

[54] **NON-INVASIVE HYPERBARIC VENTILATOR**

[76] Inventors: **Steven R. Loveland**, 601-B Jersey Ave.; **Roy L. Campbell**, Cedar Lane Park No. 25, Old Greensboro Rd., both of Winston-Salem, N.C. 27101

[22] Filed: **Jan. 2, 1974**

[21] Appl. No.: **429,534**

[52] U.S. Cl. **128/204**

[51] Int. Cl. **A61m 16/02**

[58] Field of Search.... 128/204, 203, 191 A, 191 R, 128/188, 1 B, 28, 30, 30.2, 142, 142.3, 142.7, 145.8, 298, 299

[56]

References Cited

UNITED STATES PATENTS

1,061,539	5/1913	Haertel	128/202
1,224,180	5/1917	Lake	128/298

2,543,426	2/1951	Terhaar	128/30
2,700,384	1/1955	Ivory	128/204
3,587,574	6/1971	Mercer	128/204
3,786,809	1/1974	Kitralikis	128/191 A

Primary Examiner—Richard A. Gaudet

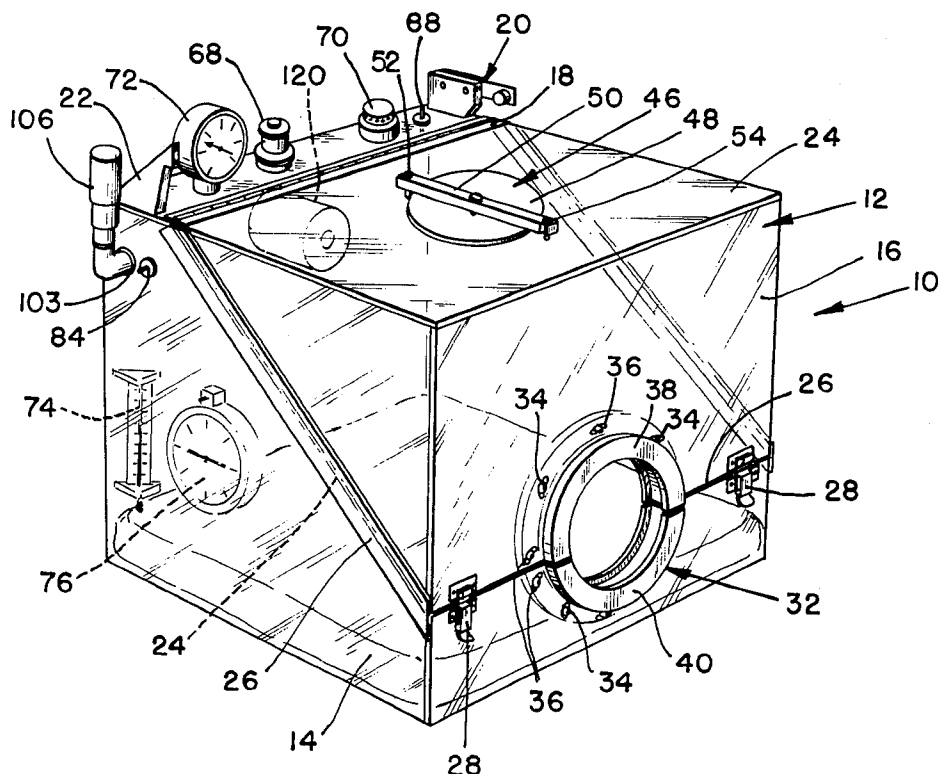
Assistant Examiner—Henry J. Recla

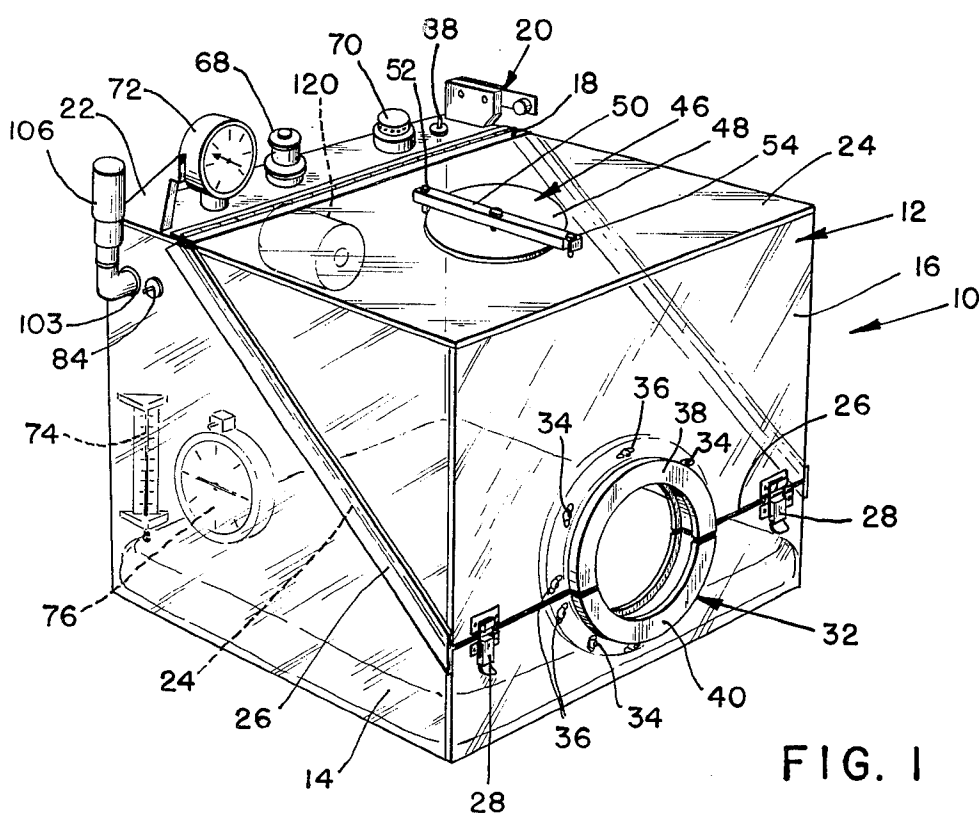
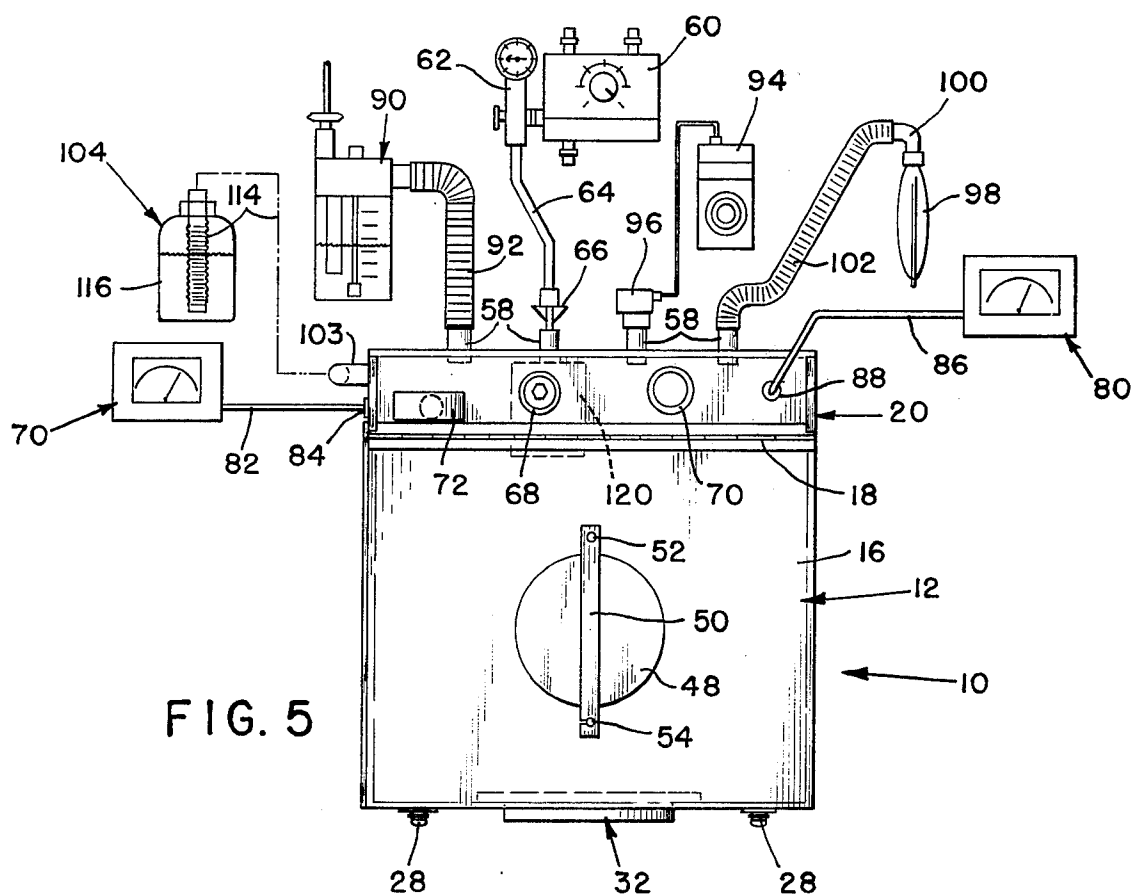
[57]

ABSTRACT

A non-invasive hyperbaric ventilator system for the bronchopulmonary disorders of patients requiring positive pressure ventilation includes a Plexiglas chamber into which the patient's head is inserted. A collar assembly around the patient's neck seals the chamber and an adjustable pressure gauge for regulating gas delivery pressures to the chamber and an expiratory resistance valve cooperate to provide intermittent pressurization and depressurization of the ventilator. The chamber is provided with a plurality of studs and ports to accommodate the attachment of adjunctive devices.

10 Claims, 7 Drawing Figures





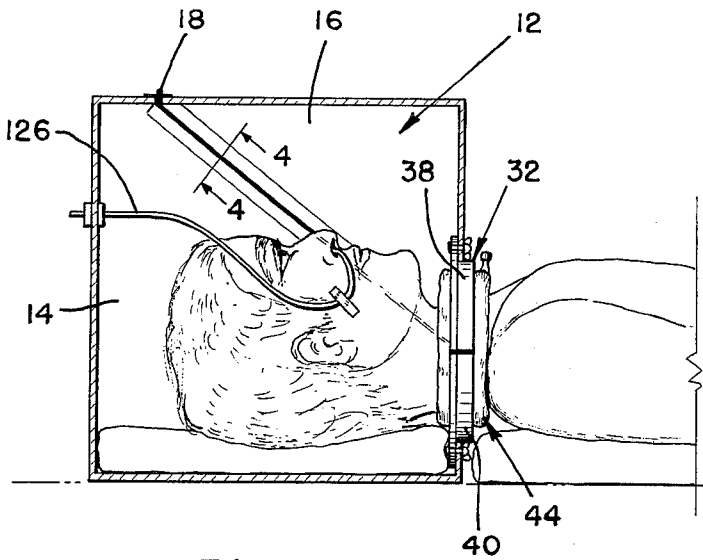


FIG. 2

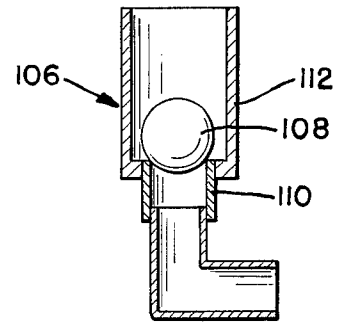


FIG. 7

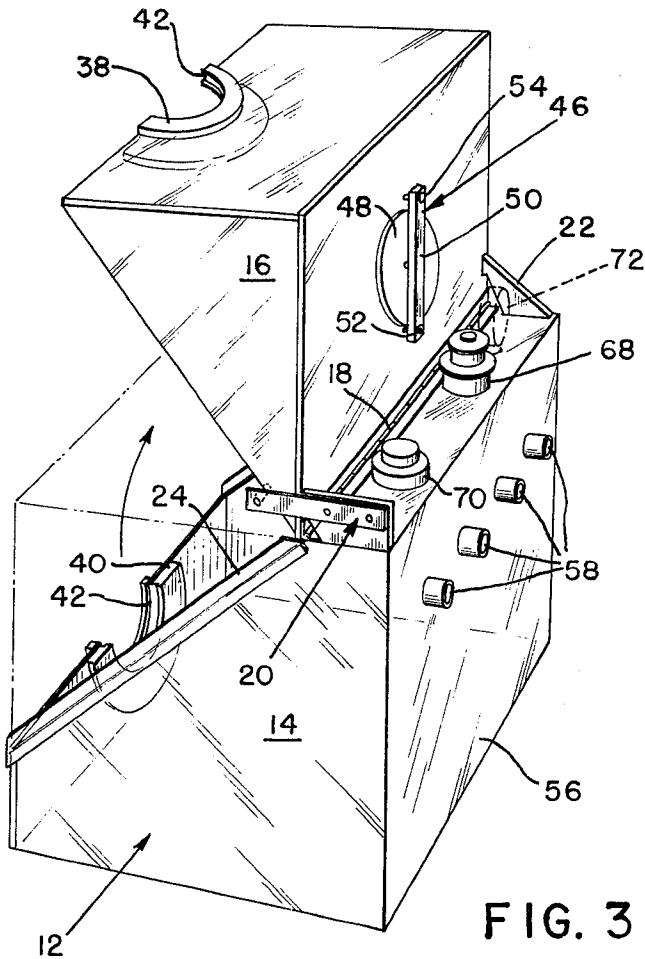


FIG. 3

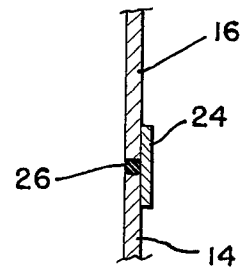


FIG. 4

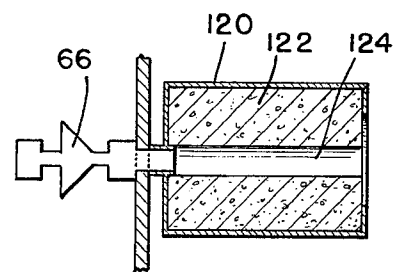


FIG. 6

NON-INVASIVE HYPERBARIC VENTILATOR

BACKGROUND, BRIEF SUMMARY AND OBJECTS OF THE INVENTION

The non-invasive hyperbaric ventilator of the present invention is for the treatment of bronchopulmonary disorders of the adult, adolescent, child or infant in acute distress requiring positive pressure ventilation of a specific type known as continuous positive airway pressure ventilation.

In normal, unassisted ventilation, inspiration is accomplished by the contraction and descent of the diaphragm musculature, creating a negative intra-pulmonary pressure. Expiration is accomplished passively by the relaxation of the diaphragm and the elastic contraction of lung tissue, thereby forcing the movement of gasses outside of the body via the generation of positive pressure within the intra-pulmonary space. Thus, normal breathing is characterized by a negative phase inspiratory effort and a positive phase expiratory process. It is important to note that at the end of the expiratory cycle, the internal pressure within the lung space is equal to, that is, at equilibrium with, the ambient pressure.

Positive Relative breathing is accomplished with the aid of a mechanical device which forces a volume of gas into the lung cavity at a certain pressure and flow rate. Thus, the inspiratory phase of positive pressure breathing is characterized by the generation of positive pressures within the lung space. At the end point of inspiration, the machine shuts off, allowing the lungs to expire their volume of gasses passively, as in normal breathing, again generating a positive pressure within the lung space. Thus, positive pressure breathing, accomplished with mechanical assistance, is characterized by a positive inspiratory phase and a positive expiratory phase. Again, as in normal breathing, pressures within the lungs at the end point of expiration equals that of the ambient atmospheric pressure. At this point, the machine will again "trigger," beginning the expiratory cycle.

Continuous positive pressure breathing is also induced with the utilization of mechanical apparatus. On the inspiratory phase, a volume of gas is forced into the lungs at a certain rate and pressure, causing the intra-pulmonary space to become positively pressurized. At the end of inspiration, the machine switches off, and allows the expiratory cycle to begin with the passive deflation of the lungs, generating positive pressure naturally. However, instead of allowing the patient's lungs to return to the ambient atmospheric pressure at the end of the expiratory cycle, a residual positive pressure gradient is introduced and maintained within the lung space. This is known as positive end expiratory pressure or peep. Thus, complete deflation of the lungs is prevented at the end of the expiratory phase. The residual pressurization at the end of the expiratory cycle is the chief therapeutic difference between continuous positive airway pressure and simple positive pressure ventilation. The net positive pressure within the lungs is mechanically adjustable within certain ranges, depending upon clinical judgment, but generally falls within the range of 5-15 centimeters of water pressure.

In the inspiratory phase of continuous positive airway pressure ventilation, the mechanical device generates a positive pressure gradient, thereby assisting or forcing the inflation of the lungs. By assisting or controlling the

patient's inspiratory efforts, his breathing cycle is mechanically regulated to varying degrees. This mechanical regimentation of the respiratory cycle is required for patients in acute respiratory distress states of various pathologic etiologies.

On the expiratory phase of continuous positive airway pressure ventilation, the lungs deflate passively but complete deflation of the lung cavity is prevented because the ambient pressure external to the lung cavity is mechanically elevated and maintained. Thus, the end point of the patient's expiratory cycle is physically reached when the intra-pulmonary pressure within the lung cavity is equilibrated with the ambient pressure in a breathing circuit or chamber external to the lungs. By manipulating this ambient pressure, the clinician is able to manipulate the residual intra-pulmonary pressures at the end of the expiratory cycle. This residual pressurization causes a physical "splinting" effect by which the small airways of the lungs are physically forced open preventing a collapse at the end of expiration when the lung would normally return to atmospheric pressure without mechanical assistance. This splinting effect, when combined with various concentrations of oxygen, serves to significantly improve the respiratory dynamics and blood gas exchange phenomena of the patient.

Positive pressure ventilation and continuous positive airway pressure ventilation have been traditionally administered with the use of various complex mechanical devices. These devices are connected to the patient's lungs via the establishment of a mechanical circuit. For a mechanical circuit to be established, a pliable prosthetic device known as an endotracheal or tracheostomy tube is inserted into the patient's trachea. In essence, the tube serves as an artificial airway to prevent collapse or obstruction of the trachea.

The mechanical ventilating device forces a volume of air into the tube during the inspiratory cycle causing the positive pressure inflation of the lung. The amount of pressure required to inflate the lung is variable, depending upon the clinical condition and size of the patient.

At the end of mechanical inspiration, the machine switches off and the patient expires passively. Expired gasses are routed through the artificial airway, into the mechanical circuit, and subsequently vented to the atmosphere.

Patients are placed on mechanical ventilators only in the presence of grave clinical conditions. Many physical problems are encountered in the management of mechanical ventilator patients, and, as such, the initiation of mechanical ventilation is considered to be a life supportive endeavor. The management of such patients requires great clinical skill, and the acquisition of expensive and complex equipment.

By virtue of the hyperbaric ventilator being non-invasive, that is, not requiring the insertion of prostatis into the patient's airways, many therapeutic benefits are derived.

The risk of nosocomial infection is greatly reduced. The insertion of a prostatis forms a direct communication for the passage of contaminated materials directly into the deep lung cavities. The hyperbaric ventilator of the present invention does not in any way destroy or bypass the body's natural physical defenses for the resistance of disease.

The risk of severe dehydration is greatly reduced. The insertion of a prostatis forms a bypass of the

body's mucosal tissues, which serve to humidify and warm inspired gasses. The ventilator of the present system in no way disrupts the integrity of these physical systems.

The risk of tracheal stenosis, tracheal malascia, damage to the vocal cords, and sub-glottal damage is eliminated with the use of this system. The above pathologies are incurred frequently with the use of an artificial prostatesis.

Because the system pressures are so low within the ventilator, the decompensation of cardiac output seen in mechanical ventilators may be reduced or eliminated.

The risk of asphyxiation due to system depressurization or hyperpressurization is substantially minimized due to the safety valve systems described and the collar assembly. Hyperbaric ventilators in infants have traditionally employed an iris collar which can be dangerously constricted under high pressure.

Other objects and advantages of the invention will become apparent when considered in view of the following detailed description.

BRIEF DESCRIPTION OF THE DRAWING

FIG. 1 is a schematic, perspective view of the ventilator chamber of the present invention with the hood in the closed position and illustrating selected instruments, valves, etc. associated therewith;

FIG. 2 is a side elevational view of the positive pressure chamber and an inflatable collar assembly for sealing a patient's head within the chamber;

FIG. 3 is a schematic, perspective view of the ventilator with the hood opened and illustrating the collar assembly;

FIG. 4 is a cross-sectional view taken along line 4—4 of FIG. 2 illustrating the seal between the hood and the base structure and the hood alignment guide;

FIG. 5 is a schematic view illustrating the top of the ventilator and further illustrating schematically the attachment of selected adjunctive devices;

FIG. 6 is an enlarged cross-sectional view of a muffler located internally of the chamber to reduce noise levels produced by the high pressure gas source; and

FIG. 7 is a cross-sectional view of the expiratory pressure valve.

DETAILED DESCRIPTION OF THE INVENTION

In the embodiment illustrated, the hyperbaric ventilator device 10 includes a chamber 12 into which a patient's head is inserted, as shown by FIG. 2. The particular configuration and construction of the chamber 12 may vary, however, in the embodiment illustrated the chamber 12 is substantially square and formed of Plexiglas or other suitable materials. The chamber 12 comprises a base structure 14 having a hood 16 pivotally attached thereto by hinge 18. The ventilator hood 16 comprises approximately fifty per cent of the total surface area of the chamber. The hood 16 can be retained in a raised position, as shown by FIG. 3, by means of a vertical hood latch 20, while over-extension of the hood is prevented by the hood rest 22. When the hood 16 is lowered, guides 24 maintain the hood 16 in alignment with the base structure 14. The guides preferably consist of strips of Plexiglas cemented to the inner surface of the base structure 14 and which extend above the edges of the base structure 14, as shown by FIGS. 3 and 4.

All inner faces of the hood 16 and base structure 14 are lined with compressible gasket material 26. In the embodiment illustrated, the gasket material 26 is cylindrical and the base structure 14 is grooved, as shown by FIG. 4, to accommodate and retain the gasket material 26. The inner face beneath the hinge 18 also is sealed with gasket material.

When the chamber hood 16 is lowered, the gaskets are compressed and the hood is retained in a closed position by two conventional spring loaded latches 28, 28.

An opening 30 is provided in the front wall of chamber 12 with approximately half of the opening being defined by the hood 16 and with the other half of the opening being defined by the base structure 14 of the chamber 12. A collar assembly 32 extends into opening 30 and is removably secured in position by plastic guide studs 34 and metal studs with wing nut fasteners 36. In order to obviate physical modifications to the chamber itself, and to accommodate collar assemblies of different sizes, depending upon a patient's neck size, the holes for receiving the metal and plastic studs are uniformly spaced. The collar assembly 32 consists of two halves 38 and 40, a half being secured releasably to the chamber base structure 14 and hood 16, respectively. The collar assembly 32 defines a trough or groove 42, FIGS. 1 and 3, for receiving an inflatable latex tube 44 which assures safe sealing of the patient's neck. The sealed surgical tube 44 of variable inflated proportions is fitted into the collar assembly to insure a comfortable and safe sealing of the neck region. The tube 44 is placed into the trough 42, gently wrapped around the patient's neck, and the hood 16 is carefully lowered and secured by latches 28. The tube 44 then is snugly inflated allowing hyperinflated areas of the tube to extend beyond the collar assembly trough 42 for maximum area seal. In the event of patient crisis, the hood 16 can be lifted to the FIG. 3 position upon manipulation of the latches 28.

The inflatable tube or collar 44 may be replaced with a foam rubber collar, not shown, sealed in plastic film. The foam rubber collar will still be delimited by the collar assembly trough 42.

A patient access port, normally closed by a porthole cover assembly 46, is provided in the top surface of the chamber 12. The assembly 46 includes a pressure sealed lid 48 removably secured in position by a spring loaded restraint arm 50. The arm 50 rotates about pivot pin 52 adjacent one end and includes a slot at the opposite end for receiving a locking member 54. Pivoting of arm 50 and removable of lid 48 permits manual manipulation of the patient's head. Additionally, an extended length rubber glove, not shown, can be sealed around the circumference of the port to allow the aseptic manipulation of the patient without gross disruption of pressures internally of the chamber 12.

The base structure 14 of the chamber 12 is provided with a plurality of openings along the rear wall 56 for receiving interchangeable plastic adapter studs 58. The studs 58, FIG. 3, are arranged to accommodate the attachment of therapeutic adjunctive devices to the chamber.

Upon inflation of the latex collar assembly 44, the patient's head is sealed into the chamber 12 which is subsequently pressurized to varying degrees with therapeutic gasses. This device does not require the insertion of an indotracheal or tracheostomy tube, and, as such, is considered to be non-invasive.

In the embodiment illustrated, the chamber 12 is primarily pressurized from a fifty pounds per square inch air or oxygen generation source. This pressure is subjected to second and third stage gradations. The therapeutic pressure range maintained within the device is 5–20 centimeters of water pressure. The air or oxygen generation source is coupled to an oxygen dilution mechanism 60, which may be of the type manufactured by Veriflow Corporation, Richmond, Cal.

The secondary pressure stage is known as a Bourdon pressure gauge 62 and may or may not be used in conjunction with the oxygen dilution source 60. The Bourdon gauge is the immediate regulative device for sensing pressures and obtaining the desired pressures within the chamber 12, and is adjusted by an integral needle valve assembly. The pressurized gasses are conveyed to the chamber 12 by high pressure hose 64 and a pressure fitting 66. A tube 120, which may be approximately four inches in length and three inches in diameter and filled with a foam rubber 122 having an opening 124 therethrough, is attached internally of the chamber 12 to the high pressure fitting 66. The foam rubber serves as a muffler to reduce the noise level produced by the high pressure gas entering the chamber.

When the chamber 12 is pressurized to the maximum desired level, the patient's safety is insured by a maximum system pressure escape valve 68 mounted at the top of the chamber base structure 14. The maximum pressure escape valve 68 is a spring loaded, adjustable pop-off valve. In the event pressures within the chamber exceeds the desired therapeutic levels, the valve 68 is activated to prevent further increase in chamber pressurization.

An anti-asphyxiation valve 70 is mounted at the top rear of the chamber 12 adjacent the pressure escape valve 68. In the event of unexpected system depressurization that has been unnoticed, patient asphyxiation is prevented by the valve 70. The valve 70 is of a conventional type, and when in the open position, aligned apertures are sealed by a rubber diaphragm. Depressurization of the system will cause the rubber diaphragm to fall downwardly and allow patient access to the ambient air. Closing of this valve 70 negates the anti-asphyxiation function.

Pressure within chamber 12 is monitored by standard pressure manometer 72 which serves as a visual indication of chamber pressure. The manometer 72, also mounted at the upper rear of chamber 12, preferably has a 0–50 centimeters of water pressure positive and negative pressure range. The thermometer 74, located within the chamber, measures temperatures. In addition, nitrogen within the chamber is monitored by a nitrogen analyzer 78, FIG. 5, while carbon dioxide gas concentrations are monitored by a capnograph 80. The nitrogen meter 70 is coupled to the chamber by hose 82 and sampling port 84 while the capnograph communicates with the chamber by hose 86 and gas sampling port 88.

Relative humidity within the chamber 12 is monitored by a hygrometer 76. Because pressurized medical gasses are generally dehumidified at the source, it is necessary to humidify gasses directed into the chamber to varying degrees, depending upon the clinical conditions of the patients. These gasses may be heated or chilled, as required. Various standard high output medical humidifiers are capable of achieving above 90 per cent relative humidity within the ventilator chamber. A

humidification device 90, FIG. 5, may be connected to the chamber 12 by corrugated tubing 92.

Provision is made for the continuous monitoring of oxygen concentrations in the ventilator by an oxygen analyzer 94 and sensor 96 connected to a stud 58. The analyzer 94 may be of the Biomarine Model 302 type. The oxygen analyzer is intended as an adjunctive device not uniquely necessary to the functioning of the ventilator.

A rubber anesthesia-reservoir bag 98 may be provided as an adjunctive device for the manual "sighing" of patients. When the chamber 12 is pressurized, the bag 98 is inflated, and can be manually constricted to introduce greater pressures to the patient's airways. The bag 98 communicates with chamber 12 through the adapter 100, tube 102 and a stud 58.

Maximum therapeutic pressure limitation is accomplished with either a water blow bottle assembly 104, as shown by FIG. 5, or a positive expiratory pressure valve 106, FIG. 1, such as manufactured by Boehringer Laboratories. Though the functions of each system are analogous, their modes of operation are dissimilar. Continuous positive airway pressure is accomplished with the application of a positive pressure gradient in both the inspiratory and expiratory phase. In the inspiratory phase, the positive pressure gradient facilitates expansion of the lungs. In the expiratory phase, the positive pressure gradient serves to keep the lungs partially inflated at the end expiratory point. This produces the splinting effect of small airways. It also requires the patient to exert more effort in the expiratory phase to displace these increased pressures, but facilitates inspiration by reducing labor.

When the patient's head is placed and sealed in the chamber 12, the chamber is pressurized to a predetermined level in the range of 50–20 centimeters of water pressure. This is the positive pressure gradient exerted on the inspiratory phase. Pressure in the chamber 12 will remain constant, a static phase, and will remain so until the beginning of the dynamic expiratory phase.

When the patient exhales, a volume of gas is displaced from the lungs. This volume of gas is displaced within the system through port 103 and the valve 106 or the blow bottle system 104. When the volume of gas is displaced by either of these systems, the chamber will depressurize to a predetermined level above atmospheric pressure. The residual pressure in the chamber exerts the splinting effects within the lung spaces to benefit the respiratory exchange of gasses. The amount of expiratory resistance is determined by adjusting the therapeutic pressure limiting system.

The Boehringer valve system 106 utilizes a dead weight principle for the generation of expiratory resistance. Balls of different mass are placed in a calibrated plastic sleeve 110, the degree of expiratory resistance being proportional to the mass of the ball. When the ball 108 is at rest in the sleeve 110, the ventilator system is sealed. However, when the patient exhales, the volume of gas that his lungs displace and subsequent addition of pressure within the chamber overcomes the gravitational weight of the ball. Thus, the ball 108 is lifted in the sleeve and a volume of gas passes from the chamber, through the sleeve 110, to the ambient environment and the chamber depressurizes to a certain level. The pressure deficit is determined by a mathematical relationship between the mass of the ball, the system pressure, and the exhaled volume of gas.

At the end of the expiratory cycle, the ball weight settles because there is no longer enough pressure within the system to support the weight in cylinder 112. The residual pressure that is momentarily maintained within the system at the end expiratory point is the pressure which produces the desired therapeutic effect. The ambient chamber pressure at the end expiratory point will equal substantially the pressure within the lungs. The pressure regulating gauge 62 will sense the chamber depressurization and initiate repressurization of the chamber. The inspiratory/expiratory cycle then is repeated.

Analogously, the blow bottle system 104 produces expiratory pressure resistance. A corrugated tube 114 extends from the port or orifice 103 into a bottle of water 116. The level of the water upon the tube 114 may be adjusted to increase or decrease expiratory resistance when exhalation takes place within the chamber. Expiratory resistance is generated by the hydrostatic force of the water. When the expiratory pressure overcomes the hydrostatic force, the tube 114 is evacuated and a volume of gas is lost to the ambient atmosphere, and the system will depressurize to an extent. Residual pressures remaining within the chamber will be determined by the depth of the tube in the water.

Therefore, by adjusting the weight of the valve 106 or the level of the water in the bottle 116, the clinician is capable of controlling the residual pressures within the system. The partial evacuation of the ventilator with the use of either system serves to maintain a continuous passage of gas through the chamber, thus facilitating the "washing out" of excessive concentrations of carbon dioxide.

The method of delivering a continuous positive airway pressure by this hyperbaric ventilator is an intermittent one, characterized by a static inspiratory phase and a dynamic expiratory phase.

Therapeutic concentrations of oxygen (21-100 per cent) are frequently administered to patients exhibiting respiratory distress. In applicants' invention, specific concentrations of oxygen can be maintained by utilizing the ventilator oxygen controller 60 or other such device in which precise quantities of oxygen can be blended with air, or by a medical humidification system 90 with variable oxygen concentration.

The oxygen controller 60 or other such device is connected to fifty psi air and oxygen sources coupled with the Bourdon gauge 62 as shown by FIG. 5. The desired concentration then is dialed in manually.

Another system utilizes the Bourdon gauge 62 and the medical humidifier 90 independently. The ventilator is connected to a fifty psi oxygen (or air) source by a high pressure hose. The ventilator is additionally, by means of a separate connection, connected to a standard high output medical humidifier, such as 90, with adjustable gas concentration potential. The humidifier is tapped into an air or oxygen source. By manipulating the gas sources for both systems, and by varying the levels of gas entrainment in the humidifier, desirable concentrations of gas can be maintained within the ventilator with reasonable accuracy.

A maso-gastric tube 126 may be routed from viscera to outside of the chamber to allow for depressurization of the stomach in the event of gas trapping. The tube can be routed outside of the system in a number of ways at the discretion of the clinician.

We claim:

1. A non-invasive hyperbaric ventilator comprising a rigid chamber having a base structure, rear, front, top and side walls, a hinged hood formed from portions of said front, side and top walls, means for sealing said hood in the chamber closed position, a collar assembly having an opening for receiving the neck of a patient, said collar assembly having one portion in the portion of the front wall of said hood and a cooperating portion in the other portion of said front wall, sealing means closing said opening in said collar assembly and engaging the neck of a patient and said chamber to seal the patient's head within said chamber to effect an air-tight chamber, means, including a gas inlet port, for regulating the therapeutic pressure within the chamber to a predetermined level and intermittently controlling the supply of gas to said chamber and facilitating expansion of the patient's lungs during inspiration, and adjustable expiratory pressure relief means communicating with said chamber for permitting displacement of a volume of gas from said chamber when the patient exhales.

2. A non-invasive hyperbaric ventilator as recited in claim 1 wherein said expiratory pressure relief means comprises a normally closed valve including a weight member displaceable by increased pressure in said chamber due to the volume of gas that the patient's lungs displace when the patient exhales thus permitting depressurization of said chamber to a selected level to control residual pressure within said chamber.

3. A non-invasive hyperbaric ventilator as recited in claim 1, wherein said expiratory pressure relief means comprises a container filled with a preselected amount of water and a conduit extending from said chamber and having an end portion selectively positioned below the water level in said container.

4. A non-invasive hyperbaric ventilator as recited in claim 1, wherein said sealing means comprises a collar assembly secured within said chamber opening and an inflatable member extending around the patient's neck and supported within said collar assembly for safe sealing of the patient's neck.

5. A non-invasive hyperbaric ventilator as recited in claim 4, wherein said chamber is provided with means releasably securing a collar assembly thereto, and said chamber opening is sufficiently large to accommodate collar assemblies of various sizes and neck sizes without modification to said chamber.

6. A non-invasive hyperbaric ventilator as recited in claim 1, and further including means for supplying a predetermined amount of moisture to the gas supplied to said chamber.

7. A non-invasive hyperbaric ventilator as recited in claim 1, wherein said chamber is formed substantially entirely of transparent material and includes a base structure, a hood assembly pivotally secured thereto, and means for sealing and releasably securing said base structure and said hood assembly together.

8. A non-invasive hyperbaric ventilator as recited in claim 1, said chamber defining a port in an upper wall thereof for providing access to the patient and a removable sealable door for normally closing said port, said chamber further including a plurality of ports for accommodating the attachment of adjunctive devices to said chamber.

9. A non-invasive hyperbaric ventilator as recited in claim 1, and further including means for providing a patient access to ambient air in the event of unexpected depressurization of said chamber.

10. A non-invasive hyperbaric ventilator as recited in claim 1, and further including means for monitoring the pressure, humidity, and temperature within said chamber.

* * * * *