United States Patent [19]

Bird

[11] **3,842,828**

[45] **Oct. 22, 1974**

[54] **PEDIATRIC VENTILATOR**

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[21] Appl. No.: **287,416**

[52] **U.S. Cl.** **128/145.8,** 128/194

[51] **Int. Cl.** **A61m 16/00**

[58] **Field of Search** ..... 128/145.8, 145.5, 145, 128/DIG. 17, 140, 142, 146.3, 146.4, 146.5, 194, 28, 142.2, 142.3, 142.4, 185, 186, 187, 191, 196, 197, 203, 274, 210, 211; 137/63 R, 494, 624.14, 596.2, 496, 525, 505.14; 251/61, 61.1–61.5

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Primary Examiner—Richard A. Gaudet
Assistant Examiner—Henry J. Recla
Attorney, Agent, or Firm—Flehr, Hohbach, Test, Albritton & Herbert

[57] **ABSTRACT**

Pediatric ventilator having an inhalation phase and an exhalation phase in its operative cycle with an inlet adapted to be connected to a source of gas under pressure. A breathing circuit is adapted to be connected to the patient. Nebulizing means is provided. Flow divider means is connected to the inlet and has one outlet coupled to the nebulizing means so that at least a portion of the inlet gas is supplied to the nebulizing means. The flow divider means includes an additional outlet coupled to the breathing circuit and has means for controlling the flow of gas through the additional outlet whereby precise control over nebulization can be obtained.

30 Claims, 23 Drawing Figures

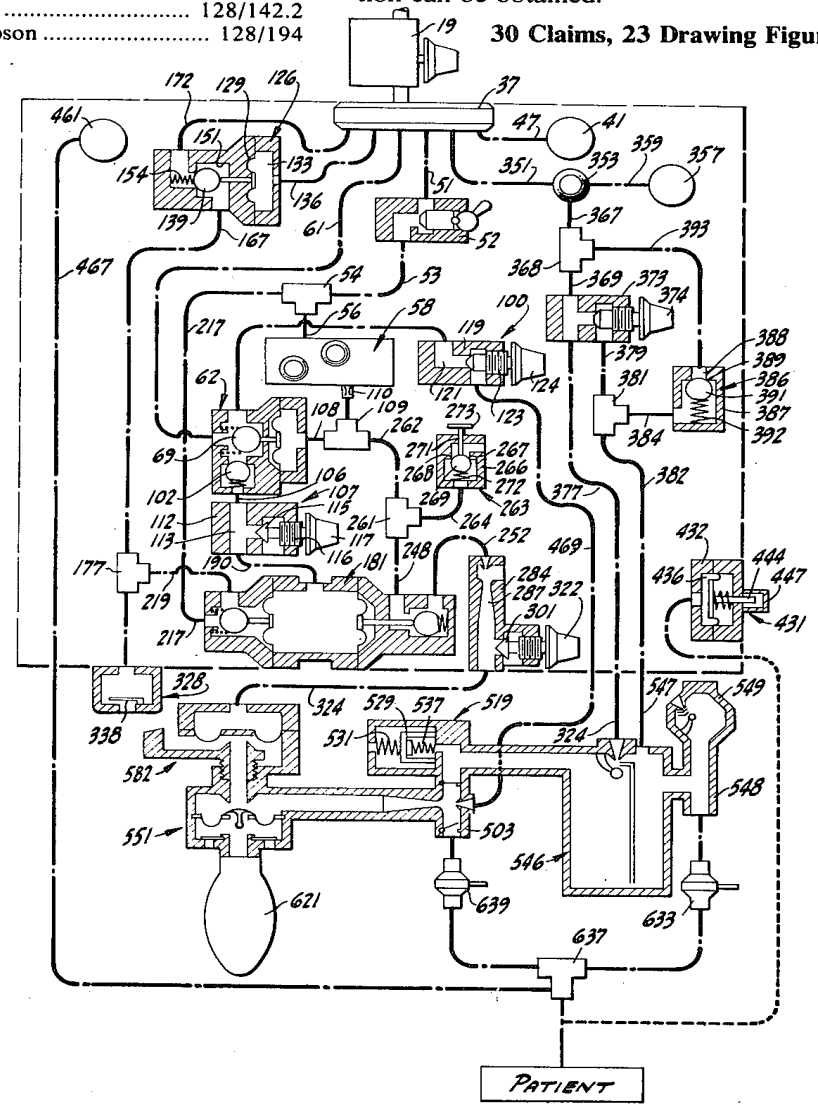

FIG-1

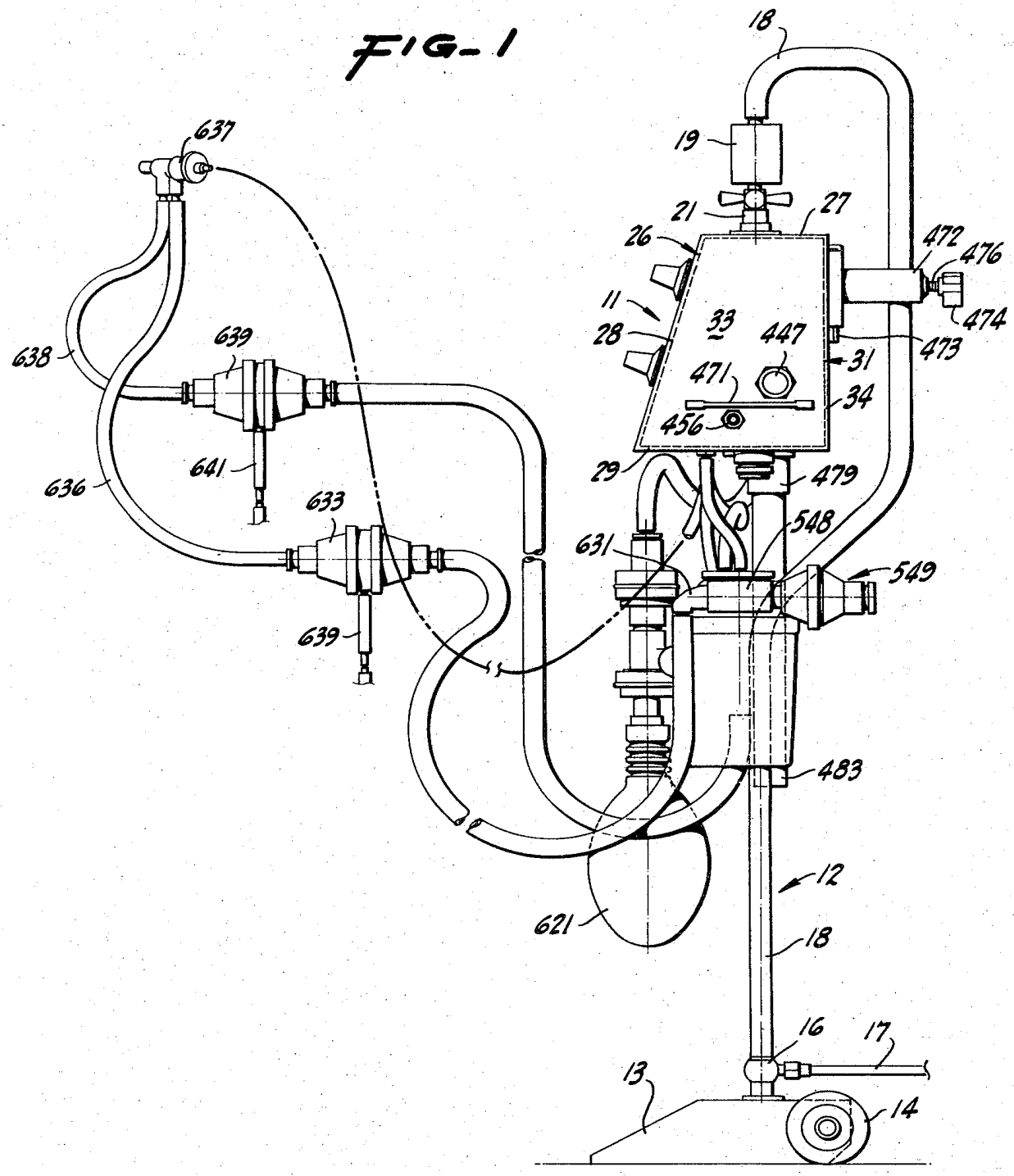
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FIG-2

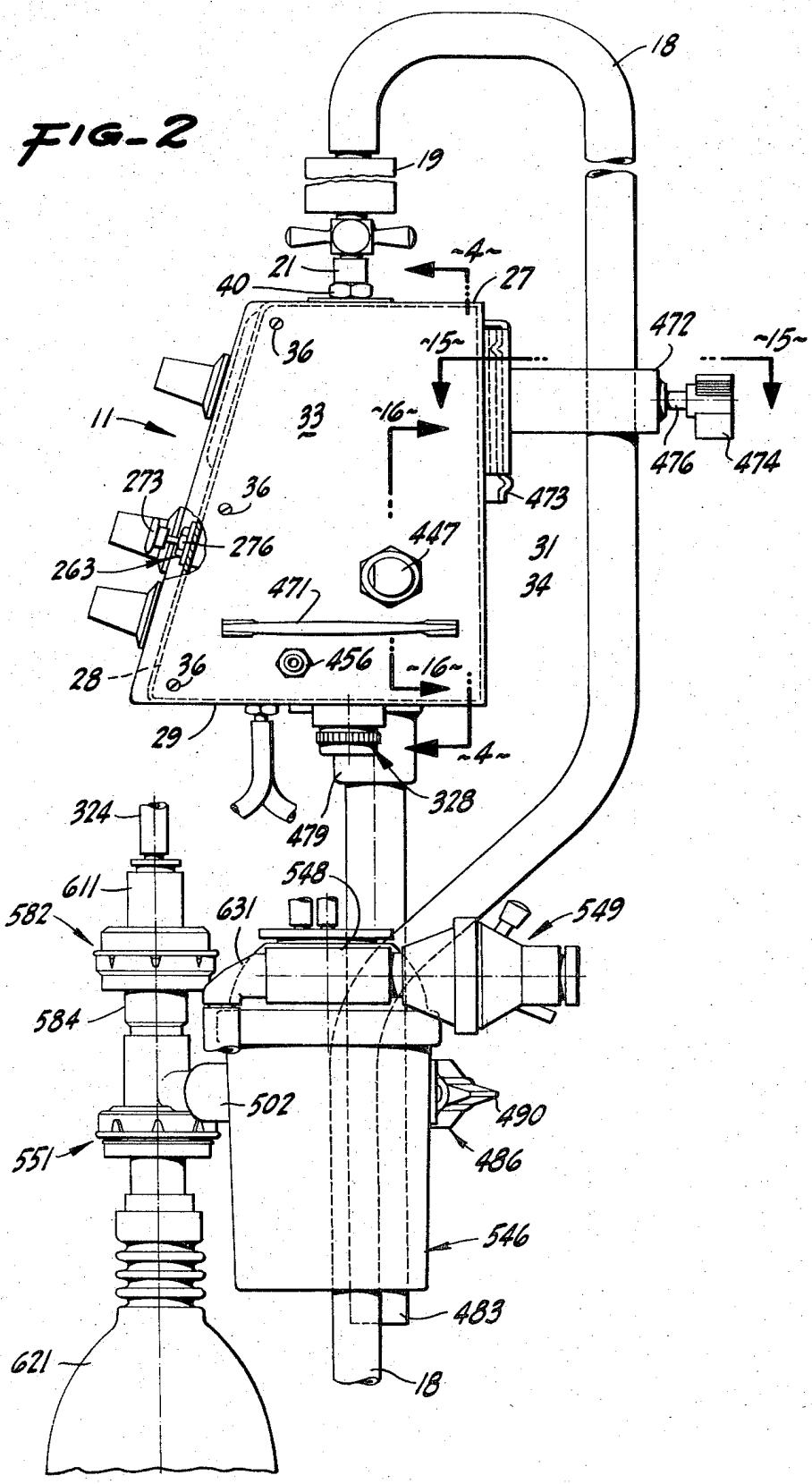
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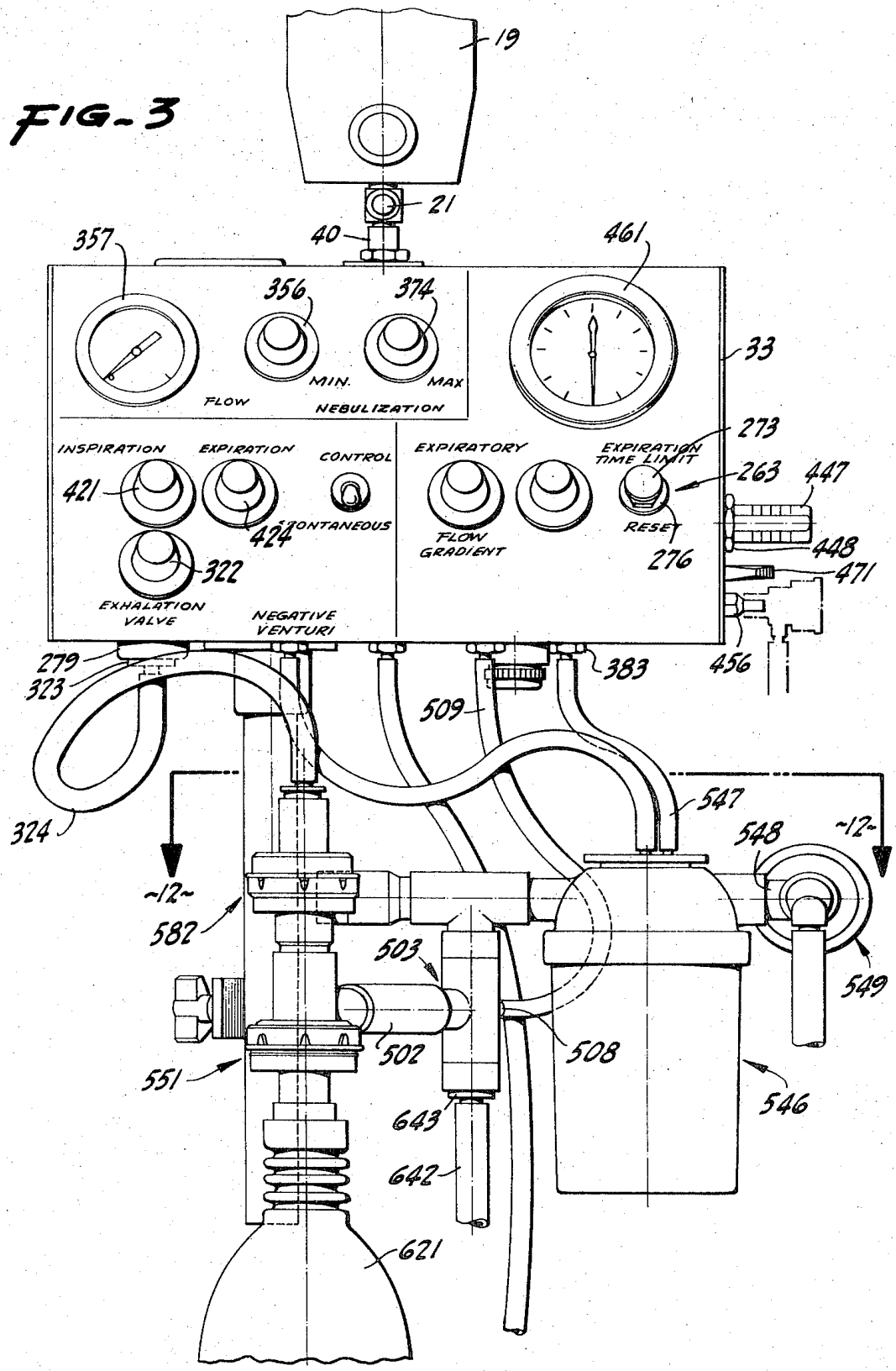
FIG-3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FLOW
MIN.
MAX
NEBULIZATION
INSPIRATION
EXPIRATION
CONTROL
EXPIRATORY
EXPIRATION TIME LIMIT
273
263
447
421
424
SPONTANEOUS
FLOW GRADIENT
RESET
448
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EXHALATION VALVE
NEGATIVE VENTURI
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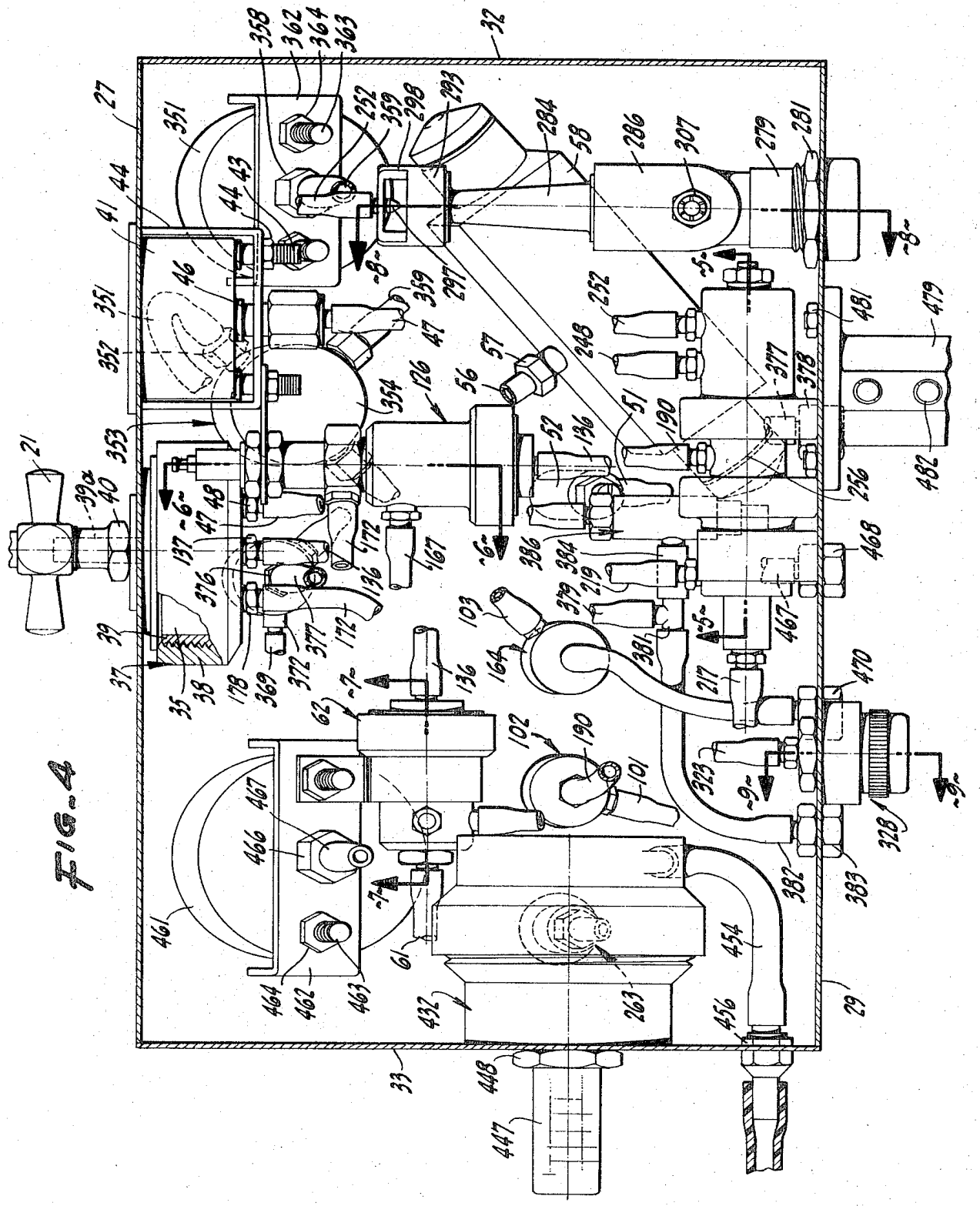


FIG-4

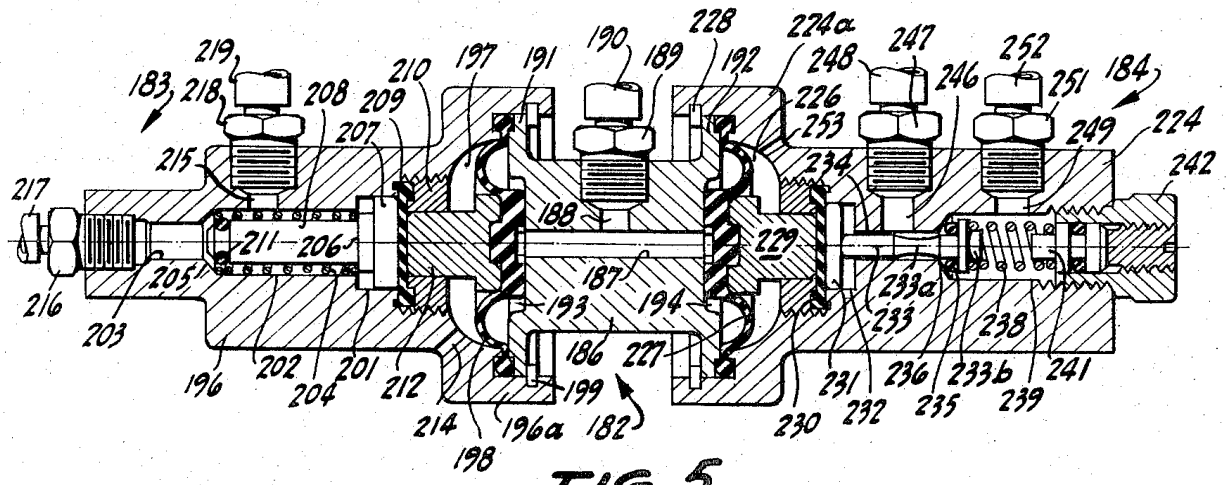
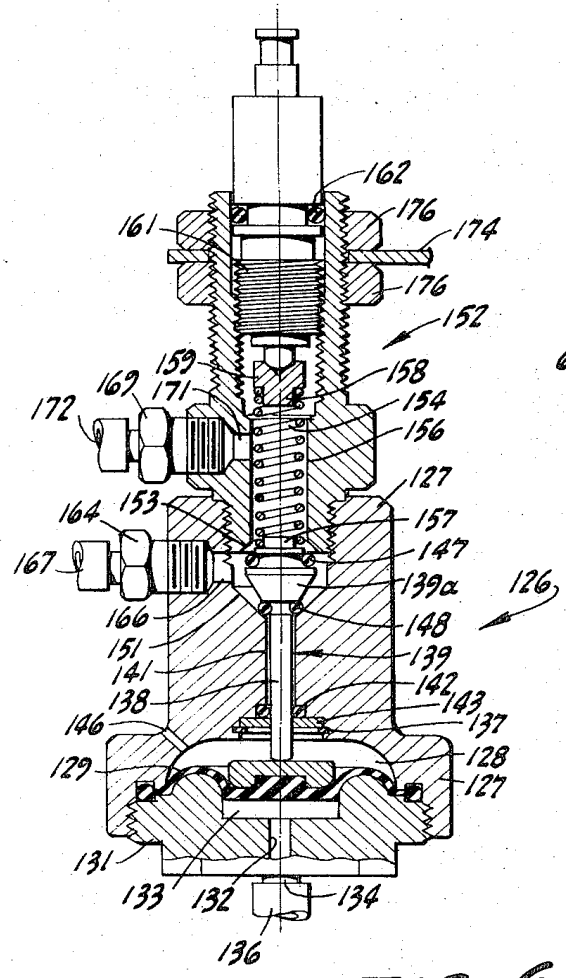


FIG-5



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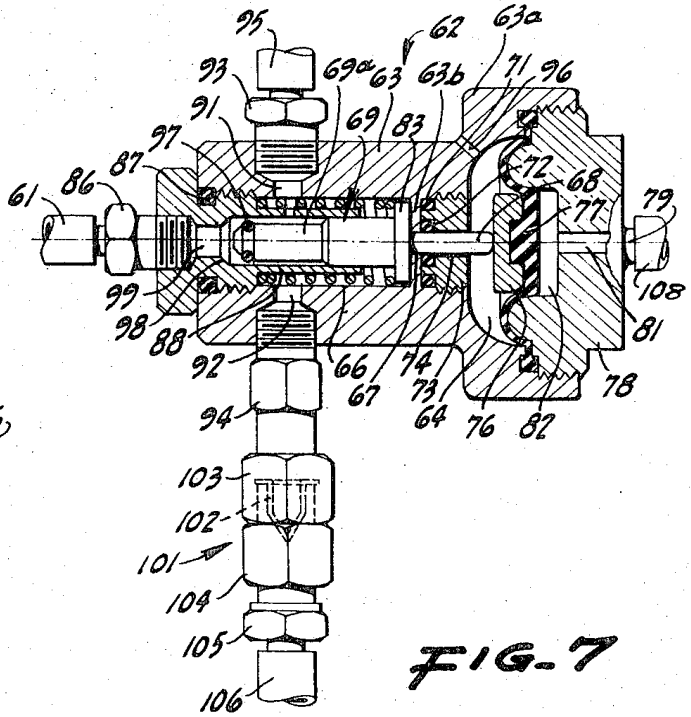


FIG-7

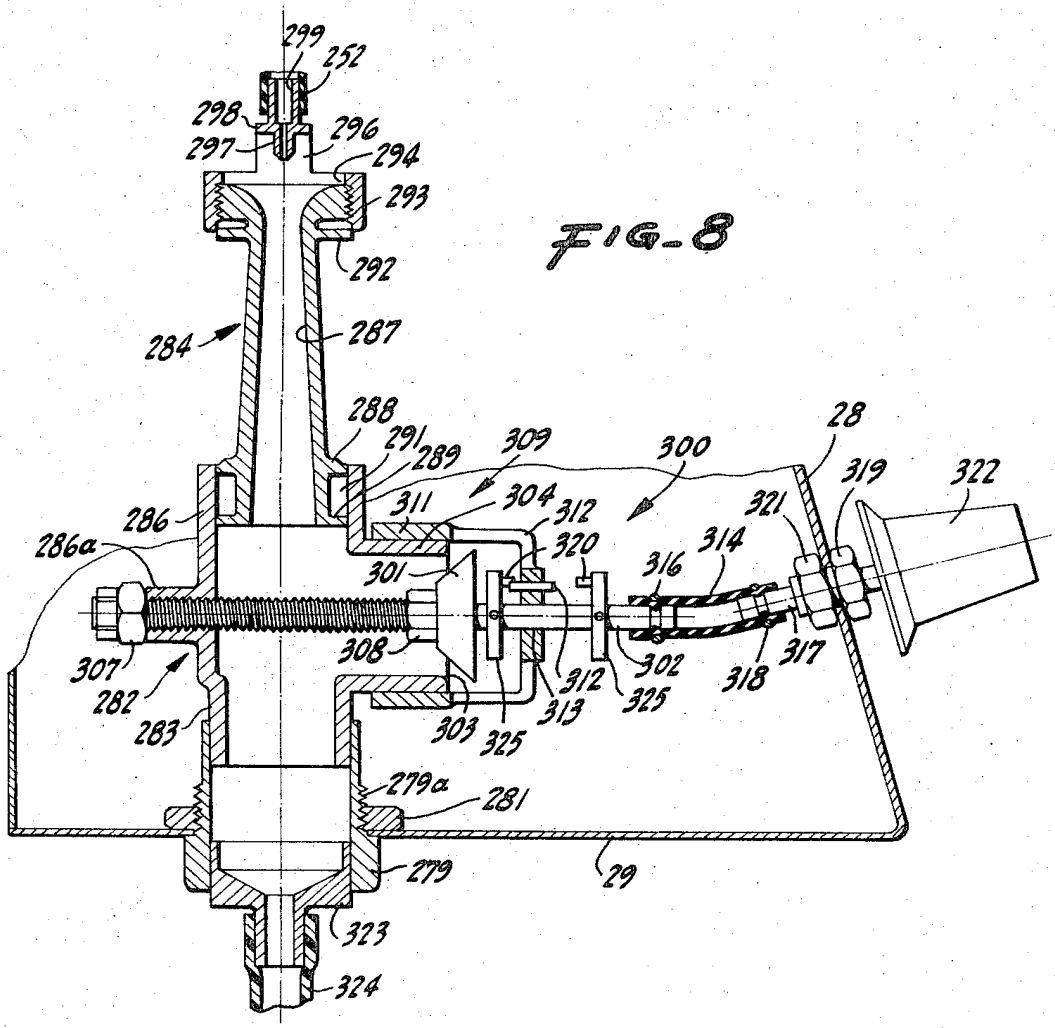
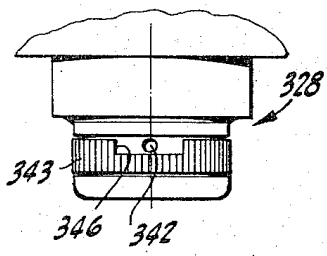


FIG-8

FIG-11



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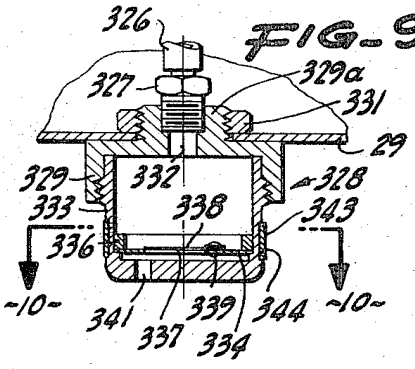

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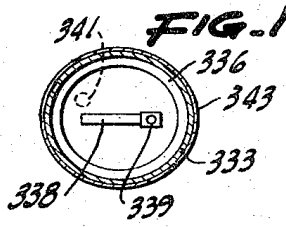
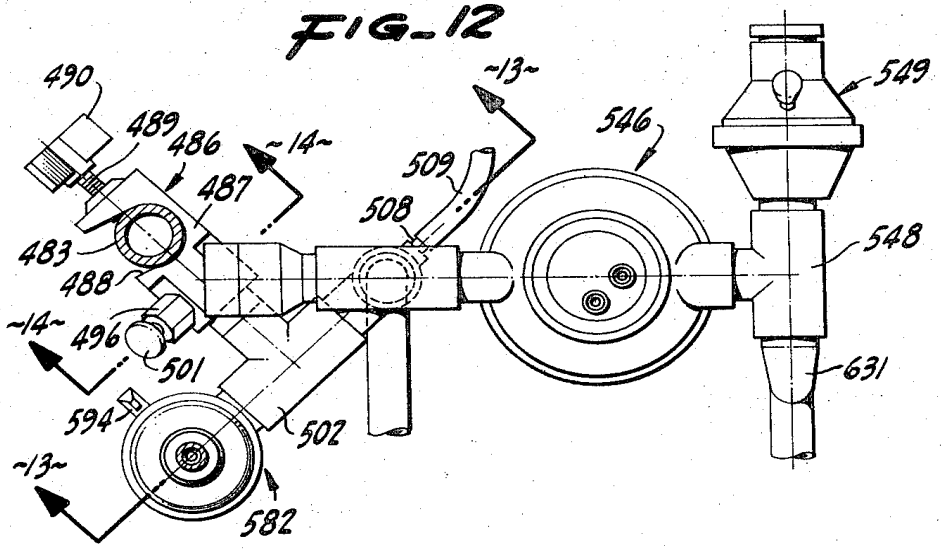
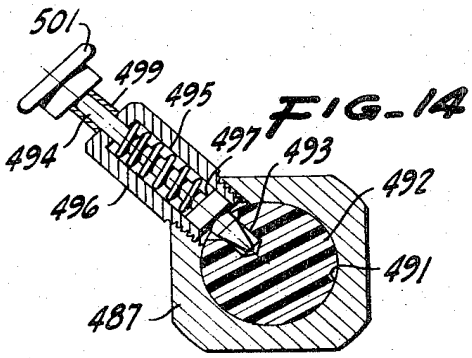


FIG_12





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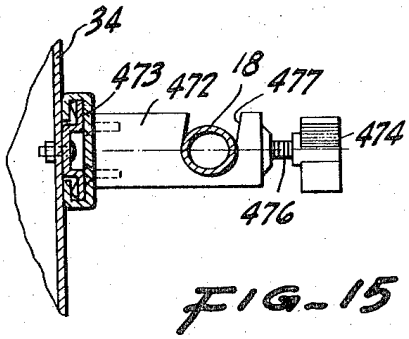
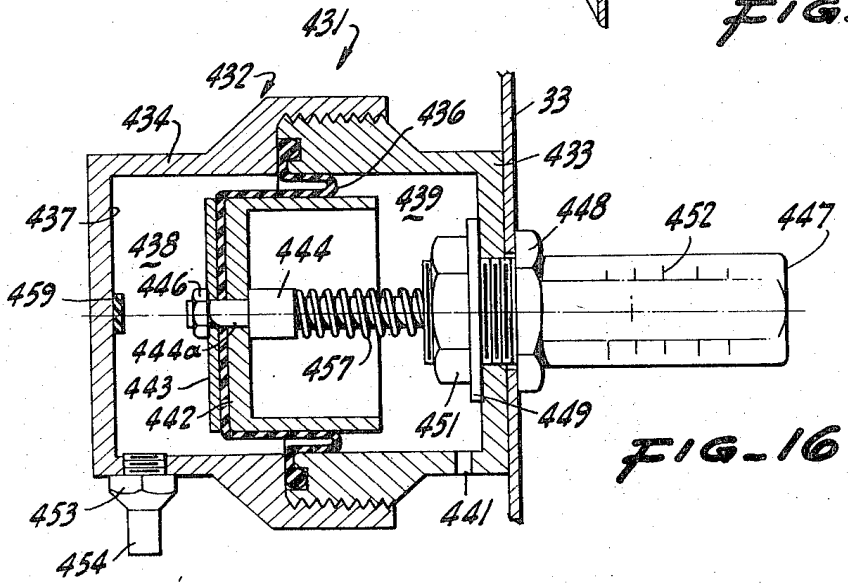


FIG_15



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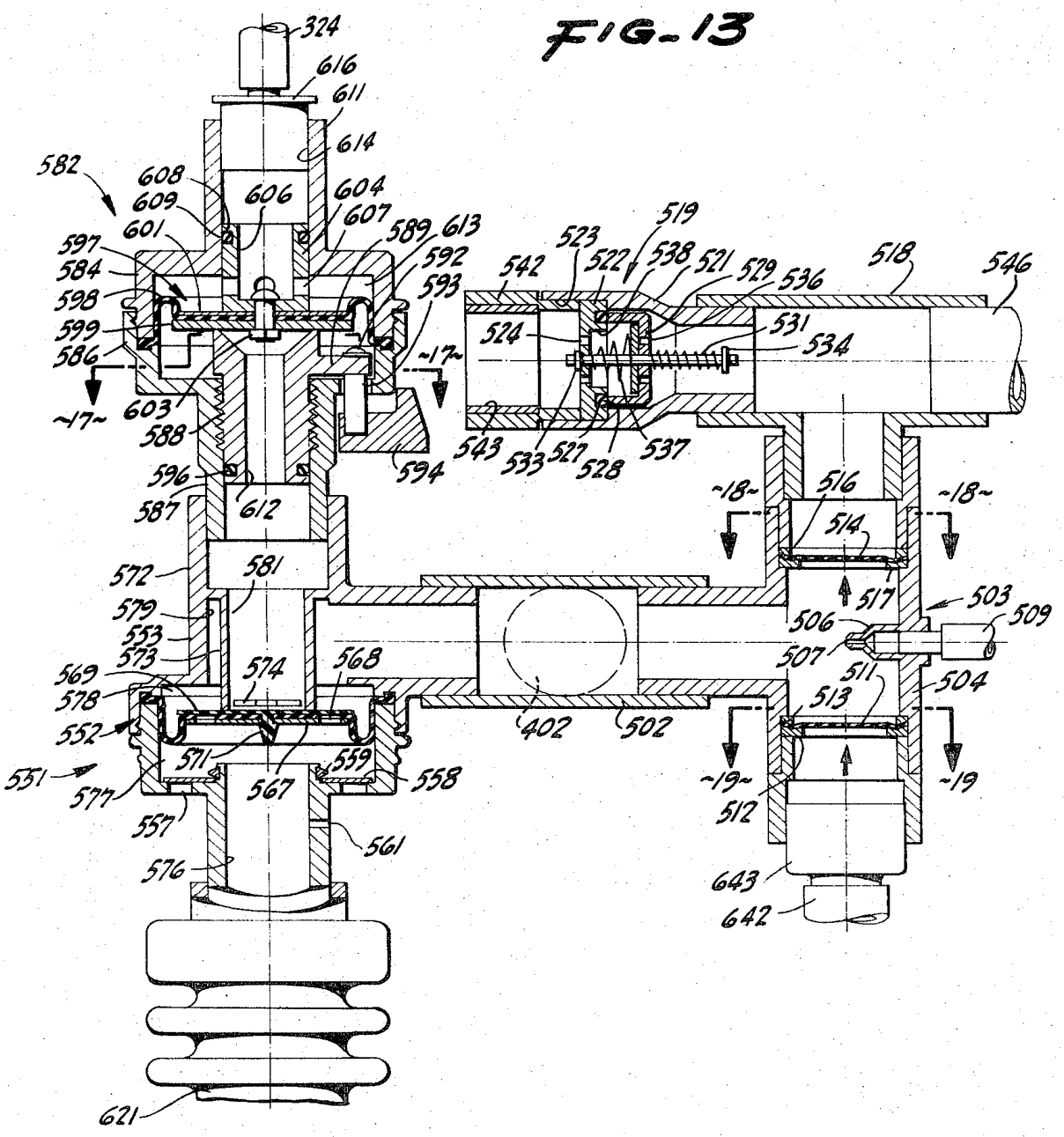
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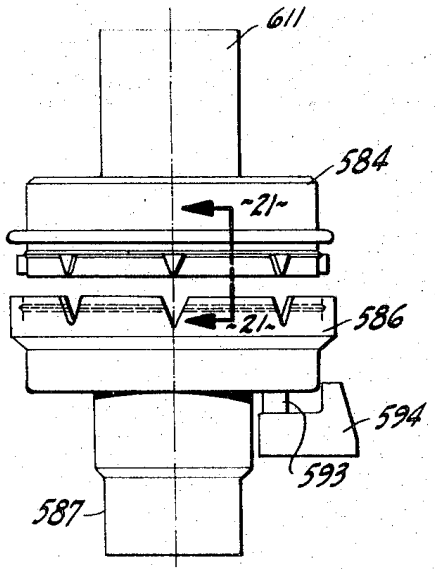


FIG-20

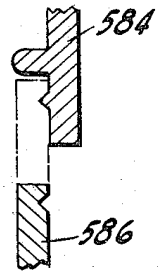


FIG-21

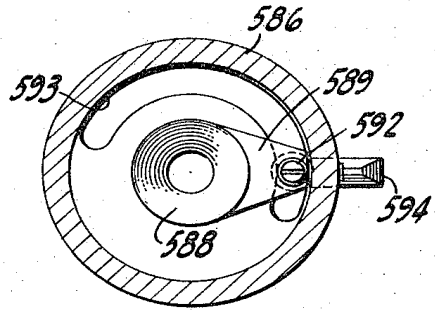


FIG-17

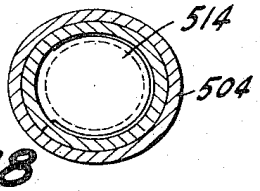
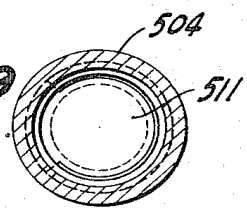


FIG-18



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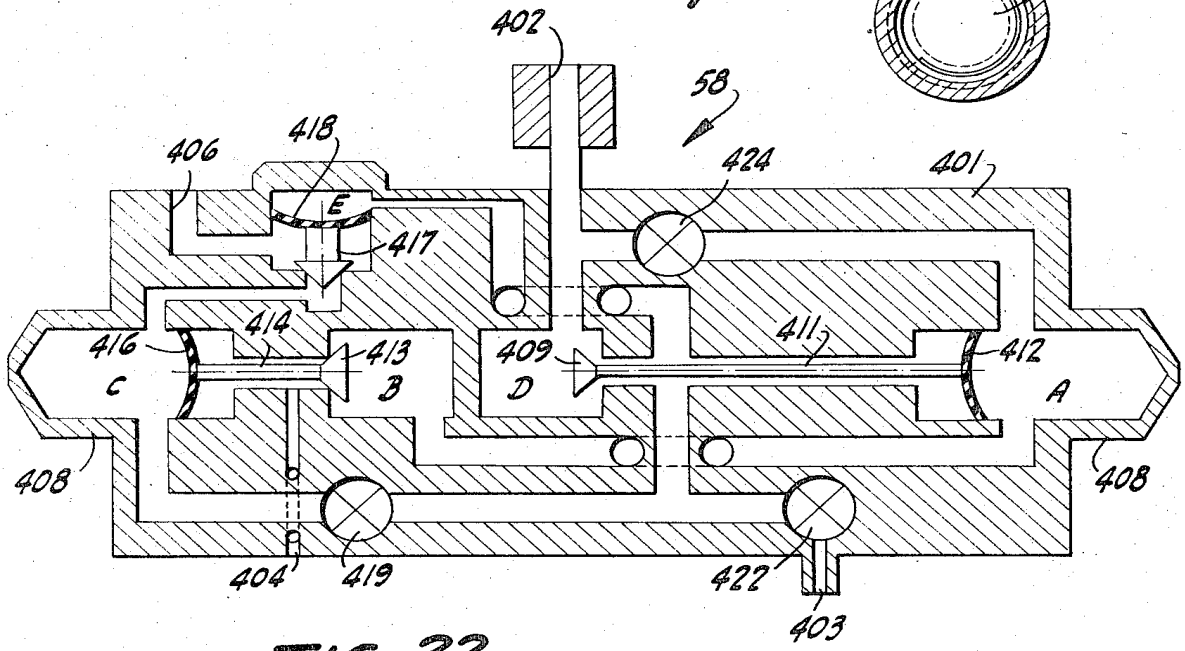

FIG-22

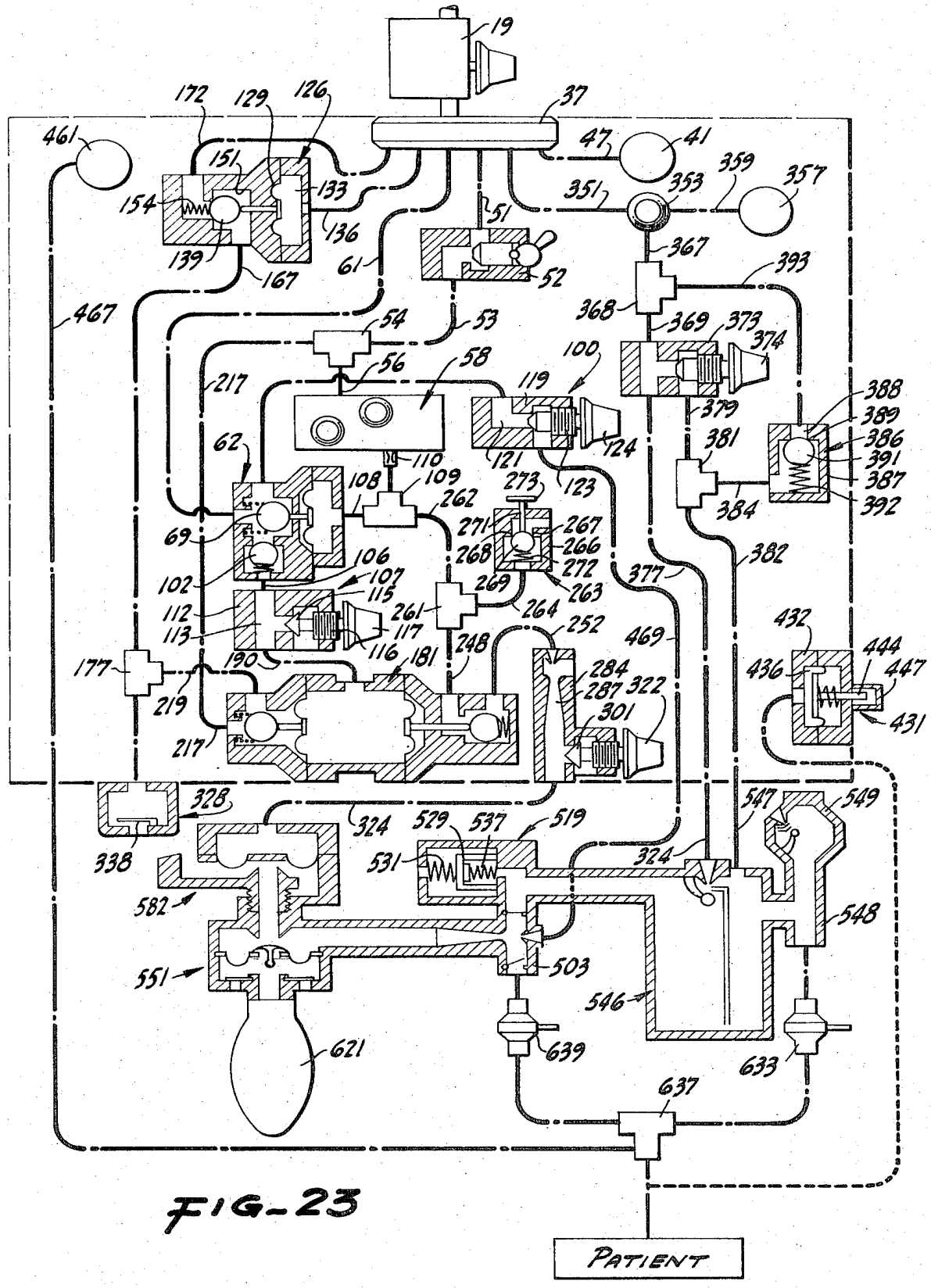
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FIG-23

PEDIATRIC VENTILATOR

BACKGROUND OF THE INVENTION

Ventilators have heretofore been provided which have been utilized on infants and small animals. However, the use of mechanical ventilators for this purpose has resulted in many problems. One of the principal problems is that to assist the breathing of infants particularly those with an inspiratory distress syndrome, a respiratory rate often in excess of 100 cycles per minute on an effective basis must be utilized. Ventilators heretofore provided have not had the desired flexibility or the precision control required for infants. There is, therefore, a need for a new and improved ventilator which can be utilized for infants and small animals.

SUMMARY OF THE INVENTION AND OBJECTS

The pediatric ventilator has an inhalation phase and an exhalation phase in its operative cycle. An inlet is provided which is adapted to be connected to a source of gas under pressure. A breathing circuit is provided which is adapted to be connected to the patient. Nebulizing means is utilized. Flow divider means is connected to the inlet and has one outlet coupled to the nebulizing means so that at least a portion of the inlet gas is supplied to the nebulizing means. The flow divider means includes an additional outlet coupled to the breathing circuit and has means for controlling the flow of gas through the additional outlet so that precision control over the operation of the nebulization means can be obtained. An exhalation valve is coupled to the breathing circuit and includes a valve member which is yieldably held in a closed position which can be utilized for maintaining a positive pressure within the breathing circuit.

In general, it is an object of the present invention to provide a ventilator and method which is particularly useful for ventilating and anesthesizing infants and small animals.

Another object of the invention is to provide a ventilator and method of the above character in which precision control over breathing circuit humidification and anesthesia vapor pressure can be obtained.

Another object of the invention is to provide a ventilator and method of the above character which is particularly useful in ventilating infants having a respiratory distress syndrome.

Another object of the invention is to provide a ventilator and method of the above character which is particularly useful in ventilating infants prior to and after surgery.

Another object of the invention is to provide a ventilator and method of the above character which makes possible spontaneous respiration with any desired safe constant positive pressure to be utilized in assisting the inspiratory phase and stabilizing the expiratory phase.

Another object of the invention is to provide a ventilator and method of the above character in which it is possible to provide the child with an inspiratory phase of the desired frequency and of any depth or duration including an inspriatory phase of the sigh type.

Anothe object of the invention is to provide a ventilator and method of the above character in which a low mean intra-thoracic pressure is utilized to minimize any disturbance of the hemodynamics of the lungs of the child.

Another object of the invention is to provide a ventilator and method of the above character in which it is possible for the physician to choose any one of a wide range of ventilatory patterns.

Another object of the invention is to provide a ventilator and method of the above character in which it is possible to maintain a constant liter flow in the breathing circuit even though there is a pressure change in the system.

Another object of the invention is to provide a ventilator and method of the above character in which it is possible to maintain relatively precise constant pressure even during utilization of the same by a child or infant.

Another object of the invention is to provide a ventilator and method of the above character in which it is possible to precisely and safely limit the inspiratory positive pressure.

Another object of the invention is to provide a ventilator and method of the above character which can be utilized for controlling the breathing rate of the infant or which can permit the infant to breathe spontaneously.

Another object of the invention is to provide a ventilator and method of the above character in which constant breathing pressures can be provided within the breathing circuit that are sub-ambient, ambient or at a positive value.

Another object of the invention is to provide a ventilator of the above character which is capable of very high cyclic rates.

Another object of the invention is to provide a ventilator of the above character in which a lock-out system is provided which measures inspiratory time so that inspiratory pressure is terminated after a predetermined period of time.

Another object of the invention is to provide a ventilator of the above character which will terminate inspiratory pressure even though the line pressure drops substantially.

Another object of the invention is to provide a ventilator of the above character which is provided with a low pressure alarm.

Another object of the invention is to provide a ventilator of the above character in which a manually operated compression bulb is incorporated therein to permit manual override of the automatic ventilatory pattern provided by the respirator.

Another object of the invention is to provide a ventilator of the above character which, in the event there is complete pressure failure, permits the baby to inhale spontaneously.

Another object of the invention is to provide a ventilator of the above character which makes it possible to precisely control the oxygen concentration to thereby prevent an excess oxygen concentration.

Another object of the invention is to provide a ventilator of the above character in which an alarm is actuated in the event the ventilator locks in the inspiratory position.

Another object of the invention is to provide a ventilator of the above character which, during the inspiratory phase after a predetermined period of time, will automatically drop back to a constant positive pressure.

Another object of the invention is to provide a ventilator of the above character which has a lock-out system which must be reset manually.

Another object of the invention is to provide a ventilator and method of the above character in which a constant liter flow can be obtained while controlling the pressure.

Another object of the invention is to provide a ventilator of the above character which can be self-tested prior to use on the patient.

Additional objects and features of the invention will appear from the following description in which the preferred embodiments are set forth in detail in conjunction with the accompanying drawing.

BRIEF DESCRIPTION OF THE DRAWING

FIG. 1 is a side elevational view of a pediatric ventilator incorporating the present invention.

FIG. 2 is a partial enlarged side elevational view of the ventilator shown in FIG. 1.

FIG. 3 is a partial front elevational view of the ventilator shown in FIG. 1.

FIG. 4 is a cross-sectional view of a portion of the ventilator shown in FIG. 1 taken along the line 4—4 of FIG. 2.

FIG. 5 is a cross-sectional view taken along the line 5—5 of FIG. 4.

FIG. 6 is a cross-sectional view taken along the line 6—6 of FIG. 4.

FIG. 7 is a cross-sectional view taken along the line 7—7 of FIG. 4.

FIG. 8 is a cross-sectional view taken along the line 8—8 of FIG. 4.

FIG. 9 is a cross-sectional view taken along the line 9—9 of FIG. 4.

FIG. 10 is a cross-sectional view taken along the line 10—10 of FIG. 9.

FIG. 11 is a side elevational view of the structure shown in FIG. 10.

FIG. 12 is a cross-sectional view taken along the line 12—12 of FIG. 3.

FIG. 13. is a cross-sectional view taken along the line 13—13 of FIG. 12.

FIG. 14 is a cross-sectional view taken along the line 14—14 of FIG. 12.

FIG. 15 is a cross-sectional view taken along the line 15—15 of FIG. 2.

FIG. 16 is a cross-sectional view taken along the line 16—16 of FIG. 2.

FIG. 17 is a cross-sectional view taken along the line 17—17 of FIG. 13.

FIG. 18 is a cross-sectional view taken along the line 18—18 of FIG. 13.

FIG. 19 is a cross-sectional view taken along the line 19—19 of FIG. 13.

FIG. 20 is a side elevational view of the structure shown in FIG. 13 with the parts separated.

FIG. 21 is a cross-sectional view taken along the line 21—21 of FIG. 20.

FIG. 22 is a schematic illustration of the control cartridge.

FIG. 23 is a schematic flow diagram of the pediatric ventilator.

DESCRIPTION OF THE PREFERRED EMBODIMENTS

The pediatric ventilator incorporating the present invention consists of a cabinet or case 11 which is supported in a suitable manner such as by a stand 12. The stand 12 is of a conventional type and consists of a base 13 which is provided with a pair of wheels 14 so that it can be readily moved from one location to another. A fitting 16 is mounted on the base 13 and is connected to a suitable supply of gas for the pediatric ventilator such as a supply of oxygen which is connected to a tube 17 that is connected to the fitting 16. An upright tubular member 18 is mounted on the fitting 16 and is in communication with the tube 17 so that the gas supplied to the tube 17 is supplies through the tubular member 18. The upper end of the tubular member 18 is bent into a U as shown and is connected to a blender 19. The blender 19 is of the type described in copending application Ser. No. 54,934, filed Mar. 23, 1970. It is utilized for obtaining the desired mixture of oxygen and air which is supplied to an inlet fitting 21 mounted on the cabinet or case 11.

The cabinet or case 11 consists of a U-shaped member 26 formed of sheet metal which is provided with a top wall 27, a front inclined wall 28 and a bottom wall 29. It also consists of an additional U-shaped member 31 consisting of a pair of spaced parallel side walls 32 and 33 and a rear vertical wall 34. The two U-shaped members 26 and 31 are fastened together with suitable means such as clips (not shown) and screws 36 to form a generally rectangular six-sided enclosure in which the front wall is inclined to the rear in an upward direction.

A manifold 37 is mounted in the cabinet or case 11 and is formed by a cup-shaped member 38 which is threaded onto a cap 39. The cap 39 is provided with a threaded portion 39a that extends through the top wall 27 and has a nut 40 mounted thereon to secure the manifold 37 to the case 11. The fitting 21 is threaded onto the portion 39a and supplies the output from the blender 19 to the mainfold 37. The fitting 21 also supports the case 11. If desired, a fliter 35 can be provided for filtering the output from the blender 19. The input to the blender 19 is such that an oxygen-air mixture is provided having a pressure which is within the range of 50 – 75 psi.

This oxygen-air mixture is supplied through the fitting 21 to the manifold 37. A filter 35 of a suitable type, such as a sintered bronze wafer, is provided in the manifold 37 for filtering the oxygen-air mixture.

The gas pressure within the manifold 37 is monitored by a pressure gauge 41 which is mounted in the top wall 27. The meter 41 is provided with a pair of threaded studs 42 which extend through a U-shaped bracket 44 that engages the rear side of the top wall 27 as shown in FIG. 4. Nuts 44 are threaded onto the studs and engage the bracket to retain the gauge within the top wall 27. The gauge is provided with a fitting 46. A flexible tube 47 has one end connected to the fitting 46 and has the other end connected to a fitting 48 mounted in the manifold 37. The pressure gauge 41 is provided with a scale ranging from 0 to 100 psi which includes a colored green area indicating the desired operating pressure from 40 to 60 psi with the preferred pressure being approximately 50 psi.

The manifold 37 is provided with another fitting (not shown) which has a tube 51 mounted thereon and which receives the oxygen-air mixture at the desired pressure and supplies it to a toggle-type control valve 52 which is mounted on the front wall 28. The control

valve 52 is connected by another tube 53 to a tee 54. The tee 54 is connected by a tube 56 to a fitting 57 mounted on a control cartridge 58. The control cartridge 58 is of a type hereinafter described. The control valve 52 is capable of assuming two positions, one of which supplies gas from the filter 37 to the control cartridge 58 which, as hereinafter described, permits the control cartridge 58 to control the operation of the ventilator. In the other position of the control valve 52, the control cartridge 58 is bypassed to permit spontaneous breathing by the patient. The first condition is the up position of the toggle valve 52 and has been identified by the indicium "Control" and the second position is the down position of the toggle valve 52 and has been identified by the indicium "Spontaneous."

A tube 61 connects the output of the manifold 37 to an interrupter cartridge 62. The interrupter cartridge 62 is provided with an outer housing 63 which is provided with an enlarged portion 63*a*. The portion 63*a* has a cup-shaped cavity 64 formed therein. The body 63 is formed with bore 66 extending longitudinally of the body and is generally in axial alignment with the cavity 64. The cavity 64 is separated from the bore 66 by a thin wall-like portion 63*b* formed integral with the housing 63 and extending across the end of the bore 66. A hole 67 is formed in the wall-like portion 63*b* and receives the stem 68 of a valve member 69. The stem 68 extends into the cavity 64. Means is provided for sealing the stem in the bore 66 and consists of a pair of O-rings 71 and 72 carried by a retaining member 73 threaded into the body 63 and which has a hole 74 formed therein through which the stem 68 extends. The valve stem 68 contacts a rigid botton 76 that engages a central portion of a flexible convoluted diaphragm 77. The outer margin of the flexible diaphragm 77 is clamped between the housing or body 63 and a cap 78 which is threaded into the housing 63. The cap 78 is provided with a fitting 79 which is integral therewith and which has the end of the tube 61 connected thereto. The fitting 79 opens into a bore 81 which is in communication with a space 82 above the diaphragm 77 as can be seen from FIG. 7.

The valve member 69 is provided with a flange or shoulder 83 which is adapted to engage one side of the wall-like portion 63*b*. Means is provided for yieldably urging the valve member with its flange so that the flange is in engagement with the wall-like portion 63*b* and consists of a coil spring 84. One end of the coil spring 84 engages the flange 83 while the other end of the coil spring is engaged by a fitting 86 that is threaded into the bore 66 and which carries an O-ring 87. The fitting 86 carries a sleeve 88 formed integral therewith which is disposed within the coil spring 84 but which surrounds the valve member 69. The sleeve 88 is provided with a pair of aligned holes 89 which extend diametrically therethrough.

The housing 63 is provided with a pair of bores 91 and 92 which extend through the body 63 and open into the bore 66. Fittings 93 and 94 are threaded into the bores 91 and 92. The cavity 64 is exposed to the atmosphere through a small bore 96 provided in the body or housing 63. The valve member 69 is provided with a portion 69*a* of reduced diameter which is disposed within the sleeve 88 and has a diameter which is slightly less than the internal diameter of the sleeve. An O-ring 97 is mounted on the end of the valve member and is adapted to engage a valve seat 98 formed on the fitting 86 to thereby occlude passage of a gas through a bore 66 provided within the fitting 86. Thus, it can be seen that the valve member is in a normally open position. When a pressure is applied to the chamber 82 to urge the diaphragm 77 to the left as viewed in FIG. 7, the valve member 69 will be moved to the left so that the valve member will occlude or close the passage 99 for a purpose hereinafter described.

The fitting 93 is connected through a tube 95 to an expiratory time limit cartridge 100 which is mounted in the front wall 28. The fitting 94 has a check valve assembly 101 connected thereto. The check valve assembly 101 consists of a valve member 102 in the form of an elastic duck bill having its outer margin clamped between the fittings 103 and 104. A fitting 105 is threaded into fitting 104 and has provided therein an unobstructed variable orificed manifold (not shown) and has a tube 106 connected thereto, which is connected to an inspiratory time limit control valve assembly 107 also mounted in the front wall 28. The fitting 79 is connected to a tube 108 which is connected to one leg of a tee 109. Another leg of the tee 109 is connected to a fitting 110 by a tube 111. The fitting 110 is mounted in the control cartridge 58 and is provided with a bleed orifice as shown schematically in FIG. 23 to maintain a back pressure in the control cartridge 58 so that there is always enough pressure to cause cyclic operation of the control cartridge 58.

The inspiratory time limit control valve assembly 107 consists of a body 112 and has a flow passage 113 extending therethrough. The body 112 is provided with an additional passage 114 which opens into the passage 113 and which also opens to the atmosphere. The passage 14 is encircled by valve seat 115 which is adapted to be engaged by a valve member 116 threaded into the body 112. The valve member 116 has a knob 117 mounted thereon. The valve assembly 107 serves as an unobstructed variable orificed manifold.

The expiratory time limit control valve assembly 100 is constructed in a similar manner and consists of a body 119 which has a flow passage 121 extending therethrough. The passage 121 is encircled by a valve seat 122 which is adapted to be engaged by a valve member 123. The valve member 123 is provided with a knob 124 for adjusting the position of the valve member.

A low pressure alarm cartridge 126 is provided within the cabinet or case 11. As shown in FIG. 6, it consists of a body 127 which is provided with an enlarged end portion 127*a* having a cavity 128 formed therein. A diaphragm 129 is disposed within the cavity and has its outer margin clamped between the enlarged portion 127*a* of the body and a cap 131 which is threaded into the body 127. Cap 131 is provided with a hole 132 which opens into a space 133 provided above the diaphragm 129. The hole 132 also extends through a nipple 134 formed integral with the cap 131. A tube 136 is mounted on the nipple 134. A button 137 is carried by the diaphragm 129 and is engaged by one end of a valve stem 138 of a valve member 139. The valve member 139 is slidably mounted in a bore 141 provided in the body 127. An O-ring 142 encircles the valve stem 138 and provides a seal for the valve stem. The O-ring 142 is held in place by a washer 143 which is retained by a retaining ring 144. The body 127 is provided with an inclined passage 146 venting the cavity 128 to the atmosphere to prevent a hydraulic lock from

developing. The valve member **139** is provided with an enlarged tapered end portion **139a** which carries a pair of O-rings **147** and **148** with the O-ring **147** being on the outer end. The portion **139***a* is disposed within a cavity **151** provided on the opposite end of the body **127** from the cavity **128.** A central body **152** has one end threaded into the cavity **151** and is provided with an inclined valve seat **153** which is adapted to be engaged by the O-ring **147** to form a sealing engagement therewith. The O-ring **148** merely serves as a bumper during movement of the valve member **139.** A spring **154** is provided in a bore **156** in the central body **152** and has one end engaging a boss **157** provided on the end of the valve member **139.** The other end of the spring engages a boss **158** carried by a button **159** which is engaged by an adjustor screw **161** threaded into the central body **152** for adjusting the preload on the compression spring **154.** An O-ring **162** is carried by the adjusting screw to establish a seal between the adjusting screw and the central body **152.** The adjusting screw is provided with a knurled stem **163** which is adapted to be grasped by hand to permit adjustment of the screw. A fitting **164** is threaded into the body **127** and is in communication with a bore **166** which opens into the recess **151.** The central body **152** is provided with a plurality of flats **168** adapted to be engaged by a wrench. A fitting **169** is threaded into the central body **152** and is in communication with a bore **171** that is in communication with the bore **156.** A tube **172** is connected to the fitting **169.**

The low pressure alarm cartridge **126** is mounted within the case **11** in a suitable manner such as by the arm **174** which is mounted on one of the studs **42** and is secured thereto by a nut **44** (see FIG. **4**). One end of the central body **152** is threaded through the arm **174** and is secured thereto by a pair of nuts **176** disposed on opposite sides of the arm threaded onto the end of the central body **152.** The tube **136** is connected to a fitting **137** provided on the manifold **37.** The tube **167** is connected to one end of a tee **177.** The tube **172** is connected to a fitting **178** provided on the manifold **37.**

A compound lock-out and alarm cartridge **181** is also provided within the cabinet or case **11.** It consists of three basic parts. There is a central part which can be identified as an accumulator **182;** one end part which can be identified as an alarm cartridge **183;** and another end part which can be identified as a lock-out cartridge **184.** The accumulator **182** consists of a body **186** formed of a suitable material such as aluminum. The body **186** is cylindrical in shape and is provided with a centrally disposed bore **187** extending therethrough. The bore **187** is in communication with another bore **188** which opens into the bore **187** and extends radially of the body **186.** A fitting **189** is threaded into the body and is in communication with the bore **187.** A tube **190** connects fitting **189** to the inspiratory time limit control valve assembly **107.** The body **186** is formed with a pair of spaced radially extending flanges **191** and **192.** Cavities **193** and **194** are provided on opposite ends of the body **186.**

The alarm cartridge **183** which is disposed on the lefthand side as viewed in FIG. **5** consists of a body **196** which has an enlarged outer end **196a** that has a cavity **197** formed therein. A diaphragm **198** is disposed in the cavity and has its outer margin clamped to the body **196** by the flange **191** of the accumulator **182.** The flange is locked in place by a retaining ring **199.** The body **196** is provided with a large centrally disposed bore **201** which is in communication with a smaller bore **202.** The bore **202** is in communication with a still smaller bore **203.** A compression spring **204** is disposed within the bore **202** and has one end engaging a valve seat **205** and has the other end engaging a shoulder **206** provided on a piston or valve-like member **208.** A flange **207** is provided on the valve-like member **208** and engages one side of a flat diaphragm **209** having its outer margin sealed to the body by a ring **210** threaded into the body. An O-ring **211** is seated on the valve-like member **208** and is adapted to establish a seal between the valve-like member **208** and the seat **205.** A member or button **212** is slidably mounted in the ring **210** and engages the inner portion of the diaphragm **198.** The member **212** engages the other side of the flat diaphragm **209.** A hole **214** is provided for venting the cavity **193** to the atmosphere. A fitting **216** is threaded into the body and is in communication with the bore **203.** A tube **217** is connected to the fitting **216** and to the tee **54** (see FIG. **23**). The body **196** is provided with a bore **215** which extends into the bore **202.** A fitting **218** is mounted in the body and is in communication with the bore **215.** A tube **219** is connected to the fitting **218** and is connected to the tee **177** (see FIG. **23**).

The lock-out cartridge **184** consists of a body **224** which has an enlarged end portion **224a** having a cavity **226** therein. A diaphragm **227** is disposed in the cavity and is retained therein by the flange **192** of the accumulator **182.** The flange **192** is retained in place by retaining ring **228.** The diaphragm carries a button **229** which engages one side of a flat diaphragm **230** having its outer margin sealed with respect to the body by a retaining ring **231** threaded into the body **224.** The button is slidably mounted in retaining ring **231.** The other side of the diaphragm **230** is engaged by a disc **231** slidably disposed in a bore **232.** A valve member **233** is slidably mounted in a bore **234** and has one end engaging the disc **231.** An O-ring **235** is provided on the valve member **233** and engages the valve seat **236.** The valve stem is provided with a necked-down or relieved portion **233a.** The outermost end portion **233b** of the valve member **233** is formed like a Pilgrim hat and engages one end of a spring **238** disposed within a larger bore **239** provided in the body **224.** The other end of the spring is engaged by a boss **241** which is threaded into an end screw **242** that is threaded into the end of the body **224.** By adjusting the boss-carrying member **241,** the compression on the spring **228** can be adjusted as desired. The body is formed with a bore **246** opening into the bore **234.** A fitting **247** is threaded into the body **224** and is in communication with the bore **246.** A tube **248** is mounted on the fitting **247.** The body **224** is provided with another bore **249** which is in communication with the bore **239.** A fitting **251** is threaded into the body and is in communication with the bore **249.** A tube **252** is connected to the fitting **251.** The body is provided with a small bore or passage **253** which opens the cavity **226** to the atmosphere.

The lock-out alarm cartridge **181** is mounted in the cabinet in a suitable manner such as by means of a U-shaped clamp **256** which is secured to the bottom wall **29** by suitable means such as a screw (not shown). The cartridge **181** can be readily mounted in the clamp or bracket **256** merely by pressing the cartridge into the bracket so that it is frictionally retained therein.

The tube 248 is connected to a tee 261. The tee 261 is connected by a tube 262 to the tee 109. The tee 261 is also connected to a lock-out reset valve assembly 263 by a tube 264. The valve assembly 263 consists of valve body 266 which has a bore 267 extending therethrough. The bore is in communication with the tube 264. The body 266 is formed with a valve seat 268 which is adapted to be engaged by a valve member 269 that carried a valve stem 271 slidably mounted in the bore 267. Spring means in the form of a compression spring 272 is provided for yieldably urging the valve member 269 into engagement with the valve seat 268. A knob 273 is mounted on the valve stem 271 and is adapted to be engaged by hand so that the valve member 269 can be depressed away from the valve seat 268. The body is formed with a bore 274 which is open to the atmosphere and which also opens into the bore 267. The body 266 is provided with an extension which extends through the front wall 28 and is secured thereto by a nut 276 which is threaded onto the extension.

An inspiratory venturi jet assembly 278 is provided within the case 11 and is connected to the tube 252 which is connected to the lock-out and alarm cartridge 181. The venturi assembly 278 consists of a body 279 which has a threaded portion 279*a* extending through the bottom wall 29 of the case 11. A nut 281 is threaded onto the threaded end portion 279*a* and serves to retain the body 279 on the bottom wall. The assembly 278 also includes a tee 282 which has one leg 283 mounted by a slip fit within the body 279. An elongate venturi body 284 is mounted in another leg 286 of the tee 282. The venturi body 284 is provided with a venturi-like passageway 287 extending longitudinally of the same. The end of the venturi body 284 which is mounted in the leg 286 is provided with a pair of spaced flanges 288 and 289 which frictionally engage the inner side walls of the leg 286. Reinforcing ribs 291 extend between the flanges 288 and 289. The other end of the body 284 is provided with a flange 282 which is engaged by a cap 293 threaded onto the body 284. The cap 293 is formed with an opening 294 that is open to the atmosphere. A U-shaped member 296 is formed integral with the cap 293 and has formed integral therewith a nozzle 297 that has a passage 298 extending longitudinally through the same which is in axial alignment with the venturi passageway 287. The nozzle 297 is spaced away from the opening 294 so that a jet of air passing from the same entrance atmospheric air and forces the same through the venturi-like passageway 287. A nipple 299 is also formed integral with the U-shaped member 296 and is in communication with the nozzle 297 and has the tube 252 connected thereto.

A spoiler 300 is provided for the venturi assembly and consists of a truncated conically-shaped valve member 301 which is mounted by friction fit upon a rod 302. The valve member 301 is adapted to engage a valve seat 303 formed on the outer end of the remaining leg 304 of the tee 282. One end of the rod 302 is threaded as shown in FIG. 8 and is threaded into a boss 286 which can be formed integral with the tee 282. A nut 307 is threaded onto the outer end of the rod 302 and limits the maximum level of the threaded rod 302 to the right as viewed in FIG. 8. A nut 308 is also threaded onto the rod and engages one side of the valve member 301. A support and guide member 309 is provided which consists of a ring 311 that slips over the outer extremity of the leg 304 and a U-shaped member 312 that is formed integral with the ring 311 and which extends over the ring. The member 312 is provided with a hole 313 through which the rod 302 extends. Thus, it can be seen that the boss 306 provides support for one end of the rod, whereas the U-shaped guide member 312 provides support for the other end of the rod. Means is provided for rotating the rod 302 to adjust the position of the valve member 301 with respect to the valve seat 303 and consists of a flexible tube 314 which has one end of the tube secured to the rod 302 by a retaining ring 316. The other end of the tube is secured to a shaft 317 by a retaining ring 318. The shaft 317 extends through a fitting 319 which is mounted in the front wall 28 and which is secured thereto by a nut 321 threaded onto the fitting 319. A knob 322 is mounted on the shaft 317 to permit rotation of the shaft 317 by rotation of the knob. A fitting 323 is mounted on the body 279 and has a tube 324 connected thereto. Stop means is provided for limiting the axial movement of the valve member 301 relative to the valve seat 303 and consists of first and second discs 325 fastened to the shaft 302 by suitable means such as set screws (not shown). The discs 325 carry pins 320 which are adapted to engage pins 315 mounted on the member 312. Thus, it can be seen that the stop means serves as high and low pressure limits as hereinafter described.

The tee 177 is connected by a tube 326 to a fitting 327 mounted in an alarm cartridge 328. The alarm cartridge 328 consists of a body 329 which is provided with a threaded extension 329a that extends through the bottom wall 29 and has a nut 331 threaded thereon to retain the body in engagement with the bottom wall 29. The body is provided with a bore 332 which is in communication with the fitting 327. A cup-shaped member 333 is threaded into the body 329 (see FIG. 9). A thin metal disc 334 is seated within a cup-shaped member 333 and is retained therein by a retaining ring 336. The disc 334 is provided with a slot 337. A flexible metal reed 338 overlies and is secured to the disc 338 by a pin 339. The cup-shaped member is provided with a hole 341 extending out of the bottom wall of the same (see FIG. 9). It also is provided with another hole 342 extending out of the side wall of the cup-shaped member (see FIG. 11). Means is provided for occluding the hole 342 and consists of a ring 343 which is rotatably mounted on the cup-shaped shaped member in a recess 344 provided on the cup-shaped member. The ring 343 is provided with a rectangular shaped cut-out 346 which can be utilized for exposing the hole 342 to the atmosphere as shown in FIG. 11.

The output from the manifold 37 is also supplied by a tube 351 that is connected to a fitting 352 of a flow regulator 353. The flow regulator 353 is of a conventional type and is provided with a body 354 to which the fitting 352 is threaded. The flow regulator 353 is mounted in the front wall 28 and has a control knob 356 to permit manual adjustment of the same. The rate of flow through the flow regulator 353 is monitored by a gauge 357 also mounted in the front wall 28. The gauge 357 is provided with a fitting 358 which is connected to a tube 359. The tube 359 is connected to a fitting 361 threaded into the body 354 of the flow regulator 353. The gauge 357 is held in place by U-shaped bracket 362 which receives threaded studs 363 carried by the gauge. Nuts 364 threaded onto the studs secure

the gauge to the bracket and retain the gauge within the front wall **28.** Another fitting **366** is threaded into the body **354** of the flow regulator **353** and has a tube **367** connected thereto. The tube **367** is connected to a tee **368.** The tee **368** is connected by a tube **369** to a nebulization control valve assembly **371.**

The nebulization control valve assembly is provided with a fitting **372** which is connected to the tube **369.** The fitting **372** is threaded into a body **373** which is secured to the front wall **28.** The nebulization control valve **371** is like the control valve **107** and is provided with a control knob **374** to adjust the flow rate therethrough. Another fitting **376** is threaded into the body **373** and is connected to a tube **377** which is connected to a fitting **378** mounted on the bottom wall **29** of the case **11.** Another fitting (not shown) is also mounted on the body **373** and is connected to a tube **379.** The tube **379** is connected to a tee **381.** The tee **381** is connected to a tube **382** which is connected to a fitting **383** mounted on the bottom wall **29.** The tee **381** is also connected to a tube **384** which is connected to a flow bypass valve assembly **386.** The flow bypass valve assembly **386** is provided with a body **387** having a flow passage **388** therethrough. A valve seat **389** circumscribes the flow passage **388** and is adapted to be engaged by a valve member **391.** A compression spring **392** yieldably urges the valve member **391** into engagement with the valve seat. The flow passage is in communication with a tube **393** which is connected to the tee **368.**

The control cartridge **58** is of a conventional type and is sold under the designation Mark 2 by Bird Corporation of Palm Springs, Calif. A similar control cartridge is disclosed in U.S. Pat. No. 3,530,890 in which the cartridge is a plurality of separate bodies rather than as a single body as shown in the drawing of the present invention. The functional diagram showing the mode of operation for the control cartridge **58** is shown in FIG. **22.** The mode of operation is very similar to that disclosed in Pat. No. 3,530,890. The control cartridge is provided with a body **401** which has been provided with a plurality of internal passages or bores which have been drilled into the body which take place with the separate bodies and the interconnecting tubing shown in Pat. No. 3,530,890. The body **401** is provided with inlet and outlet passages **402** and **403,** respectively. The body is also provided with two orifices **404** and **406** which are open to the atmosphere. The body is provided with five chambers which have been identified with the letters A, B, C, D and E. The chambers A and E have been enlarged by the use of end caps **408.** A poppet valve **409** is provided in the chamber D and is carried by a valve stem or plunger **411** slidably mounted within the body. The valve stem or plunger **411** is adapted to be engaged by a diaphragm **412** provided in the chamber A. Similarly, a valve member or poppet valve **413** is provided within the chamber B and is carried by a valve stem or plunger **414** slidably mounted in the body **401.** The valve stem or plunger **414** is adapted to be engaged by a diaphragm **416** in chamber C. A plunger **417** is mounted within the chamber D and is adapted to be engaged by a diaphragm **418** within the chamber E. An inspiratory time valve assembly **419** which is provided with a control knob **421** is mounted in the body **401.** Similarly, a flow rate control valve assembly **422** is mounted within the body **401.** An expiratory time valve assembly **424** is also mounted in the body **401** and is provided with a control knob **426** accessible from the front side of the front wall **28.**

Basically, the control cartridge **58** is of the type manufactured and sold by The Bird Corporation of Palm Springs, Calif., under the trademark MARK 2. However, it has been slightly modified to provide the controlled mode of operation hereinbefore described. It is provided with an expiratory control knob **421** and an expiratory control knob **426** with the first being utilized to control inspiratory time and the second being utilized to control expiratory time. A pressure control knob assembly normally provided with the MARK 2 is removed and a fixed orifice **110** is installed in the outlet. Stops (not shown) have been provided on the control stems (not shown) for the knobs **421** and **426** to limit the maximum controlled respiratory rates to approximately **100** cycles per minute. Adjustable external stops (not shown) under the control knobs **421** and **426** serve to establish maximum inspiratory and expiratory time limits. By way of example, maximum inspiratory time can be set at 1.5 seconds and maximum expiratory time can be set at 10 seconds.

Means is provided for testing the pediatric ventilator before use on an infant and consists of a test analog lung device **431** which consists of a body **432** (see FIG. **16**) formed of a pair of cup-shaped parts **433** and **434** threaded together as shown in the drawing to form the unitary body **432.** A diaphragm **436** of a conventional type such as a Bellofram diaphragm is mounted on the body in a cavity **437** formed within the body. The outer annular margin of the diaphragm **436** is clamped between the two parts **433** and **434** as shown to divide the cavity **437** into a chamber **438** on one side of the diaphragm and a chamber **439** on the other side of the diaphragm. The chamber **439** is open to the atmosphere through a hole **441** provided in the part **433.** An inner region of the diaphragm **436** is clamped to the bottom side of a cup-shaped member **442** by a plate **443.** A plunger **444** extends out of the cup-shaped member **442** and has a threaded end portion **444*a*** which extends through the cup-shaped member **442** and through the plate **443.** A nut **446** is threaded onto the threaded end portion **444*a*** of the plunger **444** to permanently secure the plunger **444** to the cup-shaped member **442** and also to clamp the inner region of the diaphragm **436** to the cup-shaped member **442.** The outermost end of the plunger **444** is adapted to extend into a transparent cylinder **447.** The cylinder **447** can be formed of a suitable material such as plastic. It is mounted within a fitting **448** which extends through the side wall **33** and has a washer **449** and a nut **451** mounted thereon to retain the cylinder **447** in the desired position. The cylinder **447** is provided with appropriate graduations **452.** For example, the cylinder can be calibrated in cubic centimeters from zero to **40.** A fitting **453** is threaded into the body **432** and is in communication with the chamber **438.** A tube **454** is connected to the fitting and is connected to a fitting **456** mounted on the side wall **33** (see FIG. **4**). A spring **457** is mounted coaxially on the plunger **444** and has one end engaging a shoulder **458** formed on the plunger and has the other end engaging a fitting **448.** A stop **459** formed of a suitable material such as rubber is mounted on the part **434** and serves to absorb the impact from the plunger **444** when it strikes the same.

Means is provided in the case **11** for giving direct indication of the pressure which is being supplied to the

patient and consists of a patient manometer 461 mounted in the front wall 38 and retained therein by U-shaped bracket 462. The manometer is provided with screws 463 which extend through the bracket and which have nuts 464 mounted thereon to secure the manometer to the bracket. The manometer is provided with a fitting 466 which is connected to a tube 467. The tube 467 is connected to a fitting 468 provided in the bottom wall 29. The manometer 461 may be calibrated in any suitable manner such as, for example, in millimeters of mercury with zero appearing at the 6 0' clock position and with the calibrations in positive pressure appearing in a clockwise direction from the zero position and calibrations in negative pressure appearing in a counter-clockwise direction from the zero position. Thus, for example, the manometer can be calibrated up to 200 millimeters of mercury in positive pressure and 30 millimeters of mercury in negative pressure.

A tube 469 connects the expiratory control valve assembly 100 to a fitting 470 provided on the bottom wall 29. A handle 471 is mounted on the side wall 33 of the case (see FIG. 3) and is provided for carrying the case. The cabinet or case 11 rather than being supported by the fitting 21 can be supported by a clamp 472 which is removably secured to a bracket 473 mounted on the rear wall 34 of the case. A knob 474 mounted on a screw 476 threaded into the clamp is provided. The screw 476 is adapted to engage the pipe 18 disposed in the slot 477 provided in the clamp 472 (see FIG. 15).

Means is provided for supporting the parts which are exterior of the case 11 and forming a part of the pediatric ventilator and consists of a socket type bracket 479 which is secured to the bottom wall of the case 11 by bolts 481. The bracket 479 is provided with a pair of screws 482 which engage the support pipe 483 disposed therein and extending downwardly therefrom. A clamp 486 is adapted to be mounted on the pipe. The clamp 486 consists of a body 487 which has a slot 488 formed therein and adapted to receive the pipe 483. A screw 489 is threaded into the body 487 and is adapted to engage the pipe 483 to retain it within the slot 488. A knob 490 is mounted on the screw to permit adjustment of the screw by hand. The body 487 is provided with a bore 491 which is adapted to receive an extension 492 formed of a suitable material such as plastic. The extension is provided with a hole 493 (see FIG. 14) which is adapted to accomodate a plunger 494 that is slidably mounted in a bore 495 provided in a body 496 threaded into the body 487. The plunger is provided with a shoulder 497 that is engaged by one end of a compression spring 498 that is mounted within the bore and coaxially disposed on the plunger. It can be seen that the spring 498 yieldably urges the plunger in a direction towards the hole 493 provided in the extension 492. A sleeve 499 is mounted on the plunger 494 exterior of the body 496. A knob 501 is secured to the plunger 494 to permit operation of the plunger by hand. The knob 501 engages the sleeve 499 and limits the innermost travel of the plunger 494.

The extension 492 is mounted on one leg of a tee 502. A negative venturi assembly 503 is mounted in another leg of the tee 502. The assembly 503 consists of a tee-shaped member 504. The tee-shaped member 504 is provided with a nozzle 506 formed integral therewith which has an orifice 507 which is in alignment with the central axis of the leg of the tee 504 that fits into the tee 502. The nozzle 506 is adapted to receive a fitting 508 which is connected to a tube 509 that is connected to the fitting 470 mounted on the bottom wall 29. A flapper valve 511 is mounted within the tee 504 in the lowermost leg of the same and is disposed between two rings 512 and 513 cemented into the tee. The flapper valve is biased toward the closed position shown in FIG. 13 and is movable upwardly to an open position. Another flapper valve 514 is mounted in the other leg of the tee 504 and is disposed between rings 516 and 517 also cemented in place within the tee. The flapper valve 514 is also biased toward the closed position shown in FIG. 13 and is movable upwardly into an open position. One leg of a tee 518 is mounted in the upper end of the tee-shaped member 504. The flapper valves 511 and 514 form a shuttle valve.

A double-gated safety intake or inspiratory relief and blow-out or overpressure valve assembly 519 is provided in one leg of the tee 518. The assembly 519 consists of a body 501. A disc 522 is mounted in a bore 523 provided in the body. The disc 522 is provided with a plurality of holes 524 extending therethrough which are arranged in a circle approximately mid-way between the center and the outer margin of the disc. The disc 522 is provided with an annular recess 527 on its inner side which carries an O-ring 528. The O-ring 528 is adapted to be engaged by a cup-shaped member 529. The cup-shaped gate member 529 is yieldably urged into engagement with the O-ring 528 by a compression spring 531 which engages the underside of the cup-shaped member and is mounted on a rod 532 that extends through the cup-shaped gate member 529 and the disc 522 as shown in FIG. 13. A retaining member 533 retains one end of the rod 532 in engagement with the disc 522, whereas another retaining member 534 retains the spring 531 on the rod 532. The cup-shaped gate member 529 is provided with a plurality of holes 536 which are arranged in a circle in the bottom of the cupshaped member and which surround the rod 532.

Additional spring means is provided within the cup-shaped member and consists of a relatively light spring 537 which is in the form of a helix of increasing diameter encircling the rod 532. One end of the spring 537 is disposed in a recess 538 in the dic 522, whereas the other end engages a disc-like gate member 539 slidably mounted in the rod 532 and normally closing the holes 536 of the cup-shaped member 529. A cylindrical cap 542 is mounted by a slip fit within the outer extremity of the body 521 and serves to retain the disc 522 and the associated parts within the body 521. The cap 542 is provided with an inner cylindrical liner 543.

A nebulizer 546 is mounted on the other leg of the tee 518. The nebulizer 546 is of the type described in U.S. Pat. No. 3,353,536. The tube 324 is connected to the nebulizer. Another tube 547 is connected to the fitting 383 which is connected to the tube 382. A tee 548 is mounted on the other end of the nebulizer 546. A nebulizer 549 is mounted in one leg of the tee 548. The nebulizer 549 can be of the type described in U.S. Pat. No. 3,172,406. The nebulizer can also be supplied with a gas under pressure to nebulize the contents of the nebulizer by a tube (not shown) which can be connected to the tube 324 connected to the nebulizer 546.

A non-rebreathing valve assembly 551 is mounted in one leg of the tee 502. It generally is of a type described

in copending application Ser. No. 183,822, filed Sept. 27, 1971. It consists of a housing **552** formed of an upper or outlet bell **553** and a lower part or inlet bell **554.** The two parts are generally cup-shaped and are adapted to be fastened together by a friction fit. The lower part is provided with a tubular extension **556.** The lower part or inlet bell **554** is also provided with a multi-orificed entrainment valve formed by a plurality of holes **557** arranged in a circle around the tubular extension **556** which are adapted to be covered by a resilient rubber ring **558.** The inner margin of the ring **558** is retained by a retaining ring **559** provided on the tubular extension **556.** A hole **561** is provided in the port **554** to prevent an unskilled operator from holding a patient in the apneustic position. The hole **561** bleeds down the air pressure in the passage **576** within a predetermined period of time.

A diaphragm **566,** convoluted in cross section as shown in FIG. **13,** is disposed between the upper and lower parts **553** and **554** with the outer margin of the diaphragm being clamped between the same. A metal disc **567** is bonded to the inner region of the diaphragm and is carried thereby. A plurality of holes are provided in the metal disc **567** adjacent the outer margin of the same which extend through the diaphragm. A flexible disc **569** of suitable material such as a Silastic forms a one-way flapper valve and is carried by the inner region of the diaphragm and overlies the holes **568** and normally covers the same. The disc **569** is provided with a tubular extension **571** which extends through the center of the metal disc **567** and the diaphragm **566** to secure the flexible disc to the diaphragm. The upper part **553** is provided with a tubular extension **572** which has formed therein an inner tubular extension **573** which extends downwardly so that it is generally in contact with the inner region of the disc **569** as shown in FIG. **13.** Ribs **574** extend across the lower extremity of the tubular extension **573** and generally overlie the central portion of the disc **569.** Thus, it can be seen that there is a flow passage **576** which is provided in a tubular extension **554** which opens into a chamber **577** below the diaphragm **566.** A chamber **578** is formed above the diaphragm **566** which is in communication with an annular passageway **579** provided in the tubular extension **572.** The passageway **579** opens into a passage **580** formed in a right angle extension **553a** of the upper part **553** which is mounted in the tee **502.** The annular passageway **579** serves as a circular anti-fouling collection ring which minimizes the possibility of vomitus or secretions obstructing the airway or fouling of the valve functions of the non-rebreathing valve assembly **551.** The inner tubular extension **573** provides a passage **581** which is in communication with the upper end of the tubular extension **572** and communicates with an outflow regulator assembly **582** which is mounted in the tubular extension **572.**

The outflow regulator assembly **582** consists of a housing **583** formed by upper and lower parts **584** and **586** which snap together much in the same manner as the parts **553** and **554** of the valve assembly **551.** Both of the parts are generally cup-shaped. The lower part is provided with a tubular extension **587** which fits by slip fit into the tubular extension **572.** A dampening device is provided in the lower part and consists of an inner tubular member **588** which is threaded into the tubular extension **587** of the lower part **586.** The tubular member **588** is provided with an arm **589** which is formed integral therewith. A pin **591** is secured to the arm **589** by a screw **591.** The pin **591** extends downwardly through an arcuate slot provided in the lower part **586** and has a handle **594** attached thereto which can be grasped by the hand to rotate the tubular member **588** to thereby adjust the vertical position of the same with respect to the lower part **586.** An O-ring **596** is carried by the lower extremity of the tubular member **588** to establish a good seal between the tubular member **588** and the tubular extension **587.** A diaphragm assembly is provided within the housing **583** and consists of a diaphragm **598.** The outer margin of the diaphragm **598** is clamped between the upper and lower parts **584** and **586.** The inner margin of the diaphragm carries a rigid circular disc **599** and another rigid disc **601** on the other side of the diaphragm and which are fastened thereto by a screw **602** having a nut **603** threaded thereon. A cylinder **604** which has one open end and formed of a suitable material such as plastic is also secured to the inner portion of the diaphragm **598** by the same screw **601.** The cylinder is provided with a central bore **606** which extends vertically through the same. The cylinder is also provided with a plurality of holes **607** which extend into the bore. The upper end of the cylinder is provided with an annular recess **608** which receives an O-ring **609** to establish a good seal between the cylinder **604** and a tubular extension **611** provided on the upper part **584.** From the construction described, it can be seen that the tubular member **588** is provided with a passage **612** which is in communication with the passage **581** in the tubular extension **573** and is sealed from the atmosphere by the disc **599** carried by the diaphragm assembly **597.** The chamber **613** provided above the diaphragm assembly **597** is in communication with the passage **614** formed in the tubular extension **611** through the bore **606** in the cylinder **604** and the holes **607** in the cylinder **604.** A fitting **616** is mounted in the tubular extension **611** and is connected to a tube **324.**

A fitting **621** is mounted in one leg of the tee **548.** A resilient bag **621** is mounted on the tubular extension **554** and the bag is a type which can be grasped by hand for the purpose of introducing air under pressure through the passage **576** in the tubular extension **554.** The bag is of a type which has a memory so that it will return to the shape shown in the drawing.

A fitting **631** is mounted in one leg of the tee **548** and is connected to a large tube **632.** The tube **632** is connected to a water trap **633** of a conventional type. The water trap **633** is provided with a drain tube **634** which can be connected to suitable piping to dispose of the water which is collected within the water trap. The water trap is connected to another large tube **636** which is connected to a patient adapter **637** of a conventional type. The patient adapter is also connected to another tube **638** which is connected to another water trap **639** of a type similar to water trap **633.** It also is provided with a drain tube **641.** The water trap is also connected to a large tube **642** which is connected to a fitting **643** mounted in the lower extremity of the negative venturi assembly **503.** A tube **646** is also connected to the patient adapter **637** and to the fitting **468** to supply a pressure to the manometer **461** through the tube **467.**

Operation of the pediatric ventilator and the method may now be briefly described as follows. Let it be assumed that it is desired to ventilate the lungs of an in-

fant as, for example, one which has been born prematurely and which exhibits an inspiratory distress syndrome. The ventilator is supplied with a suitable environmental gas as, for example, a mixture of oxygen and air which is supplied to the blender **19.** The ventilator is connected to the patient adapter **637** as hereinbefore described. The controls on the ventilator or respirator would be adjusted to provide approximately **15** cc of tidal volume. The tidal volume is indicated by the upper end of the plunger **444** of the test lung **531** which is utilized for determining whether the ventilator is operating in a proper manner for ventilating the lungs of the baby.

After the appropriate tidal volume has been obtained, the patient adapter **637** is connected to the patient by way of a face mask, tracheotomy tube or an endo tracheal tube inserted through the nasal route or the oral route. Since premature infants breathe at the rate of from 30 to 60 times per minute with a tidal exchange from approximately 15 to a maximum of 20 cc, it is necessary that the ventilator operate at high rates over 80 cycles per minute and possibly as high as 100 cycles per minute.

Let it be assumed that a gas under a suitable pressure as, for example, oxygen and air ranging from 40 to 100 p.s.i. and preferably approximately 50 p.s.i., is supplied to the tube **17** and to the tube **18** to the oxygen blender **19.** Thus, for example, if the gas under pressure is in the form of oxygen, the proper amount of air can be mixed with the oxygen in the blender **19.** These mixed gases are supplied to the manifold **37** and through the filter **38** carried within the manifold to be supplied through six outlets. A gauge **41** supplies a direct reading of the operational pressure within the manifold. A green wedge indicates a mandatory operational pressure range between 45 and 55 p.s.i.

This gas under pressure from the manifold **37** is supplied as from another outlet from the manifold **37** by the tube **51** to a control valve **52.** When the toggle of the control or mode selector valve **52** is in the up position as shown in FIG. **23,** the pediatric ventilator will be under the control of the control cartridge **58** which will determine the period of time covered by the inspiratory phase and the period of time covered by the expiratory phase and thereby control the respiration of the infant being ventilated. This is the "control" or "ventilator on" position. When the toggle is in the down position, the infant under ventilation will be allowed to breathe spontaneously and to set his own rate and depth of respiration. This is the "spontaneous position" of the toggle.

When the control valve **52** is in the "control" or "up" position as hereinbefore described, gas from the manifold **37** is supplied to the control cartridge **58.** The control cartridge **58** operates in a manner similar to that described in Pat. No. 3,530,890 and operates as a pneumatic spring circuit. The operation of the control cartridge **58** may be explained briefly with reference to the functional diagram shown in FIG. **22.**

Let it be assumed that the control cartridge **58** is in the inspiratory phase and that the parts are in the positions shown in FIG. **22** during this phase. When such is the case, gas from the tube **53** connected to the control valve **52** is supplied through the tee **54** and the tube **56** to the passage **402** and thence through the expiratory time valve assembly **424** into the chamber A. The gas also flows from the chamber A into chamber B where the gas is occluded by the poppet valve **413.** With the poppet valve **409** open as shown in FIG. **22,** gas is also supplied to the chamber D and flows past the poppet valve **409** into the chamber E to begin to pressurize that chamber. Gas also flows through the inspiratory timer valve **419** into the chamber C to begin to pressurize the chamber C. As the chamber E is pressurized, the valve **417** is moved to a closed position to prevent chamber C from being vented to the atmosphere through the passage **406.** The period of time occupied by the inspiratory phase is determined by the period or length of time required to pressurize the chamber C sufficient to move the poppet valve **413** to the right as viewed in FIG. **22** to open the poppet valve **413.**

As soon as the pressure in chamber C has reached a sufficient pressure to apply a force to the diaphragm **416** which is great enough to open the valve **413,** the inspiratory phase is terminated. As soon as valve **413** is opened, chamber B will be vented to the atmosphere through the passage **404.** As soon as chamber B is vented to the atmosphere, chamber A is also vented to the atmosphere through chamber B. The poppet valve **411** closes and no more gas can flow out through the flow rate valve **422** and through the outlet **403.** When this occurs, a pressure drop occurs in all the arteries or passages leading to the chamber E so that gas is bled out of the chamber E to permit the plunger **417** to be raised and to permit chamber C to thereafter be vented to the atmosphere through the passage **406.**

The closing of the poppet valve **409** terminates the inspiratory phase. Immediately thereafter, the expiratory phase commences. As soon as the chamber C is vented to the atmosphere, the poppet valve **413** moves to the closed position. The length of time or the period of the expiratory phase is determined by the amount of time it takes the gas to bleed through the expiratory time valve **424** to pressurize the chambers A and B which are now occluded by the poppet valve **413** to a sufficient pressure which, through the diaphragm **412,** will provide a force that is sufficient to open the poppet valve **409.** As soon as the poppet valve **409** is open, the expiratory phase is terminated and the inspiratory phase commences immediately thereafter with gases being supplied through the flow rate valve **422** to the outlet **403.** At the same time this begins to occur, chamber E is again pressurized to cause the valve **417** to close which again causes the chamber C to begin filling through the inspiratory time valve **419.**

Source gas is delivered from the manifold **37** through the tube **61** to the inspiratory interrupter cartridge **62.** During the expiratory controlled phase of the control cartridge **58** or during spontaneous breathing, gas under pressure is not being supplied from the control cartridge **58** through the tube **108** to one side of the diaphragm **77** so that the spring **84** urges the valve member **69** to the right as viewed in FIG. **7** so that gas being supplied from the source through the tube **61** is supplied through the bore **99** to passages **91** and **92.** The gas under pressure from the passage **92** flows through the one-way check valve **101** through the tube **106** and then to the inspiratory time limit valve **107.** It will be noted that the passage **113** through the inspiratory time limit control valve assembly **107** is unobstructed and that the needle valve member **116** provides a means for interrupting or locking out the controlled inspiratory phase of the control cartridge **58** after a preset period of inspiratory time. It is for this reason that the control

knob **117** provided for this valve assembly is identified with the designation "Inspiratory Time Limit." The gas supplied through the passage **113** is supplied through a tube **190** to the fitting **189** of a compound lock-out and alarm cartridge **181** to cause both of the diaphragms **198** and **227** in the alarm cartridge **183** and the lock-out cartridge **184** to be loaded or, in other words, to have a pressure applied to the same to cause the valve members **208** and **233** to be shifted whereby the valve member **208** is shifted from its normally closed position to an open position and the valve member **233** is shifted from its normally closed position to an open position. Source gas is applied to the alrm cartridge **183** from the tee **54** through a tube **217** and thus delivers source gas when the control switch **52** is in the "on" or "control" mode to thereby supply source gas to the passage **203.** Flow out of the alarm cartridge **183** passes through the tube **219** through the tee **177** through the tube **326** to the alarm cartridge **328.**

Let it be assumed that the control valve **52** is in the "on" or "controlled" position. During the inspiratory phase of controlled respiration, flow from the control cartridge **58** acts against the diaphragm **77** of the inspiratory interrupter cartridge **62.** As pressure is applied to the diaphragm **77,** the valve member **69** moves to the left and interrupts the flow of source gas to the lock-out and alarm cartridge **181.** As soon as there is an interruption of flow of source gas to the diaphragms **198** and **227** of the cartridge **181,** a pneumatic bleed-down commences through the entire inspiratory time limit control valve assembly **107.** The trapped gas between the lock-out and alarm cartridge **181** and the inspiratory interrupter cartridge **62** is metered to ambient by the inspiratory time limit control valve assembly **107.** If the inspiratory time established on the control cartridge **58** exceeds the bleed-down established by the inspiratory time limit control valve assembly **107,** the inspiratory phase is terminated and an audible alarm is sounded as hereinafter described.

Two simultaneous events occur when the twin diaphragms **198** and **227** are depressurized. The first is that source gas being supplied from the control cartridge **58** which is supplied through the tube **111** through the tee **109,** the tube **262,** the tee **261,** the tube **248,** through the lock-out cartridge **184,** through the tube **252** to the nozzle **297** of the inspiratory venturi jet assembly **278.** It can be seen that as soon as the diaphragm **227** is depressurized, the spring **238** will move the valve member **233** to a closed position to interrupt the flow through the lock-out cartridge **184** to thereby terminate the jet passing through the venturi jet assembly **278** to terminate the inspiratory phase. Secondly, the lock-out (inspiratory time limit) alarm is activated by flow through the inspiratory alarm cartridge **328.** This occurs when flow from the tee **54** through the tube **217** to the alarm cartridge **183** is interrupted by movement of the valve member **208** to its normally closed position under the force of the spring **204** to move the valve member **208** to an open position to permit gas to flow through the tube **19** through the tee **177** to the inspiratory alarm cartridge **328** to provide an audible alarm. This serves to warn the person who is operating the ventilator that it has automatically changed from the controlled mode to the spontaneous mode of operation.

Once the preset inspiratory time limit determined by the setting of the control valve **107** is reached, the control cartridge **58** is held in the inspiratory phase and is locked out of the breathing circuit for the patient. A controlled function for the ventilator can only be reestablished by dumping the control cartridge **58** of inspiratory gas trapped by the lock-out cartridge **184** and held behind the diaphragm **77** of the inspiratory interrupter cartridge **62.** This dumping of gas is accomplished by manually depressing the reset button **273** to release the entrapped inspiratory gases to ambient and thereby allowing the control cartridge **58** to cycle into the expiratory phase.

The lock-out cartridge is calibrated by adjustment of the adjustment screw **244.** The lock-out function is set up by adjusting the inspiratory time to maximum and expiratory time to minimum. When lock-out occurs, the venturi flow through the inspiratory venturi jet assembly **278** will cease followed by an approximately **5** second delay before the alarm cartridge **328** sounds an audible alarm. Final calibration is obtained by rotating the screw **244** until repeated reset and lock-outs demonstrate a maximum alarm lag after venturi jet lock-out of approximately 1 second.

The inspiratory time limit control valve assembly **107** is calibrated by first rotating full clockwise to stop limit the knob **117.** The knob is then turned in a clockwise direction until a three second inspiratory time is observed. Final calibration is obtained by slowly opening the inspiratory time limit control valve assembly by rotating the knob **117** in a counter-clockwise direction until a three second inspiratory time lock-out occurs.

It should be appreciated that it is possible to vary the driving pressure of the gas supplied to the inspiratory jet assembly **278** by adjustment of the screw **244** in the lock-out cartridge **184.** By adjustment of the screw **244,** it is possible to adjust the force which is applied to the valve member **233** by the spring **238** to thereby provide essentially what is a regulator to deliver gas under the desired pressure as, for example, reducing it from 50 p.s.i. to 28 p.s.i. for delivery to the inspiratory venturi jet assembly **278.** After the proper adjustment has been obtained in the screw **244,** it can be locked in place by the lock nut **242.**

It will be noted that in the construction of the lock-out and alarm cartridge **181,** the flat type diaphragm seals **209** and **227** have been provided which permit forces to be transferred but which do not permit any leakage.

The manifold **37** delivers source gas under pressure through the tube **351** to an adjustable pressure reduction regulator **353.** One outlet of this regulator **353** is connected through a tube **359** to a pressure gauge **357.** The pressure gauge is calibrated in terms of flow expressed in liters per minute and the other outlet of the regulator **353** supplies source gas through a tube **367** to a tee **368.** One leg of the tee **368** is connected by a tube **369** to the nebulization control valve assembly **371.** The other leg of the tee delivers source gas through tube **393** to the adjustable spring-loaded bypass valve assembly **386.** An adjustable pressure gradient for flow is created within the pressure reduction regulator **353.** This source gas in one path passes through an unrestricted passage in the nebulization control valve assembly **371** and thence through a tube **377** through the tube **324** to the main jet of the **500** cc nebulizer **546.** Nebulization control is obtained by adjustment of the knob **374** which controls operation of

the needle valve. When it is closed, all gas flowing into the nebulization control valve assembly **371** flows through the tube **377** to the main jet of the **500** cc nebulizer. This constitutes the maximum nebulizer flow (output) position. When the needle valve of the control valve assembly **371** is adjustably opened, partial flow is bypassed out the side of the control valve assembly **371** through the tube **379** to the tee **381** for delivery to the auxiliary flow socket located in the crown of the **500** cc nebulizer **546.** When the needle valve of the control valve assembly **371** is in the full open position, minimum flow is delivered to the nebulizer/humidifier jet of the **500** cc nebulizer **546.** When the nebulization control valve assembly **371** has the needle valve in the fully closed position, the jet orifice of the nebulizer **546** is subjected to the full flow provided by the flow regulator **353.** Since the nebulizer jet cannot accommodate the full flow, the bypass valve assembly **386** opens by permitting the valve member **391** to be pushed downwardly as viewed in FIG. **23** against the force of the spring **392** to permit source gas to pass through the bypass valve assembly **386** into the tee **381** and back through the tube **382** where it is directed to the auxiliary flow socket of the nebulizer **546.** Thus, the bypass valve assembly **386** serves as a pressure governor to maintain calibrated flow values in the breathing circuit. It is important that the auxiliary flow line **382** never be restricted.

From the foregoing, it can be seen that the source gas for the breathing circle or breathing circuit is supplied to the main nebulizer **546** through the tubes **324** and **547.** This gas which is supplied to the nebulizer **546** is humidified and flows out of the nebulizer into a tee **548** and thence into the tube **632** through the water trap **633,** the tube **636** to the patient adapter **637** and down through the physiological airway and into the lungs of the patient. When the gas is exhaled from the lungs, it is supplied through the patient adapter **637** through the tube **638,** the water trap **639,** the tube **642** and then passes an expiratory check valve **511** through the negative venturi assembly **503** (see FIG. **13**) and thence through and across the top of the diaphragm **566** of the non-rebreathing valve assembly **551.** Thereafter, the expiratory gases flow to ambient through the outflow regulator assembly **582.**

All inflow to the breathing circle or circuit of the ventilator is totalized by the flow rate meter **357,** which is expressed in LPM. By delivering source gases through and jet and auxiliary port of the 500 cc nebulizer/-humidifier **546,** the source gases are delivered in a main stream in the nebulizer for maximum himidification by the nebulizer. Fresh humidified source gases are constantly flowing into the inspiratory side of the breathing circle from the nebulizer. The lungs of the patient being treated are connected to the breathing circuit through a common inspiratory/expiratory airway fitting or adapted **637.** At any constant inflow of inspiratory gases, pressures within the breathing circle are controlled by decreasing or increasing expiratory outflow resistance. Physiological demands within the breathing circle do not cause a notable pressure drop during inspiration providing the flow of source gases into the breathing circle equals or exceeds the physiological inspiratory flow rates. There is a pressure balance within the circle, provided the outflow valve has sufficient reserve to accommodate phasic physiological expiratory flows without demonstrating an indicated pressure rise. Breathing within the system is at extremely low values providing that the inflow of source gases exceeds physiological ventilation.

The outflow regulator assembly **582** plays a major role in regulating pressures within the breathing circle. Expiratory gas enters the regulator assembly **582** through a non-restricted passage or orifice **581** carried by the tubular member **588.** As explained previously, this tubular member is adjustable longitudinally by use of the handle **594.** Travel is limited by the travel of the pin **591** in the crescent-shaped or arcuate slot **593.** Outflow resistance from the orifice or passage **612** is controlled by hard plastic disc **599** carried on the inside bottom of the convoluted diaphragm **597.** A vented piston **604** is carried by the diaphragm **597** as hereinbefore described and is provided for minimizing or eliminating chatter while at the same time providing aligned movement between the movable member **588** carrying the orifice **612** and the valve seat disc **599.** The vented piston is a chatter dampener eliminating or minimizing low frequency chatter and also dampening high frequency chatter when lubricated with a controlled viscosity agent.

The outflow valve regulator **582** permits the operator of the ventilator to select a constant positive pressure within the breathing circle after any available rate of inflow is established. Constant positive pressures are developed by moving the member **588** having the orifice **612** therein against the floating seat **599** carried by the diaphragm **597.** The elastic forces inherent in the design of the convoluted diaphragm act to supply an increasing resistance as the member **588** is moved upwardly against the seat **599.** The design of the outflow orifice **612** and the seat **599** is such that the breathing pressures within the orifice act against a fixed area of the seat with an opening tendency. Countering these opening forces are adjustable elastic forces holding the seat against the orifice. Thus, it can be seen that the design of the outflow regulator **582** is such that the breathing pressures within the orifice or passage **612** act against a fixed area of the seat with an opening tendency. Countering the opening forces are adjustable elastic forces holding the seat against the orifice. When the pneumatic opening force exceeds the elastic closing forces, the seat is forced away from the orifice and respiratory gases flow out of the breathing circle to ambient through the arcuate slot **593.** By moving the control lever **594** from left to right, elastic resistance is increased as the orifice is moved up against the seat. This makes it possible for the operator to select a specific constant positive pressure within the breathing circle. By way of example, constant positive pressures from zero to 20 mm of mercury can be developed within the operating range of the ventilator.

Regulator assembly **582** also provides peak inspiratory pressure limiting during controlled ventilation. When the output pressure of the inspiratory venturi assembly **278** is directed to the top of the outflow valve diaphragm **597** through the tube **324,** a secondary closing force is developed. Thus, resistance to outflow from the breathing circuit caused by increasing mechanical pressure against the seat can function in two stages: first, an adjustable elastic force can limit constant positive pressures within the breathing circuit, while peak inspiratory positive pressure limiting is a function of pneumatic leverage acting directly against the seat

through the top surface of the outflow diaphragm **597.**

The total constant output of the inspiratory venturi assembly **278** acts against the outflow diaphragm **597,** the peak inspiratory pressure limit would be in excess of **80** mm of mercury, providing that the rate of inflow is sufficiently high for the length of inspiration to allow time for the pressure rise within the breathing circuit to reach the 80 mm of mercury relieving pressure established by pneumatic pressure against the seat within the outflow valve regulator **582.**

When the maximum inspiratory pressure limit established by the inspiratory and venturi assembly **278** is reduced, the peak inspiratory positive pressure limit is also lowered. To provide for an adjustable means of establishing peak inspiratory pressure limiting, an adjustable mechanical spoiler assembly **300** is provided and is interposed between the distal end of the inspiratory venturi assembly **278** and the top of the housing of the outflow regulator. A spoiler is formed by an adjustable orifice venting the distal ventui and the top of the outflow diaphragm **597** to ambient. As the valve member or spoiler gate is adjustably moved away from the spoiler orifice, venturi-generated pressure against the top of the valve flow diaphragm are decreased, reducing the peak inspiratory positive pressure limit. Therefore, a constant flow venturi acts against a constant diaphragm surface area with relief pressure governing accomplished by variable spoiling of a constant venturi flow/pressure against the outflow regulator diaphragm.

Peak inspiratory pressure limiting can be precisely selected after a constant source gas inflow and inspiratory time have been selected. Pressure limiting between **10** and **60** mm of mercury is established by low and high stops carried by the first and second discs **325** fastened to the shaft **302** carrying the valve member **301.** Maximum controlled inspiratory positive pressure limits only can be reached with sufficient source gas inflow and inspiratory time.

The non-rebreathing valve assembly **551** in combination with the shuttle valve assembly formed by the flapper valves **511** and **514** in combination provide means for providing a total manual back-up controlled ventilation should a major mechanical failure occur in the automatic control functioning of the ventilator or if the source gas is interrupted. This can be seen by examining FIG. **13.** When the compression bulb **621** is manaully compressed, the non-rebreathing valve assembly **551** enters the inspiratory controlled phase. As gas from the compression bulb **621** is forced up into the chamber **577** below the diaphragm **566,** a closing force is applied to the resilient ring **558** of the circular multi-orifice entrainment valve provided in the base of the inlet bell **554.** Simultaneously with the closing of the entrainment valve, the diaphragm **566** (with a convoluted cross-section and a centrally constrained one-way flapper valve **569**) is forced upwardly against the lower extremity of the inner tubular extension **573** thereby sealing the central outlet formed by the passage **581** with the top central portion of the flapper valve **573.** As pressure continues to build up under the diaphragm **566,** gas from the compression bulb **621** is forced up through the holes **568** lifting the outer rim of the circular flapper valve **573** normally covering the holes **568.** The gas from the compression bulb **621** then enters the passageway **579,** the passage **580** through the tee **502** and then through the negative venturi assembly **503** and then finally out of the top inspiratory flapper valve **514** of the shuttle valve into the inspiratory side of the breathing circuit.

It should be appreciated that the only time the inspiratory flapper valve **514** opens is during the controlled inspiratory phase of manual ventilation. During normal operations, the flapper valve **514** acts as a one-way check valve (remaining closed), preventing inspiratory gases being delivered backwards through the shuttle valve to the expiratory portion of the breathing circuit.

It is possible to control ventilation manually with the non-rebreathing valve assembly **551** without delivering ambient air into the breathing circuit. This is accomplished by increasing the inflow of source gases into the breathing circuit until inflow rates are approximately double those of physiological inspiratory flow rates. The non-rebreathing valve assembly **551** is then used to occlude the outlet port **581** now passing air from the compression bulb **621** through the inspiratory valve **573.** This technique requires compression of the bulb **621** only until the valve **573** is moved to engage the tubular extension **573** to occlude the passage **581.** Inspiratory air is then supplied to the patient from the inflow from the ventilator. The inspiratory phase is terminated when the pressure on the compression bulb is released opening the outflow passage **581.**

The small bleed-down orifice **561** in the non-rebreathing valve assembly has been provided so that there will be a bleeddown of the pressure within the chamber **577** so that the outlet passage **581** will not be occluded by the valve member **569** beyond a predetermined period of time. This will prevent an inexperienced operator from holding a lung in an apneustic position beyond physiological limits.

Additional safety means is provided in the form of the inspiratory relief and over-pressure valve assembly **519** which is mounted above the flapper valve **514** of the shuttle valve. When the inspiratory demand pressure is below −3 Hg, ambient inflow of air will occur. This air passes inwardly through the holes **524** into the cup-shaped member **529** to urge the cup-shaped member to the right against the force of the spring **531** (see FIG. **13**) so that the ambient air can flood into the tee **518** and into the breathing circuit to be supplied to the lungs of the patient.

In the event there is an occlusion in the outflow side of the breathing circuit and pressures of over **65** mm of Hg occur in the breathing circuit, the breathing circuit will be vented to ambient through the valve assembly **519.** This air under pressure will pass through the holes **536** and apply pressure against the gate member **539** to open the same against the force of the spring **537** to permit the air to pass through the holes **524** to ambient to overcome the over-pressure condition. As soon as the over-pressure condition has ceased, the gate **539** will be moved to a position to occlude the holes **536.**

If the inspiratory air introduced through the gate valve **529** is insufficient, additional ambient air can be delivered through the holes **557** through the entrainment valve **558** up through the holes **568** and through the flapper valve **567** and thence up through the flapper valve **514** into the breathing circuit. Thus, it can be seen there are dual sources for inspiratory air.

The above procedure is advantageous when enriched gases are being delivered to the patient as, for example, a 40 percent oxygen mixture. By merely operating the compression bulb **621** so as to cause the valve **573** to occlude the outlet passage **581**, it is possible to supply air having the same oxygen enrichment merely by increasing the amount of source gases being supplied to the patient. In the event it is absolutely necessary to supply additional air from the compression bulb **621**, there will be some minor dilution of the oxygen enriched gases being supplied to the patient.

In operation of the pediatric ventilator, when it is desired to enhance the flow gradient out of the lung during expiratory phase, gas is supplied from the interrupter cartridge **62** through the line **95**, through the expiratory control valve assembly **100**, through tube **469**, through tube **509** to the nozzle **506** provided in the negative venturi assembly **503** to provide a jet of gas passing from a nozzle **507**. The jet of gas passes into a venturi-like passage formed by the tee-shaped member **504** to thereby create a negative pressure within the region between the flapper valves **511** and **514** within the shuttle valve body or member **504** and particularly above the expiratory shuttle valve **511** to thereby enhance the flow of expiratory gases from the lungs of the patient. The amount of pressure drop within the member **504** is related to the velocity of flow of gases from the expiratory venturi nozzle **506** and can be controlled by the expiratory flow gradient control knob **124**.

During controlled ventilation under the control of the control cartridge **58**, the expiratory venturi functions only during the expiratory phase. By producing an increased pressure drop to ambient through the expiratory side of the breathing circle, mechanical resistance to exhalation can be minimized or totally removed. This becomes of major importance when controlled respiratory rates above 30 cycles per minute because tidal volumes can be greatly increased by more rapid emptying of the lungs. The use of a sub-ambient expiratory flow gradient will in most cases reduce functional residual volumes if properly applied.

During operation of the ventilator in the spontaneous breathing mode, the expiratory flow gradient function can be used to precisely control pressures within the breathing circuit. This is accomplished by using the expiratory venturi to overcome the mechanical resistance caused by flow through the breathing circle.

The nebulizer **549** can be utilized for applying desired medication as, for example, Racemic Epinephrine, which can be utilized for reducing mucosal and submucosal edema in the patient's airways. When the nebulizer **549** is being utilized, the tube **324** is removed from the 500 cc nebulizer **546** and inserted in the nebulizer **549**. If desired, the opening in the 500 cc nebulizer from which the tube has been removed can be closed by a cap (not shown) during use of the nebulizer **549**.

As explained previously, before making a final airway connection to the patient, the ventilator can be preclinically function checked by use of the test analog lung device **431** by connecting the patient adapter **637** to the fitting **456** as shown in FIG. **4**. The device **431** acta as an apneic mechanical analog of an individual lung. It can be utilized for determining the desired flow rate. The ventilator can be adjusted by the operator to obtain the desired characteristics for the flow before the ventilator is connected to the infant or patient.

In summary of the operation of the pediatric ventilator, the source of gases for the ventilator is a metered calibrated source of mixed respiratory gases. These gases are introduced into the breathing circuit by a flow splitter. The flow splitter is the nebulization control valve which proportions a common inlet gas source into two outflows, increasing one outflow proportionally and decreasing the other outflow. The needle valve of the flow splitter can be calibrated in percent nebulization. One of the two outflows is connected to the driving jet which is utilized with either of the two nebulizers. The other enters the breathing circuit through a bypass. The flow splitter provides precise control over the breathing circuit humidification or anesthesia vapor pressure by directing a known proportion of amount of gas through a liquid which can be water or anesthesia or even a medicine to deliver a thermally compensated vapor with or without medicine into the breathing circuit. Respiratory gases flow from the nebulizer or anesthesia vaporizer into the breathing circuit to the patient adapter or Y. The inspiratory respiratory gases enter the physiological airways of the patient which, after use by the patient, are exhaled and leave through the patient adapter and pass through the exhalation side of the shuttle valve through a venturi section.

Although the ventilator has been described principally for use with the ventilation of infants and particularly premature babies, it is possible to ventilate children up to the age of nine to ten years with such a ventilator with great ease. In addition, it is possible to utilize the same for the ventilation of small animals. Also, the ventilator can be utilized for applying anesthesia as well as normal respiratory gases to patients.

It is apparent from the foregoing that there has been provided a new and improved pediatric ventilator and method which has many applications and which can be utilized for supplying conventional respiratory gases and for administering anesthesia. It is particularly adapted for use with premature babies, infants and children. In addition, it can be utilized on small animals. Respiration can either be controlled by the ventilator or it can be spontaneous under the control of the patient. When spontaneous, the breathing can be from a slightly supercharged breathing circuit provided by the ventilator which can supply a basic rate and depth controlled respiratory pattern.

I claim:

1. In a ventilator for use with a source of gas under pressure generally in the range of 50–75 p.s.i. and having an inhalation phase and an exhalation phase in its operative cycle, an inlet adapted to be connected to said source of gas, a breathing circuit adapted to be connected to the patient, flow regulating means for adjusting the rate of flow of gas from the inlet, nebulizing means coupled to the breathing circuit and having main jet flow means and auxiliary flow means and flow divider means connected to the flow regulator means and using said gas having a pressure ranging from 50–75 p.s.i., said flow divider means having one outlet coupled to the main jet flow means of the nebulizing means so that at least a portion of the inlet gas is supplied to the nebulizing means and an additional outlet coupled to the auxiliary flow means of the nebulizing means, said flow divider means including adjustable flow splitting means in the auxiliary flow path for controlling the flow of gas through the additional outlet whereby pre-

cise control over the operation of the nebulization means can be obtained by directing a precise portion of the inlet gas to the main jet flow means of the nebulizing means without substantial change to the pressure and rate of flow of the gas being supplied to the patient.

2. A ventilator as in claim **1** together with a bypass valve assembly having a flow passage therein and having a valve member yieldably held in a closed position to occlude the flow passage, means coupling the bypass valve to the breathing circuit and means coupling the inlet to the bypass valve assembly whereby when sufficient pressure is created on the valve member by the gas supplied from the inlet, the valve member automatically will be moved to an open position to permit additional gas to bypass said valve member and to enter the breathing circuit.

3. A ventilator as in claim **1** together with emergency intake valve means connected into the breathing circuit.

4. A ventilator as in claim **1** together with an additional nebulizing means coupled to the breathing circuit and wherein the additional outlet is coupled to the additional nebulizing means.

5. A ventilator as in claim **1** together with an outflow regulator assembly said assembly including a housing having an outlet and first and second inlets formed therein in communication with the outlet in the housing, valve means within the housing movable between open and closed positions with respect to said outlet to interrupt the communication between the first and second inlets and the outlet, diaphragm means in the housing engaging the valve member and yieldably urging the valve member toward a closed position and manually adjustable means for varying the yieldable force applied by the diaphragm means to the valve member.

6. A ventilator as in claim **5** wherein said means for varying the yeildable force includes means for adjusting the position of the valve member to vary the pressure which the diaphragm exerts against the valve member to thereby vary the pressure required to move the valve member to the open position to permit exhalation gases to pass from the first inlet to ambient through the outlet.

7. A ventilator as in claim **6** wherein said means adjusting the position of the valve member includes a valve seat member adapted to be engaged by the valve member and threadedly mounted in the housing for movement toward and away from the valve member by rotational movement of the valve seat member.

8. A ventilator as in claim **5** wherein said diaphragm means forms first and second chambers in said housing together with means for supplying gas under pressure to the second chamber at predetermined intervals so that an additional positive pressure is required for moving the valve member out of engagement with the valve seat member during said predetermined intervals.

9. In a ventilator for use with a source of gas under pressure and having an inhalation phase and an exhalation phase in its operative cycle, an inlet adapted to be connected to said source of gas, a breathing circuit adapted to be connected to the patient, nebulizing means, flow divider means connected to the inlet, said flow divider means having one outlet coupled to the nebulizing means so that at least a portion of the inlet gas is supplied to the nebulizing means, said flow divider means including an additional outlet coupled to the breathing circuit and having adjustable flow splitting means for controlling the flow of gas through the additional outlet whereby precise control over the operation of the nebulization means can be obtained by directing a precise portion of the inlet gas to the nebulizing means and an outflow regulator assembly having an outlet and first and second inlets, the assembly having a valve member movable between open and closed positions with respect to said outlet, yieldable means engaging the valve member and yieldably urging the valve member toward a closed position, manually adjustable means engaging the valve member for adjusting the force applied by the yieldable means to hold the valve member in the closed position, means forming a first venturi-like passage having an inlet and having an outlet connected to the first inlet of the regulator assembly, means for supplying a jet of gases to said means forming a first venturi-like passage to create a negative pressure within the means forming a venturi-like passage and means coupling the inlet of the first means forming a first venturi-like passage to the breathing circuit.

10. A ventilator as in claim **9** together with means connected to the second inlet of the regulator assembly for supplying a gas under pressure in substantial coincidence with the inhalation phase.

11. In a ventilator for use with a source of gas under pressure and having an inhalation phase and an exhalation phase in its operative cycle, an inlet adapted to be connected to said source, a breathing circuit adapted to be connected to the patient, nebulizing means and flow divider means connected to the inlet, said flow divider means having one outlet coupled to the nebulizing means so that at least a portion of the inlet gas is supplied to the nebulizing means, said flow divider means including an additional outlet coupled to the breathing circuit and having means for controlling the flow of gas through the additional outlet whereby precise control over thhe operation of the nebulization means can be obtained and outflow regulator assembly having an outlet and first and second inlets, the assembly having a valve member yieldably held in a closed position means forming a first venturi-like passage having an inlet and having an outlet connected to the first inlet of the regulator assembly, means for supplying a jet of gases to said first means forming a venturi-like passage to create a negative pressure within the means forming a venturi-like passage and means coupling the inlet of the first means forming a venturi-like passage to the breathing circuit, said means coupling the inlet of the means forming a venturi-like passage to the breathing circuit including a shuttle valve assembly having first and second valve members disposed on opposite sides of the means forming a venturi-like passage, both of said valve members being movable between open and closed positions in the same directions.

12. A ventilator as in claim **11** wherein each of said valve members is provided with means for normally retaining the same in a closed position, said first valve member being movable to an open position during the exhalation phase and the second of said valve members being movable to an open position during the inhalation phase.

13. A ventilator as in claim **12** together with inspiratory relief valve means coupled to the breathing circuit and to the shuttle valve whereby when a predetermined

below atmospheric condition is created within the breathing circuit, ambient air will be permitted to enter the breathing circuit.

14. A ventilator as in claim **13** together with pressure relief means coupled to the breathing circuit and relieving the pressure in the breathing circuit whenever the pressure in the breathing circuit exceeds a predetermined pressure above atmospheric.

15. In a ventilator for use with a source of gas under pressure and having an inhalation phase and an exhalation phase in its operative cycle, an inlet adapted to be connected to said source of gas, a breathing circuit adapted to be connected to the patient, nebulizing means and flow divider means connecting to the inlet, said flow divider means having one outlet coupled to the nebulizing means so that at least a portion of the inlet gas is supplied to the nebulizing means, said flow divider means including an additional outlet coupled to the breathing circuit and having means for controlling the flow of gas through the additional outlet whereby precise control over the operation of the nebulization means can be obtained, an outflow regulator assembly having an outlet and first and second inlets, the assembly having a valve member yieldably held in a closed position, means forming a first venturi-like passage having an inlet and having an outlet connected to the first inlet of the regulator assembly, means for supplying a jet of gases to said first means forming a venturi-like passage to create a negative pressure within the means forming a venturi-like passage and means coupling the inlet of the first means forming a venturi-like passage to the breathingcircuit and a non-rebreathing valve assembly coupled to the first inlet of the outflow regulator assembly, said non-rebreathing valve assembly including a housing having an inlet and first and second outlets, a diaphragm disposed in the housing and forming first and second chambers in the housing, said diaphragm having an opening therein permitting communication between said first and second chambers, and valve means carried by the diaphragm for closing said opening in the diaphragm, said diaphragm being movable so that said valve means carried by the diaphragm occludes the first outlet in the housing to prevent communication between said second chamber and the first outlet, said housing being formed with an additional opening in said housing venting said first chamber to the atmosphere and valve means carried by the housing for normally closing said additional opening, a compression bulb connected to said inlet and means connecting the second outlet of the housing to the outlet of the means forming the venturi-like passage.

16. A ventilator as in claim **15** wherein said housing is provided with a normally open bleed-down orifice in communication with the first chamber in the housing.

17. A ventilator as in claim **15** wherein said means connected to the second inlet of the regulator assembly includes a second venturi assembly connected to the second inlet of the regulator assembly together with a control cartridge for automatically supplying gas under pressure to said second venturi assembly during the inhalation phase.

18. A ventilator as in claim **17** together with an inspiratory time limit control valve assembly adapted to be connected to said source of gas and for causing an alarm to be sounded when a predetermined inhalation time limit has elapsed.

19. A ventilator as in claim **18** together with lock-out means controlled in synchronism with said inspiratory time limit control assembly for locking out the flow of gases from said control cartridge to said second venturi assembly after said predetermined inhalation time limit has elapsed.

20. A ventilator as in claim **19** together with means for resetting said lock-out means to permit said control cartridge to automatically control the operation of said ventilator.

21. A ventilator as in claim **19** wherein said inspiratory time limit control valve assembly and said lock-out means are interconnected so that they operate substantially simultaneously.

22. In a ventilator having an inspiratory phase and an expiratory phase in its operative cycle for use with a source of gas under pressure, an inlet adapted to be connected to said source of gas under pressure, a breathing circuit adapted to be connected to the patient, means for supplying mainstream flow of gases from said inlet to said breathing circuit, an outflow regulator assembly connected to the breathing circuit, said outflow regulator assembly including a housing having first and second inlets and an outlet, means connecting said first inlet to the breathing circuit, a valve member, a diaphragm mounted in the housing secured to the valve member and forming first and second chambers within the housing with the first chamber being in communication with the first inlet and the outlet and the second chamber being in communication with the second inlet, a valve seat member disposed within the first chamber and adapted to be engaged by the valve member for occluding the passage between the first inlet and the outlet in the housing, said diaphragm applying a yieldable force urging the valve member into engagement with the valve seat member, means for adjusting the position of the valve seat member to thereby vary the yieldable force applied by the diaphragm to the valve member and means for supplying gas under pressure to the second inlet of the housing, said means for supplying gas under pressure includes a control cartridge for controlling the flow of gas whereby gas is supplied to said second inlet during the inspiratory phase.

23. A ventilator as in claim **22** together with timing means for actuating an alarm when a predetermined inspiratory time has elapsed.

24. In a ventilator having an inspiratory phase and an expiratory phase in its operative cycle for use with a source of gas under pressure, an inlet adapted to be connected to said source of gas under pressure, a breathing circuit adapted to be connected to the patient, means for supplying mainstream flow of gases from said inlet to said breathing circuit, an outflow regulator assembly connected to the breathing circuit, said outflow regulator assembly including a housing having first and second inlets and an outlet, means connecting said first inlet to the breathing circuit, a diaphragm mounted in the housing and forming first and second chambers within the housing with the first chamber being in communication with the first inlet and the outlet and the second chamber being in communication with the second inlet, a valve member disposed within the first chamber and adapted to be engaged by the diaphragm assembly for occluding the passage between

the first inlet and the outlet in the housing, means for supplying gas under pressure to the second inlet of the housing, said means for supplying gas under pressure including a control cartridge for controlling the flow of gas whereby gas is supplied to said second inlet during the inspiratory phase, timing means for actuating an alarm when a predetermined inspiratory time has elapsed and lockout means for locking out the supply of gas to said second inlet when said predetermined inspiratory time has elapsed.

25. A ventilator as in claim **24** together with reset means for resetting the lock-out means.

26. In a ventilator having an inspiratory phase and an expiratory phase in its operative cycle for use with a source of gas under pressure, an inlet adapted to be connected to said source of gas under pressure, a breathing circuit adapted to be connected to the patient, means for supplying mainstream flow of gases from said inlet to said breathing circuit, an outflow regulator assembly connected to the breathing circuit, said outflow regulator assembly including a housing having first and second inlets and an outlet, means connecting said first inlet to the breathing circuit, a diaphragm mounted in the housing and forming first and second chambers within the housing with the first chamber being in communication with the first inlet and the outlet and the second chamber being in communication with the second inlet, a valve member disposed within the first chamber and adapted to be engaged by the diaphragm assembly for occluding the passage between the first inlet and the outlet in the housing and means for supplying gas under pressure to the second inlet of the housing, said means for supplying gas under pressure including a control cartridge for controlling the flow of gas whereby gas is supplied to said second inlet during the inspiratory phase, said means for supplying gases to said second inlet of said regulator assembly including means forming an inspiratory venturi-like passage and means for introducing a jet of gas into said passage under the control of said control cartridge.

27. A ventilator as in claim **26** together with means for spoiling the venturi effect in said passage to thereby change the pressure applied to the diaphragm in the outflow regulator assembly without changing the pressure in the mainstream flow to said breathing circuit.

28. In a ventilator for use with a source of gas under pressure and having an inhalation phase and an exhalation phase in its operative cycle, an inlet adapted to be connected to said source of gas, a breathing circuit adapted to be connected to the patient, means for supplying gas from the inlet to the breathing circuit, an outflow regulator assembly having an outlet and first and second inlets, said assembly having a valve member yieldably held in a closed position, and means connecting the inlet to the breathing circuit and to said outflow regulator assembly, said means including means forming a first venturi-like passage having an inlet and having an outlet connected to the first inlet of the regulator assembly, means for supplying a jet of gases to said means forming a first venturi-like passage to create a negative pressure within the means forming a venturi-like passage and means coupling the inlet of the means forming a first venturi-like passage to the breathing circuit, said means coupling the inlet of the means forming a venturi-like passage to the breathing circuit including a shuttle valve assembly having first and second valve members disposed on opposite sides of the means forming a venturi-like passage, both of said valve members being movable between open and closed positions in the same directions.

29. In a ventilator having an inspiratory phase and an expiratory phase in its opertive cycle for use with a source of gas under pressure, an inlet adapted to be connected to said source of gas under pressure, a breathing circuit adapted to be connected to the patient, means for supplying a mainstream flow of gases from said inlet to said breathing circuit, an outflow regulator assembly connected to said breathing circuit for controlling the flow of expiratory gases from the breathing circuit, and a non-rebreathing valve assembly connected into said breathing circuit, said non-rebreathing valve assembly including a housing having an inlet and first and second outlets, said housing having means forming a valve seat surrounding the first outlet, valve means movable between open and closed positions with respect to said valve seat, a diaphragm disposed in the housing and forming first and second chambers in the housing, means securing said valve member to said diaphragm, said diaphragm having an opening therein permitting communication between said first and second chambers, and valve means carried by the diaphragm for closing said opening in said diaphragm, said diaphragm being movable so that the valve member carried by the diaphragm is moved into engagement with said valve seat to occlude the first outlet in the housing to thereby prevent communication between said second chamber and the first outlet, said housing being formed with an additional opening in said housing venting said first chamber to the atmosphere and valve means carried by the housing for normally closing said additional opening, a compression bulb connected to said inlet of said housing and means connecting the first and second outlets of said housing into the breathing circuit.

30. A ventilator as in claim **29** wherein said housing has a bleed down orifice formed therein in communication with the first chamber in the housing.

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