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(54) **Title:** PRESSURE MONITOR FOR PNEUMATIC VITRECTOMY MACHINE

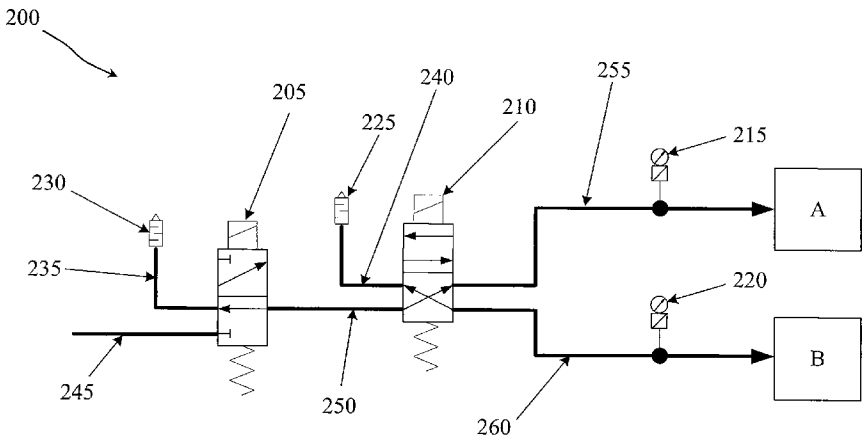


Fig. 2

(57) **Abstract:** A system for a pneumatically-powered vitrectomy machine includes an output port, a venting valve, a venting manifold, a pressure transducer, and a controller. The output port provides pressurized gas to a vitrectomy probe. The venting valve is located close to the output port. The venting manifold fluidly connects the venting valve to a venting port. The venting port vents pressurized gas from the venting manifold. The pressure transducer is located near the output port. The pressure transducer is configured to read a pressure of a gas near the output port. The controller is adapted to receive information about the pressure and activate the venting valve. When the information received from the pressure transducer indicates a fault condition, the controller directs the venting valve to open.

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UNITED STATES PATENT APPLICATION

FOR

Pressure Monitor for Pneumatic Vitrectomy Machine

by

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FIELD OF INVENTION

The present invention relates to a pneumatic module for a surgical machine and more particularly to a monitor and gas release valve located near the output end of a vitrectomy machine.

BACKGROUND OF THE INVENTION

Several conditions of the eye threaten sight. Epiretinal membrane (ERM), also known as macular pucker and cellophane retinopathy, is a condition characterized by growth of a membrane across the macula, or central retina of the eye. This condition may be thought of as the growth of scar tissue across the macula, thus interfering with central vision. The ERM typically contracts, causing distortion of the central retina, thus producing distortion of vision. Most patients will note that either straight objects appear wavy and crooked and/or central vision is reduced, depending on the severity of the condition.

Epiretinal membranes may be associated with other conditions of the eye, however, the large majority are idiopathic, which means that the cause is unknown. Some of the disorders which are occasionally associated with ERM's include previous retinal detachments and surgery thereof, inflammatory conditions (uveitis), retinal tears, and branch retinal vein occlusion (BRVO) and central retinal vein occlusion (CRVO).

Another condition is a macular hole. A macular hole is almost always a spontaneous development that occurs predominantly in aging women. The development of a macular hole progresses through several stages, and with each progressive stage the vision may worsen. It has been postulated that shrinkage of the vitreous humor may produce traction on the fovea (central macula), thereby producing the hole itself. However, the cause of macular holes remains under investigation.

The retina, which lines the inside of the posterior wall of the eye, may occasionally become detached for various reasons. Most commonly, retinal detachment occurs as a result of a tear or hole in the retina, which develops as a result of a posterior vitreous separation (PVS). The retinal tear or hole allows fluid to enter the subretinal space, thus detaching the retina.

The retina receives oxygen and nutrients from the underlying choroid (vascular layer) of the eye. When a retinal detachment occurs, the detached retina begins to dysfunction, and ultimately, necrosis (death) ensues as a result if the retina is not reattached to the underlying choroid. As such, a retinal detachment is an urgent condition. The detached retina should be recognized and treated promptly.

Vitreo-retinal procedures may be appropriate to treat these and other serious conditions of the back of the eye. Vitreo-retinal procedures include a variety of surgical procedures performed to restore, preserve, and enhance vision. Vitreo-retinal procedures treat conditions such as age-related macular degeneration (AMD), diabetic retinopathy and diabetic vitreous hemorrhage, macular hole, retinal detachment, epiretinal membrane, CMV retinitis, and many other ophthalmic conditions.

The vitreous is a normally clear, gel-like substance that fills the center of the eye. It makes up approximately 2/3 of the eye's volume, giving it form and shape before birth. Certain problems affecting the back of the eye may require a vitrectomy, or surgical removal of the vitreous.

A vitrectomy may be performed to clear blood and debris from the eye, to remove scar tissue, or to alleviate traction on the retina. Blood, inflammatory cells, debris, and scar tissue obscure light as it passes through the eye to the retina, resulting in blurred vision. The vitreous is also removed if it is pulling or tugging the retina from its normal position. Some of the most common eye conditions that require vitrectomy include complications from diabetic retinopathy such as retinal detachment or bleeding, macular hole, retinal detachment, pre-retinal membrane fibrosis, bleeding inside the eye (vitreous hemorrhage), injury or infection, and certain problems related to previous eye surgery.

The retinal surgeon performs a vitrectomy with a microscope and special lenses designed to provide a clear image of the back of the eye. Several tiny incisions just a few millimeters in length are made on the sclera. The retinal surgeon inserts microsurgical instruments through the incisions such as a fiber optic light source to illuminate inside the eye, an infusion line to maintain the eye's shape during surgery, and instruments to cut and remove the vitreous.

In a vitrectomy, the surgeon creates three tiny incisions in the eye for three separate instruments. These incisions are placed in the pars plana of the eye, which is located just behind the iris but in front of the retina. The instruments which pass

through these incisions include a light pipe, an infusion port, and the vitrectomy cutting device. The light pipe is the equivalent of a microscopic high-intensity flashlight for use within the eye. The infusion port is required to replace fluid in the eye and maintain proper pressure within the eye. The vitrector, or cutting device, works like a tiny guillotine, with an oscillating microscopic cutter to remove the vitreous gel in a controlled fashion. This prevents significant traction on the retina during the removal of the vitreous humor.

The surgical machine used to perform a vitrectomy and other surgeries on the posterior of the eye is very complex. Typically, such an ophthalmic surgical machine includes a main console to which numerous different tools are attached. The main console provides power to and controls the operation of the attached tools.

The attached tools typically include probes, scissors, forceps, illuminators, and infusion lines. Each of these tools is typically attached to the main surgical console. A computer in the main surgical console monitors and controls the operation of these tools. These tools also get their power from the main surgical console. Some of these tools are electrically powered while others are pneumatically powered.

In order to provide pneumatic power to the various tools, the main surgical console has a pneumatic or air distribution module. This pneumatic module conditions and supplies compressed air or gas to power the tools. Typically, the pneumatic module is connected to a cylinder that contains compressed gas. Most commonly, surgeons use cylinders of nitrogen at 3600 psi. The condition and output of these cylinders affect the operation of the surgical machine.

The proper gas pressure must be provided by the pneumatic module to the tools in order to insure their proper operation. Providing too high a gas pressure can lead to operational problems. Too high a pressure can damage equipment or lead to a malfunction during surgery. In either case, the instrument itself may be damaged.

It would be desirable to incorporate a gas pressure system in an ophthalmic surgical machine to protect the equipment.

SUMMARY OF THE INVENTION

In one embodiment consistent with the principles of the present invention, the present invention is a system for a pneumatically-powered vitrectomy machine. The system includes a first output port, a venting valve, a first venting manifold, a first pressure transducer, and a controller. The first output port provides pressurized gas to a vitrectomy probe. The venting valve is located close to the first output port. The first venting manifold fluidly connects the venting valve to a first venting port. The first venting port vents pressurized gas from the first venting manifold. The first pressure transducer is located near the first output port. The first pressure transducer is configured to read a first pressure of a gas near the first output port. The controller is adapted to receive information about the first pressure and activate the venting valve. When the information received from the first pressure transducer indicates a fault condition, the controller directs the venting valve to open.

In another embodiment consistent with the principles of the present invention, the present invention is a system for a pneumatically-powered vitrectomy machine. The machine includes first and second output ports, first and second venting manifolds, first and second pressure transducers, an output valve, a venting valve, and a controller. The first and second output ports provide pressurized gas to a vitrectomy probe. The output valve directs pressurized gas to the first output port and the second output port. The venting valve is located close to the first output port and the second output port. The first venting manifold connects the venting valve to a first venting port. The first venting port vents pressurized gas from the first venting manifold. The second venting manifold connects the venting valve to a second venting port. The second venting port vents pressurized gas from the second venting manifold. The first pressure transducer is located near the first output port and is configured to read a first pressure of a gas near the first output port. The second pressure transducer is located near the second output port and is configured to read a second pressure of a gas near the second output port. The controller is adapted to receive information about the first pressure and the second pressure and activate the venting valve. When the information received from the first or second pressure transducer indicates a fault condition, the controller directs the venting valve to open.

In another embodiment consistent with the principles of the present invention, the present invention is a method of operating a pneumatically-powered vitrectomy machine. A first pressure of a gas near a first output port to which a vitrectomy probe is attached is monitored. A second pressure of a gas near a second output port to

which the vitrectomy probe is attached is monitored. A fault condition based on the first or second pressure is detected. A venting valve is opened after the fault condition has been detected.

It is to be understood that both the foregoing general description and the following detailed description are exemplary and explanatory only and are intended to provide further explanation of the invention as claimed. The following description, as well as the practice of the invention, set forth and suggest additional advantages and purposes of the invention.

BRIEF DESCRIPTION OF THE DRAWINGS

The accompanying drawings, which are incorporated in and constitute a part of this specification, illustrate several embodiments of the invention and together with the description, serve to explain the principles of the invention.

Figure 1 is a block diagram of a pneumatically-powered ophthalmic surgery machine according to an embodiment of the present invention.

Figure 2 is a schematic of a pressure monitor system for a pneumatically powered vitrectomy machine according to an embodiment of the present invention.

Figure 3 is a schematic of a portion of a pressure monitor system for a pneumatically powered vitrectomy machine according to an embodiment of the present invention.

Figure 4 is a flow chart of one method of operation according to an embodiment of the present invention.

DETAILED DESCRIPTION OF THE EMBODIMENTS

Reference is now made in detail to the exemplary embodiments of the invention, examples of which are illustrated in the accompanying drawings. Wherever possible, the same reference numbers are used throughout the drawings to refer to the same or like parts.

Figure 1 is a block diagram of a pneumatically powered ophthalmic surgical machine according to an embodiment of the present invention. In Figure 1, the machine includes gas pressure monitor system 110, proportional controller 120, proportional controller 130, and tools 140, 150, 160, and 170. The tools 140, 150, 160, and 170 can be, for example, scissors, vitrectomy probes, forceps, and injection or extraction modules. Other tools may also be employed with the machine of Figure 1.

As shown in Figure 1, gas pressure monitor system 110 is fluidly coupled via a manifold to proportional controller 120 and proportional controller 130. A single manifold may connect gas pressure monitor system 110 to proportional controller 120 and proportional controller 130, or two separate manifolds may connect gas pressure monitor system 110 to proportional controller 120 and proportional controller 130, respectively. Proportional controller 120 is fluidly coupled to tools 140 and 150 by, for example, a manifold and tubing. Likewise proportional controller 130 is fluidly coupled to tools 160 and 170 by, for example, a manifold and tubing.

In operation, the pneumatically powered ophthalmic surgery machine of Figure 1 operates to assist a surgeon in performing various ophthalmic surgical procedures, such as a vitrectomy. A compressed gas, such as nitrogen, provides the power for tools 140,150, 160, and 170. The compressed gas passes through gas pressure monitor system 110, through one or more manifolds to proportional controllers 120 and 130, and through additional manifolds and/or tubing to tools 140, 150, 160, and 170.

Gas pressure monitor system 110 functions to monitor the pressure of compressed gas from a gas source as it enters the machine. Proportional controllers 120 and 130 serve to distribute the compressed gas received from gas pressure monitor system 110. Proportional controllers 120 and 130 control the pneumatic power delivered to tools 140, 150, 160, and 170. Various valves, manifolds, and tubing are used to direct compressed gas from gas pressure monitor system 110,

through proportional controllers 120 and 130, and to tools 140, 150,160, and 170. This compressed gas actuates cylinders, for example, in tools 140, 150, 160, and 170.

Figure 2 is a schematic of a pressure monitor system for a pneumatically powered vitrectomy machine according to an embodiment of the present invention. In Figure 2, the pressure monitor system includes venting valve 205, output valve 210, pressure transducers 215 and 220, mufflers 225 and 230, venting manifolds 235 and 240, manifolds 245, 250, 255, and 260, and output ports A and B.

Venting manifold 235 fluidly connects venting valve 205 to muffler 230. Manifold 245 is also fluidly connected to venting valve 205. Venting valve 205 is fluidly connected to output valve 210 by manifold 250. Venting manifold 240 fluidly connects output valve 210 to muffler 225. Manifold 255 fluidly connects output valve 210 to output port A. Manifold 260 fluidly connects output valve 210 to output port B. Pressure transducer 215 is fluidly connected to manifold 255. Likewise, pressure transducer 220 is fluidly connected to manifold 260.

In the embodiment of Figure 2, venting valve 205 is a standard two-way valve. As is commonly known, the valve has a solenoid that operates to move the valve to one of the two positions depicted in Figure 2. As shown, the valve is in a venting position. Pressurized gas can pass from manifold 250, through venting valve 205, through venting manifold 235, and out of muffler 230. In the other position, venting valve 205 allows pressurized gas to pass from manifold 245, through venting valve 205, and into manifold 250 where it can provide power to the vitrectomy probe (not shown). Venting valve 205 is controlled by a controller (not shown).

Output valve 210 is a standard four-way valve. As is commonly known, the valve has a solenoid that operates to move the valve to one of the two positions depicted in Figure 2. As shown in Figure 2, the valve is in a position to provide pressurized gas to output port A, and to vent pressurized gas from output port B. In this position, pressurized gas can pass from manifold 250, through output valve 210, through manifold 255, and to output port A where the pressurized gas provides pneumatic power to a vitrectomy probe (not shown). Pressurized gas in manifold 260 can pass through output valve 210, venting manifold 240, and muffler 225 where it is exhausted to the atmosphere. In the other position, output valve 210 allows pressurized gas to pass from manifold 250, through output valve 210, through manifold 260, and to output port B where the pressurized gas provides pneumatic power to a vitrectomy probe (not shown). Pressurized gas in manifold 255 can pass

through output valve 210, venting manifold 240, and muffler 225 where it is exhausted to the atmosphere. Output valve 210 is controlled by a controller (not shown).

The vitrectomy probe (not shown) that is attached to output ports A and B acts as a cutting device. The cutter is moved by a cylinder that in turn is moved by pressurized gas. The cylinder oscillates as pressurized gas is alternately directed to output ports A and B. Such a vitrectomy device is designed to provide about 5,000 cuts per minute.

Pressure transducers 215 and 220 operate to read an atmospheric pressure of the gas contained in manifolds 255 and 260, respectfully. In other words, pressure transducer 215 reads the pressure of the compressed gas that is adjacent to it in manifold 255. Likewise, pressure transducer 220 reads the pressure of the compressed gas that is adjacent to it in manifold 260. In the embodiment of Figure 2, pressure transducers 215 and 220 are common pressure transducers. Pressure transducers 215 and 220 are capable of reading pressure of a compressed gas and sending an electrical signal containing information about the pressure of the compressed gas to a controller (not shown).

Manifolds 235, 240, 245, 250, 255, and 260 are all configured to carry compressed gas. In the embodiment of Figure 2, these manifolds are machined out of a metal, such as aluminum. These manifolds are air tight, contain various fittings and couplings, and are designed to withstand relatively high gas pressures. These manifolds maybe manufactured as individual pieces or they maybe manufactured as a single piece. For example, manifolds 235, 240, 245, 250, 255, and 260 may be machined from a single piece of aluminum.

Mufflers 225 and 230 are common mufflers designed to suppress the noise made by escaping gas. These mufflers are typically cylindrical in shape.

In operation, pressurized gas is directed alternately to output ports A and B to operate the vitrectomy probe. Venting valve 205 is operated in a position that allows pressurized gas to pass from manifold 245, through venting valve 205, and into manifold 250. Output valve 210 is alternated between its two positions very rapidly to provide pressurized gas to output ports A and B. In one position, pressurized gas can pass from manifold 250, through output valve 210, through manifold 255, and to output port A where the pressurized gas provides pneumatic power to a vitrectomy

probe (not shown). Pressurized gas in manifold 260 can pass through output valve 210, venting manifold 240, and muffler 225 where it is exhausted to the atmosphere. In the other position, output valve 210 allows pressurized gas to pass from manifold 250, through output valve 210, through manifold 260, and to output port B where the pressurized gas provides pneumatic power to a vitrectomy probe (not shown). Pressurized gas in manifold 255 can pass through output valve 210, venting manifold 240, and muffler 225 where it is exhausted to the atmosphere. Output valve 210 is controlled by a controller (not shown).

In this manner, pressurized gas is provided to output port A while pressurized gas in manifold 260 is allowed to vent through a venting port to which muffler 225 is attached. Likewise, pressurized gas is provided to output port B while pressurized gas in manifold 255 is allowed to vent through a venting port to which muffler 225 is attached. Due to the quick response of the output valve selected, pressurized gas can be alternated very quickly between manifolds 255 and 260. This allows the vitrectomy probe (not shown) to operate at very high cut rates of about 5,000 cuts per minute.

Pressure transducers 215 and 220 monitor the system for a fault condition. When a fault condition is detected in the vitrectomy probe, the pressurized gas is vented to prevent damage to the equipment. In this case, venting valve 205 is in the position shown in Figure 2. In this case, pressurized gas can pass from manifold 250, through venting valve 205, through venting manifold 235, and out of a venting port to which muffler 230 is attached. In the valve positions shown in Figure 2, pressurized gas in manifold 260 can pass through output valve 210, venting manifold 240, and out of a venting port to which muffler 225 is attached. Pressurized gas in manifold 255 can pass through output valve 210, manifold 250, venting valve 205, venting manifold 235, and out of a venting port to which muffler 230 is attached. If the output valve is in the other position, pressurized gas in manifold 255 can pass through output valve 210, venting manifold 240, and out of a venting port to which muffler 225 is attached. Pressurized gas in manifold 260 can pass through output valve 210, manifold 250, venting valve 205, venting manifold 235, and out of a venting port to which muffler 230 is attached.

As noted, pressure transducers 215 and 220 monitor the gas pressure in manifolds 255 and 260, respectively. Pressure transducers 215 and 220 detect fault conditions that may be present during the operation of the vitrectomy probe. In one fault condition, the gas pressure in one or both manifolds 215 and 220 may exceed a

threshold thereby posing a threat to the equipment. In such a case, the vitrectomy probe may be damaged.

The placement of venting valve 205 close to the output ports A and B allows gas to be quickly vented, effectively turning off the vitrectomy probe to prevent damage to the probe. In general, the faster the pressurized gas can be exhausted from the system in the event of a fault condition, the more likely it is that damage can be prevented.

Figure 3 is a schematic of a portion of a pressure monitor system for a pneumatically powered vitrectomy machine according to an embodiment of the present invention. In Figure 3, controller 300 and interfaces 305, 310, 315, and 320 are depicted along with venting valve 205, output valve 210, and pressure transducers 215 and 220.

In the embodiment of Figure 3, controller 300 receives pressure information from pressure transducers 215 and 220 via interfaces 305 and 310, respectively. In this manner, pressure transducer 215 is electrically coupled to controller 300 via interface 305, and pressure transducer 220 is electrically coupled to controller 300 via interface 310. Controller sends control signals to venting valve 205 and output valve 210 via interfaces 315 and 320, respectively.

Controller 300 is typically an intergraded circuit capable of performing logic functions. In this manner, controller 300 is in the form of a standard integrated circuit package with power, input, and output pins. In various embodiments, controller 300 is a valve controller or a targeted device controller. In such a case, controller 300 performs specific control functions targeted to a specific device, such as a valve. In other embodiments, controller 300 is a microprocessor. In such a case, controller 300 is programmable so that it can function to control valves as well as other components of the machine. In other cases, controller 300 is not a programmable microprocessor, but instead is a special purpose controller configured to control different valves that perform different functions.

Controller 300 is configured to receive signals from pressure transducer 215 via interface 305 and from pressure transducer 220 via interface 310. These signals, for example, correspond to readings of gas pressure in manifolds 255 and 260, respectively. Controller 300 is also configured to send output signals via interfaces 315 and 320 to venting valve 205 and output valve 210, respectively. These output

signals allow controller 300 to control the operation of venting valve 205 and output valve 210.

Interfaces 305 and 310 are designed to carry signals from pressure transducers 215 and 220 to controller 300. In this case, interfaces 305 and 310 are common electrical conductors such as wires. Likewise, interfaces 315 and 320 carry signals from controller 300 to venting valve 205 and output valve 210. Interfaces 305, 310, 315, and 320 may be one or more wires or buses designed to carry electrical or data signals.

Figure 4 is a flow chart of one method of operation according to an embodiment of the present invention. In Figure 4, one method of operating the pressure monitor system of Figures 2 and 3 is described. In 405, a fault condition is sensed by sensing a first and / or second gas pressure at a first and / or second output port of a vitrectomy probe. In 410, a determination is made as to whether a fault condition has been detected. If a fault condition has been detected, then in 415, a venting valve is opened, and in 420, and indication of the fault condition is provided. If a fault condition has not been detected in 410, then the method returns to 405.

The indication of a fault condition, which in some instances is a high gas pressure, can be provided visually or audibly. If visually, a light emitting diode may be illuminated, an indication may appear on a display, or a similar visual event may occur. If audibly, a warning sound may be emitted. Any other type of indication or combination of visual and audible indications may be provided in accordance with the various embodiments of the present invention.

From the above, it may be appreciated that the present invention provides an improved system and methods for monitoring the gas pressure in a pneumatic module of a vitrectomy machine. The present invention provides features designed to protect the equipment from harm due to high gas pressure. The present invention is illustrated herein by example, and various modifications may be made by a person of ordinary skill in the art.

Other embodiments of the invention will be apparent to those skilled in the art from consideration of the specification and practice of the invention disclosed herein. It is intended that the specification and examples be considered as exemplary only, with a true scope and spirit of the invention being indicated by the following claims.

WHAT IS CLAIMED IS:

1. A system for a pneumatically-powered vitrectomy machine comprising:

a first output port for providing pressurized gas to a vitrectomy probe;

a venting valve located close to the first output port;

a first venting manifold connecting the venting valve to a first venting port, the first venting port for venting pressurized gas from the first venting manifold;

a first pressure transducer located near the first output port, the first pressure transducer configured to read a first pressure of a gas near the first output port; and

a controller adapted to receive information about the first pressure and activate the venting valve;

wherein when the information received from the first pressure transducer indicates a fault condition, the controller directs the venting valve to open.

2. The system of claim 1 further comprising:

a second output port for providing pressurized gas to the vitrectomy probe.

3. The system of claim 1 further comprising:

a second venting manifold connecting the venting valve to a second venting port, the second venting port for venting pressurized gas from the second venting manifold.

4. The system of claim 1 further comprising:

a second pressure transducer located near the second output port, the second pressure transducer configured to read a second pressure of a gas near the second output port.

5. The system of claim 4 wherein when the information received from the second pressure transducer indicates a fault condition, the controller directs the venting valve to open.

6. The system of claim 1 further comprising a muffler attached to the first venting port.

7. The system of claim 1 wherein the fault condition is indicated by a high gas pressure.

8. The system of claim 1 wherein the output valve is located between the venting valve and the first output port.

9. The system of claim 8 wherein the output valve is a four-way valve and the venting valve is a two-way valve.

10. A system for a pneumatically-powered vitrectomy machine comprising:

a first output port for providing pressurized gas to a vitrectomy probe;

a second output port for providing pressurized gas to the vitrectomy probe;

an output valve for directing pressurized gas to the first output port and the second output port;

a venting valve located close to the first output port and the second output port;

a first venting manifold connecting the venting valve to a first venting port, the first venting port for venting pressurized gas from the first venting manifold;

a second venting manifold connecting the venting valve to a second venting port, the second venting port for venting pressurized gas from the second venting manifold;

a first pressure transducer located near the first output port, the first pressure transducer configured to read a first pressure of a gas near the first output port;

a second pressure transducer located near the second output port, the second pressure transducer configured to read a second pressure of a gas near the second output port; and

a controller adapted to receive information about the first pressure and the second pressure and activate the venting valve;

wherein when the information received from the first or second pressure transducer indicates a fault condition, the controller directs the venting valve to open.

11. The system of claim 10 further comprising a muffler attached to the first venting port.

12. The system of claim 10 wherein the fault condition is indicated by a high gas pressure.

13. The system of claim 10 wherein the output valve is located between the venting valve and the first output port.

14. A method of operating a pneumatically-powered vitrectomy machine comprising:

monitoring a first pressure of a gas near a first output port to which a vitrectomy probe is attached;

monitoring a second pressure of a gas near a second output port to which the vitrectomy probe is attached;

detecting a fault condition based on the first or second pressure; and

opening a venting valve after the fault condition has been detected.

15. The system of claim 14 wherein the fault condition is indicated by a high gas pressure.

16. The method of claim 14 further comprising:

providing an indication of the fault condition.

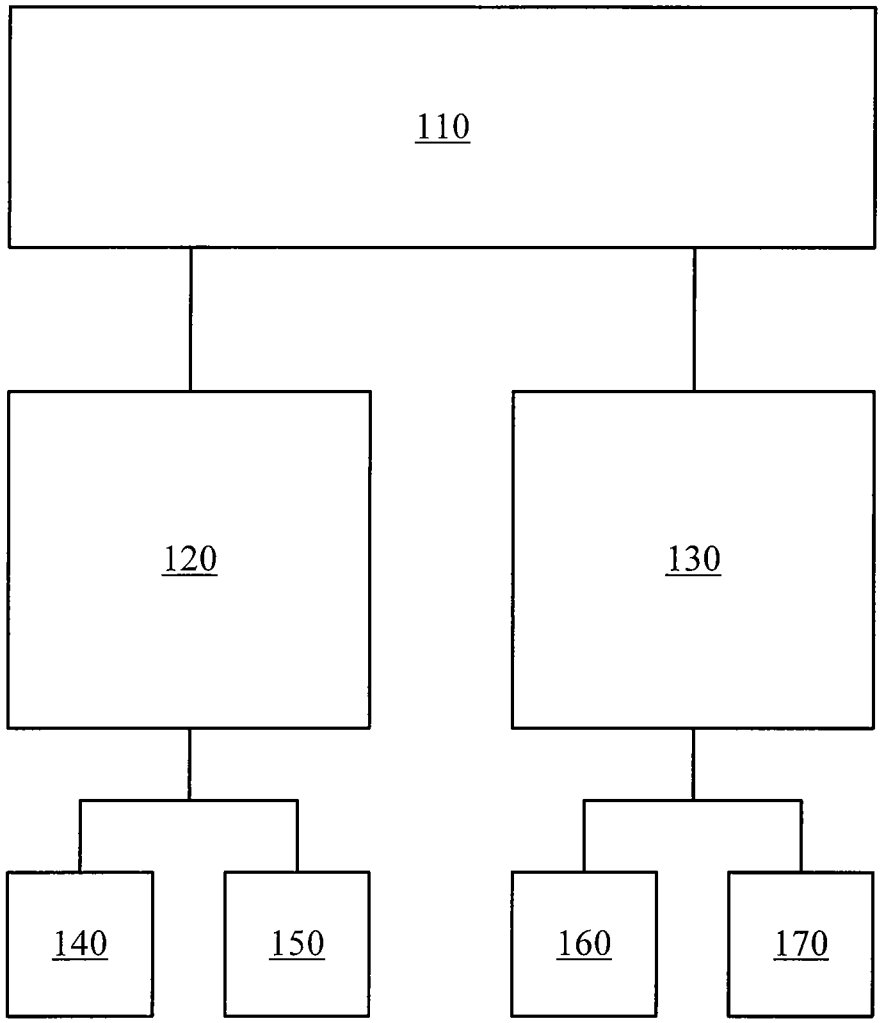


Fig. 1

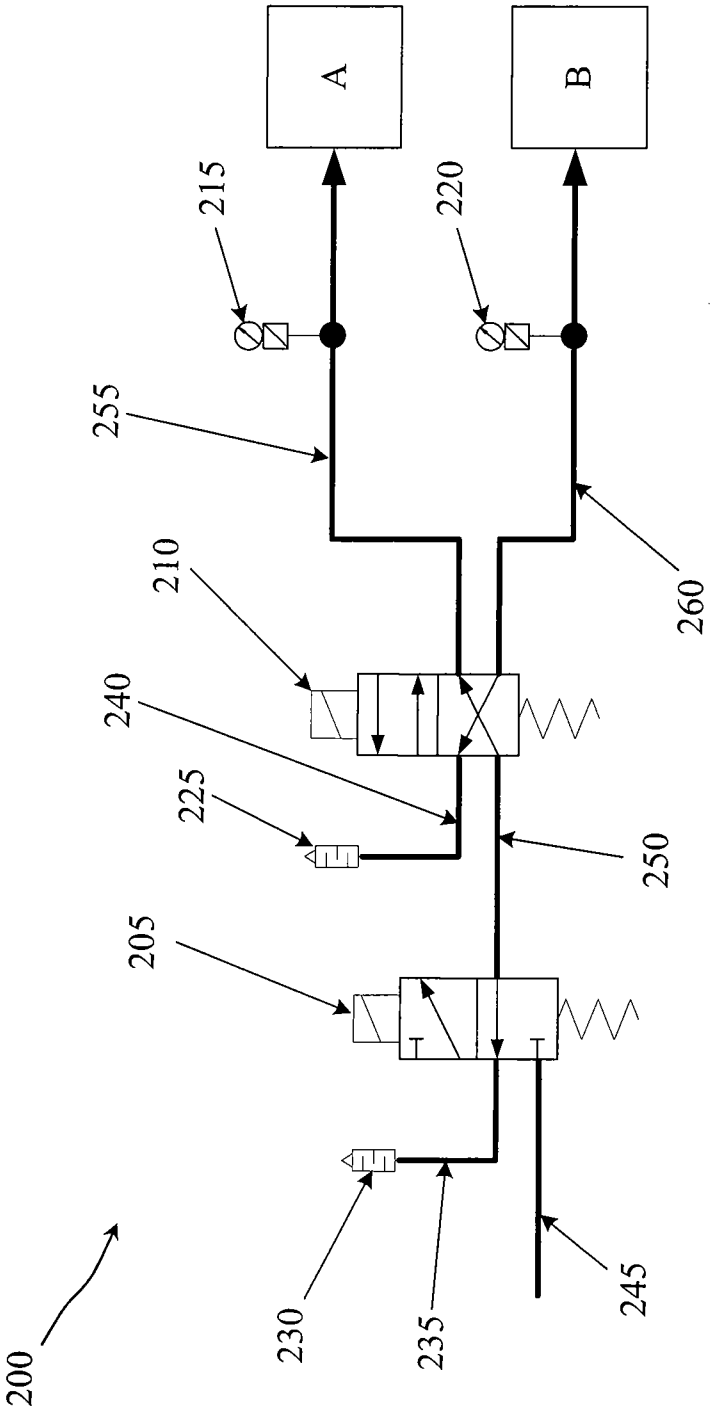


Fig. 2

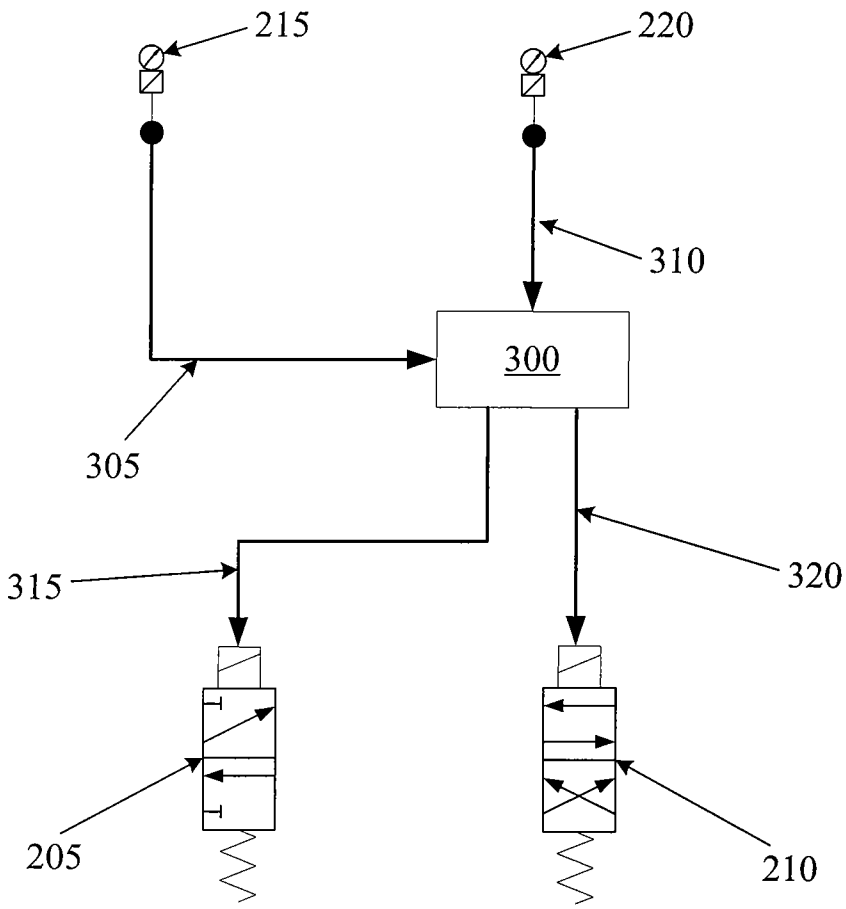


Fig. 3

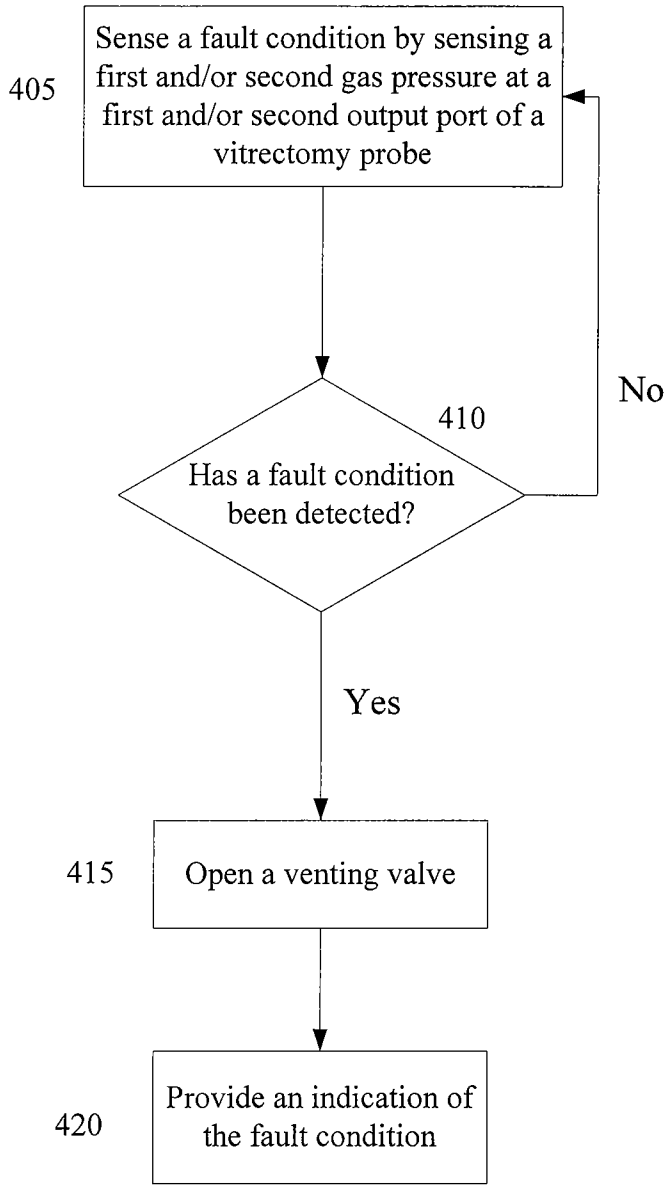

405
Sense a fault condition by sensing a first and/or second gas pressure at a first and/or second output port of a vitrectomy probe
410
Has a fault condition been detected?
No
Yes
415
Open a venting valve
420
Provide an indication of the fault condition

Fig. 4