a pair of stopper plates that are separated vertically and placed substantially parallel to each other. The separation between the stopper plates increases when the pressure stabilizer 110 expands, and decreases when the pressure stabilizer 110 contracts. If the pressure stabilizer 110 expands abnormally more due to high pressure, then one of the stopper plates may come in contact with a touch switch to indicate the high volume of air present in the pressure stabilizer 110.

[0048] Figs. 1(e) illustrates components of stabilizing unit 102 arranged in the outer chamber 124, in accordance with an implementation of the present subject matter. As shown, the components of the CPAP device 100 are compactly arranged and connected. Further, the physical parameters of the components may provide an additional advantage to the operator during the operation of the device.

[0049] For instance, the pressure stabilizer 110 may be in ellipsoidal shape, which optimally occupies volume of the outer chamber 124 and thereby providing other components to be compactly arranged. In other implementations, the pressure stabilizer 110 may be in other shapes, such as spherical, cylindrical, etc. Further, the pressure stabilizer 110 may be made of natural rubber latex, neoprene, or elastomeric material to provide a high elongation, tensile strength, and increased longevity.

[0050] For instance, Table 1 and Table 2 illustrate a set of experimental results carried out to determine the relaxation time of the pressure stabilizer 110 based on its usage. The relaxation time refers to the amount of time a constant pressure is provided by the pressure stabilizer.

Table 1: Relaxation Time

Number of Cycles (Inflation & Deflation)	Set Flowrate in LPM	Set PEEP in cm of H2O	Balloon Thickness in mm	Peak Input Pressure in cm of H2O	Relaxation time in Sec (with in allowable flow & pressure range)
0	5	5	0.6	42	58
500	5	5	0.475	36.5	46
1000	5	5	0.455	36	45

[0051] As shown above, the pressure stabilizer 110 was subjected to high number of cycles (1000 approx.), however, it produced a minimum relaxation time for 45s without failure.

Table 2: Relaxation Time

Date	Number of Cycles (Inflation & Deflation)	Set Flow rate in LPM	Set PEEP in cm of H2O	Balloon Thickness in mm	PIP in cm of H2O	Relaxation time in Sec (with in

						allowable flow & pressure range)
16-08-16	1	5	5	0.6	42	56
18-08-16	10	5	5	0.495	37	46
24-08-16	25	5	5	0.45	34	40

[0052] As shown above, even after 25 number of cycles of inflation and deflation, the pressure stabilizer 110 works by meeting all the functional requirements without failure/burst and with maximum 25% of reduction in the thickness.

[0053] In one implementation, as shown in Fig. 1(f), the different components of the CPAP device are similar as described with reference to Fig. 1(d) and Fig 1(e), but are arranged to form a substantially horizontal casing. In addition, the CPAP device has a contour comprising of a tray 135 to hold the neonate over the device. This makes the CPAP device 100 easier to use during transportation.

[0054] Fig. 2 illustrates a method 200 for providing a continuous positive airway pressure. The method 200 described is in congruence with reference to the CPAP device 100 described earlier, however, it will be understood that the method 200 can be implemented in other devices also.

[0055] At block 202, the input airflow is supplied by the first gas source unit 104 to the pressure stabilizer 110. The input airflow has a variable flow rate and may be supplied by a piston pump assembly. The input air may flow through the one-way valve to the inlet port of the stabilizing unit 102.

[0056] At block 204, the flow of the input airflow is stabilized by the stabilizing unit 102. The pressure stabilizer 110 has a first opening that receives the input airflow from the first gas source unit 104 and absorbs the variations in the flow rate of the input airflow by expanding and contracting. The second opening of the pressure stabilizer 110 releases a continuous flow of air at controlled pressure.

[0057] At block 206, the flow meter 112 generates a regulated flow of output air based on a preset flow rate. The air released from the pressure stabilizer 110 flows

towards the flow meter 112. The flow meter 112 comprises the flow control valve which provides a controlled output airflow by means of an actuator depending on the difference between flow rate of the air and the preset flow rate. Based on this the regulated flow rate of the output air flow is generated.

[0058] At block 208, the output airflow is transferred from the outlet port 118 of the stabilizing unit 102 by the nasal cannula 120 to the patient. The nasal cannula 120 may be a lightweight tube offering minimum friction to the output airflow.

[0059] At block 210, a positive pressure is maintained by the valve 122, which is connected to the nasal cannula 120. The nasal cannula 120 may be coupled to a humidifier to humidify the output airflow. The valve 122 maintains the positive pressure in the lungs by controlling the amount of air exhaled by the patient.

[0060] Further, with reference to the above-mentioned embodiments of the present subject matter, a consolidated data obtained from different experiment analyses have been disclosed. The experimental analyses involve the measurement of parameters like pressure, flow rate, volume, by varying the configurations of the CPAP device.

[0061] Fig. 3(a) and 3(b) illustrates the variation in pressure and flow rate of the input airflow and the variation in pressure and flow rate of the output airflow, respectively. In one implementation, the gas source unit 104is a manual pumping unit and the pressure stabilizer 110 is a balloon. The output end of the manual pumping unit is connected to pressure gauge 116 and flow meter 112, which measure the pressure and flow rate of the input airflow. The measurement of pressure and flow rate at different locations in the device is depicted in Table 1, Table 2, and Table 3, below. In this analysis, the measurements are recorded by repeating the experiment 5 times to examine the variations in pressure and flow rate.

Table 1: Input Pressure & Flow Rate of input airflow

Experiment No.	Pressure (mm of H_2O)	Flow rate (LPM)
1	260-0	16-0
2	270-0	17-0
3	260-0	17-0
4	260-0	17-0
5	270-0	16-0
Average	264	16.6

Table 2: Pressure and flow rate at balloon output		
Experiment No.	**Pressure (mm of H_2O)**	**Flow rate (LPM)**
1	150	14
2	160	15
3	160	15
4	150	14
5	145	13
Average	153	14.2

Table 3: Output Pressure & Flow Rate at Peep valve		
Experiment No.	**Output Pressure (mm of H_2O)**	**Flow rate (LPM)**
1	5	5
2	6	6
3	6	6
4	5	5
5	4.5	4
Average	5.3	5.2

[0062] As depicted in the tables and the Fig. 3(a) and 3(b), the variations in the input pressure and flow rate is controlled and a constant range of pressure and flow rate is achieved at the balloon output. The flow meter 112 connected to the second opening of the balloon generates a regulated flow rate and pressure. Therefore, the CPAP device 100 provides an output airflow having constant pressure and flow rate from an input airflow having variable pressure and flow rate.

[0063] In another experimental analysis, a three-port valve may be used in the CPAP device 100. The three-port valve provides a T-joint configuration that connects the manual pumping unit, the flow meter112 and the balloon of the stabilizing unit 102 at the remaining ports. The input pressure and flow rate of the input airflow provided by the manual pumping unit is measured by the pressure gauge 116 and flow meter 112 connected to the gas source unit 104. Fig. 3(c) illustrates the variation in pressure and flow rate achieved by the CPAP device 100 having T-joint configuration and Table 4 provides the measured values of pressure and flow rates at input and output. In this analysis, the measurements are recorded by repeating the experiment 5 times to examine the variations in pressure and flow rate.

Table 4: T-joint configuration with balloon

Condition	Exp. No.	Input pressure (mm of H2O)	Input flow (LPM)	Outputpressure beforeflow controls(mm of H2O)	Output Flowbefore flow controls (LPM)
With PEEP 5 cm of H_2O	1	260	16	Max- 220,Min - 0	Max- 18, Min – 0
	2	270	17	Max- 230,Min - 0	Max- 17, Min – 0
	3	280	18	Max- 220,Min - 0	Max- 18, Min – 0
	4	280	17	Max- 210,Min - 0	Max- 19, Min – 0
	5	270	17	Max- 220,Min - 0	Max- 19, Min - 0
	Average	272	17	~	~

[0064] The pressure and flow rates are measured by applying 30 strokes per minute in the manual pumping unit. The balloon only partially inflates or contracts when the input gas is provided by the gas source unit. Therefore, a pulsating output is generated by the device, i.e., the pressure and flow rate is not constant and cannot be used as breathing support.

[0065] In yet another experimental analysis, the balloon was removed to study the performance of the CPAP device. Fig. 3(d) illustrates the variation in the pressure and flow rate in the CPAP device 100 without the pressure stabilizer 110, i.e., balloon. The input pressure and flow rate is measured by the pressure gauge 116 and flow meter 112 connected to the manual pumping unit. The pressure and flow rates are measured on applying 30 strokes per second in the manual pumping unit. Below, Table 5 provides the measured values of pressure and flow rates at input and output.

Table 4: Without balloon

Condition	Exp. No.	Input pressure (mm of H2O)	Input flow (LPM)	Outputpressure before flow controls (mm of H2O)	Output Flow before flow controls (LPM)
With PEEP 5 cm of H_2O	1	260	16	Max- 250,Min - 0	Max- 19, Min – 0
	2	270	17	Max- 260,Min - 0	Max– 20, Min – 0
	3	280	18	Max- 250,Min - 0	Max- 19, Min – 0
	4	280	17	Max- 260,Min - 0	Max- 19, Min – 0
	5	270	17	Max- 260,Min - 0	Max- 19, Min - 0
	Average	272	17	~	~

[0066] The pressure stabilizer 110 provides a mechanism to absorb the variations in pressure and provides a continuous flow at a controlled pressure.

Therefore, in absence of such a pressure and flow absorbing mechanism the CPAP device 100 provides a pulsating output.

[0067] Further, another experiment analysis to compare the performance of bag valve mask and manual pumping unit is performed. The bag valve mask is of three types classified on the basis of their volume: Adult bag valve mask, Child bag valve mask, and infant bag valve mask. A rebreathing bag is used as a pressure stabilizer 110 in the analysis. Further, the rebreathing bag may be a latex type or a non-latex type.

[0068] The experimental analysis determines the maximum pressure provided by the bag valve masks and the manual pumping unit. In addition, the experimental analysis also determines the number of squeezes or strokes required to generate a constant pressure and the relaxation time.

Table 6: Maximum pressure and relaxation time

Experiment A: For 60 sec of time		**Rebreathing bag with 2 liter capacity**				**Condition: Set PEEP (cm of H_2O) & set flow rate (LPM)**		
Pumping type	**Capacity (ml)**	**Experiments**	**Number of squeezes / strokes**	**Balloon diameter (cm)**	**Volume (L)**	**Max. Pressure (cm of H_2o)**	**Pressure stable**	**Relaxation time**
Adult bag valve mask	1600	1	30	15	1.8	32	After 15 squeezes	15
Child bag valve mask	500	1	63	15	1.8	33	After 40 squeezes	15
Infant bag valve mask	240	1	106	13	1.2	18	Not stable	10
Pumping unit	280	1	95	15.5	2.0	34	After 16 strokes	16

[0069] The manual pumping unit provides the highest pressure and relaxation time. Further, the manual pumping unit requires lesser number of strokes so that the

CPAP device provides a constant pressure and airflow despite having a relatively less volume. Although, the Infant bag valve mask is easy to squeeze a constant pressure is not provided by the CPAP device 100 when it is the gas source unit 104.

[0070] Further, in yet another experimental analysis the volume of different pressure stabilizers 102 is determined. The analysis is performed by comparing the balloon and the rebreathing bag as pressure stabilizers and the data is depicted in Table 7 and Table 8. In the experiments, the manual pumping unit is connected to the balloon or the rebreathing bag, which is connected to the flow meter 112 and the pressure gauge 116.

[0071] The volume of gas present in the balloon and rebreathing bag is calculated from ideal gas law. According to the ideal gas law,

$PV = nRT$, or

$V = nRT / P$

where,

P is the pressure of the gas,

V is the volume of the gas,

n is the amount of substance of gas (also known as number of moles)

R is the ideal, or universal, gas constant, equal to the product of the Boltzmann constant and the Avogadro constant.

T is the temperature of the gas.

Inflated Balloon Experiment-1										
Strokes	**Stroke rate (strokes / s)**	**Balloon circumference (cm)**	**Radius (cm)**	**Volume (cm^3)**	**Pressure inside balloon (cm of H_2O)**	**Volume conversion (cm^3 to L)**	**Pressure(atm)**	**No. of moles**	**$V_1 = (P_2 . V_2) / P_1$**	**Air volume V= nRT / P**

5	1	33	5.25	606.71	17	0.61	1.0165	0.03	0.61	0.64
10	1	43	6.84	1342.2	18	1.34	1.0174	0.06	1.36	1.42
15	1	49	7.80	1986.2	18.2	1.99	1.0176	0.09	2.01	2.09
20	1	54	8.59	2658.3	18.3	2.66	1.0177	0.12	2.69	2.80
25	1	59	9.39	3467.3	18.5	3.47	1.0179	0.15	3.51	3.66
30	1	63.5	10.1	4322.7	18.5	4.32	1.0179	0.19	4.38	4.56
35	1	66	10.5	4853.6	18.7	4.85	1.0181	0.22	4.92	5.12
40	1	70	11.1	5790.6	19	5.79	1.0184	0.26	5.87	6.10
45	1	72	11.4	6301.3	19.2	6.30	1.018	0.28	6.39	6.64
50	1	74	11.7	6841.1919.6	19.5	6.84	1.018	0.31	6.94	7.21
55	1	76	12.09	7411.01	19.5	7.41	1.0189	0.33	7.51	7.81
60	1	78	12.41	8011.02	19.5	8.01	1.0189	0.36	8.12	8.44
65	1	80	12.73	8643.83	19.5	8.64	1.0189	0.39	8.76	9.11
70	1	81.5	12.97	9139.22	19.6	9.14	1.0190	0.41	9.27	9.63
75	1	83	13.21	9653.19	19.6	9.65	1.0190	0.43	9.79	10.17

[0072] Further, the pressure inside the balloon is calculated by the pressure gauge 116. The pressure gauge 116 may be connected to the second of the balloon to measure to the pressure of the air in the balloon.

5

Rebreathing Bag Experiment-2							
Radius of Bag	**Volume of Bag**	**Inside pressure of**	**Volume conversion (cm^3 to**	**Pressure (atm)**	**Number of moles**	**$V_1=(P_2V_2)/P_1$**	**Air volume V=**

(cm)	(cm^3)	Bag (cm of H_2O)	liter)		(n)		nRT/P (L)
7.50	1767.38	32	1.77	1.0310	0.08	1.81	1.84
8.00	2144.94	32	2.14	1.0310	0.10	2.20	2.23
8.50	2572.77	32	2.57	1.0310	0.11	2.64	2.68
9.00	3054.02	32	3.05	1.0310	0.14	3.13	3.18

[0073] Both the balloon and the rebreathing bag expand and contract to absorb variations in pressure and provide continuous flow of air at controlled pressure. However, the balloon can store a higher volume of air than the rebreathing bag and the rebreathing bag can withstand a greater pressure of air in comparison to the balloon.

[0074] Fig. 4 illustrates a waveform representing change in lung pressure during inhalation and exhalation. The waveform 402 represents the change in lung pressure during the breathing cycle without the CPAP device 100. The breathing process is a consequence of change in pressure and volume of lungs. As the lung pressure decreases, the volume of the lungs increases and air from the atmosphere flows into the lungs. On the other hand, the process of exhalation occurs due to elastic recoil of the lung tissue which causes an increase the lung pressure and decrease in volume. Therefore, air flows out of the lungs to the atmosphere. In the waveform 402, the positive peak pressure exerted by lungs to exhale is represented by E and the negative peak pressure to inhale is represented by I.

[0075] The waveform 404 represents the change in the lung pressure during breathing cycle with CPAP device 100. The CPAP device 100 maintains a positive pressure in the lungs to prevent the alveoli in the lungs from collapsing. The minimum positive pressure is represented by I in the waveform 404. Therefore, the positive pressure is maintained by the CPAP device at the end of exhalation.

[0076] Figs. 5(a) and 5(b) illustrate yet another embodiment of a CPAP device 500, in accordance with an implementation of the present subject matter. Fig. 5(a) illustrates an external view of the device and Fig. 5(b) illustrates the components and their interconnections. The device 500 as illustrated in Figs. 5(a) and 5(b) corresponds to another implementation of the device 100 as described earlier.

[0077] As shown in Fig. 5(a), the device 500 includes an input port 504, which can be connected to an Ambubag or other manual oxygen/ air input device and an output port 506 that can be used to provide the pressurized air/ oxygen to an infant. The device 500 has various casings, such as top casing 508-1, back casing 508-2, bottom casing 508-3, front casing 508-4, and balloon casing 508-5, that form the external perimeters of the device 500. A power switch 510 can be used to power on/off the device 500. The working of the device can be monitored using the flowmeter 512, LED panel 514, and pressure gauge 516. Further, an oxygen port 518 can be provided to connect to a source of pressurized oxygen in addition to or alternatively to the manual input source. Fig. 5(b) illustrates the interconnections between the various components of the device 500, including an ambubag, an oxygen cylinder, various valves, and the pressure stabilizer, such as a balloon.

[0078] It will be understood that the CPAP device as described in various implementations above can have various other features in addition to those described with respect to various implementation. For example, the device can have an inbuilt oxygen concentrator and air-oxygen mixer/ blender. Further, the device can have an inbuilt active humidifier to provide heated humidified gas to the neonate. In addition to using a pressure gauge, the device can use a pressure sensor to detect the lung resistance and control the outflow or/and pressure of the product. Further, the device can have an electronic/ mechanically controlled intermittent pressure and flow output and an inbuilt bubble based CPAP pressure control also.

[0079] The device as per the various implementations can be used for the resuscitation of the neonatal and pediatric population. Although the subject matter has

been described in considerable detail with reference to certain examples and implementations thereof, other implementations are possible. As such, the scope of the present subject matter is not limited to the description of the preferred examples and implementations contained therein.

5

I/We claim:

1. A Continuous Positive Airway Pressure (CPAP) device (100) comprising:

a stabilizing unit (102) comprising:

a first inlet port (108) to receive an input airflow at a variable flow rate;

a pressure stabilizer (110) for stabilizing pressure of the input airflow, wherein the pressure stabilizer (110) receives the input airflow through the first inlet port (108) and absorbs variations in the pressure of the input airflow by expansion or contraction to provide a continuous airflow at controlled pressure; and

a flow meter (112) to receive the air from the pressure stabilizer (110) and to provide a regulated flow rate of an output airflow based on a preset flow rate through an outlet port (118) of the stabilizing unit (102);

a nasal cannula (120) connected to the outlet port (118) of the stabilizing unit (102) to receive the output airflow; and

a valve (122) connected to the nasal cannula (120) to maintain a Positive-end Expiratory Pressure.

2. The CPAP device (100) as claimed in claim 1, further comprises a first gas source unit (104) connected to the inlet port (108), wherein the first gas source unit (104) is manually operated to provide the input airflow at the variable flow rate.

3. The CPAP device (100) as claimed in claim 2, wherein the first gas source unit (104) includes a venturi to receive gas from an oxygen cylinder and a piston pump assembly and provide the mixture of oxygen and air to the stabilizing unit (102).

4. The CPAP device (100) as claimed in claim 2, wherein the first gas source unit (104) is one or more of a piston pump assembly, bag valve mask, and a foot pump.

5. The CPAP device (100) as claimed in claim 2, further comprises a one-way valve between the stabilizing unit (102) and the first gas source unit (104).

6. The CPAP device (100) as claimed in claim 1, wherein the stabilizing unit (102) comprises a second inlet port (134) to receive an airflow.

7. The CPAP device as claimed in claim 6, further comprises a E-module (128), wherein the E-module (128) comprises:

a battery (132); and

a second gas source unit (130) powered by the battery (132) and connected to the second inlet port (134) for providing a continuous airflow at controlled pressure.

8. The CPAP device (100) as claimed in claim 7, wherein the second gas source unit (130) comprises at least one of an air compressor or an air pump.

9. The CPAP device (100) as claimed in claim 1, further comprises a third gas source unit, wherein the third gas source unit comprises an oxygen cylinder or a compressed gas source.

10. The CPAP device (100) as claimed in claim 1, wherein the flow meter (112) comprises:

a flow control valve to control the flow rate of the output airflow; and

an actuator to actuate the flow control valve based on the preset flow rate.

11. The CPAP device (100) as claimed in claim 1, wherein the pressure stabilizer (110) comprises:

a first opening to receive the input airflow; and

a second opening to discharge a continuous airflow.

12. The CPAP device (100) as claimed in claim 11, wherein the stabilizing unit (102) comprises a pressure relief valve (114) connected to the second opening of the pressure stabilizer (110) to reduce excess pressure in the CPAP device (100).

13. The CPAP device (100) as claimed in claim 1, wherein the stabilizing unit (102) comprises a pressure gauge (116) connected to the flow meter (112) to measure pressure of the output airflow.

14. The CPAP device (100) as claimed in claim 1, wherein the valve (122) is a pressure control valve connected to the nasal cannula (120) to maintain the positive end expiratory pressure of 5 cm of H_2O.

15. The CPAP device (100) as claimed in claim 14, wherein a humidifier is connected to the pressure control valve to humidify the output airflow.

16. A method for providing a Continuous Positive Airway Pressure (CPAP), the method comprising:

selecting a gas source unit (104, 130);

supplying, by a first gas source unit (104), an input airflow having a variable flow rate to a pressure stabilizer (110) when the first gas source unit (104) is selected;

stabilizing, by the pressure stabilizer (110), the input airflow by expansion and contraction to absorb variations in pressure and provide a continuous airflow at controlled pressure;

generating, by a flow meter (112), a regulated flow rate of an output airflow based on a preset flow rate;

transferring, by nasal cannula (120), the output airflow generated by the flow meter (112) to a patient; and

maintaining, by a valve (122), a pressure equivalent to the Positive-end expiratory pressure.

17. The method as claimed in claim 16, wherein a constant flow rate input airflow is provided by an air compressor or air pump when a second gas source unit (130) is selected.

18. The method as claimed in claim 16, wherein a constant flow rate input airflow is provided by an oxygen cylinder or compressed gas source when a third gas source unit is selected.

19. The method as claimed in claim 16, wherein the input airflow is supplied by manually operating the first gas source unit (104) connected to the pressure stabilizer (110).

20. The method as claimed in claim 16, wherein the expansion and contraction of the pressure stabilizer (110) absorbs excess pressure applied by the input airflow.

21. The method as claimed in claim 16, wherein the regulated flow rate of the output airflow is generated through an aperture of the flow meter (112).

22. The method as claimed in claim 16, wherein the positive-end expiratory pressure is maintained by the valve (122) by controlling flow of air exhaled from the lungs.

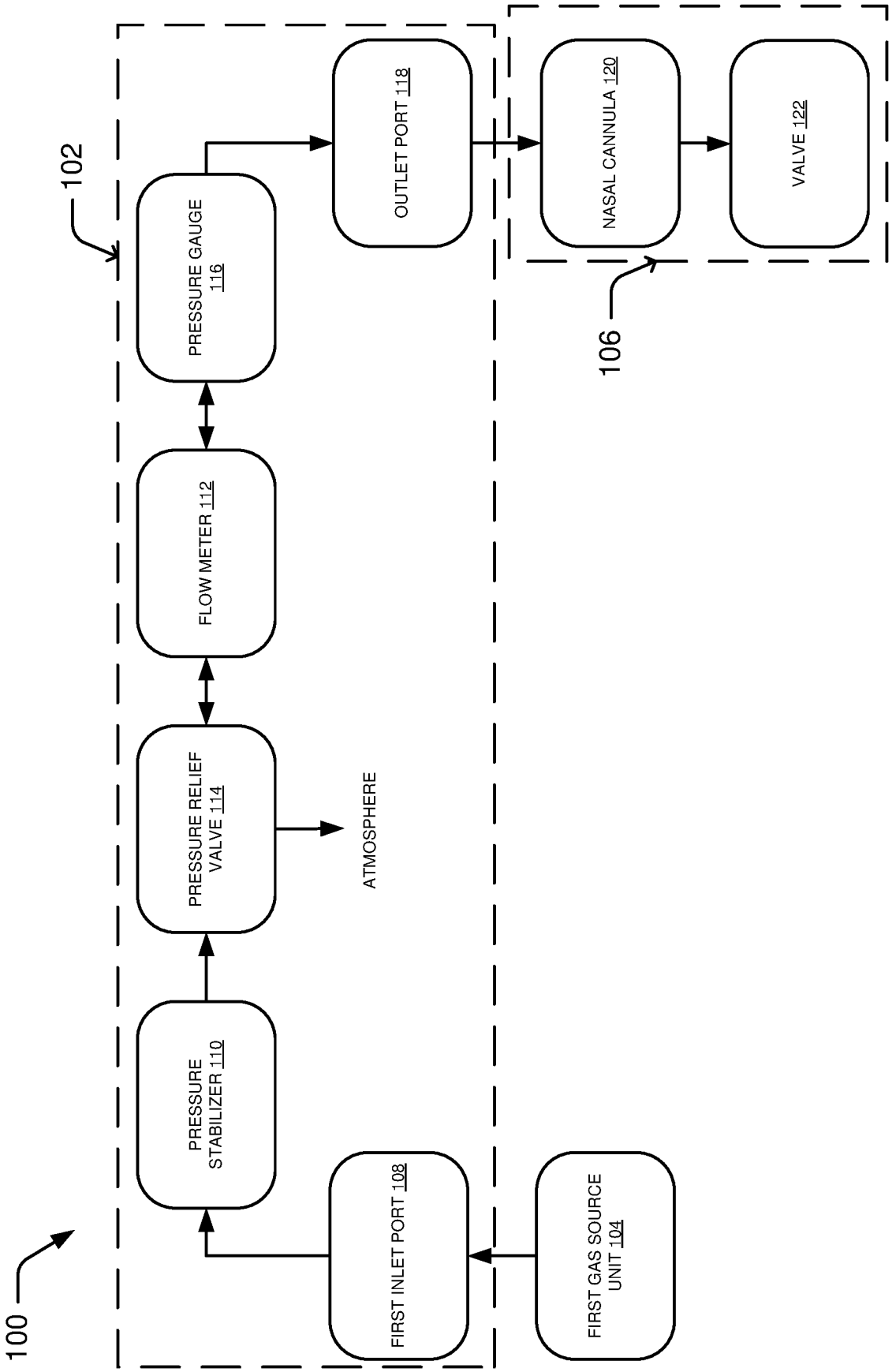
100
102
FIRST GAS SOURCE UNIT 104
FIRST INLET PORT 108
PRESSURE STABILIZER 110
PRESSURE RELIEF VALVE 114
ATMOSPHERE
FLOW METER 112
PRESSURE GAUGE 116
OUTLET PORT 118
106
NASAL CANNULA 120
VALVE 122

Fig. 1(a)

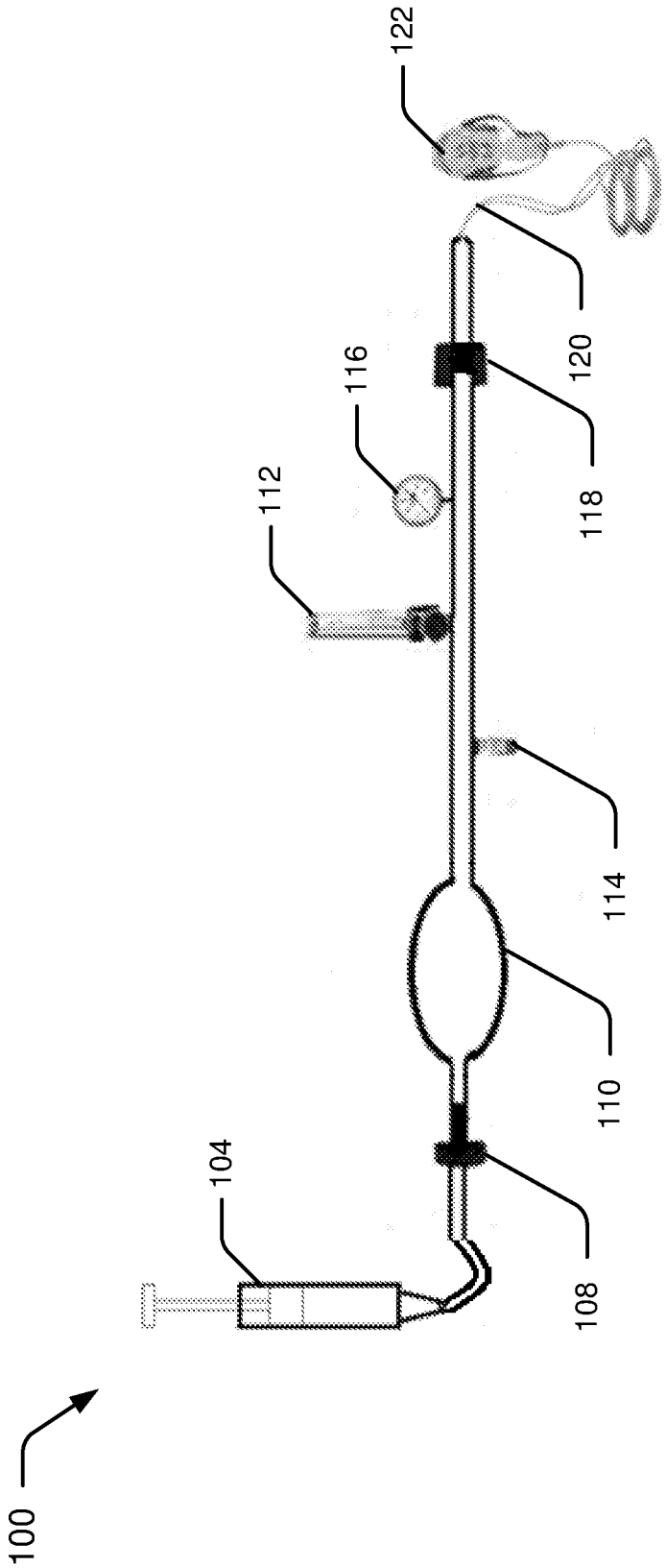

Fig. 1(b)

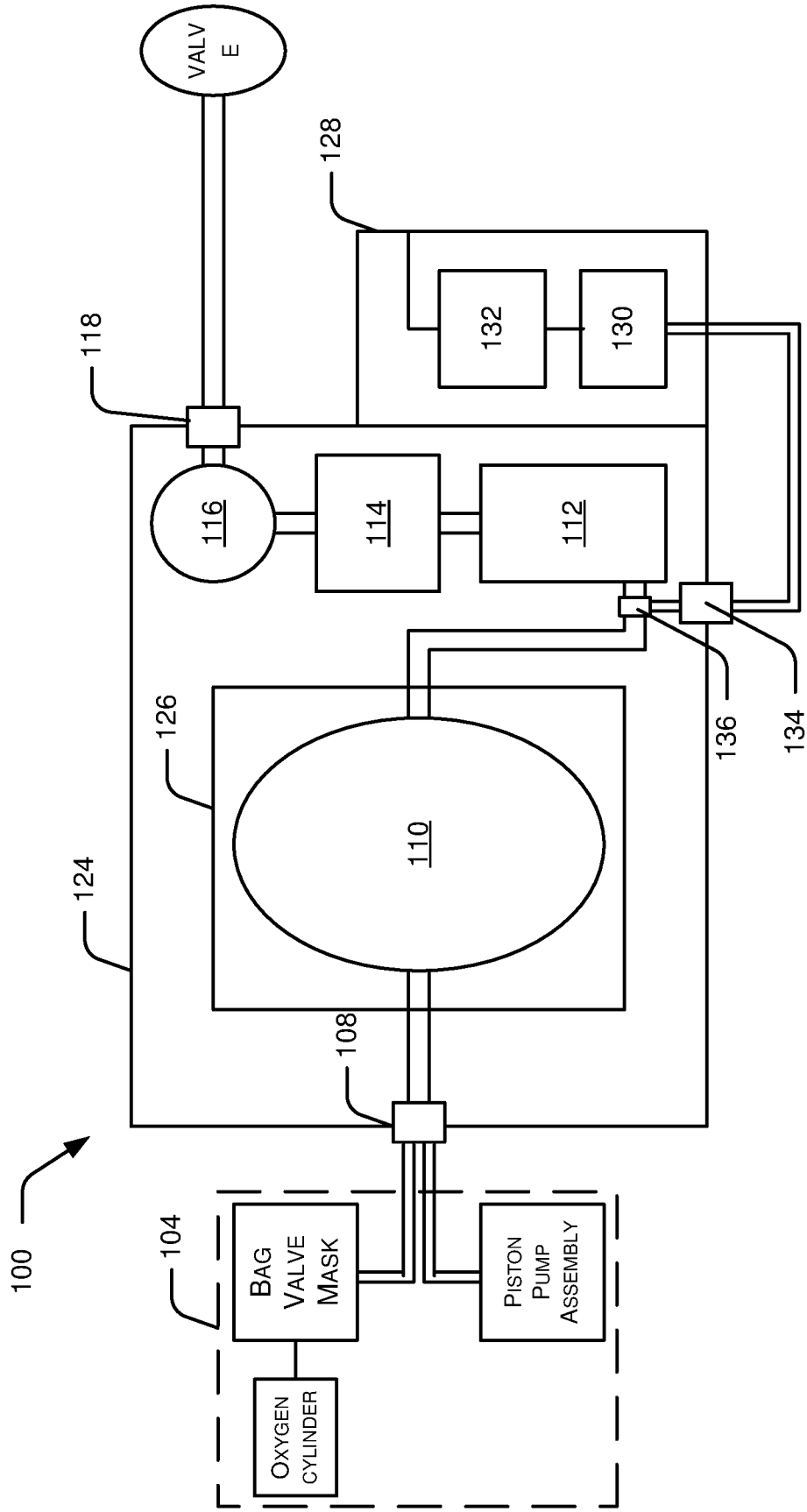
VALV
E
128
132
130
118
116
114
112
126
110
124
136
134
108
100
104
BAG
VALVE
MASK
PISTON
PUMP
ASSEMBLY
OXYGEN
CYLINDER

Fig. 1(c)

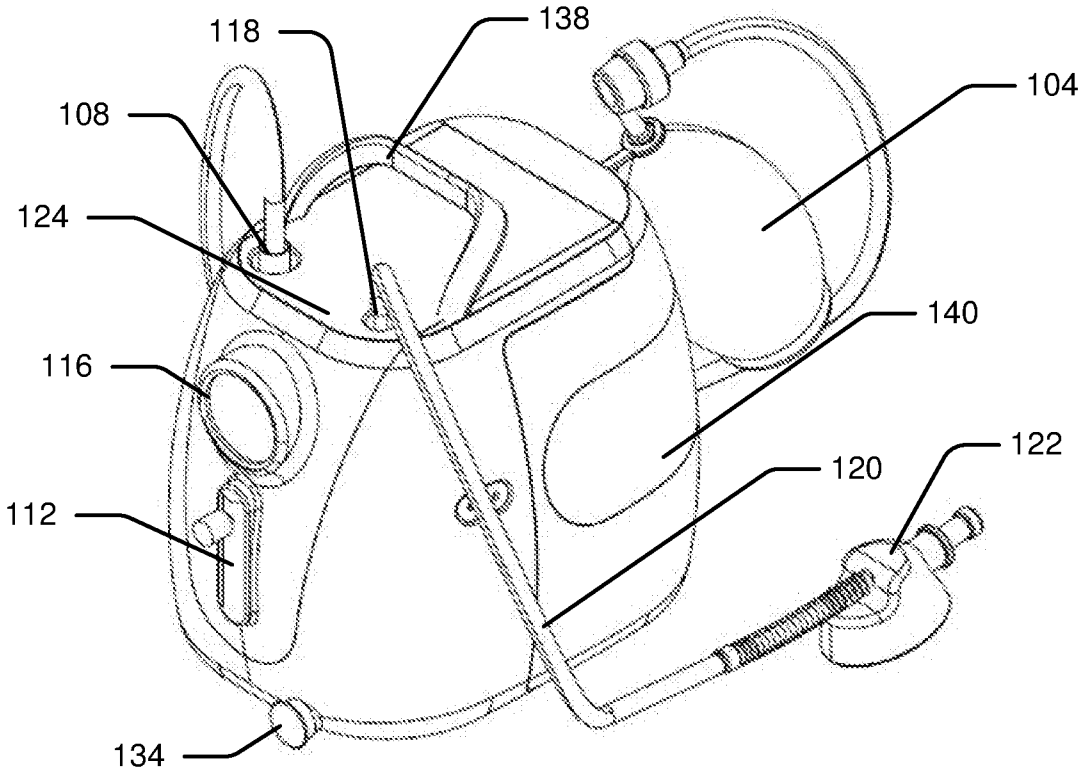
118
138
104
108
124
140
116
122
120
112
134

Fig. 1(d)

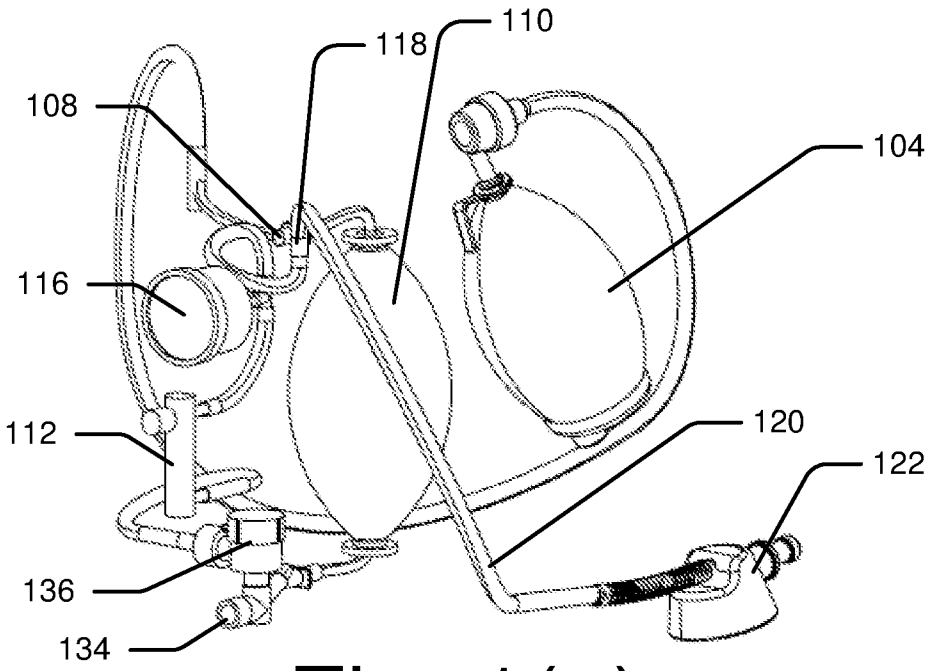
110
118
108
104
116
112
120
122
136
134

Fig. 1(e)

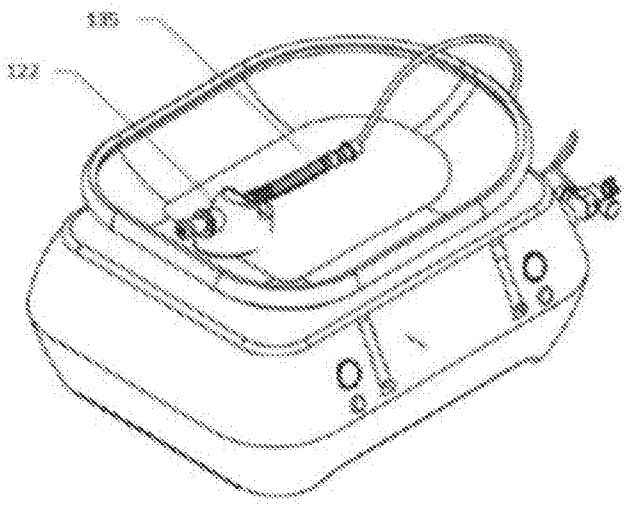

Fig. 1(f)

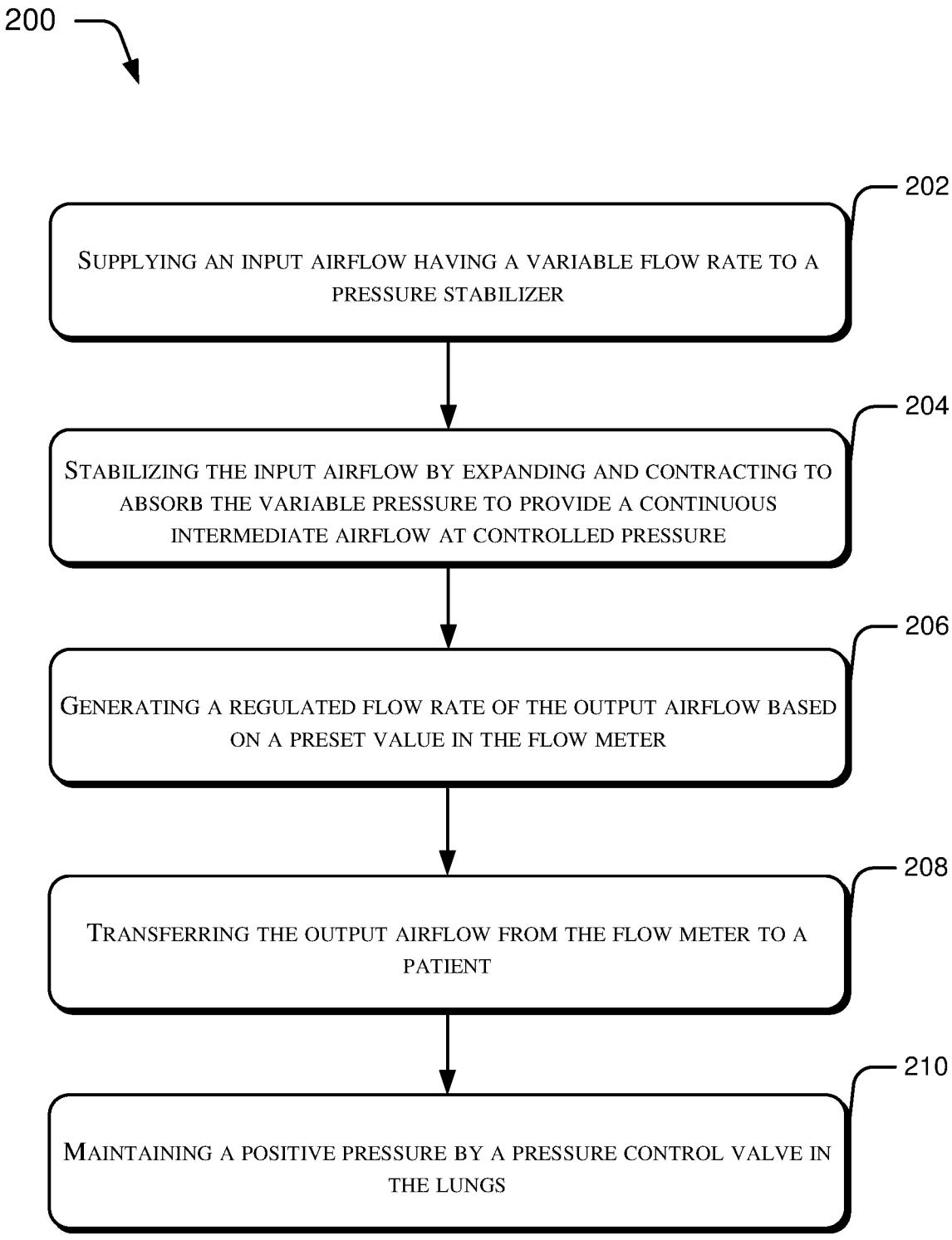
200
202
SUPPLYING AN INPUT AIRFLOW HAVING A VARIABLE FLOW RATE TO A PRESSURE STABILIZER
204
STABILIZING THE INPUT AIRFLOW BY EXPANDING AND CONTRACTING TO ABSORB THE VARIABLE PRESSURE TO PROVIDE A CONTINUOUS INTERMEDIATE AIRFLOW AT CONTROLLED PRESSURE
206
GENERATING A REGULATED FLOW RATE OF THE OUTPUT AIRFLOW BASED ON A PRESET VALUE IN THE FLOW METER
208
TRANSFERRING THE OUTPUT AIRFLOW FROM THE FLOW METER TO A PATIENT
210
MAINTAINING A POSITIVE PRESSURE BY A PRESSURE CONTROL VALVE IN THE LUNGS

Fig. 2

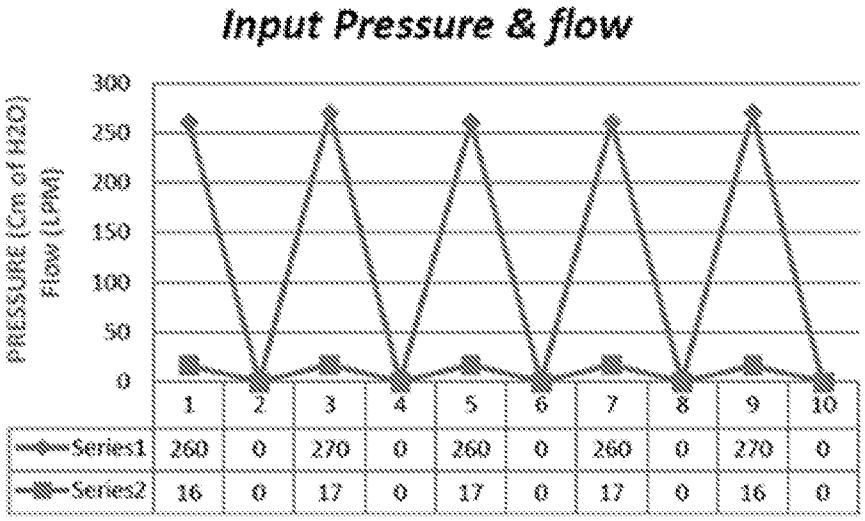
Input Pressure & flow
PRESSURE (Cm of H2O)
Flow (LPM)
300
250
200
150
100
50
0
1 2 3 4 5 6 7 8 9 10
Series1 260 0 270 0 260 0 260 0 270 0
Series2 16 0 17 0 17 0 17 0 16 0

Fig. 3(a)

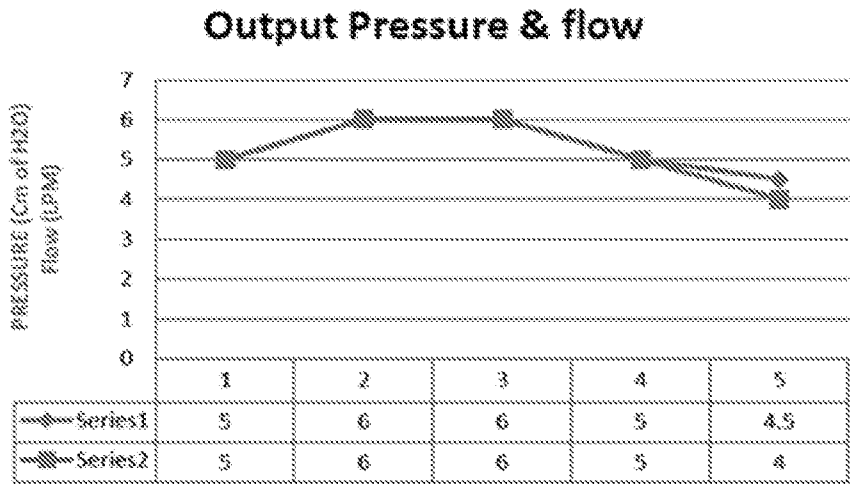
Output Pressure & flow
PRESSURE (Cm of H2O)
Flow (LPM)
7
6
5
4
3
2
1
0
1 2 3 4 5
Series1 5 6 6 5 4.5
Series2 5 6 6 5 4

Fig. 3(b)

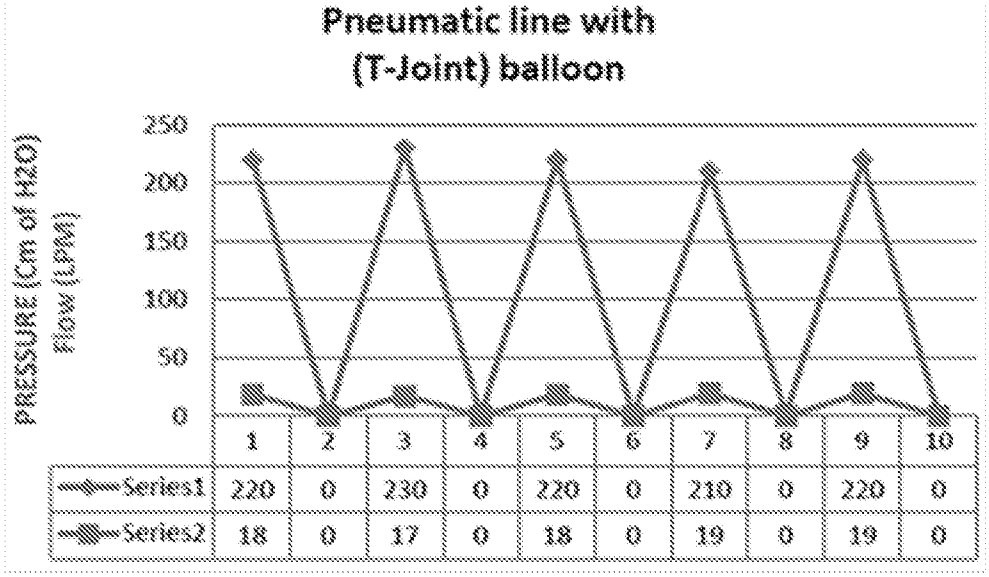
Pneumatic line with
(T-Joint) balloon
PRESSURE (Cm of H2O)
Flow (LPM)
250
200
150
100
50
0
1 2 3 4 5 6 7 8 9 10
Series1 220 0 230 0 220 0 210 0 220 0
Series2 18 0 17 0 18 0 19 0 19 0

Fig. 3(c)

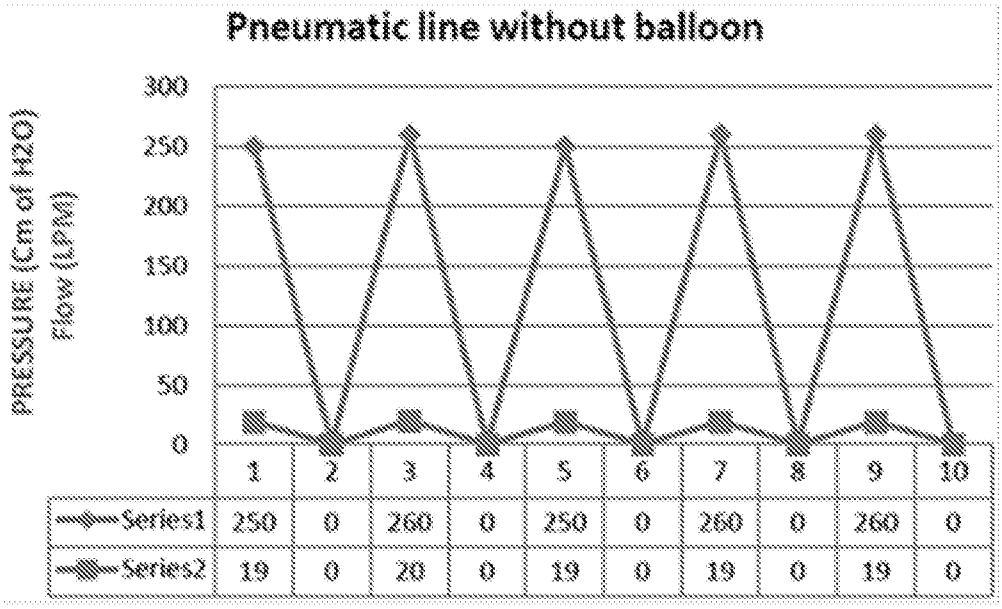
Pneumatic line without balloon
PRESSURE (Cm of H2O)
Flow (LPM)
300
250
200
150
100
50
0
1 2 3 4 5 6 7 8 9 10
Series1 250 0 260 0 250 0 260 0 260 0
Series2 19 0 20 0 19 0 19 0 19 0

Fig. 3(d)

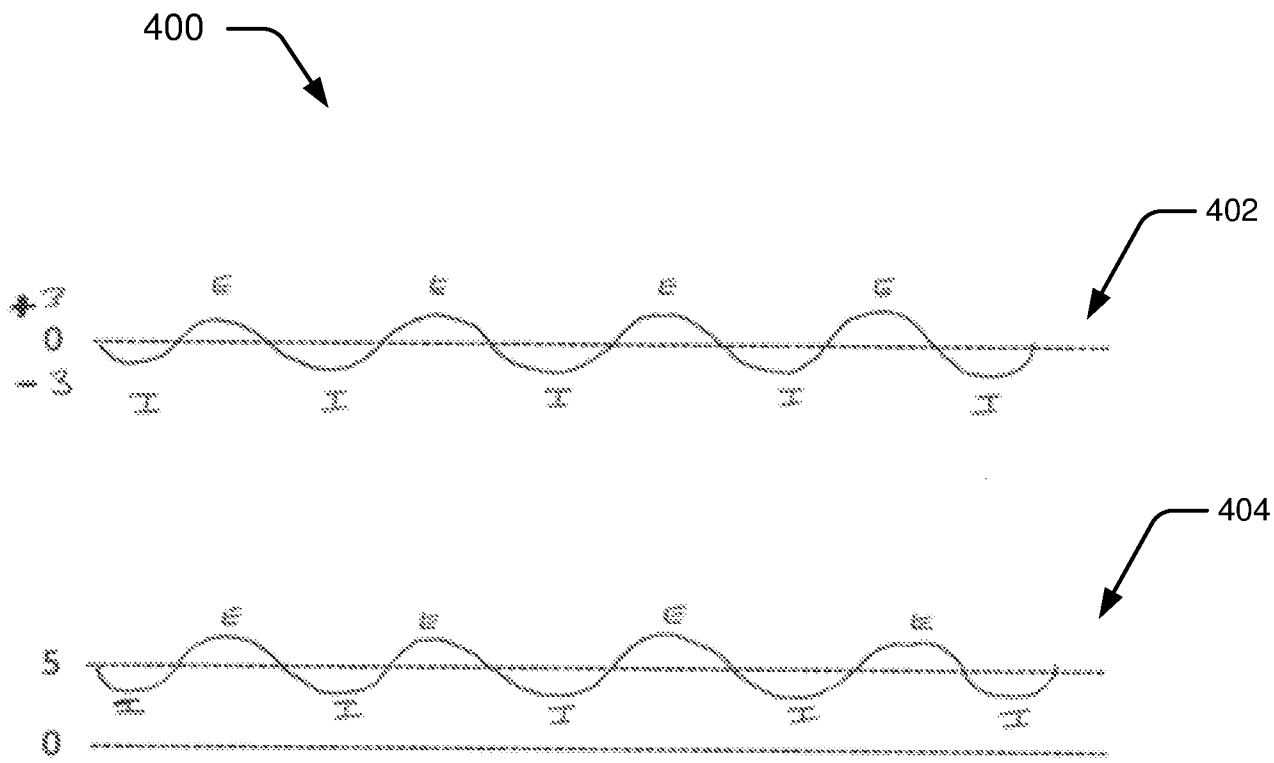

Fig. 4

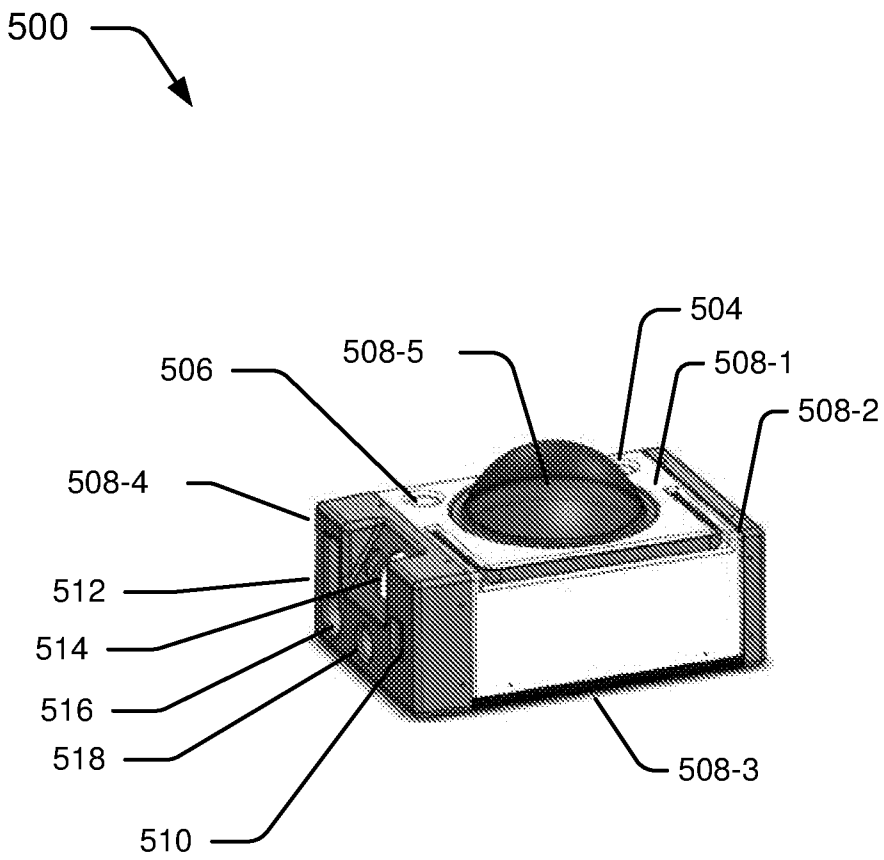

Fig. 5(a)

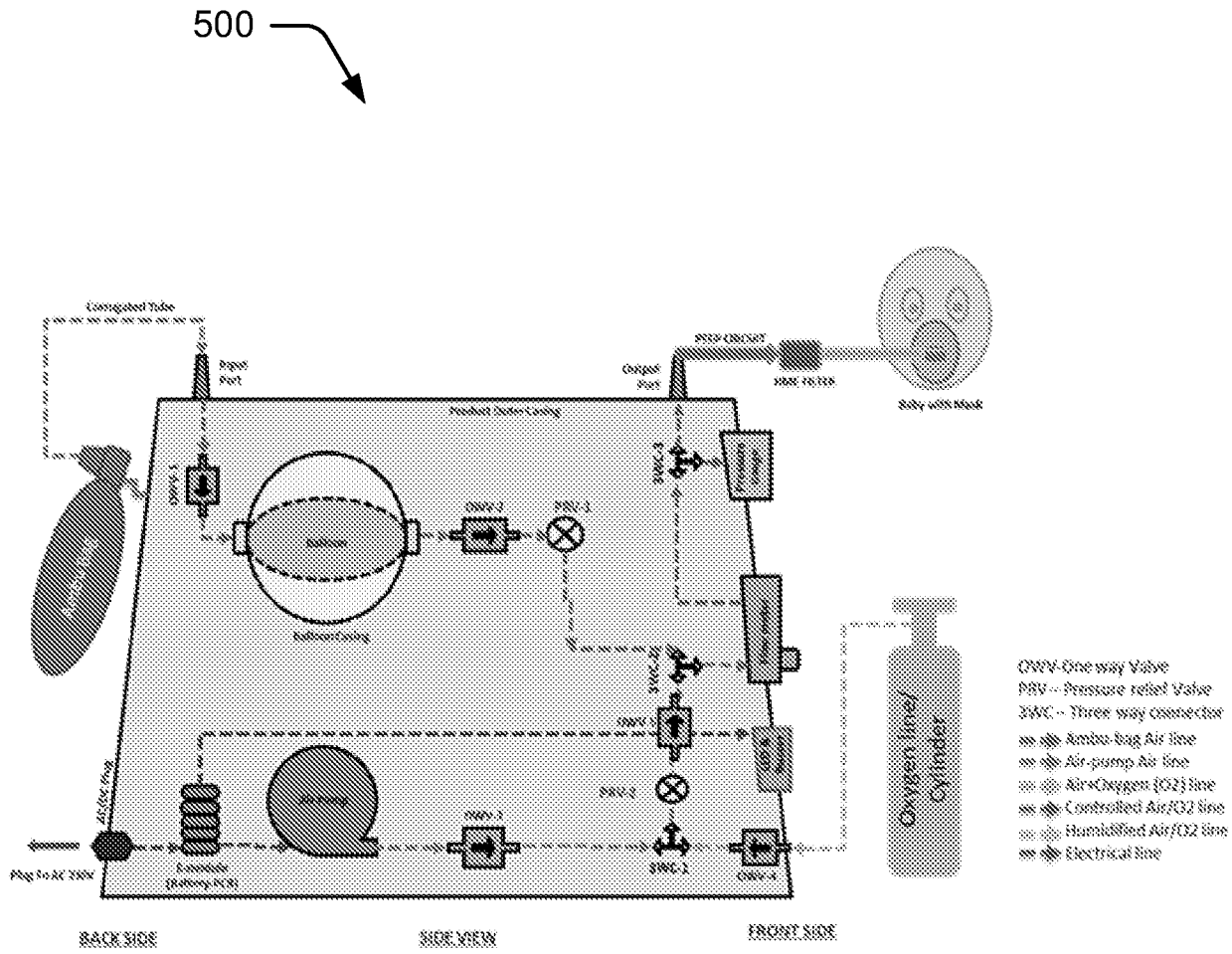
500
Corrugated Tube
Input Port
Output Port
Baby with Mask
Patient Safety Casing
Balloon
Balloon Casing
Oxygen Tank/ Cylinder
OWV-One way Valve
PRV – Pressure relief Valve
3WC – Three way connector
Ambu-bag Air line
Air-pump Air line
Air+Oxygen (O2) line
Controlled Air/O2 line
Humidified Air/O2 line
Electrical line
BACK SIDE
SIDE VIEW
FRONT SIDE

Fig. 5(b)

INTERNATIONAL SEARCH REPORT

International application No.
PCT/IN2018/050029

A. CLASSIFICATION OF SUBJECT MATTER
A61M16/00,A61M16/20 Version=2018.01

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

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

A61M

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

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

Patseer, IPO Internal Database
KEYWORDS: CPAP, AIR COMPRESSOR, AIR PUMP, BATTERY

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US2013104886A1 (BARKER, Dean Atony et al.) 02-MAY-2013 (02-05-2013) CLAIMS 16-21 AND Paragraphs [0023], [0047], [0057], [0059].	1-15
Y	AU2007314070B2 (DUNN, David et al) 05-JUNE-2014 (05-06-2014) CLAIMS 1-5 AND Paragraphs [0004-0010], [0086-0090].	1-15

☐ Further documents are listed in the continuation of Box C. ☒ See patent family annex.

* Special categories of cited documents:
"A" document defining the general state of the art which is not considered to be of particular relevance
"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
23-02-2018	23-02-2018

Name and mailing address of the ISA/	Authorized officer
Indian Patent Office Plot No.32, Sector 14,Dwarka,New Delhi-110075	Sudhir kumar
Facsimile No.	Telephone No. +91-1125300200

INTERNATIONAL SEARCH REPORT

International application No.
PCT/IN2018/050029

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.: 16-22
because they relate to subject matter not required to be searched by this Authority, namely:
The subject-matter of the claims 16-22 is a method for providing continuous positive airway pressure (CPAP) which relates to a treatment method by using the therapy, which does not require an international search by the International Searching Authority in accordance with PCT Article 17(2) (a) (i) and [Rule 39.1(iv)].

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

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

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

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

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

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

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

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

Remark on Protest

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

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

☐ No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT
Information on patent family members

International application No.
PCT/IN2018/050029

Citation	Pub.Date	Family	Pub.Date
US 2013104886 A1	02-05-2013	US 2016354574 A1	08-12-2016
		CA 2968099 A1	03-11-2011
AU 2007314070 (B2	05-06-2014	US 2015083121 A1	26-03-2015
		JP 2011502547 A	27-01-2011