IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

PRECISION MEDICAL, INC. 300 Held Drive Northampton, PA 18067 Plaintiff v. **GENSTAR TECHNOLOGIES, INC. d/b/a GENTEC** Serve: John L. Sun (Registered Agent) 3550 Wilshire Boulevard, Suite 1250 Los Angeles, CA 90010 and **TENACORE HOLDINGS, INC.** Serve: William G. Bissell (registered agent) 110 Newport Center Drive, Suite 200 Newport Beach, CA 92660 Defendant(s)	)	Civil Action No. ____

COMPLAINT FOR PATENT INFRINGEMENT

1. This is an action for preliminary injunction, permanent injunction, declaratory relief and damages pursuant to the patent laws of the United States, 35 U.S.C. § 101 *et seq.*

PARTIES

2. Plaintiff Precision Medical, Inc. ("Precision Medical") is a Pennsylvania corporation with a principal place of business at 300 Held Drive, Northampton, PA 18067. Precision Medical manufactures respiratory products including oxygen regulators, portable liquid oxygen systems, air-oxygen blenders, oxygen conserving devices, nebulizer compressors, battery operated & AC aspirators, air compressors, vacuum regulators and flowmeters.

3. Defendant Genstar Technologies, Co. ("Genstar") is a California corporation with a principal place of business at 4525 Edison Avenue, Chino, California.

4. Defendant Tenacore Holdings, Inc., Co. ("Tenacore") is a California corporation with a principal place of business at 647 Young Street, Santa Ana, California.

JURISDICTION AND VENUE

5. This court has jurisdiction of this matter pursuant to 28 U.S.C. §§ 1331 and 1338(a) because this action arises under the patent laws of the United States, Title 35 U.S.C. § 101 *et seq.*

6. Venue is proper in this District pursuant to 28 U.S.C. §§ 1391(b) and (c) and 1400(b), because this is a civil action not founded solely on diversity of citizenship, because a substantial part of the events or omissions giving rise to the claim occurred in this District, and because Genstar and Tenacore (collectively the "Defendants") reside in this District, inasmuch as, on information and belief, each of the Defendants has committed acts of infringement and contributed to and/or induced acts of infringement within the Commonwealth of Pennsylvania and this District. Further, on information and belief, each of the Defendants, directly, or through intermediaries (including distributors, dealers, resellers and others), ships, distributes, offers for sale, sells, and advertises its products and/or services in this District, including infringing products.

FACTS

The '308 Patent

7. Precision Medical is the owner of U.S. Patent 5,599,308 ("the '308 Patent"), for an "Intermittent Vacuum Regulator with Timing Module," which was filed on September 19, 1995, and issued on February 4, 1997. A true and correct copy of the '308 Patent is attached as Exhibit A and incorporated herein by reference.

8. Maintenance fees for the ’308 Patent have been paid, and Precision Medical has placed the required statutory notice on all vacuum regulators manufactured and sold under the ’308 Patent.

The Infringement

9. Defendants are direct competitors of Precision Medical.

10. Defendants are infringing the ’308 Patent directly, and/or jointly with other entities, by importing into the United States, without authority, and/or by making, using, selling, and/or offering for sale in the United States, including within the Commonwealth of Pennsylvania, without authority, their respective continuous/intermittent vacuum regulators, which embody the patented inventions claimed in the ’308 Patent.

11. Each of the Defendants is infringing the ’308 Patent literally and/or under the doctrine of equivalents.

12. At a minimum, each of the Defendants is infringing claims 1, 2, 3, 4 and 6 in the ’308 Patent, and Defendants may be infringing other claims as well.

13. On information and belief, Defendant’s infringement is willful.

14. On information and belief, Defendants are selling their infringing products at a price that is substantially lower than Precision Medical’s.

15. Since the Defendants began their infringing activity, Precision Medical has seen a substantial decline in sales of its products.

16. Since the Defendants began their infringing activity, Precision Medical has also seen a substantial decline in its market share.

17. On information and belief, Precision Medical will continue to see decreasing sales and market share in the future, if the infringing activity is not halted, as well as suffer other damage and irreparable harm.

CLAIMS INCIDENT TO THE DEFENDANTS' INFRINGEMENT

18. Precision Medical hereby realleges and incorporates by reference, as if fully set forth herein, its previous allegations in paragraphs 1–17, *supra*.

19. Defendants are infringing the '308 Patent, causing substantial harm to Precision Medical due to lost sales and market share.

20. On information and belief, each of the Defendants will continue to infringe the '308 Patent causing immediate and irreparable harm to Precision Medical due to lost sales and market share, unless this court enjoins and restrains the Defendants' activities.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff, Precision Medical, Inc., respectfully requests that this Court enter judgment in its favor and against Defendants Genstar Technologies, Co. and Tenacore Holdings, Inc., Co. as follows:

A. Determining that U.S. Patent No. 5,599,308 is valid, enforceable, and infringed by each of the Defendants;

B. Entering a preliminary injunction against each of the Defendants, enjoining them; their respective directors, officers, agents, employees, successors, subsidiaries, assigns; and all persons acting in privity, concert, or participation with each of the Defendants, respectively, from making, using, selling, or offering for sale in the United States, or importing into the United States, any and all products and/or services embodying the patented inventions claimed in the '308 Patent;

C. Entering a permanent injunction against each of the Defendants, enjoining them; their respective directors, officers, agents, employees, successors, subsidiaries, assigns; and all persons acting in privity, concert, or participation with each of the Defendants, respectively, from making, using, selling, or offering for sale in the United States, or importing into the United

States, any and all products and/or services embodying the patented inventions claimed in the ’308 Patent;

D. Awarding Precision Medical such damages to which it is entitled, pursuant to 35 U.S.C. § 284;

E. Awarding Precision Medical enhanced damages, pursuant to 35 U.S.C. § 284;

F. Awarding Precision Medical pre-judgment and post-judgment interest as allowed by law;

G. Awarding Precision Medical its costs, expenses, and fees, including reasonable attorneys’ fees, pursuant to 35 U.S.C. § 285; and,

H. Awarding such other and further relief as the Court deems just, equitable, and proper.

DEMAND FOR JURY TRIAL

Plaintiff, Precision Medical, Inc. hereby demands a trial by jury in this case.

DATE: October 1, 2010

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EXHIBIT A

US005599308A

United States Patent [19]

Krupa

[11] **Patent Number: 5,599,308**

[45] **Date of Patent: Feb. 4, 1997**

[54] **INTERMITTENT VACUUM REGULATOR WITH TIMING MODULE**

[76] Inventor: **Michael A. Krupa**, 4070 Heather Ct., Northampton, Pa. 18067

[21] Appl. No.: **530,933**

[22] Filed: **Sep. 19, 1995**

[51] **Int. Cl.**[6] **F16K 17/00**

[52] **U.S. Cl.** **604/118**; 604/120

[58] **Field of Search** 604/118, 119, 604/120, 317, 319, 320; 137/624.11, 624.13, 103, 907

[56] **References Cited**

U.S. PATENT DOCUMENTS

4,930,997 6/1990 Bennett .

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OTHER PUBLICATIONS

The Principles of Vacuum & Its Use in the Hospital Environment Ohmeda 12 page brochure 1985.

Pediatric Vacutron — Continuous/Intermittent Allied Healthcare Products, Inc. Aug. 1988.

Operation Manual For Intermittent Suction Unit Published By Ohio Medical Products, Date Unknown.

Primary Examiner—Sam Rimell

Attorney, Agent, or Firm—Caesar, Rivise, Bernstein, Cohen & Pokotilow, Ltd.

[57] **ABSTRACT**

A vacuum regulator having a timing module that provides intermittent vacuum and is modular in design permitting easy removal and replacement without having to disassemble the entire vacuum regulator.

6 Claims, 7 Drawing Sheets

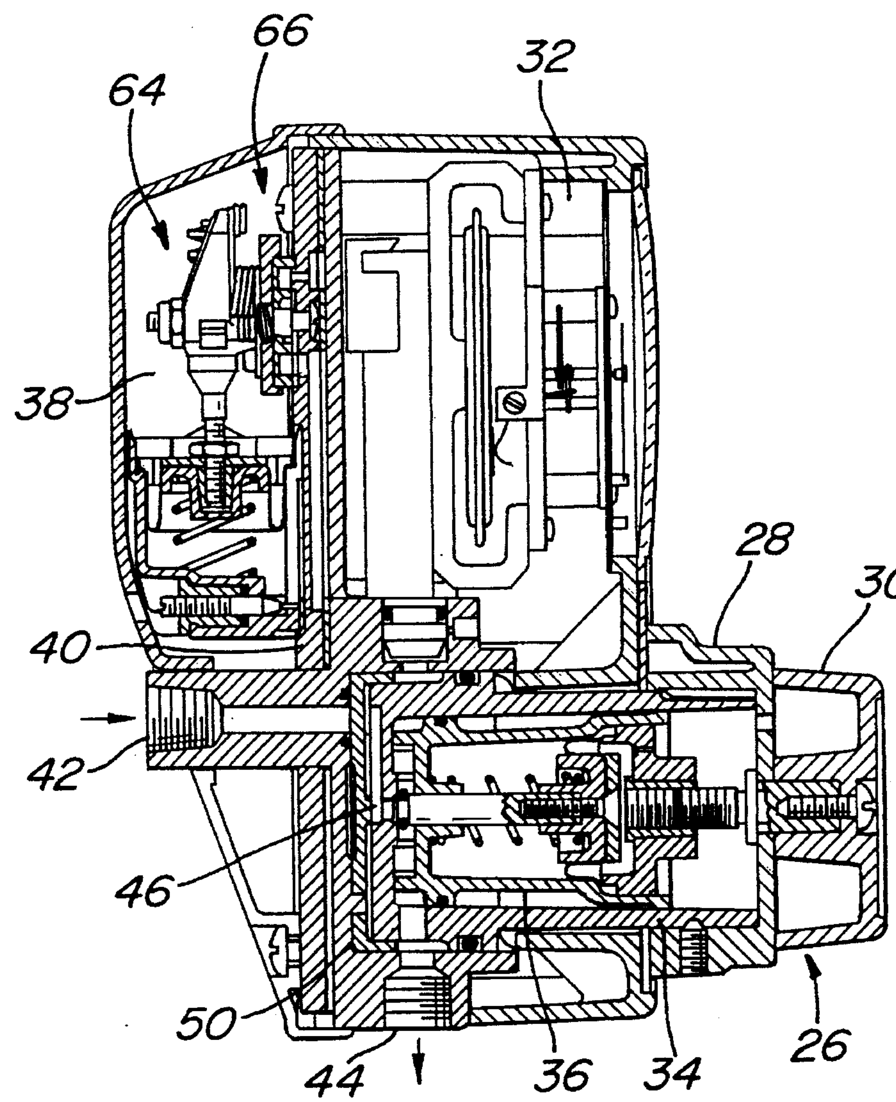
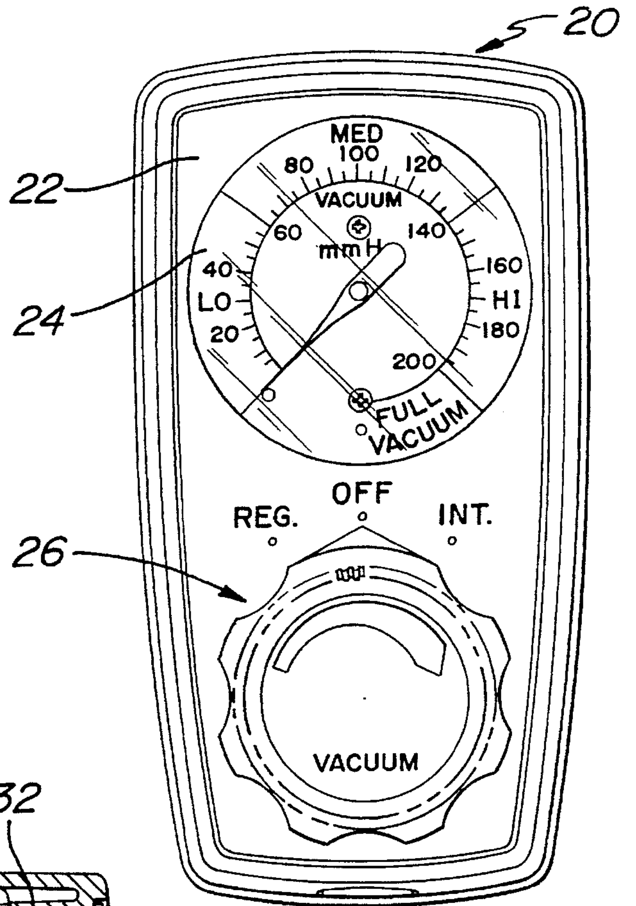


FIG. 1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MED
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VACUUM
60
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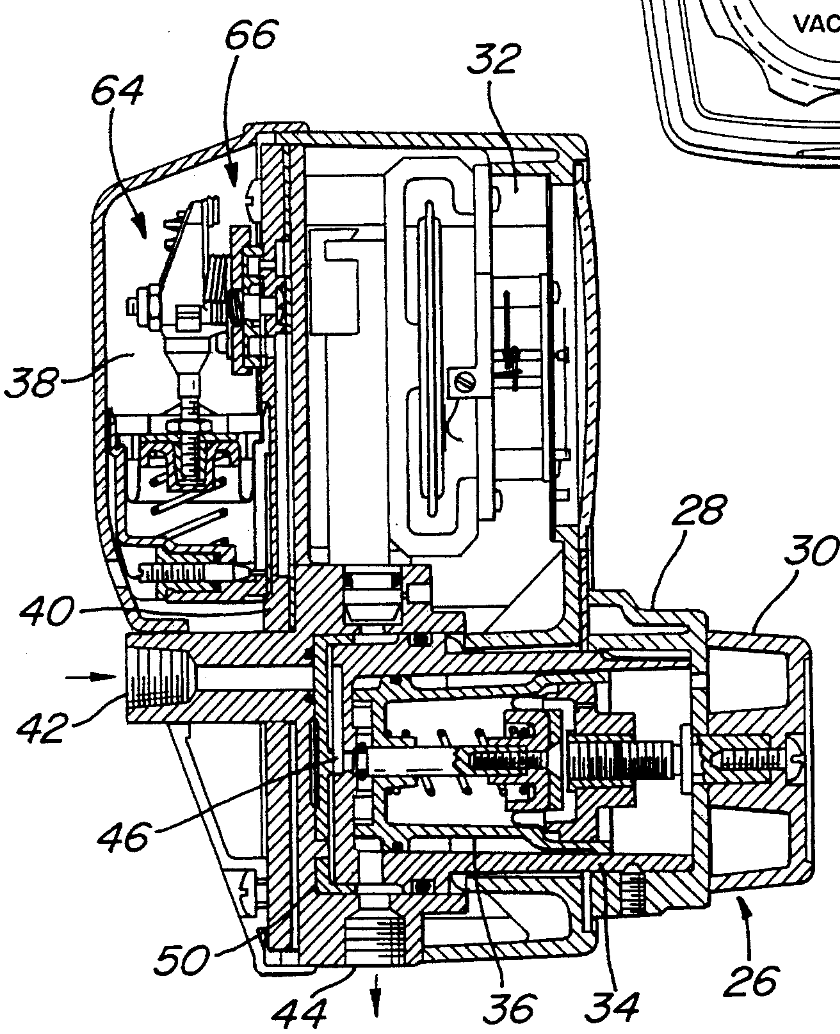
200
FULL
VACUUM
OFF
REG.
INT.
VACUUM

FIG. 2


66
64
32
38
28
30
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34
26

FIG. 3

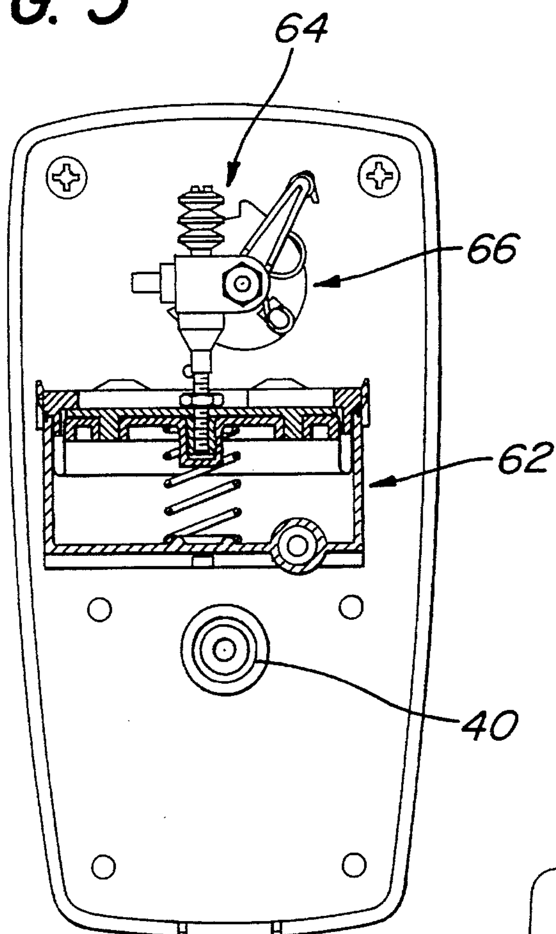
64
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FIG. 4

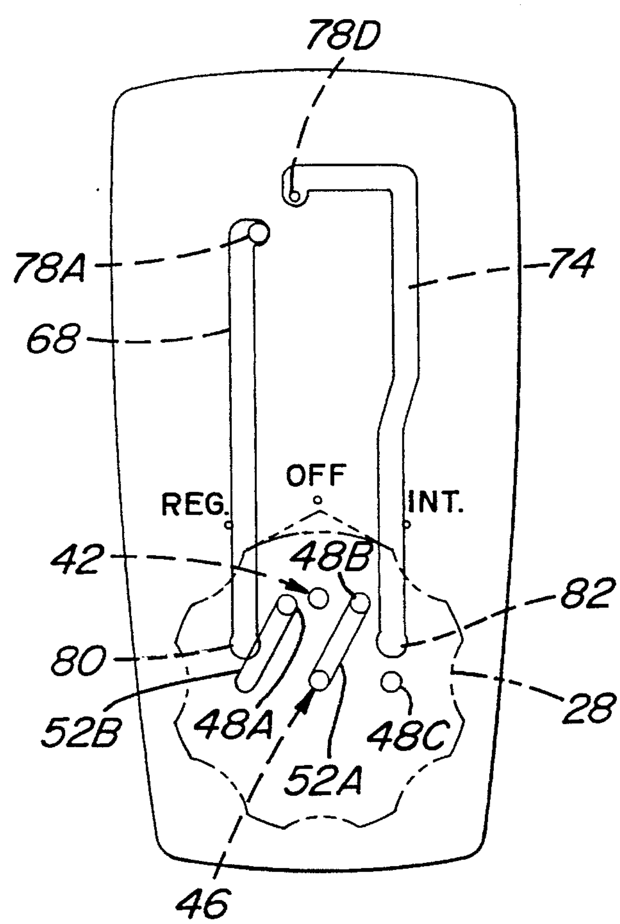
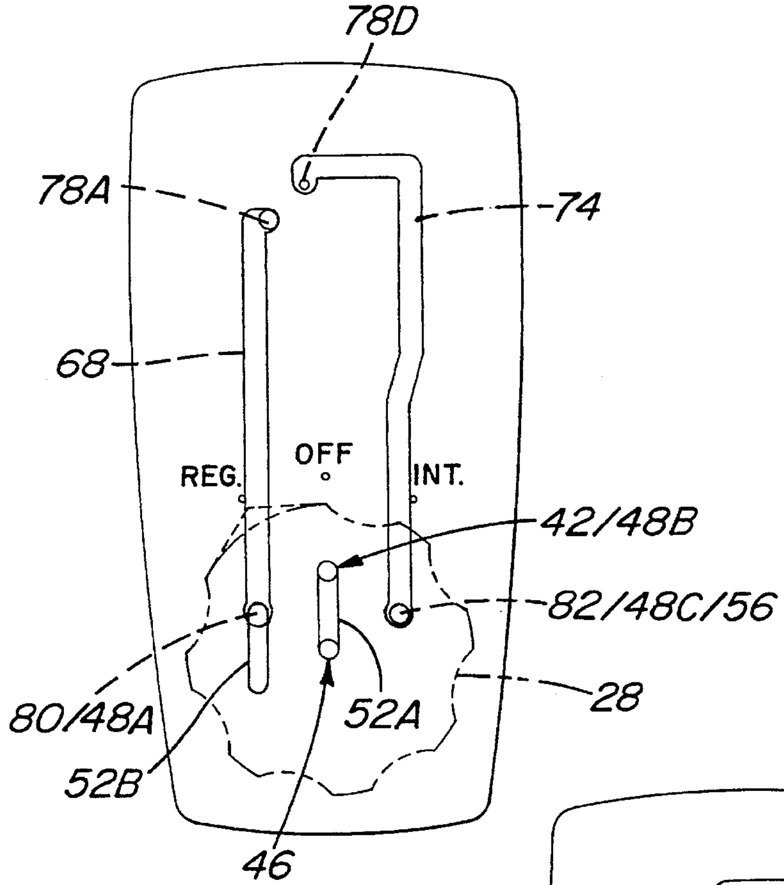

78D
78A
74
68
OFF
REG.
INT.
42
48B
82
80
52B
48A
48C
28
52A
46

FIG. 5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REG.
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INT.
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82/48C/56
80/48A
52A
28
52B
46

FIG. 6

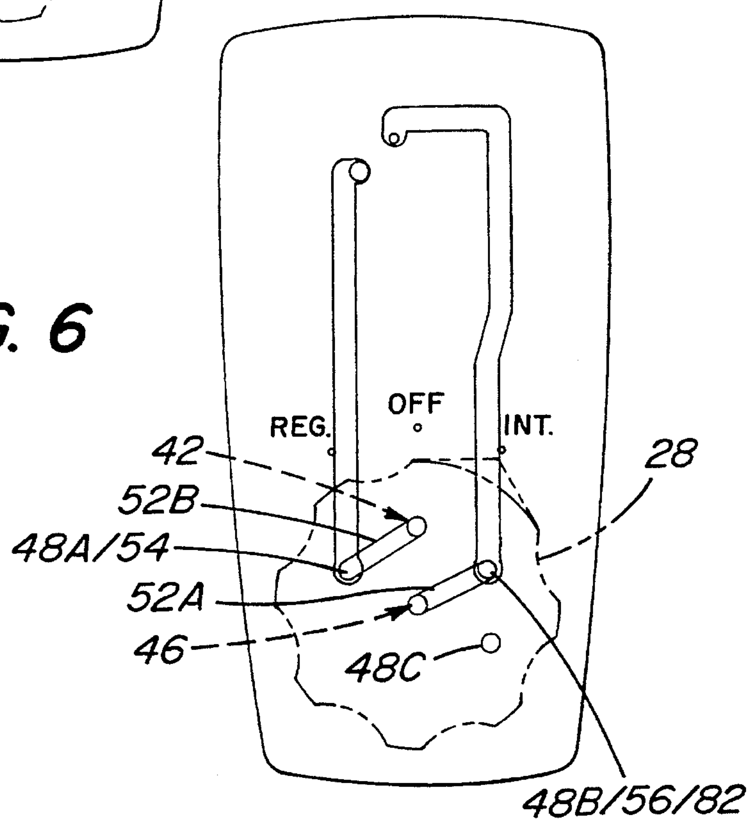
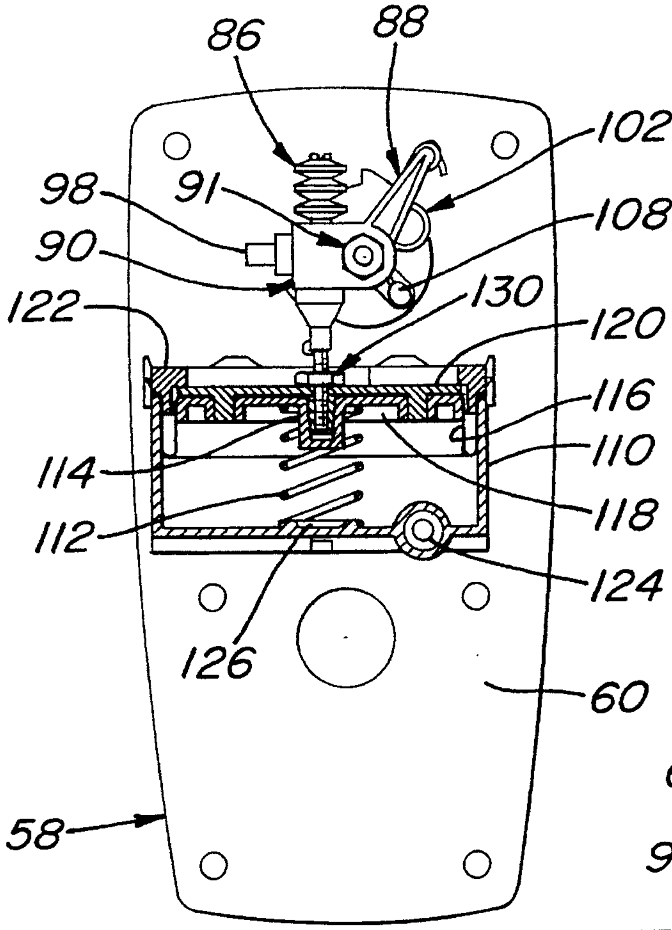

REG.
OFF
INT.
42
28
52B
48A/54
52A
46
48C
48B/56/82

FIG. 7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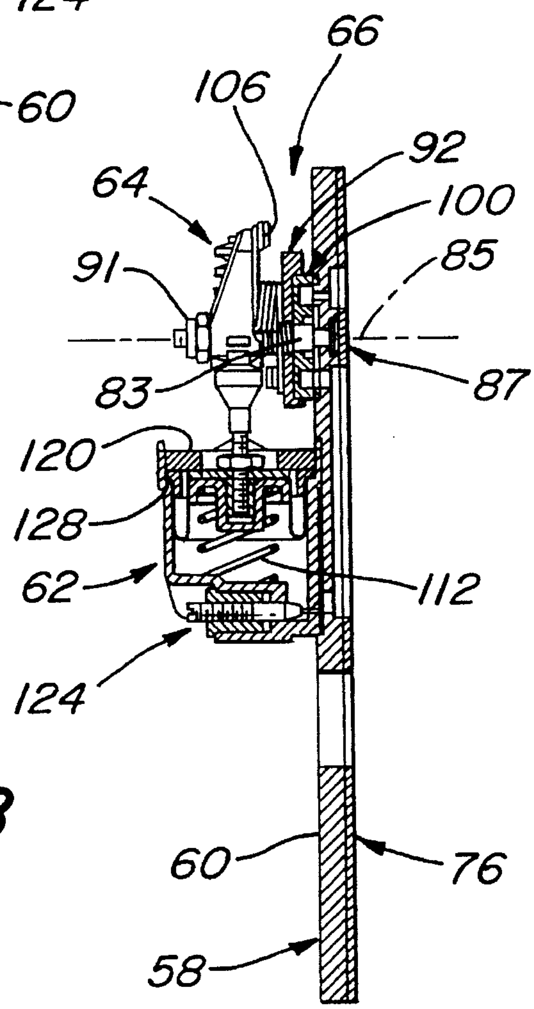
66
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100
85
91
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83
120
128
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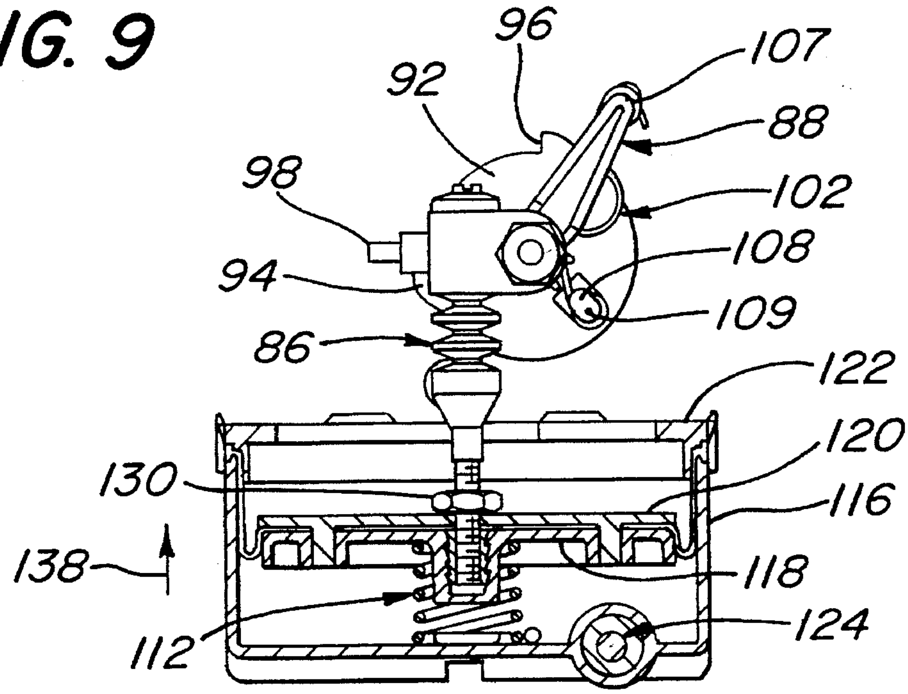
62
124
60
76
58

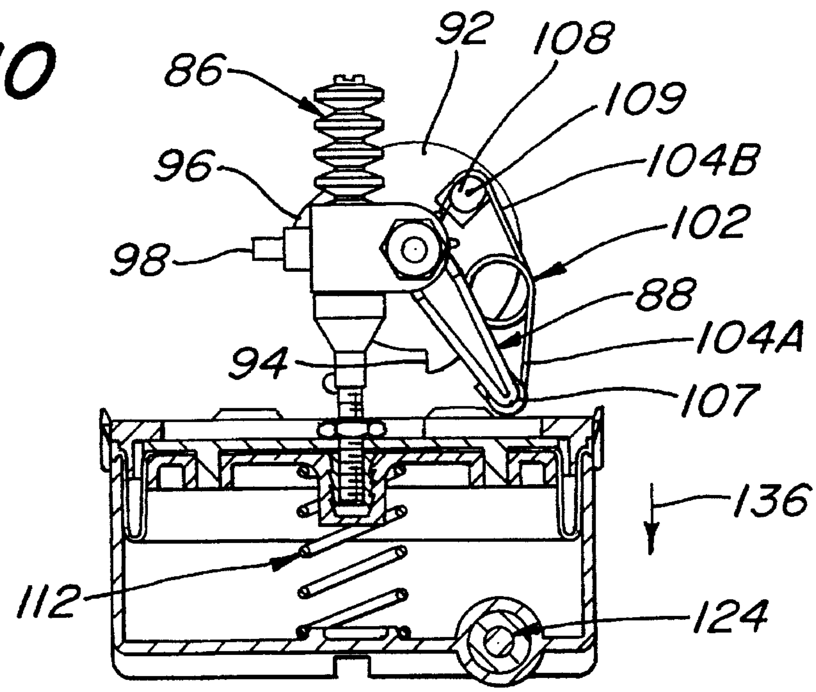
FIG. 8

FIG. 9



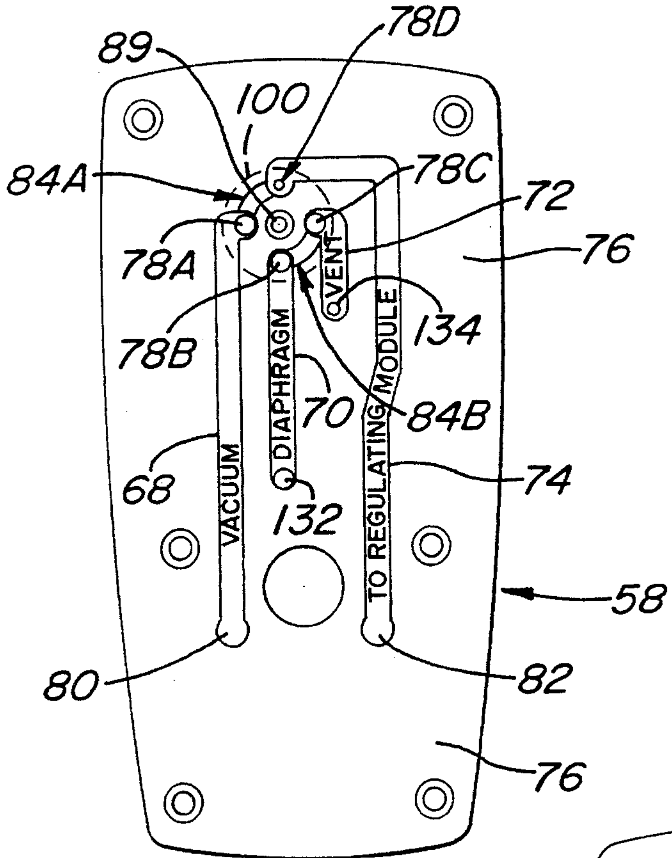
ON STATE

FIG. 10



OFF STATE

FIG. 11



ON STATE

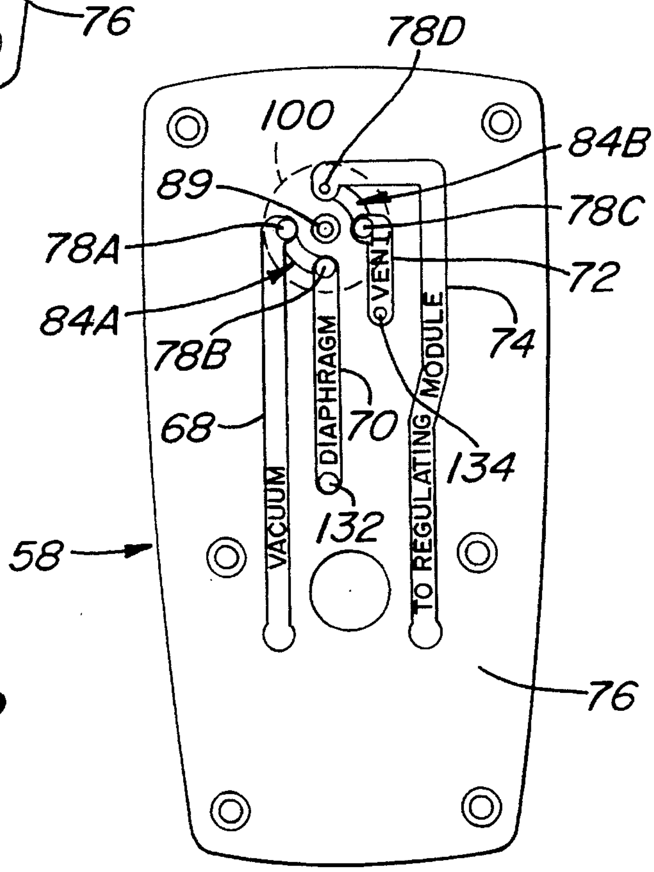


FIG. 12

OFF STATE

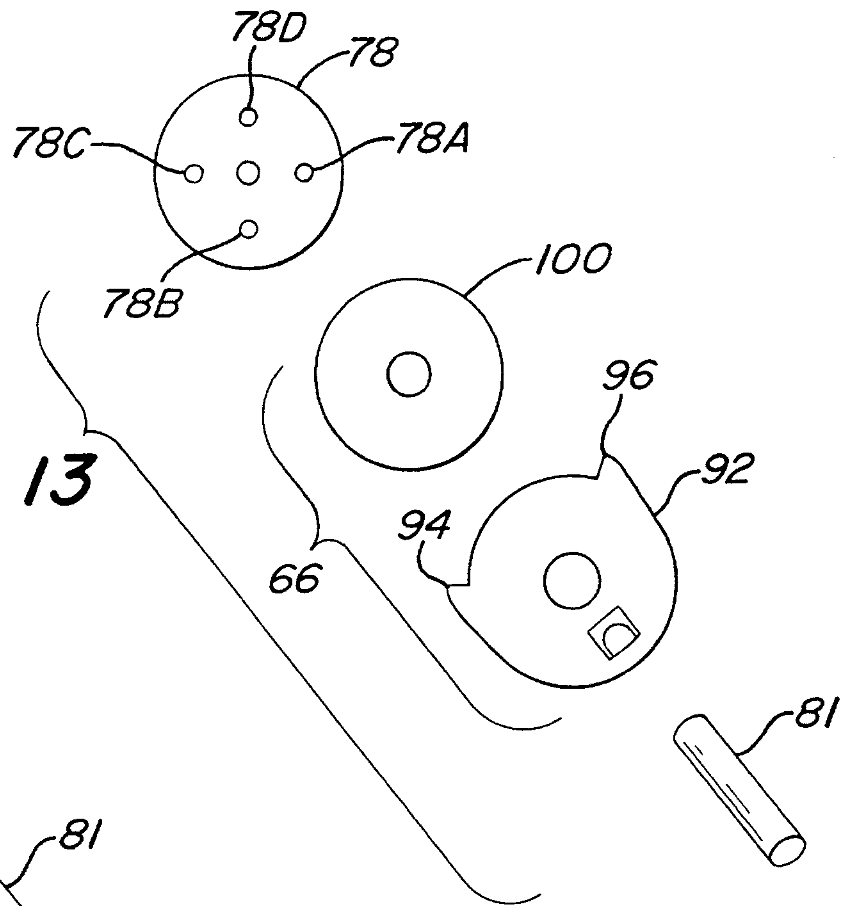

78D
78
78C
78A
78B
100
96
92
94
66
81

FIG. 13

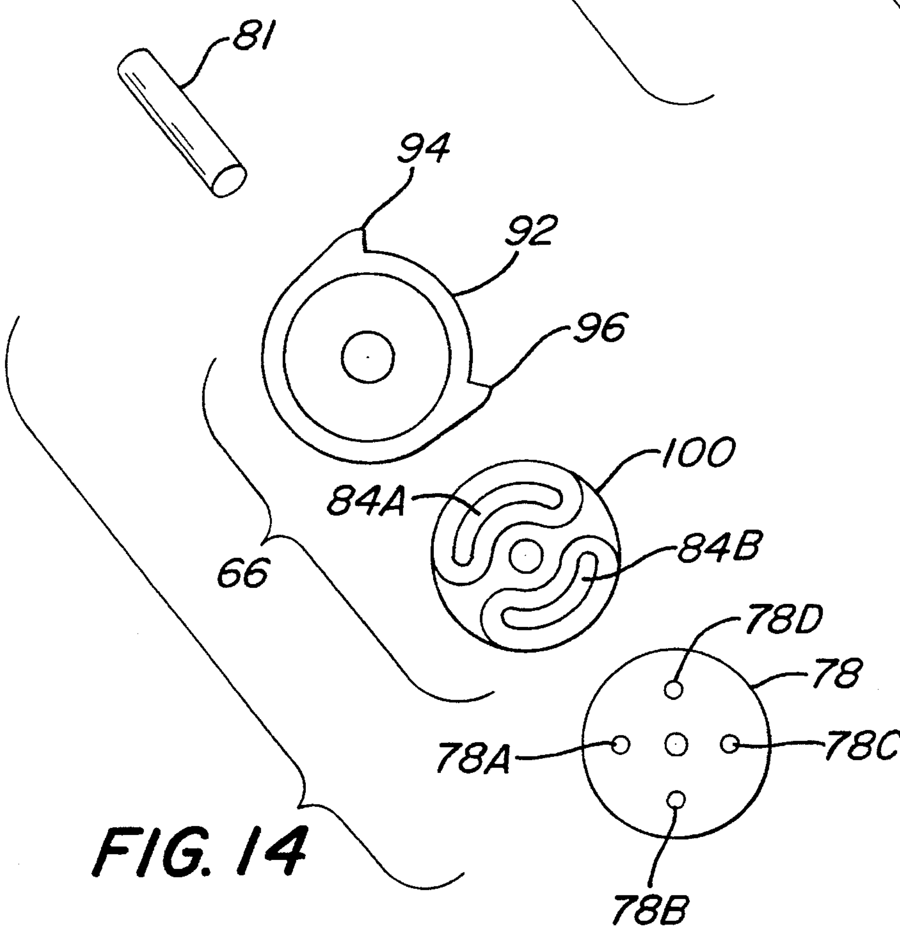

81
94
92
96
100
84A
84B
66
78D
78
78A
78C
78B

FIG. 14

INTERMITTENT VACUUM REGULATOR WITH TIMING MODULE

FIELD OF THE INVENTION

This invention relates generally to the field of medical pressure devices, more particularly, to an intermittent vacuum regulator that intermittently turns on the vacuum delivered through a catheter and intermittently turns off the vacuum on a regular timing cycle to permit the release of blockages.

BACKGROUND OF THE INVENTION

The aspiration of fluids from a patient is accomplished by providing a vacuum source through a catheter to the internal body area of the patient requiring aspiration. Typically, unregulated hospital vacuum line pressure is approximately between 19" to 25" of mercury (Hg.).

The use of vacuum regulators as medical devices is well known to achieve such aspiration of fluids. Generally such vacuum regulators are attached to a vacuum outlet in the wall of the patient's hospital room. Known vacuum suction regulators include a variable vacuum regulator, the vacuum gauge and a mechanical mechanism which cycles the vacuum on and off at predetermined timed intervals. Certain of these vacuum regulators are mechanical devices which use the vacuum source as a means of powering the cycling mechanism. Through practice it has been determined that a preferred off and on cycle is at such ratio that the vacuum regulator will be effective for twice the time that it is on as compared with the time that it is off. This two to one ratio is the ratio usually employed in currently available vacuum regulators even where this ratio can be varied as in an available intermittent vacuum regulators such as the one marketed under the name Vacutron sold by Allied Healthcare Products, Inc. of St. Louis, Mo.

Such known mechanical intermittent vacuum regulators achieve vacuum cycling by means of precise air flow into and out of an air chamber. In the Vacutron intermittent regulator there is a spring loaded mechanism in combination with a diaphragm assembly that controls the rotating valve. This mechanism is rather large and is not modular, i.e., failure of any of the springs, clevis arms, diaphragm, etc. requires the disassembly of the entire mechanism. A field service representative would either have to be called out or the faulty unit returned to the manufacturer for repair. Such a device allows the volume in the chamber to increase and decrease on a periodic basis. The diaphragm will be connected to a mechanism that cycles to the vacuum on and off. In order to control the on/off time periods two needle valves control the air flow into and out of the diaphragm. Problems arise with such known devices due to the fact that the on/off time periods are fairly long and the total air chamber volume is quite small. Therefore, in order to operate at such small flow rates, the valve openings themselves are also small. The small valve openings make the timing of the intermittent regulator sensitive to clogging by means of small dirt particles in the vacuum line.

There are other types of known mechanical intermediate vacuum regulators which utilize vacuum as a means to power the regulators. However, they are operated by a pneumatic logic type system. Such devices are also subject to becoming clogged by means of small dirt particles.

OBJECTS OF THE INVENTION

Accordingly, it is the general object of this invention to provide an apparatus and a method of use which addresses the aforementioned needs.

It is a further object of this invention to provide a timing module that can operate from a varying vacuum line pressure of 19"–25" Hg.

Another object of the present invention is to provide an apparatus that avoids the complexity of prior devices and yet retains the essential functions of the prior devices as well as being easily serviced.

SUMMARY OF THE INVENTION

These and other objects of the present invention are achieved by providing an intermittent vacuum regulator with a timing module wherein the timing module is easily separated from the main body of the intermediate vacuum regulator. Such main body includes a main body housing which holds a vacuum gauge or vacuum indicating means as well as the mode switching and vacuum adjustment means. The timing module includes a needle valve to permit variation of the various 2:1 ratios.

The timing module is detachably secured to the main body housing and in the preferred embodiment includes a ceramic switching valve comprised of ceramic discs. There are two modes of operation, namely, an "off" mode (no vacuum to patient) and an "on" mode (which allows vacuum to patient).

During the "off" mode the vacuum is ported to a diaphragm assembly via the ceramic switching valve. In this mode the vacuum also evacuates the diaphragm chamber at a rate determined by a needle valve opening in the base of the diaphragm chamber. This has the effect of pulling down on the diaphragm to compress a spring. A push rod is provided and is connected to the diaphragm. In the "off" mode where the vacuum has evacuated the diaphragm chamber, the push rod moves downwardly and rotates a lever arm counterclockwise through a gear interconnect. There is a toggle spring which is connected to the lever arm. Once the two pivot points of the toggle spring at the lever arm and ceramic valve cross over the center line of each other, the ceramic valve will flip to the "on" mode.

During the "on" mode (vacuum to patient) the ceramic valve is positioned to port vacuum to the patient. The diaphragm chamber is then vented to atmosphere via the ceramic switching valve. The compressed diaphragm spring then pushes on the diaphragm which has the effect of pulling atmospheric air into the chamber at a rate determined by the needle valve opening. This allows the diaphragm to move upwardly. The push rod (attached to the diaphragm) also moves upwardly to rotate the lever arm clockwise by the gear interconnect. Once the two pivot points of the lever arm toggle spring and the ceramic valve cross over the center line of each other, the valve flips to the "off" mode.

An important feature of the invention is that the components of the timing module are mounted on a back plate which is secured to the main regulator housing by screws. Hospital personnel can easily remove these screws and replace the timing module in the event there is a problem in the operation of the intermittent regulator, such as clogged passageways. This is a significant improvement over prior art devices which would require sophisticated servicing.

DESCRIPTION OF THE DRAWINGS

Other objects and many of the attendant advantages of this invention will be readily appreciated as the same becomes better understood by reference to the following detailed description when considered in connection with the accompanying drawings wherein:

FIG. **1** is a front view showing the front face of the vacuum regulator of the present invention;

FIG. **2** is a cross-sectional side view of the present invention;

FIG. **3** is a plan view of the timing module portion of the present invention;

FIG. **4** is a phantom view of the pneumatic coupling portion of the timing module when the mode select switch in the OFF mode;

FIG. **5** is a phantom view similar to FIG. **4** when the mode select switch in the REGULATE mode;

FIG. **6** is a phantom view similar to FIG. **4** when the mode select switch in the INTERMITTENT mode;

FIG. **7** is an enlarged plan view of the timing module;

FIG. **8** is a cross-sectional side view of the timing module;

FIG. **9** is a cross-sectional view of the diaphragm assembly when ambient pressure is ported therein;

FIG. **10** is a cross-sectional view of the diaphragm assembly when vacuum is ported therein;

FIG. **11** is a plan view of the back plate of the timing module depicting ambient pressure flow to the diaphragm assembly of FIG. **9**; and

FIG. **12** is a plan view of the back plate of the timing module depicting vacuum flow to the diaphragm assembly of FIG. **10**.

FIGS. **13** and **14** are views respectively showing the valve disk **78**, rotatable valve coupler **100** and the circular valve housing **92** in operative spaced relation to each other and taken from a first side and a second side.

DESCRIPTION OF THE PREFERRED EMBODIMENT OF THE INVENTION

Referring now in greater detail to the various figures of the drawing wherein like reference characters refer to like parts, an intermittent vacuum regulator (hereinafter "IVR") with timing module constructed in accordance with the present invention is shown generally at **20** in FIG. **1**.

The face plate **22** of the IVR **20** comprises a vacuum gauge **24** and a control knob **26**. As shown in FIG. **2**, the control knob **26** comprises a mode select switch **28** and a regulator adjusting knob **30**. The mode select switch **28** has three settings (OFF, REGULATE, INTERMITTENT) that totally shuts off the vacuum (OFF), or permits the user to select a particular vacuum level (REGULATE) or intermittently turns the vacuum on and off at a 2:1 ratio (INTERMITTENT). Setting the mode select switch **28** to the REGULATE mode delivers a regulated vacuum (to a level set by the regulator adjusting knob **30** as indicated on the gauge **24**) on a continuous basis to the patient. Setting the mode select switch **28** to the INTERMITTENT mode delivers a regulated vacuum on an intermittent basis to the patient.

As shown more clearly in FIG. **2**, the IVR **20** basically comprises a gauge module **32**, a switching module **34** that houses a regulating module **36** controlled by the control knob **26**, and a timing module **38** that couple to a main casting **40**. An input vacuum line (not shown) delivers hospital vacuum (19" to 25" Hg.) to the IVR **20** via an inlet coupling **42**. Regulated vacuum, whether continuous or intermittent, is then delivered to the patient from an outlet coupling **44** via an output line (not shown). As shown in

FIGS. **4–6**, selection by the user, via the mode select switch **28**, of one of the three modes (OFF, REGULATE, INTERMITTENT) causes the inlet coupling **42** to be coupled to no port (FIG. **4**, OFF mode), to a regulator input port **46** (FIG. **5**, REGULATE mode), or to the timing module **38** (FIG. **6**, INTERMITTENT mode) which then feeds the hospital vacuum to the regulator input port **46**.

In particular, the port holes **48**A, **48**B and **48**C are located in a seal cap **50** (FIG. **2**), driven by the mode select switch **28**, that aligns the inlet coupling **42** accordingly. In the OFF mode (FIG. **4**), the inlet coupling **42** is not coupled to the regulator input port **46** and as such no vacuum is being delivered to the patient. In the REGULATE mode (FIG. **5**), the inlet coupling **42** is directly coupled to the regulator input port **46** by a coupling **52**A, with the port hole **48**B being aligned with the inlet coupling **42**, thereby delivering hospital vacuum to the regulating module **36**. In the INTERMITTENT mode (FIG. **6**), the inlet coupling **42** is coupled to a vacuum input port **54** of the timing module **38** by a coupling **52**B and the vacuum outlet port **56** of the timing module **38** is coupled to the regulator input port **46** by the coupling **52**A, thereby delivering an intermittent hospital vacuum to the regulating module **36**.

It should be understood that when the INTERMITTENT mode is selected, the timing module **38** (as will be discussed in detail later) converts the continuous hospital vacuum into an intermittent vacuum having an ON time (i.e., vacuum is "on") that is twice the OFF time (i.e., vacuum is "off"). Once this intermittent vacuum is created by the timing module **38**, the intermittent vacuum is then fed to the regulating module **36** via the regulator input port **46**, where the ON portion of the intermittent vacuum is regulated to a level that is set by the regulator adjusting knob **30**. Therefore, any subsequent reference that states that the intermittent vacuum is delivered to the patient implies that the intermittent vacuum is actually communicated to the regulating module **36** where the ON portion of the intermittent vacuum is regulated to the level set by the regulator adjusting knob **30** and then delivered to the patient.

It should also be noted at this point that the generation of a continuous regulated vacuum is well-known in the art and as such will not be discussed hereinafter. However, the generation of an intermittent vacuum, described in the manner set forth below, that is then regulated is the novel aspect of the IVR **20**.

The timing module **38** is operative only when the user selects the INTERMITTENT setting of the mode select switch **28**. As can be seen in FIGS. **7–8**, the timing module **38** comprises a base plate **58** having a front side **60** that supports a diaphragm assembly **62**, valve control means **64** and valve means **66**. The back side (FIGS. **11** and **12**) of the base plate **58** contains a vacuum channel **68**, a diaphragm channel **70**, a vent channel **72** and a regulator channel **74**. It should be understood that a gasket **76**, having the same shape as the back side of the base plate **58** and with channels corresponding to channels **68–74**, is fixedly secured to the back side of the base plate **58**. When the timing module **38** is installed in the IVR **20**, the gasket **76** is in contact with the main casting **40** to form a tight seal.

In addition, there are four port holes of a valve disk **78** that are in pneumatic communication with the valve means **66**. The valve disk **78** is fixedly secured within the base plate **58**. Port hole **78**A is an outlet for the vacuum channel **68**, port hole **78**B is an inlet hole to the diaphragm assembly **62**, port hole **78**C is outlet hole for ambient pressure and port hole **78**D is an inlet hole to the patient channel **74**; port hole **78**D comprises an 8 liters/minute restrictor. It should be noted that when the timing module **38** is coupled to the IVR **20**, the vacuum input port **54** (FIGS. **4–6**) is disposed directly over the lower end **80** of the vacuum channel **68**, thereby bringing hospital vacuum into the timing module **38** via the vacuum channel **68**; moreover, the vacuum output port **56** (FIGS. **4–6**) is disposed directly over the lower end **82** of the regulator channel **74**, thereby providing the intermittent vacuum to the regulator input port **46**.

The intermittent "ON/OFF" cycle is established when the valve means **66** couples the four port holes (**78**A–**78**D) of the valve disk **78** in particular pairs. In particular, during the "ON" portion of the intermittent cycle (FIG. **9**), the valve means **66** comprises a rotatable valve coupler **100** having a first coupling **84**A (FIG. **11**) that operates to couple port hole **78**A to port hole **78**D and has a second coupling **84**B that operates to couple port hole **78**B to port hole **78**C; this coupling action delivers vacuum to the patient while porting the diaphragm assembly **62** to ambient pressure. As shown in FIG. **14**, the valve disk **78** has a face in contact with the couplings **84**A and **84**B of the valve coupler **100**. During the "OFF" portion of the intermittent cycle (FIG. **10**), the first coupling **84**A (FIG. **12**) operates to couple port hole **78**A to port hole **78**B while the second coupling **84**B operates to couple port hole **78**C to port hole **78**D; this coupling action ports vacuum to the diaphragm assembly **62** while delivering ambient pressure to the patient (i.e., shutting off the vacuum to the patient). Thus, as will be discussed in detail later, the valve means **66** is always in either one of two states: an ON state, where port holes **78**A and **78**D are coupled together and port holes and **78**B and **78**C are coupled together; an OFF state, where port holes **78**A and **78**B are coupled together and port holes **78**C and **78**D are coupled together. The valve control means **64**, in combination with the diaphragm assembly **62**, act to cycle the valve means **66** between the ON/OFF states at a rate that is always in the ratio of 2:1 (i.e., the vacuum is delivered to the patient for twice the time that it is off). As will also be discussed later, the actual ON/OFF times can be varied by the user (e.g., 5 seconds ON/2.5 seconds OFF, 8 seconds ON/4 seconds OFF, 16 seconds ON/8 seconds OFF) but these ON/OFF times are always in the ratio of 2:1.

The valve control means **64** (FIGS. **7** and **8**) comprises a push rod **86** and a geared lever arm **88** (e.g., a pinion gear having a portion of its circumference integral with a lever arm) coupled to a lever arm) that are coupled in a worm gear fashion. Downward vertical displacement of the push rod **86** causes the geared lever arm **88** to rotate in a counterclockwise direction about an axis **85** while upward vertical displacement of the push rod **86** causes the geared lever arm **88** to rotate in a clockwise direction. The rotation of the geared lever arm **88** is transferred to the valve means **66** by a bushing **81** that is directly coupled between the geared lever arm **88** and the circular valve housing **92**, to be discussed below. Vertical displacement of the push rod **86** is controlled by the diaphragm assembly **62** as will be discussed later. A rod bracket **90** ensures that the push rod **86** displacement is entirely vertical with no tilting. (It should be noted that the bushing **81** (FIGS. **13–14**) is hidden from view in FIG. **8** since it is located inside a load spring **83**.)

The valve means **66** (FIGS. **13–14**) comprises a ceramic circular housing **92** (FIGS. **9**, **10**, **13** and **14**) having a first stop **94** and a second stop **96** located at predetermined positions on the periphery of the housing **92**. These stops **94** and **96** alternately engage a base plate stop **98** that is secured to the front side **60** (FIG. **7**) of the base plate **58**. Permanently secured within the housing **92** is the circular valve coupler **100** (FIGS. **13–14**) that includes the first coupling **84**A (FIG. **14**) and the second coupling **84**B (FIG. **14**). Hence, the housing **92**/valve coupler **100** rotate together as a unit as determined by the rotation of geared lever arm **88** about the axis **85**. The predetermined positions of the stops **94** and **96** along the periphery of the housing **92** are designed to position the first coupling **84**A and the second coupling **84**B over the corresponding port holes **78**A–**78**D, as discussed previously. Thus, during the ON portion of the intermittent cycle, the stop **94** is in contact with the base plate stop **98** (FIG. **9**). During the OFF portion of the intermittent cycle, the stop **96** is in contact with the base plate stop **98** (FIG. **10**). As stated above a bushing **81** (FIGS. **13–14**) directly couples the geared lever arm **88** to the valve means **66**. Therefore, as the geared lever arm **88** rotates about the axis **85**, the bushing **81** allows the valve means **66** to rotate about the same axis **85**. Both the valve control means **64** and the valve means **66** are rotatably secured along the axis **85** by, among other things, a screw **87** that is inserted in an opening **89** (FIGS. **11–12**) through the valve means **66**, through the bushing **81**, through the geared lever arm **88** and then secured by a nut **91**.

The counterclockwise/clockwise motion of the lever arm **88** is what controls the valve means **66**. In particular, a toggle spring **102** comprises spring arms **104**A and **104**B (FIG. **10**). The spring arm **104**A is coupled to the lever arm tip **106** (FIG. **8**), forming a pivot point **107**, (FIGS. **9–10**), and the spring arm **104**B is coupled to the ceramic circular housing **92** via a catch **108**, forming a pivot point **109**. The toggle spring **102**, in combination with the stops **94/96** contacting the base plate stop **98**, cause the valve means **66** to "snap" or "flip" into the ON state or into the OFF state. Hence, there is no in-between state of the valve means **66**. As the lever arm **88** rotates either in a clockwise motion or in a counterclockwise motion, once the spring arm **104**A (attached to the pivot point **107**) and the spring arm **104**B (attached to the pivot point **109**) cross over the center line of each other, the valve means **66** flips to the OFF state or to the ON state, respectively.

The diaphragm assembly **62** controls the vertical displacement of the push rod **86**. As shown in FIG. **7**, the diaphragm assembly **62** comprises a housing **110**, a spring **112**, an insert **114**, a rolling diaphragm **116**, an inner plate **118**, an outer plate **120**, a cover **122** and a needle valve **124**. One end of the push rod **86** is secured within the threaded insert **114** which in turn is seated within the inner plate **118**. The inner plate **118** is disposed on top of the spring **112**. The other end of the spring **112** is secured around a boss **126** on the bottom of the housing **110**. The rolling diaphragm **116** is disposed over top of the inner plate **118**; the edges of the rolling diaphragm **116** are secured in a shoulder **128** that encompasses the inside periphery of the housing **110**. The rolling diaphragm **116** is sandwiched between the inner plate **118** and the outer plate **120**. The push rod **86** is secured to the outer plate **120** with a nut **130**. The cover **122** forms an air tight seal around the edges of the rolling diaphragm **116** against the shoulder **128**. Thus, the timing rod **86**, the insert **114**, the inner plate **118**, the rolling diaphragm **116** and the outer plate **120** form a vertically-displaceable assembly that is driven by the pressure present within the housing **110** against an upward biasing force of the spring **112**.

The needle valve **124** (FIG. **8**) controls the rate at which the vacuum evacuates the diaphragm assembly. In particular, a diaphragm assembly input port hole **132** (FIGS. **11** and **12**) at one end of the diaphragm channel **70** is coupled to the needle valve **124** (FIG. **8**) through the base plate **58**. Hence, when the valve means **66** is positioned in the OFF state, the vacuum is ported to the diaphragm assembly **62** and the position of the needle valve **124** controls the rate of evacuation by the vacuum. On the other hand, when the valve means **66** is in the ON state, the diaphragm channel **70** is coupled to the vent channel **72** which has an ambient pressure port hole **134** that brings ambient pressure into the diaphragm assembly **62** also through the needle valve **124**; this permits the vertically-displaceable assembly to move upward in the direction of the bias from the spring **112**. A porous filter (not shown) is included at the input port hole **132** to filter out, and thereby prevent, any blockage of the needle valve **124**; this porous filter does not affect the operation of the vacuum/vent flows.

In a preferred embodiment of the timing module **38**, the dimensions/characteristics of the following components of the timing module **38** determine the 2:1 timing ratio:

- length of the geared lever arm **88**, from the center line of the gear (of geared lever arm **88**) to the center line of the pivot point **107**: 0.710";
- a 0.384" diameter gear (of geared lever arm **88**) with 30° gear spacing interfaced with a 0.300" diameter push rod **86**;
- distance from the center line of the circular valve housing **92** to the center line of the pivot attachment point **109**: 0.339";
- strength of the toggle spring **102** (from the center line of the pivot point **107** to the center line of the pivot point **109**): 0.900" made from 0.024" diameter stainless steel wire having a diameter of 0.250" consisting of 5 coils;
- an average approximate volume of the diaphragm assembly housing **110**: 1.2 inches^3;
- the spring **112** (inside the diaphragm assembly housing **110**) having a free length of 1.325" with an outside diameter of 0.500" comprising a stainless steel wire of a 0.035" diameter consisting of 5½ coils;
- rolling diaphragm **116** being of a material thickness of 0.018" in a nominal rectangular configuration of 1.830"×0.720".

Operation of the timing module **38** is as follows: During the OFF state, (i.e., FIG. **10**, no vacuum to the patient), the vacuum is ported to the diaphragm assembly **62** via the valve means **66**, thereby causing the vertically-displaceable assembly to move downward in the direction indicated by the arrow **136**. The vacuum evacuates the diaphragm assembly **62** at a rate determined by the needle valve **124** opening and pulls down on the rolling diaphragm **116**, thereby compressing the spring **112**. The push rod **86** which is connected to the rolling diaphragm **116** moves downward and rotates geared lever arm **88** counterclockwise. Once the two pivot points of the toggle spring **102** cross over the center line of each other, the valve means **66** flips to the ON state.

During the ON state (FIG. **9**, i.e., vacuum is being delivered to the patient), the valve means **66** is positioned to port the vacuum to the regulating module **36**. The diaphragm assembly **62** is then vented to ambient pressure, thereby causing the vertically-displaceable assembly to move in the direction indicated by the arrow **138**. The compressed spring **112** within the diaphragm assembly **62** then pushes on the rolling diaphragm **116** and pulls ambient pressure air into the diaphragm assembly **62** at a rate determined by the needle

valve **124** opening, thereby allowing the rolling diaphragm **116** to move upward. The push rod **86** is therefore driven upward and rotates the geared lever arm **88** clockwise. Once the two pivot points of the toggle spring **102** cross over the center line of each other, the valve means **66** flips to the OFF state.

It should be noted that the user can vary the length of time of the ON and OFF state by adjusting the needle valve **124** (e.g., 5 seconds ON/2.5 seconds OFF, 8 seconds ON/4 seconds OFF, 16 seconds ON/8 seconds OFF). However, the valve control means **64** (i.e., the push rod **86**, geared lever arm **88**, toggle spring **102**, etc.) and the diaphragm assembly **62** (i.e., the toggle spring **102**, the spring **112**, the rolling diaphragm **116**, etc.) are designed to fix the ON/OFF states at a 2:1 ratio.

Without further elaboration, the foregoing will so fully illustrate my invention that others may, by applying current or future knowledge, readily adopt the same for use under various conditions of service.

I claim:

1. An intermittent vacuum regulator having a timing module in combination with a valve means for controlling the position of said valve means between one of two states, said module comprising:

- a base plate having a plurality of channels and apertures for conveying vacuum pressure in a first state or ambient state in a second state;
- a diaphragm assembly coupled thereto;
- a gear coupled to a lever arm that is in contact with said valve means;
- said diaphragm assembly having a diaphragm, coupled to said gear, that is exposed to a vacuum source and ambient pressure alternately said diaphragm disposed within said diaphragm assembly to form a movable wall of said diaphragm assembly, said alternating exposure causing said gear to move in a first direction or a second direction, respectively, movement in said first direction defining an off time and movement in said second direction defining an on time and also defining a timing ratio.

2. The timing module of claim **1** wherein said valve means comprises a stationary disk having a plurality of apertures coupled to respective channels in said base plate.

3. The timing module of claim **2** wherein said valve means further comprises a housing including a circular valve having couplings attached thereto, said housing being rotatable to pneumatically couple said plurality of apertures of said stationary disk in respective pairs.

4. The timing module of claim **1** wherein said timing ratio is defined as 2:1.

5. The timing module of claim **1** being modular to permit the removal of said timing module from the intermittent vacuum regulator and the replacement of said timing module with another timing module within the intermittent vacuum regulator.

6. The timing module of claim **1** further comprising a needle valve coupled to said diaphragm assembly, said needle valve permitting the establishment of a plurality of 2:1 ratios.

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