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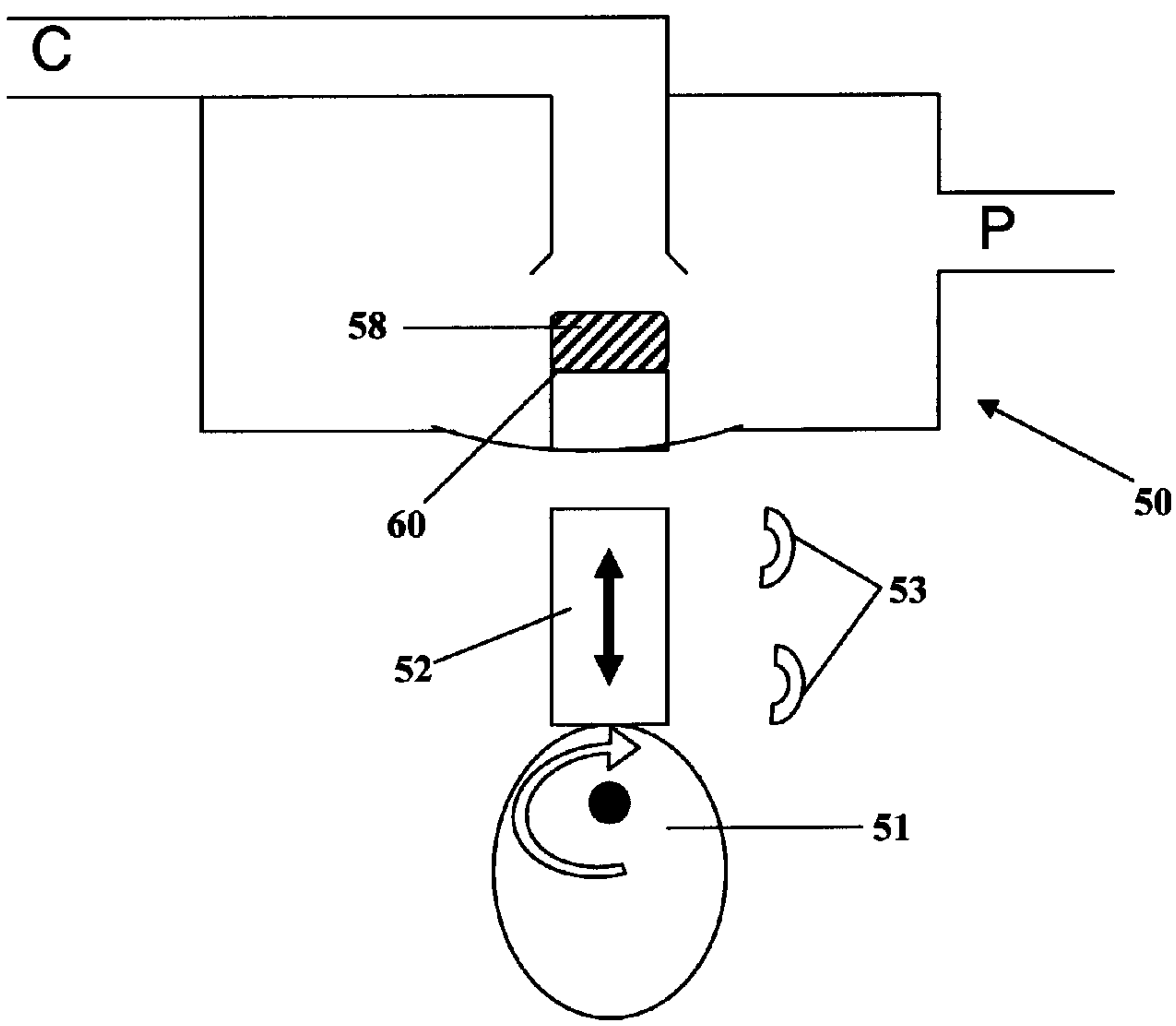
(54) Title: SYSTEM AND METHOD FOR PERITONEAL DIALYSIS



(57) Abrégé/Abstract:
The invention consists of a cartridge for a peritoneal dialysis (PD) system, comprising: a) a pressure-sealed cartridge containing a mixing chamber, an entrance chamber and a ballast chamber; b) one or more inlet/outlet ports in said entrance chamber, said ports being fully pressure-sealed when closed; c) a pressure-sensing region in the entrance chamber, capable of measuring total pressure and pressure fluctuations within the cartridge; and d) an outlet from the mixing chamber to a patient line, wherein said pressure sensing region enables measurement of pressure changes in said cartridge. The invention further consists of a peritoneal dialysis system using the aforementioned cartridge, and a method of performing peritoneal dialysis using the aforementioned system or cartridge.

ABSTRACT

The invention consists of a cartridge for a peritoneal dialysis (PD) system, comprising: a) a pressure-sealed cartridge containing a mixing chamber, an entrance chamber and a ballast chamber; b) one or more inlet/outlet ports in said entrance chamber, said ports being fully pressure-sealed when closed; c) a pressure-sensing region in the entrance chamber, capable of measuring total pressure and pressure fluctuations within the cartridge; and d) an outlet from the mixing chamber to a patient line, wherein said pressure sensing region enables measurement of pressure changes in said cartridge. The invention further consists of a peritoneal dialysis system using the aforementioned cartridge, and a method of performing peritoneal dialysis using the aforementioned system or cartridge.

SYSTEM AND METHOD FOR PERITONEAL DIALYSIS

Field of the Invention

[0001] The present invention relates to processes of medical treatment, and apparatus for use therein. More specifically, it relates to processes of peritoneal dialysis (PD) conducted on human patients, apparatus for use therein, component parts for assembly into such an apparatus, and procedures for manipulating and adjusting processes using such an apparatus.

Background of the Invention

[0002] For patients suffering from low kidney functions, dialysis is the standard treatment for replicating the function of a normal human kidney. There are two types of dialysis procedures in use, hemodialysis (HD), which circulates the patient's blood through filters located outside the body, and peritoneal dialysis (PD), which uses the peritoneal membrane of the patient's abdominal cavity as a filter to remove toxins via specialized solutions (dialysates).

[0003] Compared with HD, PD is a very gentle modality, with its slow corrective action more resembling that of the natural kidney. It is operationally simple, eliminates the need for venipunctures and has lower operational costs. Because the system is not an extracorporeal one, there is no need for a high degree of heparinization, a factor that is especially important in the case of diabetic patients. However, to date HD has continued to dominate in the treatment of End-Stage Renal Disease (ESRD) patients.

[0004] In a continuing effort to provide adequate PD treatment for the varied population of patients in need, clinicians have developed a number of different forms of the APD modality of treatment. These include the APD modalities of:

[0005] (i) Continuous Cycling Peritoneal Dialysis (CCPD); a method of performing PD in which an automated cycler performs 4 to 6 regular exchanges every night;

[0006] (ii) Intermittent Peritoneal Dialysis (IPD); a method of performing PD in hospitals or at home with an automatic cycler two or three times a week for a period of about eight to twenty hours each time;

[0007] (iii) Nightly Peritoneal Dialysis (NPD); a method of performing nightly peritoneal dialysis at home for patients with high efficiency peritoneal membranes. Such patients do not fare well with long dialysate dwell times.

[0008] (iv) Tidal Peritoneal Dialysis (TPD); This modality utilizes an initial maximum dialysate fill volume (usually three liters) and periodically, during a long and continuous dwell time, drains a fraction of the infused volume (usually one-third, the tidal volume) and re-infuses about a similar amount, adjusting for ultrafiltration (excess fluid removed from the patient's body during kidney dialysis) into the patient.

[0009] These modalities all involve an infusion phase, during which the dialysate (normally glucose) is introduced into the peritoneal cavity, a dwell phase during which the dialysate is essentially at rest in the peritoneal cavity, and a draining phase following the dwell phase, when the dialysate is expelled from the peritoneal cavity.

Brief Reference to the Prior Art

[0010] United States Patent 6,226,047 to Dadson, issued May 2001, describes an automated PD machine which is capable of monitoring the interperitoneal pressure during the PD process. Such pressure monitoring is very advantageous in practice. For example, it allows diagnostic information to be obtained from the patient in real time during the dialysis process, so that process conditions can be adjusted and optimized as the process proceeds.

[0011] Automatic PD machines of the type generally described in the aforementioned Dadson patent comprise a number of inter-connected sections and parts, some of which are used over again with the same or even with different patients, in different PD processes, and others of which are used once only or a few times only. In each case, there is a requirement for assembly and connection of the various parts prior to the commencement of a PD process, either by the health care professional or by the patient.

[0012] If peritoneal cavity pressure readings of the necessary accuracy for delivering worthwhile diagnostic information during the PD process are to be obtained, it is necessary that complete, leak-proof sealing of the various parts that communicate with the peritoneal cavity during the process, and their connection to one another, be achieved and maintained. It is in addition highly desirable that the operator should be able to check and confirm that the required degree of sealing has been achieved and maintained during the process. Otherwise, worthless or misleading diagnostic pressure readings may be obtained from the peritoneal cavity.

[0013] Additionally, current techniques of PD afford no ability to monitor the pressure build-up in the peritoneum during either the Dwell sequence or during the Fill sequence. Also, current PD solutions are of fixed composition and cannot be systematically adjusted either in their constituent parts or in the concentration of each constituent during a treatment. The ability to monitor peritoneal pressure readings and dynamically adjust PD solution composition in response would be of great benefit and provide improved PD treatment.

[0014] The present invention seeks to provide automatic PD machines, and processes for their operation, which at least in their preferred embodiments fulfill one or more of these requirements.

[0015] It is an object of this invention to partially or completely fulfill one or more of the above-mentioned needs.

Summary of the Invention

[0016] The invention consists of a cartridge for a peritoneal dialysis (PD) system, comprising: a) a pressure-sealed cartridge containing a mixing chamber, an entrance chamber and a ballast chamber; b) one or more inlet/outlet ports in said entrance chamber, said ports being fully pressure-sealed when closed; c) a pressure-sensing region in the entrance chamber, capable of measuring total pressure and pressure fluctuations within the cartridge; and d) an outlet from the mixing chamber to a patient line, wherein said pressure sensing region enables measurement of pressure changes in said cartridge.

[0017] The invention further consists of a peritoneal dialysis system using the aforementioned cartridge, and a method of performing peritoneal dialysis using the aforementioned system or cartridge.

[0018] Other and further advantages and features of the invention will be apparent to those skilled in the art from the following detailed description thereof, taken in conjunction with the accompanying drawings.

Brief Description of the Drawings

[0019] The invention will now be described in more detail, by way of example only, with reference to the accompanying drawings, in which like numbers refer to like elements, wherein:

Figure 1 is a cut-away view of the cartridge of the present invention;

Figure 2 is a cut-away view of the entrance chamber and sealing elements;

Figure 3 is a schematic of the inlet port sealing mechanism;

Figure 4 is a top view of the cartridge;

Figure 5 is a schematic of one embodiment of the sealing mechanism; and

Figure 6 is a schematic of another embodiment of the sealing mechanism.

Detailed Description of the Preferred Embodiments

[0020] The inventive system presented herein consists of a disposable cartridge for use in a complete peritoneal dialysis system. The cartridge provides for the input of dialysate solution components, the mixing of these components and the transmission of the mixed solution to the patient, all within a pressure-sealed unit. The operating features of the cartridge are set out in more detail in the following description.

[0021] A peritoneal dialysis system, as known in the art, consists basically of a set of fluid bags to hold the dialysate solution(s), a dialysis machine for pumping fluid into and out of the patient, and an outlet to deliver solution to and from the patient with a catheter in the peritoneal cavity. The inventive cartridge present herein forms part of the dialysis machine and acts as the pumping and fluid delivery portion of the dialysis machine. Other elements, such as a power supply, operator controls, etc. are assumed to be consistent with the known art of dialysis machines, subject to any modifications required for operation of the cartridge.

[0022] As shown in **Figure 1**, the cartridge **10** consists of a number of discrete chambers. There is an entrance chamber **20**, with a series of input/output ports **22** and a pressure-sensing region **24** at one end. The entrance chamber **20** is connected to a ballast chamber **30**, which preferably has a heating element (not visible) and a corrugated fluid path **32** to provide time for the fluid to be heated to a suitable entry temperature on a continuous basis. The ballast chamber is coupled to the mixing chamber **40**, by the entrance chamber from which the fluid is pumped out of the cartridge to the patient. A top view of the cartridge **10** as shown in **Figure 4** indicates the orientation of the input/output ports **22** and pressure sensing region **24**.

[0023] The input/output ports **22**, as shown in **Figure 2**, contain compressible sealing elements **50** to ensure that the ports are completely closed when not in use, and properly opened when in use. The sealing elements **50** are shown in greater detail in **Figure 3**, with specific embodiments in **Figures 5** and **6**. Preferably, the sealing element **50** consists of a compressible seal **58**, a spring-loaded anchor point **60** for compressing the seal **58**, a plunger **52** coupled to a cam **51** to open and close the seal **58**, extremity detectors **53** to monitor the position of the plunger **52** and a force detector (not shown) which in combination with extremity detectors **53** detects and confirms whether the sealing element **50** is in a fully closed or fully open position. The force detector preferably operates by sensing the change in current in the motor driving the plunger **52** arising from the resistance created by the plunger **52** and seal **58** as they contact the closed position.

[0024] The pressure-sensing region **24** in the entrance chamber **20** allows for continuous monitoring of the pressure in the cartridge **10**. As the cartridge is completely pressure-sealed, the pressure in the cartridge **10** also reflects the pressure in the patient's peritoneal cavity. Thus, pressure changes in the cavity can be monitored non-invasively, and in real-time, enabling on-the-fly changes in the patient's treatment. These changes can be as simple as adjustments to the flow rates, or more complex, such as changing the composition of the dialysate solution. This latter change is facilitated by the ability of the cartridge to mix the dialysate solution from components within the cartridge **10** itself, as opposed to the standard usage of pre-mixed dialysate solutions. Use of pre-mixed solutions is still possible, but will limit the changes that can be made during the PD process.

[0025] A schematic of a preferred embodiment of the cassette and a plunger are shown in **Figure 5**. This is an illustration of a typical input/output port **22** that opens inside the entrance chamber **20** (see **Figure 1**). In operation, an upward movement of the plunger **52** pushes against the sealing membrane **54** which pushes the valve body header **56** upwards and causes the soft head **58** to compress the spring **60** into the port **22**, thereby sealing the port **22**. The extremity detectors **53** (shown in **Figure 3**) and force detector (not shown) are monitored to confirm sufficient force has been applied to soft head **58** to seal the port **22**.

[0026] In this closed position, the input/output port **22** is completely closed and isolated from all input/output ports **22** in communication with the entrance chamber **20**.

[0027] To reach the open state, the plunger **52** moves down, allowing the spring **60** applying a restoring force P2 to the soft head **58**, pushing the soft head **58** away to open the input/output port **22**, allowing it to communicate with the inside of the entrance chamber **20**. Again, the extremity sensors 53 and the force sensor are monitored to confirm the sealing force has been removed. Hence, liquid can be transferred from or input into an attachment to the input/output port **22** accordingly.

[0028] When transferring solution through the input/output port, the syringe pump generates a positive force P1 that pressurizes the occlusion chamber. To maintain the port opened, the restoring force P2 generated by spring must be greater than force P1 generated by the syringe pump. Otherwise P1 will push in between the sealing membrane and the hard header, push behind the hard header to close the outlet of the input/output port. It is important that the restoring force P2 be greater than the induced force P1 from the pump.

[0029] When withdrawing solution from receptacle attached to the input/output port, the syringe pump generates a negative force P'1 that transmits equally into the occlusion chamber. This induced negative force P'1 would attempt to collapse the sealing chamber. This would force the header head to move upwards to close and seal off the output of the input/output port.

[0030] In this mode, the restoring force P2 must be strong enough to overcome the induced negative pressure P'1 and force the inlet of the input/output port opened. The spring arms are also designed to apply forces P3 and P4 to assist the restoring force P2 to keep the input/output port opened. In this preferred embodiment, the relationships of the pressures could be expressed as follows;

$$P2 > |P1| \text{ (negative or positive)}$$

$$P5 > |P1| + P2 + P3 + P4$$

[0031] It is understood that other arrangements and other force applications such as springy plastic arm assemblies, air pressures and/or vacuums, could be used to achieve the same or similar outcomes as explained above.

[0032] An alternate embodiment of the occlusion system is shown in the schematic of **Figure 6**. In this embodiment the semi-rigid head **56** is expanded to form the sealing membrane **54** of the entrance chamber **20**. There is further a locking head **72** extending beyond the sealing membrane **54** that engages with a slot **74** located in the modified head of the plunger **52**. In this embodiment, the head of plunger **52** moves up or down to apply the positive and the negative forces to close or open accordingly, the output of the input/output port. Again, this embodiment must be such that P5>P1 is realized as discussed above.

[0033] Other methods could be used to achieve the result created by these embodiments. As another example, corrugations may be built into a semi-rigid sealing membrane, or the soft head glued or fastened to a semi-rigid sealing membrane. The criteria is that confirmation that the inlet/outlet port **22** is fully open or closed must be provided, and that, in the closed position, P5>P1 such that the closed port is completely pressure-sealed.

[0034] A desirable aspect of any PD system is the requirement for an absolute sterile environment. Disposable components are made sterile at the point of manufacture and supplied as a sterile packaged to the end user. Sterility is only broken at the point of use. It is well known that this sterility can now be inadvertently compromised at this stage, for example, by touch contamination by the user. A technique pioneered by US patent 5,053,003 known as "flush before fill" is in standard use today to protect against sterility compromise. The cartridge 10 is capable of sterilization according to this technique.

[0035] After insertion of the cartridge 10 into the dialysis machine, the machine can check to see if the cartridge has been correctly inserted and all of its ports can be opened and closed on demand as follows. The cartridge 10 is inserted into the machine with volume V1 preset at $V1_{initial}$ prior to sterilization. The machine will open port C, the port that allows liquid flow between V3 and V1 (see **Figure 1)** and then reduce $V1_{intial}$ to

$V1_{begin}$. Since all of the other ports are closed the pressure in the cartridge will increase as the volume decreases in accordance with Boyle's law. A controller in the machine will watch this pressure for a preset time. If the pressure is unchanged during this set time then the operator is instructed to open all of the fluid line clamps and again the system will monitor the pressure. If the pressure is unchanged the machine will indicate that the system is air tight and hence liquid tight.

[0036] The machine will then cycle all of the ports from closed to opened and back to closed a number of times (at least 3). Then all of the ports are closed and $V1_{begin}$ is reduced to $V1_{final}$. Again, according to Boyle's law the pressure in the mixing volume V2 will increase from its value at V_{begin}. The machine will then monitor this pressure. If it remains constant it implies (a) all of the ports can be opened and closed effectively and (b) there is no unintentional fluid path between the large ballast volume and the mixing volume. The next phase is to connect all of the liquids that will be used to constitute the dialysate and perform the "flush before fill" routine as follows.

[0037] The admission of air into the peritoneal cavity must be avoided. Air, if unsterilized, is a source of infection and if sterilized it is a source of discomfort for the patient. The first step in the flush before fill routine is to remove all air from the fluid paths that lead to the patient.

[0038] The machine opens ports P and C and expands from V1 to V_{begin}. This will draw sterile liquid C into V3. Port C is then closed and port D is opened. Port D, the drain port, is preferably located at the highest point of the cartridge when the cartridge is located in the machine. Therefore, any air is automatically channeled to this point. Volume V_{begin} is changed to V_{final} expelling any air that was removed from V3. Port D is closed and the cycle repeated. After approximately 5 or 6 such cycles all of the air in V3 and V2 will be removed and V3 and V2 will be filled with sterile fluid.

[0039] The machine will then open ports A and P. Liquid A is drawn into V1 via V2. Port D is opened, Port A is closed and the liquid in V1 is expelled via V2. This can be repeated as often as required. The same process is repeated for liquid B. Using this process all of the fluid lines and the cartridge itself can be flushed (flush before fill) with sterile liquid to remove any trace contaminants that may have been deposited during the set up phase of the treatment.

[0040] In operation of the dialysis machine, fluid bags containing the components parts of a dialysate solution are coupled to the input/output ports **22** and the ports **22** are opened and closed in sequence to bring the various component solutions into the entrance chamber **20**. The fluid then flows into the ballast chamber **30**, preferably along a corrugated or similar path **32** to permit the fluid to be brought to temperature before it enters the mixing chamber **40** and is pushed out into the patient.

[0041] During operation, the pressure of the fluid in the cartridge is measured. As the whole system is pressure-sealed, changes in the pressure of the cartridge reflect changes in the pressure exerted upon/by the peritoneal membrane in the patient's body. By monitoring and measuring these pressure changes, adjustments to the treatment of the patient can be made immediately, rather than having to be delayed to the next course of dialysis, as with current methods.

[0042] This concludes the description of a presently preferred embodiment of the invention. The foregoing description has been presented for the purpose of illustration and is not intended to be exhaustive or to limit the invention to the precise form disclosed. Many modifications and variations are possible in light of the above teaching and will be apparent to those skilled in the art. It is intended the scope of the invention be limited not by this description but by the claims that follow.

What is claimed is:

1. A cartridge for a peritoneal dialysis (PD) system, comprising:

a) a pressure-sealed cartridge containing a mixing chamber, an entrance chamber and a ballast chamber;

b) one or more inlet/outlet ports in said entrance chamber, said ports being fully pressure-sealed when closed;

c) a pressure-sensing region in the entrance chamber, capable of measuring total pressure and pressure fluctuations within the cartridge; and

d) an outlet from the mixing chamber to a patient line,

wherein said pressure sensing region enables measurement of pressure changes in said cartridge.

2. The cartridge of claim 1, wherein said cartridge is disposable.

3. The cartridge of any of the preceding claims, wherein the inlet/outlet ports include one or more: extremity sensors, force sensors and a combination thereof to determine the open/closed status of the inlet/outlet ports.

4. The cartridge of any of the preceding claims, wherein the inlet/outlet ports are pressure sealed using a plunger which contacts a sealing membrane to drive a soft header into and out of the port.

5. The cartridge of any of claims 1-3, wherein the inlet/outlet ports are pressure sealed using a plunger which is locked to a soft header and drives said soft header into and out of the port without contact a sealing membrane.

6. A peritoneal dialysis system, comprising:

a) a pressure-sealed cartridge containing:

i) a mixing chamber, an entrance chamber and a ballast chamber;

ii) one or more inlet/outlet ports in said entrance chamber, said ports being fully pressure-sealed when closed;

iii) a pressure-sensing region in the entrance chamber, capable of measuring total pressure and pressure fluctuations within the cartridge; and

iv) an outlet from the mixing chamber to a patient line,

wherein said pressure sensing region enables measurement of pressure changes in said cartridge; and

wherein said peritoneal dialysis system enables modification of treatment of the patient in response to pressure changes measured through the cartridge.

7. The peritoneal dialysis system of claim 6, wherein said cartridge is disposable.

8. A method of performing peritoneal dialysis, comprising:

a) providing a peritoneal dialysis system according to any of the preceding claims;

b) measuring and monitoring pressure changes in said cartridge; and

c) modifying treatment of said patient in response to said pressure changes.

9. The method of claim 8, wherein said cartridge is disposed of after one course of peritoneal dialysis patient treatment.

Application number / numéro de demande: 2574537

Figures: 1-2-4

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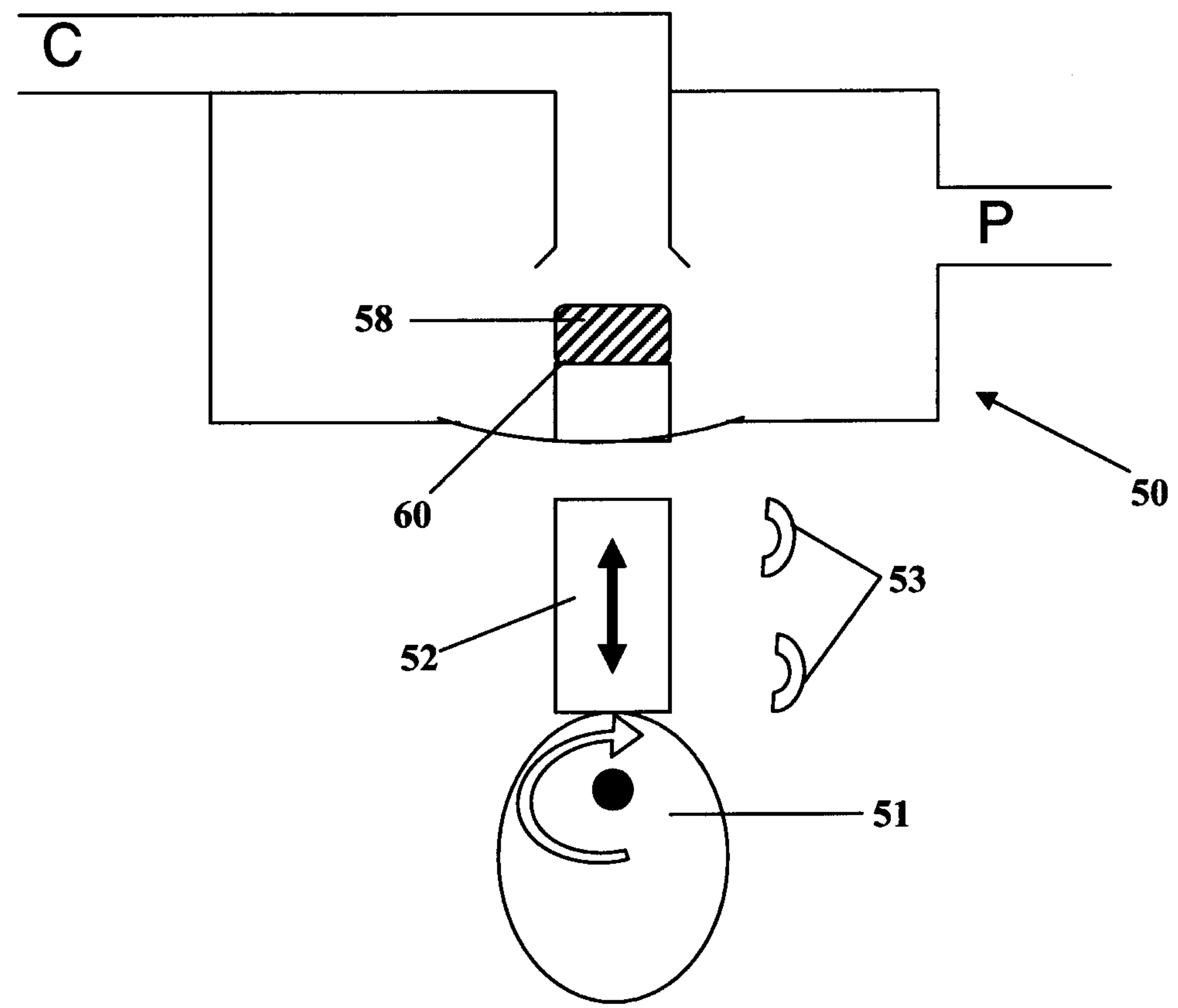


FIGURE 3

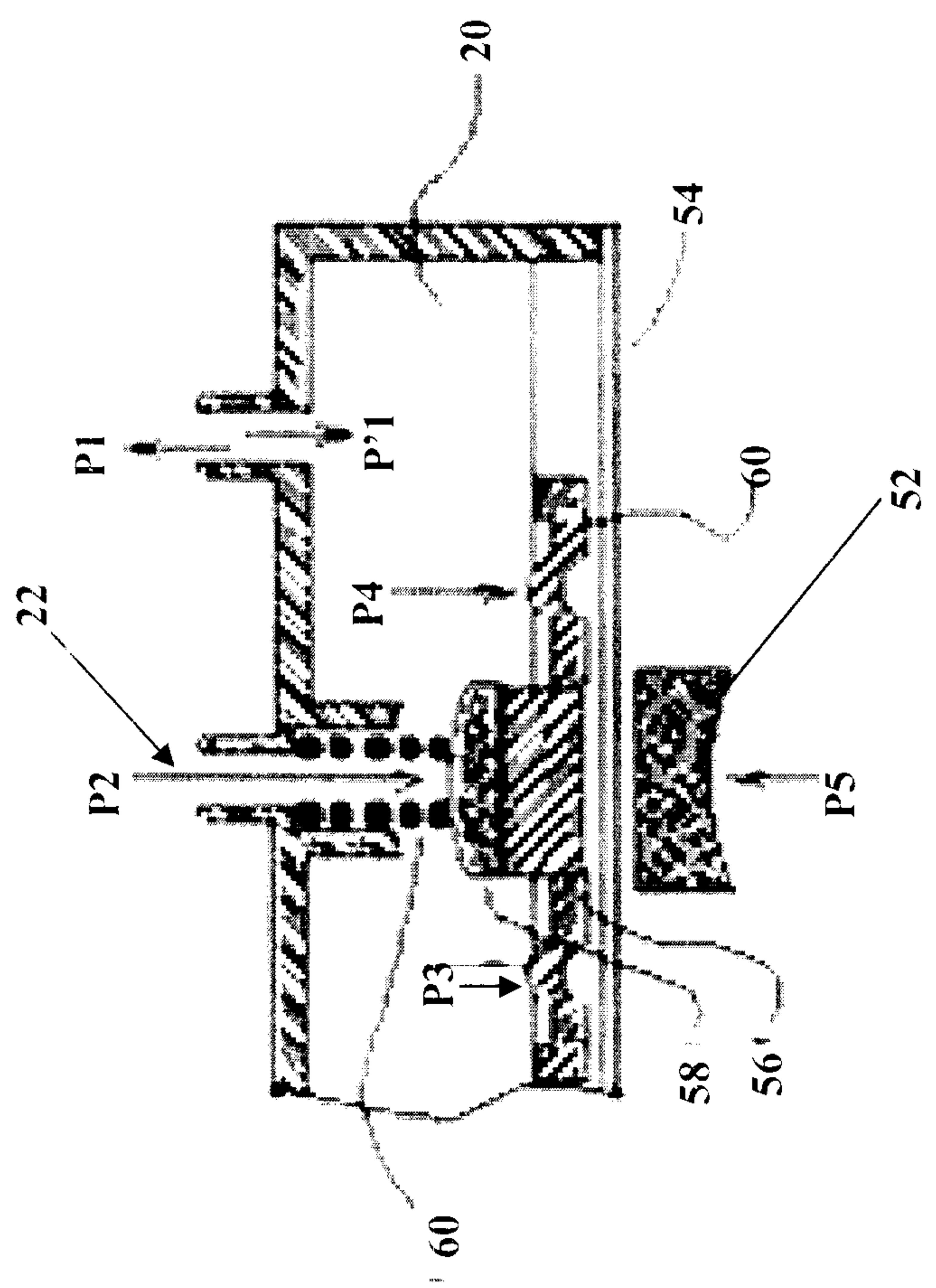


FIGURE 5

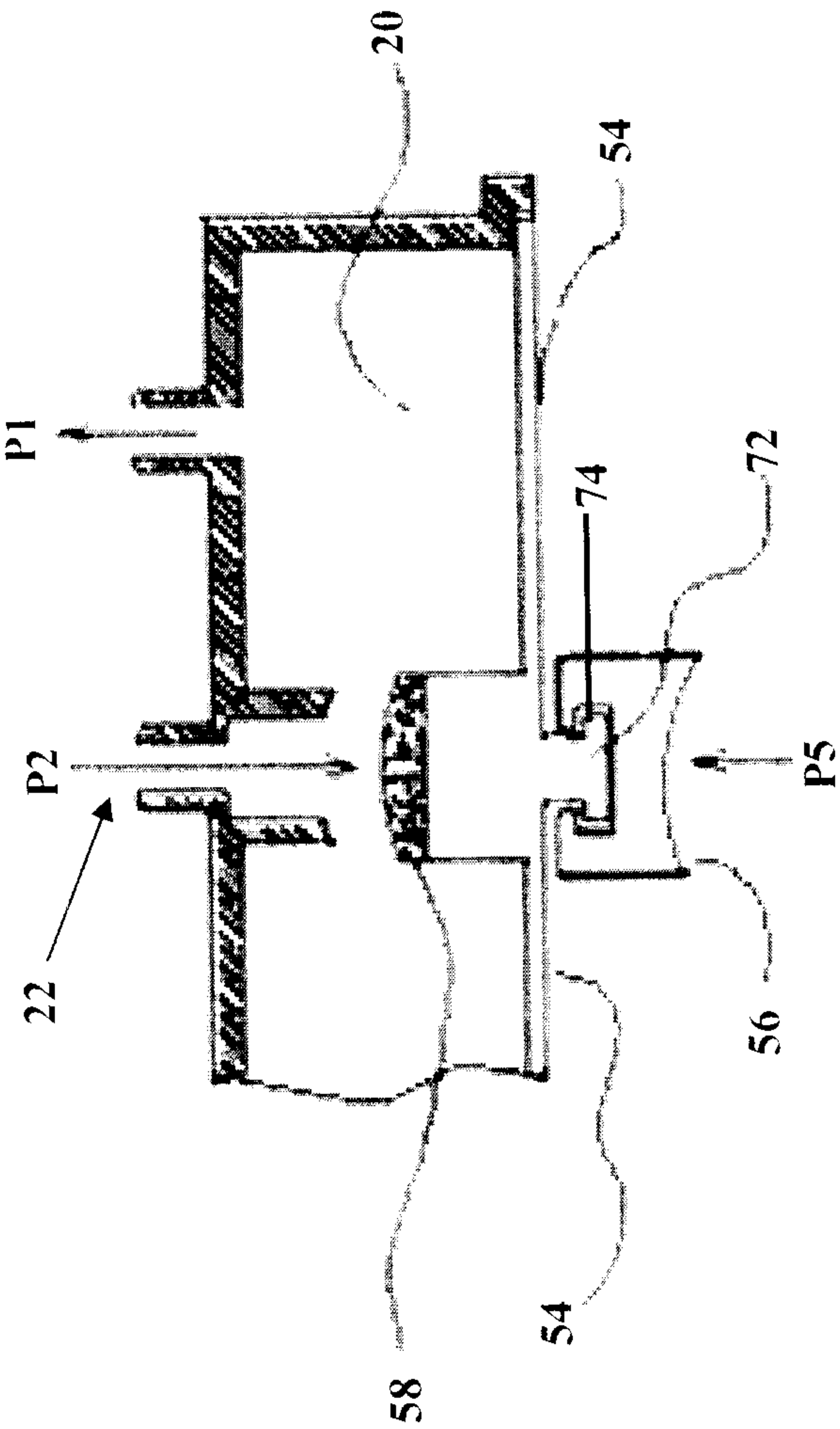
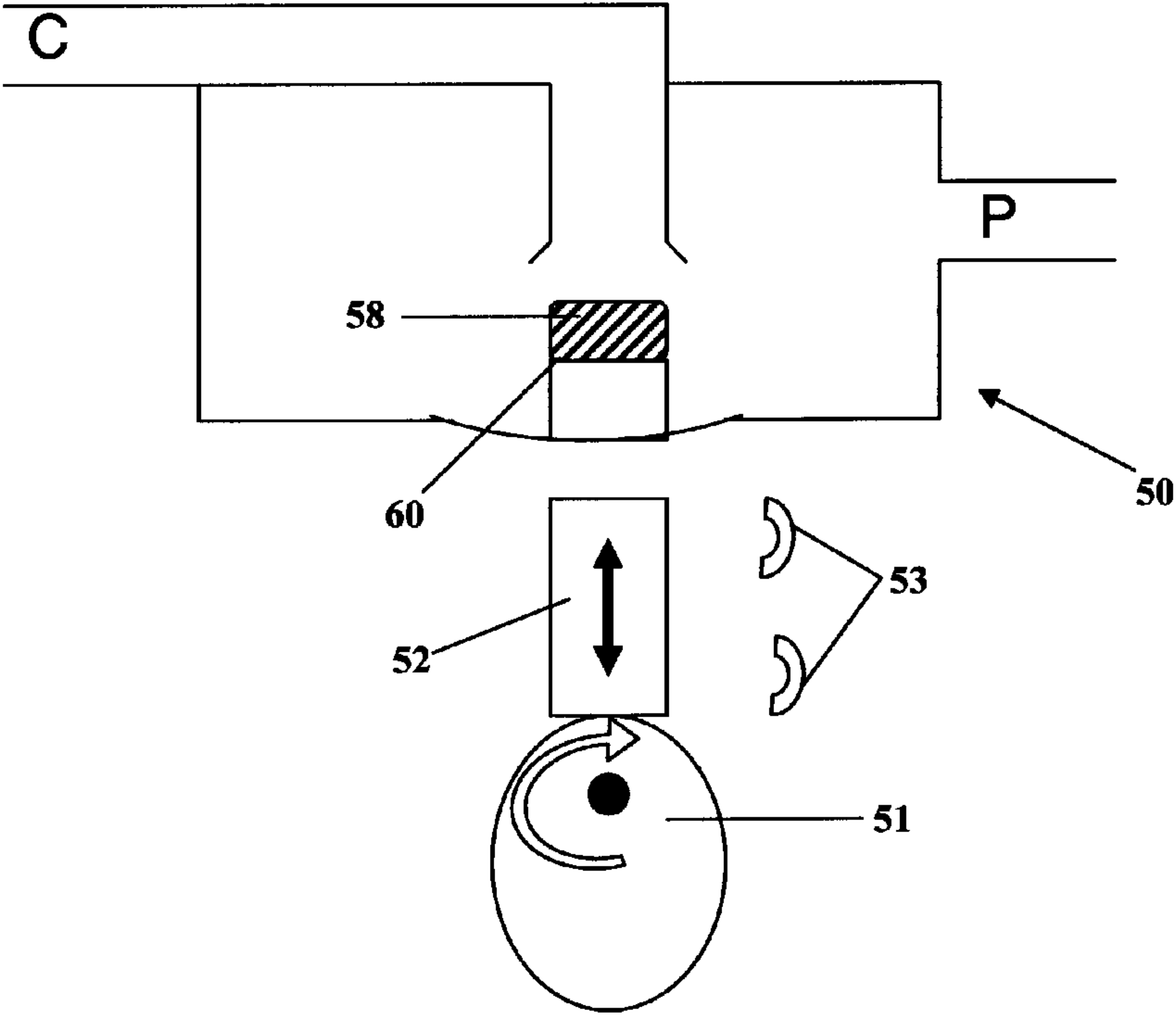


FIGURE 6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