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[56]

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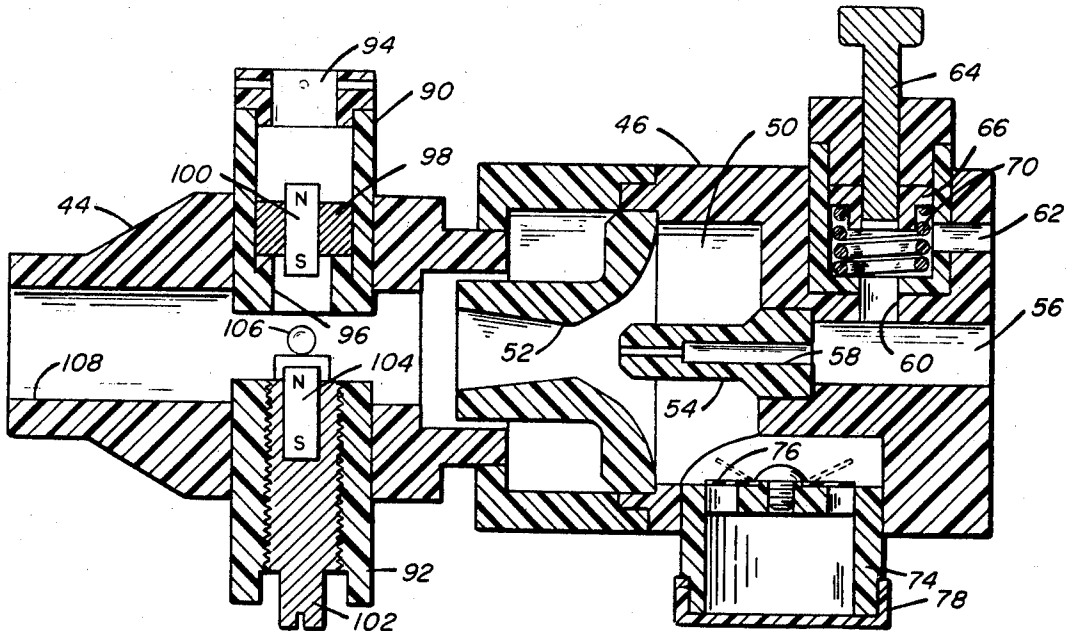
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[54] **INTERMITTENT POSITIVE PRESSURE
 BREATHING DEVICE**
 10 Claims, 5 Drawing Figs.

[52] U.S. Cl. 128/145.6
 [51] Int. Cl. A62b 7/00
 [50] Field of Search 128/28,
 145.5—145.8, 194

ABSTRACT: An intermittent positive pressure breathing - (IPPB) device permits variable adjustment of maximum flow rates, terminal flow rates, and nebulization for patients having various lung disorders.



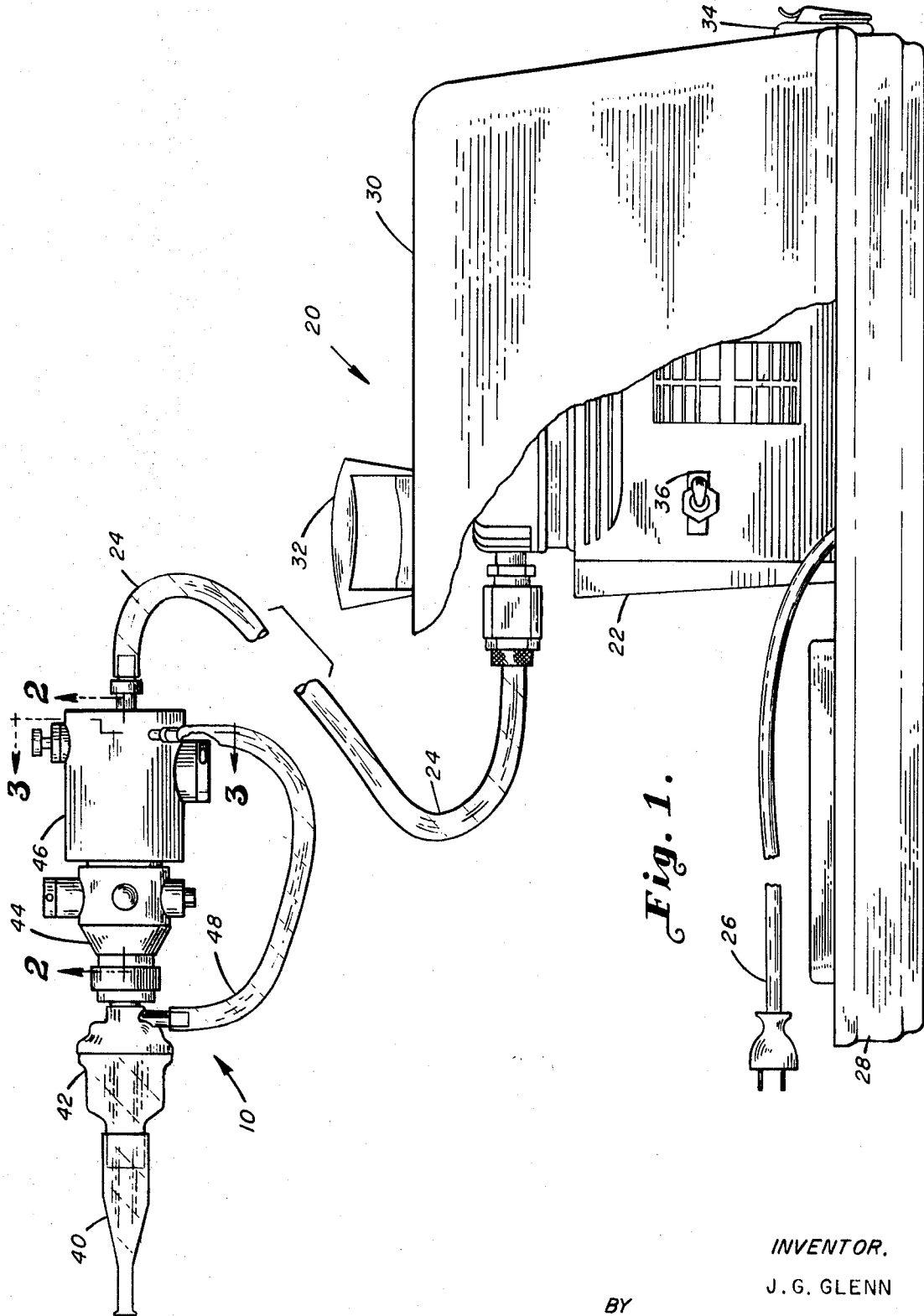


Fig. 1.

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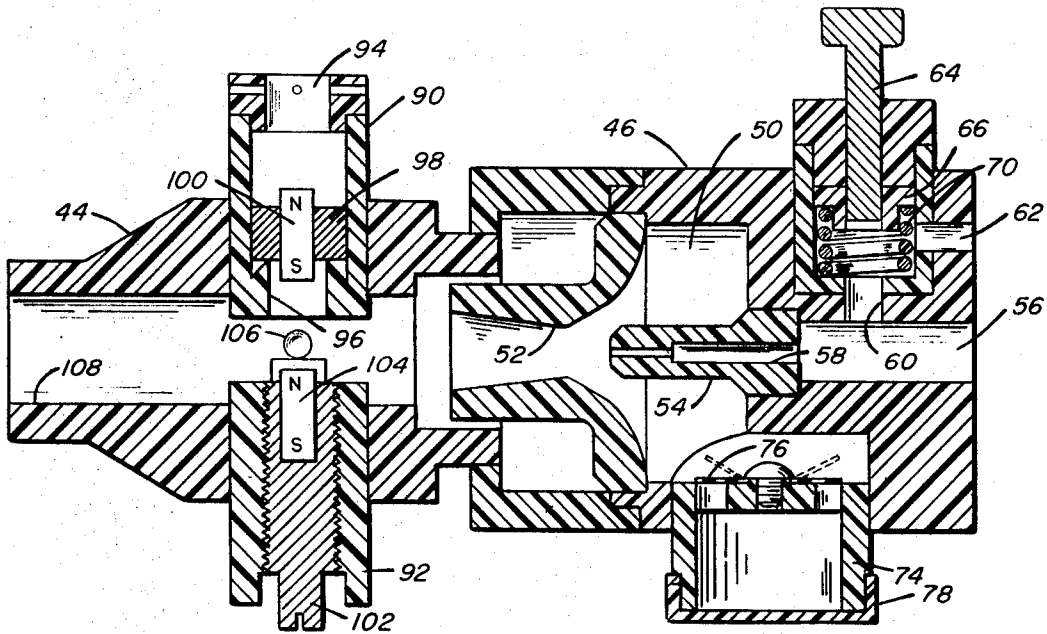


Fig. 2.

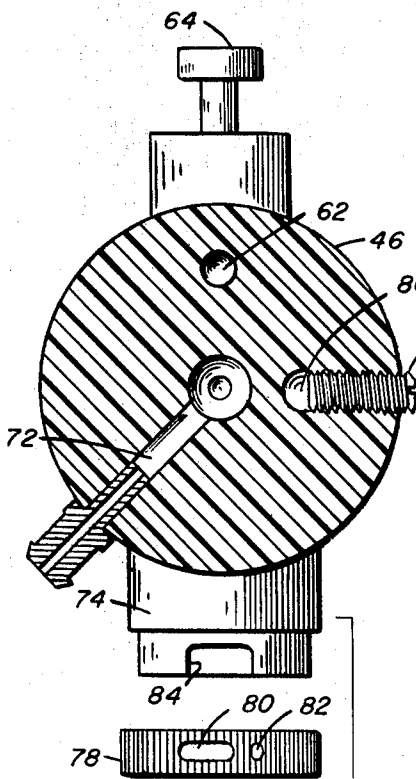


Fig. 3.

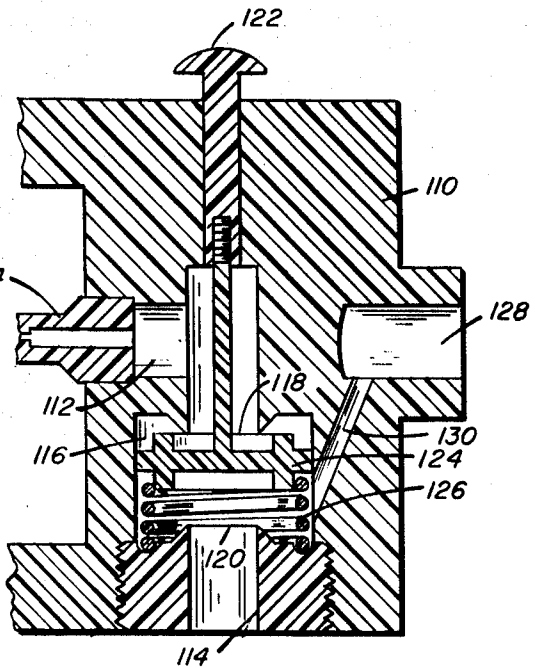


Fig. 4

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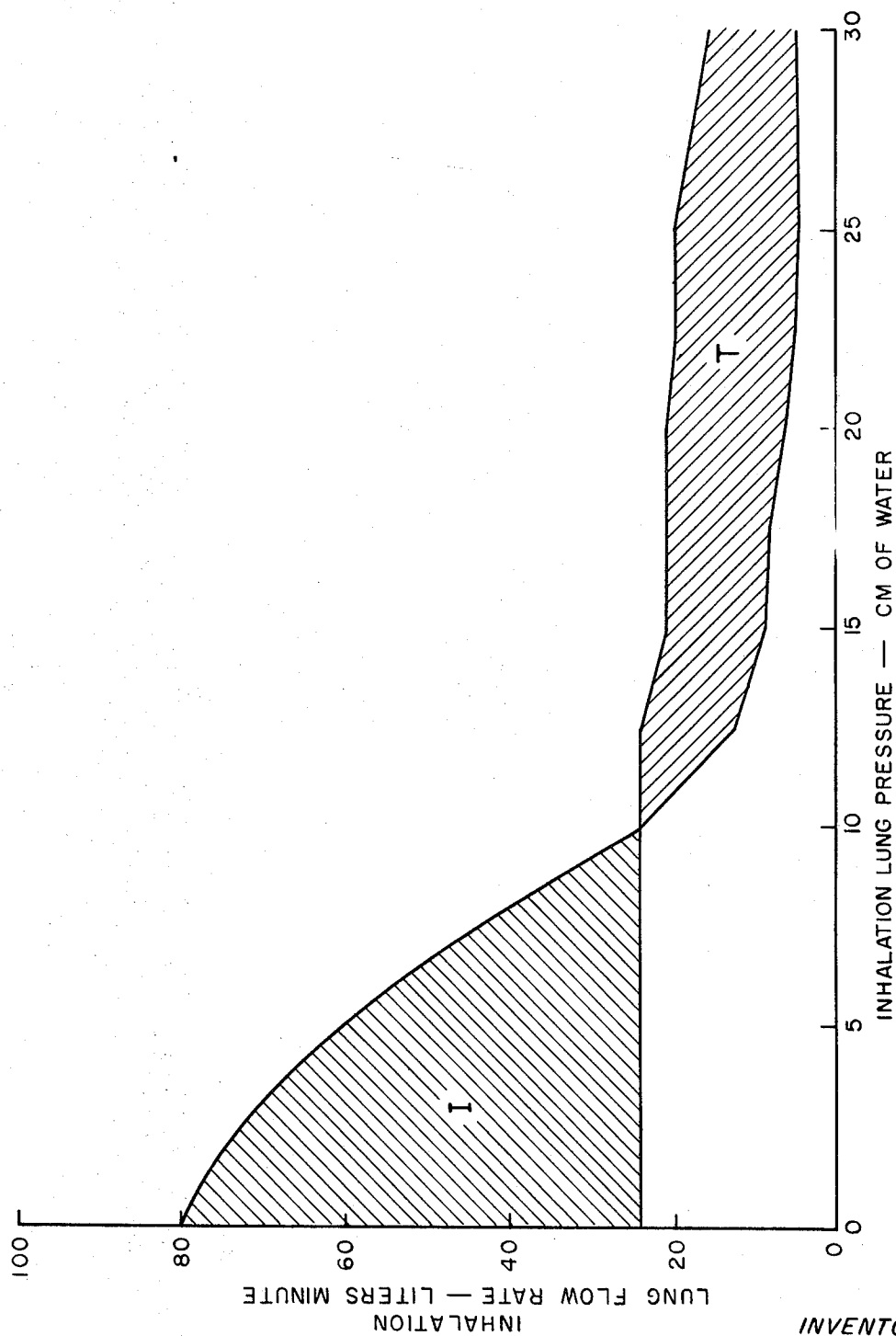


Fig. 5.

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INTERMITTENT POSITIVE PRESSURE BREATHING DEVICE

BACKGROUND OF THE INVENTION

This invention relates to surgical inhalation apparatus and processes. Bronchial asthma, chronic bronchitis and obstructive emphysema are lung disorders caused by a reduction in the caliber of the airways due to mucus, edema, inflammation, bronchial collapse, spasm or combinations of these phenomena. The obstruction to a patient's airflow results in subsequent impairment of breathing or pulmonary function. Rate of flow within the lung and associated airway system is primarily a function of the resistance. As the obstruction becomes more severe a point is reached at which further increases in pressure cause little increase in flow. The patient's work to overcome this resistance and to create greater pressure then begin to create other medical problems including heart failure.

One category of intermittent positive pressure breathing devices known do not permit sufficient initial and terminal flow rate control independently of pressure settings and are therefore ineffective in reducing the high flow resistances encountered in severe obstructive lung diseases. These instruments however increase turbulence resulting in increased pressure and actually add to the resistance due to the disease itself. As a result in many instances of use patients are literally short of breath.

A second category of instrument, in an attempt to reduce terminal inhalation flow, must also reduce initial flow characteristics causing excessive time to ventilate obstructed lungs.

A yet third category of apparatus is based on changing input pressure to the device, thus changing initial flow, terminal flow and nebulizer output.

SUMMARY

Accordingly, this invention has for its primary purpose and object the overcoming of the problem associated with known prior art devices and to provide an IPPB device which permits independent adjustment and control of the inspiratory flow pressure and flow rates to match the particular degree of an individual patient's condition. It is believed that normal inhalation comprises a high flow rate initial phase followed by a lower flow rate terminal phase. As airway obstructions increase the terminal phase becomes of greater importance in effective lung ventilation. The apparatus and process of this invention permits adjustable initial high flow rates to fill the unobstructed areas of the lung while permitting adjustable lower flow rates of terminal flow to fill the congested areas of the lungs. Particularly the invention provides a more complete filling of the patient's lungs within a relatively short period and without a great deal of patient work. Further, the device and the methods of this invention permit adjustment of the initial and terminal flow rates and rate of nebulization for adding medicament to the patient's lungs.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is an elevational assembly view of the apparatus comprising this invention.

FIG. 2 is a sectional view taken along the line 2-2 of FIG. 1.

FIG. 3 is a sectional view taken along the line 3-3 of FIG. 1.

FIG. 4 is a sectional view of a modification form of this invention.

FIG. 5 is a graphic display of the operating characteristics of the apparatus of this invention.

DESCRIPTION OF THE PREFERRED EMBODIMENTS

Referring now to FIG. 1 the apparatus of this invention generally includes a mouthpiece and valve assembly 10, motor-driven compressor 22 and carrying case housing 20. The latter includes a motor-driven compressor 22 and an outlet conduit 24. Electrical power to the motor driven compressor 22 is supplied through electrical conduit 26. The housing

itself includes a lower base portion 28 to which an upper portion 30 including a carrying handle 32 is attached by means of latches as at 34. The motor-driven compressor is controlled by toggle switch 36. The mouthpiece and valve assembly 10 includes a mouthpiece 40, a nebulizer 42 for the introduction of medicament in a vaporous or a finely divided form, a relief valve 44 and a main valve control body 46 all of which are more fully hereinafter described. A bypass air supply conduit 48 is connected between the air inlet and the nebulizer to drive the latter by aspiration. All of the parts are assembled in substantially the sequence shown in FIG. 1 except in those instances where it is desired to omit the intermediate relief valve body portion 44 which is hereinafter more fully described.

As shown in FIG. 2, valve body 46 includes an annular flow chamber 50 which terminates at the forward end with a throat 52 into which a nozzle 54 is placed for incoming air from the compressor inlet manifold chamber 56. Interconnecting with manifold chamber 56 is the nozzle flow passage 58 and bypass flow passage 60 and 62 which are controlled by hand-operated valve 64, causing plunger 66 to go downward sealing the bypass opening 60. Spring 70 is biased normally retaining valve 64 upward in bypass condition until depressed. Additionally, as best shown in FIGS. 1 and 3 the nebulizer flow conduit 48 is connected to the manifold chamber 56 by passageway 72. An annular flow control check valve body 74 includes a resilient flapper-type valve 76, the dotted lines of which show the inlet flow position. The check valve is adaptable to either a fully opened position at the bottom thereof or further controlled by a cap 78 as best shown in FIG. 3. Adjustment openings 80 and 82 cooperate respectively across slot opening 84 of the check valve body and hence control the amount of airflow into the flow chamber 50. Interconnecting with the flow chamber 50 is an exhaust conduit 86, the opening of which is controllable by threaded member 88. Forward of the valve body 46 is a relief valve body portion 44 shown, in this embodiment, attached thereto. This portion includes opposed upper and lower cylindrical members 90 and 92 respectively. The upper cylindrical member includes an opening 94 in the top thereof and has a valve seat 96 internally. A valve 98 is adapted to seat thereon and has included therewith a magnet 100 oriented as shown. The lower opposite cylinder 92 includes an adjustable threaded member 102 which at its inner end includes a magnet 104 aligned in such a way that the innermost pole is opposite the innermost pole of magnet 100 hence tending to attract each other and normally maintain the valve 98 seated. An additional opening 106 may be provided to interconnect with the flow channel 108 of body 44 for the attachment of measuring or calibration devices or for separate oxygen supply as desired. Otherwise, the opening 106 is normally plugged or maintained closed.

Referring now to FIG. 4 a modified valve body 110 is adapted for use with a pure oxygen source to be substituted for body 46. A nozzle 54 is attached to chamber 112 which interconnects with vertical passageway 114 and is divided at an inner chamber 116 to form an upper valve seat 118 and a lower valve seat 120. A hand-operated valve plunger 122 includes a valve body 124 which is adapted to seat against either the upper or the lower valve seats 118 and 120. A spring 126 maintains the valve normally in an exhaust position wherein oxygen, input at manifold 128, passes through passageway 130 into chamber 116 and thence outward through the lower part of vertical chamber 114. Upon depressing plunger 122 the oxygen input is directed into the upper portion of chamber 114 into manifold 112 and through nozzle 54.

OPERATION

In operation, a physician, knowing of a particular patient's breathing needs, capabilities and general physical condition will calibrate the breathing assembly of this invention. Normally to accomplish this a test pressure gauge is connected into the port 106, for example, and replace the mouthpiece with a test lung. The control valve is depressed and the pres-

sure indicator will move up to the setting of the valve 44 and will drop back to about 10 cm. pressure. The highest point reached before the indicator starts to fall is the prescribed pressure setting typically 12 to 20 cm. of water. If pressure adjustment is required, to suit patient needs and capabilities, set-screw 102 is turned to increase pressure and vice versa. Other adjustments can be made as set forth hereinafter.

Initial flow rate adjustments, with a constant input from the compressor, occur using the check valve 74. Without the cap adjustment device shown in FIG. 3 the highest flow rate, usually about 85 to 90 liters/min., occurs into the patient's air-flow system. Using the cap and placing the ports 80 and 82 opposite the opening 84 will provide a flow range of from approximately 25 to 70 liters/min. Terminal flow adjustment occurs by opening (reduce flow) or closing (increase flow) of orifice 86 as setscrew (or knurled knob) 88.

With the apparatus assembled and calibrated as shown in FIG. 1 the patient places the mouthpiece 40 into his mouth and makes a tight seal with the lips. In some instances a nose clip may be necessary to prevent loss of air through the nose. Upon simultaneous depression of the plunger 64 of the flow control valve the patient gently inhales normally through the mouthpiece and allows the lungs to be filled by slowly expanding his chest to a comfortable degree. Pressure will begin to build up in the lungs as they are filling taking about 3 to 5 seconds to reach a safe level prescribed by the physician. When the prescribed pressure, capable of being accepted by the patient in his particular condition, has been reached the relief valve 98 of the valve body 44 will open to allow excess air entering through the inlet tubing 24 manifold 56 and nozzle 54 to escape. In many instances when the chest is expanded to a comfortable degree by the patient and he stops, there is still a noticeable degree of pressure building within the lungs without any further work being done by the patient. At this point the patient may release the flow control plunger or the excess air will be exhausted through the relief valve body 44. Prior to the operation the nebulizer may be filled with the exact amount and type of medication prescribed which also enters the patient's lung cells to clean, reduce infection and improve ventilation.

In those instances where greater oxygen enrichment or pure oxygen is to be utilized in the treatment the unit such as that shown in FIG. 4 is shown wherein the oxygen cylinder outlet or oxygen pipeline outlet may be connected to passageway 128, the control of the plunger valve 122 and the rest of the mechanism identical to that shown in FIG. 2.

In some instances it is possible to utilize the apparatus of this invention excluding the relief valve portion 44 which includes the magnetic valve therewith, adding only the nebulizer and mouthpiece unit directly downstream of the nozzle throat 52. The primary difference being that such an assembly does not provide an obvious or audible pressure break or sound from the relief valve to the patient that the control pressure has been reached. The operation is similar in that after the plunger 64 is depressed and normal inhalation the lungs will fill with air (or oxygen). When the chest is expanded to a comfortable degree there is a noticeable degree of pressure build-up in the lungs without patient work when there is a pause for a second or two then the flow control plunger is released as also the seal with the lips about the mouthpiece then exhaling. In this embodiment adjustment screw 88 is used to limit pressure.

Additional modification includes the adaptability of having an oxygen enrichment in an embodiment and assembly as shown in FIGS. 1 and 2 by directly attaching the input oxygen to port 106 which is uncovered or unplugged.

The design and theoretical operation of this invention may be considered with regard to the chart of FIG. 5. The venturi air-entraining principle to accomplish lung ventilation has been used heretofore in intermittent positive pressure breathing apparatus. With such unit a higher rate of flow is permissible at the start of the inhalation cycle yet will compensate to reduce the flow rate after the pressure rises in the pa-

tient's lungs. The maximum flow into a patient's lungs will vary over a wide range generally with a high of 45 to 60 liters/min. This invention considers the concept that there are two basic flow processes in the inhalation cycle of a patient. This is the initial flow rate (I) and the terminal flow rate (T). The use of a venturi nozzle and a flow intake chamber 50 and check valve inlet 74 alone usually provides the type of initial flow characteristic desired. However, there is a loss of control over the terminal flow condition. This invention permits adjustment of pressure, initial flow and terminal flow and nebulization which can be varied without affecting each other. As such the apparatus of this invention uses the venturi principle to reduce flow initially closing the check or flutter valve 76 as the pressure rises in the lungs of the patient to about 10 cm. of water pressure. The adjustable orifice exhaust port 86 reduces flow more gradually in the interest of effectively ventilating the airways of the lungs and delivering medication to the lung periphery. If in certain situations it is required to reduce terminal flow still further this is accomplished by increasing the opening of the exhaust port which is equipped with either a setscrew 88 or some form of a knurled hand adjustment knob. In reference to the chart of FIG. 5 that portion shaded and identified as I is the initial flow rate characteristic which may be adjusted according to the size of the flutter valve opening or further adjusted by the relationship of cap 78, openings 80 and 82 relative to the opening 84 of the check valve 74. That is, if opening 82 for example is the only opening of the check valve there will be a lower initial flow rate. This flow rate for initial flow may be designated by the formula: $F=80.7-3.05p-0.259p^2$ where F equals flow rate in liters per minute and p equals pressure in centimeters of water.

The terminal flow area shaded and designated by the letter T is further adjusted relative to the opening of the exhaust port 86 and may be designated by the formula: $F=46.3-2.621p+0.0417p^2$.

This invention has been described with reference to specific and preferred embodiments. It will be apparent, however, that other modifications can be made without departing from the spirit and scope of the invention. Accordingly, this invention should be construed not to be limited to the embodiment herein described but should be limited by the scope of the appended claim with relation to the existing prior art.

I claim:

1. Apparatus for lung ventilation comprising, a breathing manifold assembly

a venturi chamber body connected to said assembly having:

an injector nozzle,

a venturi throat,

a venturi chamber behind said throat and around said nozzle, the position of said nozzle outlet relative to said throat to permit high initial flow rate, within the range of 25—90 liters/min. to said assembly,

an intake check valve located in communication with said chamber to permit flow unidirectionally into said chamber,

a variable size exhaust port to provide communication from the chamber to the exterior,

means to supply fluid pressure to said nozzle inlet, and

a flow control bypass valve connected to said inlet which, when closed, forces said fluid into said nozzle.

2. Apparatus according to claim 1 including a relief valve downstream of said venturi chamber body adapted to open upon a given pressure created within said lungs.

3. Apparatus of claim 2 wherein said valve provides an audible signal on opening.

4. Apparatus of claim 3 wherein said valve includes

a valve seat,

a valve, having a magnet therein, seatable upon said seat,

a magnet adjustably situated opposite said valve magnet and oriented to attract said valve magnet until a given pressure overcomes said magnetic force to open said valve seat.

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5. Apparatus of claim 1 wherein said intake check valve includes adjustment means to vary the intake flow rate into said chamber.

6. Apparatus of claim 1 wherein said breathing manifold assembly includes a mouthpiece,

a nebulizer separately supplied with a portion of fluid pressure from said nozzle inlet.

7. Apparatus of claim 1 wherein said apparatus includes a separate motor driven compressor to supply fluid pressure to said nozzle inlet.

8. A patient's inhalation therapy method comprising the steps of:

providing flow of lung acceptable fluid to an inhalation means, and

phasing said flow to provide, at the output of said means, an initial inhalation phase in which said flow rate is rapidly

reducing followed by a terminal inhalation phase in which said flow rate is gradually reducing, said initial phase flow rates and said terminal phase flow rates being adjustable to preselected values independently of each other and independent of the desired ultimate pressure, within said patient's lungs, at the end of said inhalation.

9. Method of claim 8 wherein the flow rate of said initial phase is within the range of about 20 to about 100 liters per minute reducing to said lower value at a given pressure within the range of 5 to 15 centimeters of water.

10. Method of claim 8 wherein flow rate (F_i) for said initial inhalation phase follows the approximate formula: $F_i = 80.7 - 3.05 - 0.259p^2$; and said flow rate (F_t) for said terminal inhalation phase follows the approximate formula: $F_t = 46.3 - 2.621bp + 0.0417p^2$ where p = pressure in cm of water.

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