# United States Patent

**Federico et al.**

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## [54] MONITORING SYSTEM FOR PHYSIOLOGICAL SUPPORT SYSTEMS


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[52] **U.S. Cl.** ..... **128/1 R**

[51] **Int. Cl.** ..... **A61b 19/00**

[58] **Field of Search** ..... 128/1 R, DIG. 3; 3/1, DIG. 2



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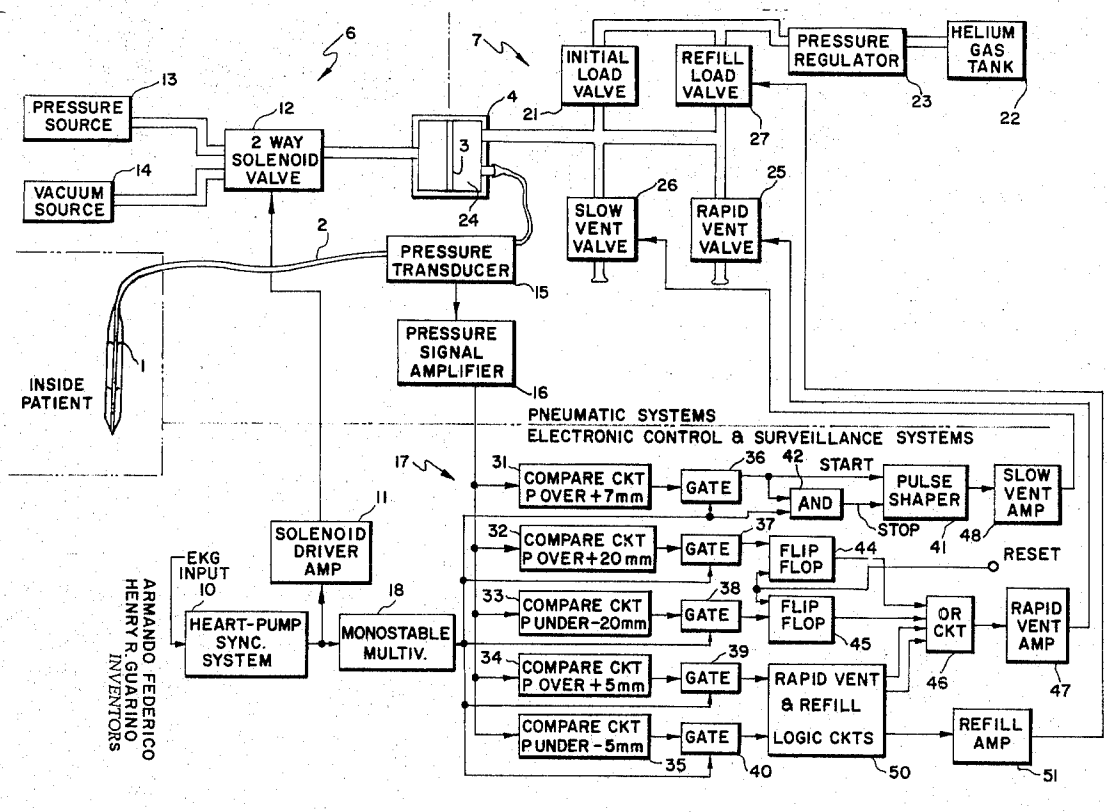
[57] **ABSTRACT**

A system for automatically monitoring and controlling the fluid load in physiological support systems. The system samples gas pressure at fixed periods and adds fluid or vents fluid from the system to prevent malfunction and the catastrophic results.


**16 Claims, 3 Drawing Figures**



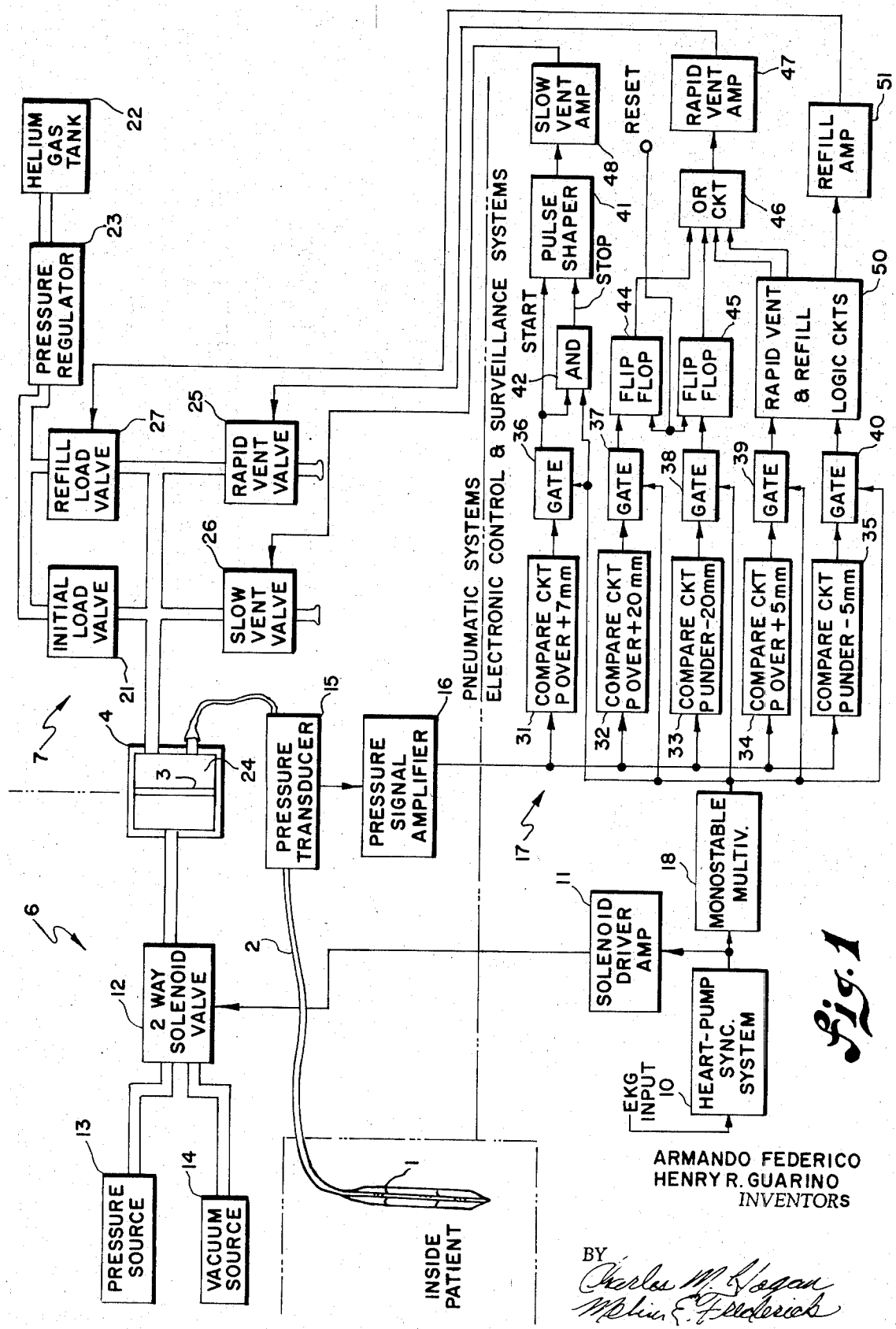



Fig. 1

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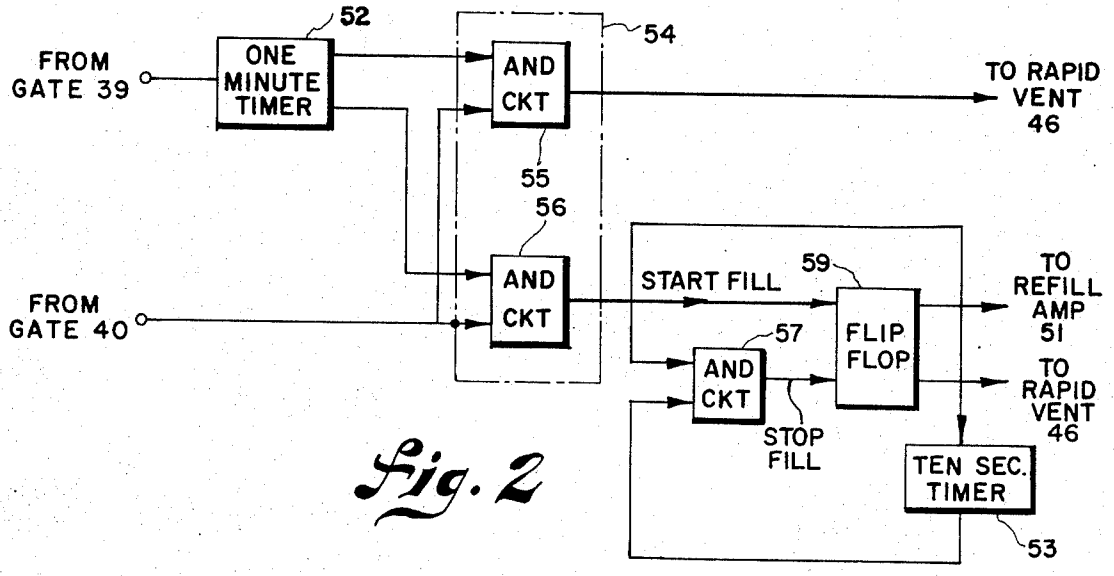


Fig. 2

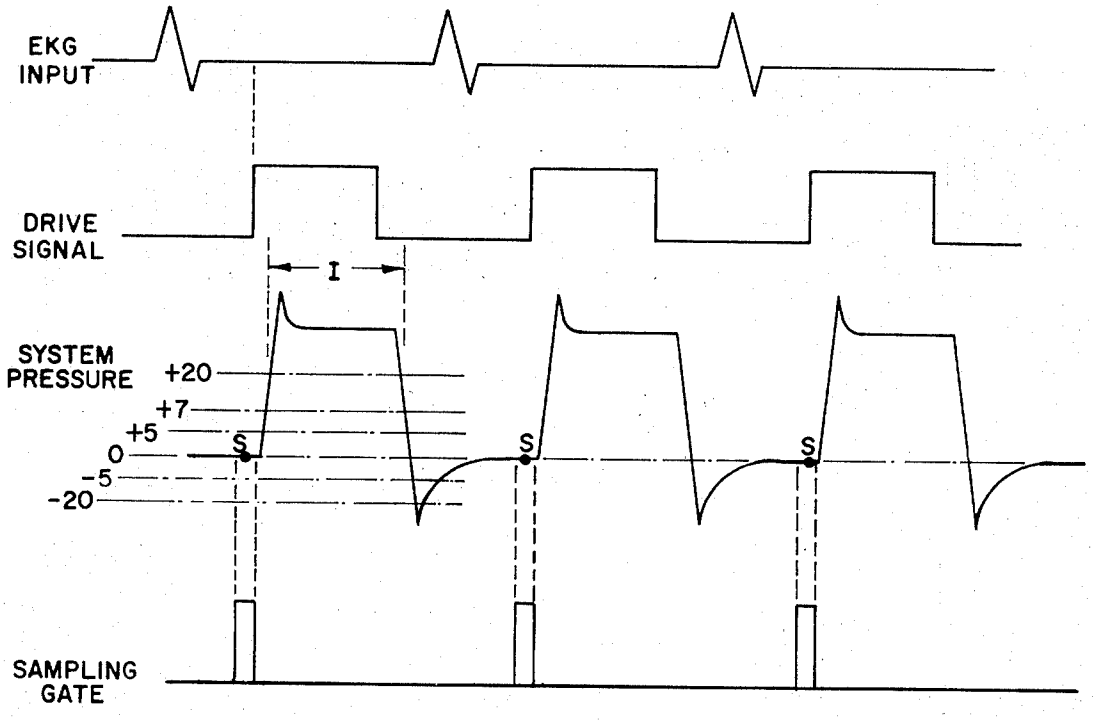


Fig. 3

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# MONITORING SYSTEM FOR PHYSIOLOGICAL SUPPORT SYSTEMS

This invention relates to physiological support systems which require a membrane separation between blood and a fluid. These systems fall into two categories. The first type is a mechanical device to support cardiac action such as left ventricular assist device. In this type of support system pressure is exerted upon and transmitted across a membrane in contact with the blood. Blood is displaced with the creation of controlled pressure changes which tend to reduce cardiac effort and pump blood systemically. The membrane which separates the driving gas or liquid from the blood in these devices is subjected to repeated bending stresses and requires superior mechanical properties. The second general category of devices are diffusion system. Examples of these are the membrane oxygenator type of artificial lung and the hemodialysis type of artificial hiding. In these types of devices the membrane serves to separate the blood from the diffusion gas or liquid and is permeable to the substances which are exchanged from fluid to flood or vice versa, versa, The separating membrane must be generally quite thin in relation to its surface area. One possible hazard of both categories of devices is the development of gas leaks and the embolization of fluid into the bloodstream. The physiologic consequences of such an event depend on the amount and type of fluid embolized. The body's tolerance for most foreign fluids in bulk amount is not large. Therefore, it may now be seen that major leaks in most if not all cases would be a catastrophic event and that a patient must be protected against such an event.

It is one purpose of the present invention to provide an improved heart assist apparatus which augments blood flow during diastole and decreases myocardial effort during systole.

Heretofore, mechanical assistance to the failing heart has been attempted by veno-arterial pumping, arterio-arterio pumping, and a variety of counterpulsation techniques including intra-aortic balloon pumping. In the counterpulsation, it is necessary for the pump to be synchronized with the patient's heart. Furthermore, most if not all of these systems include a fluid powered pump. The fluid is usually gas and exerts pressure on a flexible member or membrane, which in turn exerts a force on the blood. Thus, the fluid or gas load pump is separated from the blood and great care is taken to insure against leakage of gas into the blood or leakage of blood into the gas load system.

It is another object of the present invention to provide automatic load fluid or gas surveillance for such systems.

It is another object to provide a monitoring system for such heart pumps that will be fail-safe, reducing danger to the patient.

It is a further object to provide a monitoring system for such heart pumps that will cause the pump to be fail-safe, in the event of pressure extremes in the fluid load pressure and/or excessive leakage between the blood and the load fluid.

One type of heart pump, the intra-arterial balloon pump and more particularly the intra-aortic balloon pump, consists of a balloon attached to a catheter, which is introduced into the patient's femoral artery and positioned in the descending aorta to provide



benign cardiac assistance to the patient. A constant amount of load gas is required in the system at all times to insure proper inflation and deflation of the balloon which is controlled by a volumeter that increases and decreases the pressure on the load gas. However, due to leaks, diffusion, and accidental malfunction of the operation parts, gas may leak from the system. Excessive amounts of gas leaking into the patient's blood system must be stopped to protect the patient. Also, excessive leaks from the gas system outside the patient's body, which indicate a substantial failure in the system must be stopped. On the other hand, minor leaks due to osmosis through the balloon or the catheter, or minor leaks from the system outside the patient's body, or slight increases in pressure due to pinched catheter line can be remedied by filling or venting the load gas to maintain proper operating pressure.

It is another object of the present invention to provide a gas surveillance system for such an intra-aortic balloon pump, which meets at least some of these safety requirements.

It is another object that the surveillance system be fail-safe so that the balloon pump in the patient's body imposes the least restriction to blood flow upon failure.

In accordance with the present invention, the gas pressure load in an intra-arterial or intra-aortic pump is measured during quiescent periods between pump impulses and the load system is filled or vented slowly if pressure is within a safe region to maintain ideal pressure load. If pressure is outside the safe region, the system is rapidly vented to collapse the balloon so that it will provide minimal resistance to blood flow. The surveillance system also vents to collapse the balloon if filling to maintain the desired pressure occurs too frequently or if it takes too long to fill to maintain normal operating pressure. Either of these indicates there is excessive leakage somewhere in the load system.

The novel features that are considered characteristic of the present invention are set forth in the appended claims. The invention itself, however, both as to its organization and method of operation, together with other objects and advantages, will be best understood from the following description of a specific embodiment of the invention, taken in conjunction with the accompanying drawings, in which:

FIG. 1 is a block diagram and schematic showing the pneumatic gas load system, the intra-aortic pump and the electronic control and surveillance system which responds to, for example, electrocardiograph equipment monitoring the patient;

FIG. 2 is a block diagram showing the circuits in the rapid vent and refill logic of the surveillance system; and

FIG. 3 shows waveforms in the surveillance system, including a waveform representative of system load pressure and various levels identified with safe and unsafe operation.

Turning first to FIG. 1, there is shown a block diagram and schematic of a pneumatic system and an electronic control and surveillance system, which function together to control an intra-aortic balloon 1, attached to a catheter 2, which is introduced into the patient's femoral artery and positioned in the descending aorta to provide a benign cardiac assist to the patient. The pneumatic system consists principally of two separate

pneumatic systems separated by the membrane 3 in isolating piston 4. It is through the isolating piston, and most particularly the membrane 3 in the isolating piston that pressure pulses are delivered from the initiating pneumatic system 6 to the pump load pneumatic system 7. The gases in the systems 6 and 7 may be different because the requirements of the systems are different. For example, the pump load system which extends into the body of the patient through the intra-aortic balloon 1 preferably contains helium which dissolves easily in the blood without injurious effect on the patient. Other gases which are not substantially injurious are carbon dioxide and oxygen and while these gases are heavier they may also be used because there is a tolerance by the patient to dissolve these gases in the blood. Nitrogen, on the other hand, could cause damage or injury to the patient, because of the low toleration for nitrogen in the blood. These considerations must be made because of the possibility of gas leaking from the catheter or the balloon into the patient's blood. Such considerations are not necessary with regard to the gas load in the initiating pneumatic system 6 because there is little possibility of it entering the patient's blood system.

Clearly, the patient's toleration for the gas, which loads the pump pneumatic system 7, will be one of the factors to determine when gas leakage from the system could be harmful to the patient and so constitute a malfunction and require shutdown or venting. The purpose of the electronic control and surveillance system, shown in FIG. 1, is twofold. First, it provides electrical trigger to the initiating pneumatic system 6 that drives the isolating piston 4; and second, in the pump load system 7 it responds to the pressure of the load gas in the intra-aortic balloon and by providing a signal to the pneumatics which maintains that pressure within predetermined limits, refills the system where a leakage not excessively harmful to the patient has occurred or vents the system shutting it down where the leakage has been excessive or where pressure is beyond prescribed pressure limits, indicating a serious malfunction in the system. The system shuts down by venting so as to collapse the intra-aortic balloon. The balloon is collapsed so that it is least obstructive to blood flow in the aorta.

The intra-aortic balloon pump must be synchronized with the patient's heartbeat. More particularly, the balloon must be pulsed or inflated with pressure during the diastolic phase of the heart cycle. During this phase, as already described, the left ventricle of the heart which feeds the aorta is in dilation, the aortic valve is closed and the aorta is normally distended. At this point, the balloon is inflated and so it aids the aorta to force the blood through the capillaries and other vessels of the patients's body. A representation of the pressure pulses to the balloon is shown by the waveform in FIG. 3 designated System Pressure. The duration I of a pulse in this waveform represents the pumping interval and the point S between pulses indicates a sample point when the pressure to the balloon is sampled and examined by the surveillance system, to determine whether it is within prescribed limits or a dangerous malfunction threatens. The point S in the pumping cycle represents the quiescent or zero pressure, which loads the pump between pumping intervals.

The pumping interval is approximately two-thirds of the whole cycle when the patients's pulse rate is 77 beats per second. This interval may be reduced to about one-half the pump full cycle when the patient's pulse rate is between 100 and 120 beats per second. An electrical system which responds to the output of an electrocardiograph (EKG) unit monitoring the patient's heartbeat provides an electrical drive signal for controlling the pneumatic system 6 that initiates a pressure pulse to the balloon and also triggers a sampling pulse for sampling balloon pressure. This system is designated the heart-pump sync system 10 and produces a drive pulse which is positioned in the heart diastole phase, depending on the patient's pulse rate. A suitable heart-pump sync system of this sort is described in U.S. Pat. No. 3,452,739, which is assigned to the same assignee as the present invention. The signal output of the EKG is represented by the waveform denoted EKG input, shown in FIG. 3, and the drive signal output from the heart-pump sync system 10 is represented by the waveform designated Drive Signal in FIG. 3.

The drive signal is amplified by amplifier 11 and energizes the solenoid valve 12 in the pneumatic system 6. This valve connects the isolating piston 4 to a pressure source 13 or a vacuum source 14 and so distends the diaphragm 3 in the isolating piston to deliver pressure pulses to the pump load in the pneumatic system 7. The pressure pulses are transmitted from the piston 4 to the intra-aortic balloon pump 1 via the catheter 2.

Pressure to the pump is monitored by a pressure transducer 15 in contact with the catheter. The electrical signal from the transducer is amplified by amplifier 16 and fed to the electronic surveillance system, denoted generally by the numeral 17. This signal, the system pressure signal, is shown by the waveform in FIG. 3, designated System Pressure. In the surveillance system the system pressure signal is sampled during the interval of Sampling Gate pulses, also shown in FIG. 3. These pulses are generated by a monostable multivibrator 18, in response to the Drive Signal pulses from the heart-pump sync system 10.

In operation, the pneumatic system 7 is initially filled with load gas through valve 21 from a tank of helium gas 22, through a pressure regulator 23. The load gas reservoir 24 in the isolating piston 4 is filled to a maximum gauge pressure of 15 mm, as set by the gas load regulator 23. This amount of initial load gas in the reservoir is variable depending on the size of the balloon used, type of load gas, and the length of the catheter. When the balloon is not pumping, it is deflated and the pressure in the catheter is established at safe operating limits for the system, which are by way of example between +7 and −5 mm of pressure for helium. When the system is pumping, the surveillance system 17 samples the pressure between pump pulses and commands corrective action. If the sampling is within the limits +7 to −5 mm no action is taken. However, if the sample is not within these limits, corrective procedures are introduced to insure proper and safe operation of cardiac device implanted in the patient. If an unsafe over pressure condition exists, for example; at any one sample the pressure is +20 mm or greater when helium is used, the surveillance system 17 actu-

ates rapid vent valve **25**, which quickly vents the pump pneumatic system to atmosphere thereby relieving any gas stored in the isolating piston. This also shuts off the initiating pneumatic system **6** by means which are not shown. If the pressure is in the +7 or +20 mm range, a slow vent valve **26** is opened, releasing the excess gas to atmosphere with a controlled release rate until a pressure of below +7 mm is achieved. Restoration to a safe operating region is normally accomplished within a few heart cycles. If the pressure drops to a low pressure, a typical range for example being between −5 and −20 mm, refill load valve **27** is actuated to replenish the gas load in pneumatic system **7**. However, before refilling, the surveillance system **17** asks if the time from he last high normal pressure of +5 mm to which the system is refilled has occurred within the last minute. If it is greater than a minute, refill load valve **27** is opened to replenish the gas load to the high normal pressure of −5 mm. However, if the refill valve is opened continuously for more than 10 seconds, it is assumed there is a leak present in the system and so the refill valve **27** is shut and the rapid vent valve **27** is opened, shutting down the system just as when an over pressure exceeding +20 mm occurs. On the other hand, if the refill load valve **27** is open for less than 10 seconds, and the system is restored to the high normal operating pressure of 5 mm. The system is allowed to continue pumping. When the system pressure drops −20 mm or less, rapid vent **25** is also opened as this indicates that a failure has occurred and the patient is in danger.

In the surveillance system **17**, signal compare circuits **31** to **35**, which may be commercially available voltage comparators, compare the voltage of the pressure signal from amplifier **16** with preset voltages representing the pressure limits designated and when the pressure signal exceeds, or is less than, the designated limit called for by the compare circuit, the circuit produces an output signal. More particularly, circuit **31** produces an output signal when the pressure signal exceeds a reference representing +7 mm pressure. Circuit **32** produces an output when the pressure signal exceeds a reference representing +20 mm of pressure. Circuit **33** produces an output when a reference signal representing −20 mm exceeds the pressure signal. Circuit **34** produces an output when the pressure signal exceeds the reference signal representing 5mm of pressure and circuit **35** produces an output when a reference signal representing −5 mm exceeds the pressure signal. The outputs from circuits **31** to **35** are gated by gates **36** to **40** and the gates are controlled by Sampling Gate pulses shown in FIG. **3** generated by multivibrator **18**. Thus, the outputs of the gates are binary signals representing the occurrence of the events indicated during the sample gate intervals, which fall between the system pressure pulses as shown by waveforms in FIG. **3**.

The output of gate **36** is a negative voltage pulse representing the occurrence of the condition determined by circuit **31**. The negative pulse occurs if the condition occurs, such as, for example, a pressure exceeding a reference pressure of +7 mm. The negative pulse initiates a slow vent control signal from pulse shaper **41** amplified by slow vent amplifier circuit **48**, which controls the vent valve **26**. This slow vent control signal is terminated when the output of gate **36** is a positive level when the system is below +7 mm and is determined by AND circuit **42**. Thus, the slow vent valve **26** vents the system continually following initiation and until the system pressure is decreased below +7 mm and a sampling gate pulse disappears.

The outputs of gates **37** and **38** represent the occurrence of an extreme condition, for example, a pressure over or under +20 mm requiring rapid venting of the system and so these gates trigger flipflop circuits **44** and **45**, which feed through OR gate **46** to amplifier **47** that energizes rapid vent valve **25**. This shuts down the system as danger points have been exceeded. Thereafter, when the defects are corrected, flipflop **44** and **45** are reset and ready again to initiate rapid vent in case pressure exceeds the extreme limits.

The outputs from gates **39** and **40** trigger rapid vent and refill logic circuits **50**. These circuits feed signals through OR circuit **46** to the rapid vent amplifier **47** to cause rapid venting of the system in accordance with the logic already described and also perform the logic to determine whether the system will be refilled. If refill is called for, then a signal from circuits **50** is amplified by refill amplifier **51** which energizes refill load valve **27**.

The logic circuits in **50** are shown in FIG. **2**, which is a simple block diagram of logic elements. This consists of a 1 minute timer **52** which responds to the output of gate **39** producing a pulse of 1 minute interval, when the pulse output from gate **39** is positive indicating a high normal pressure of +5 mm. Similarly, the output from gate **40** initiates a pulse at a low normal pressure of −5 mm. The logic in circuits **54**, which includes an AND circuit **55** and an AND circuit **56** questions first whether the lower pressure limit −5 mm, which requires refilling, has been reached and then asks whether one minute has elapsed since the pressure was last above +5 mm. If the answer to both of these is no, it means the system is losing pressure too rapidly and so there is a serious leak and the system must be shut down. The output of AND circuit **55** is fed through the OR circuit **46** to energize the rapid vent valve **25** that initiates shutdown of the system. On the other hand, if the answer is yes, meaning that refill is required and the pressure has not been above +5 mm during the last minute, then the output of AND circuit **56** generates a fill signal to the flipflop **59**. The output of the flipflop **59** and a 10 second delay pulse from timer **53** are combined by AND circuit **57**. The logic here asks the further question in response to a yes answer from circuit **54** "Is the system still filling after 10 seconds?" If the answer to this is yes, then the indication is that the system has not been restored to an operating condition and it must be shut down. Thus a yes answer in the output of AND circuit **57** commands the system to vent and shut down because refilling is taking too long. However, if the pressure reaches a high normal of +5 mm with 10 seconds, the filling is stopped. This logic is further implemented by double input flipflop circuit **59**. One stage of the flipflop controlled by AND circuit **56** feeds through OR circuit **46** to control rapid vent valve **25** and the other feeds through refill amplifier **51** to control refill valve **27**.

It is envisioned that the timers mentioned above may be eliminated along with the high normal comparator (+5 mm) circuit if it is desired to use an analog refill

system and/or it is desired to eliminate the 1 minute and 10 seconds timing functions along with the high normal pressure functions as described hereinabove. Such a circuit is activated whenever the pressure drops to the low normal level of −5 mm pressure. This will automatically activate the refill load valve. The rate of refilling is made at least substantially equal to the rate at which the human body may safely absorb the load gas utilized. If this rate of refill is inadequate to maintain the normal operating pressure and the system drops below the safe limit of −20 mm pressure, the system will rapidly vent and shut down as previously described. Further, if the refill rate is sufficient to bring the system to within the safe operation range, the patient will not be endangered because the rate of adding the gas can be safely absorbed by the human body. If the fill rate increases the pressure to the upper limit of the system, a feedback loop or the like shuts down the fill function at the desired high normal pressure of, for example, +5 mm.

The embodiment of the invention described herein both as to general and specific functions and general and specific structures illustrates the best known use of the invention. It will be apparent to those skilled in the art that the invention has use also in control and surveillance of pressure in other types of circulatory assist pumps, where the pump is located inside or outside of the patient.

What is claimed is:

1. In a circulatory assist system which sequentially actuates a blood pump by controlling fluid load pressure to the pump, the combination comprising:
   a. sensing means for sensing pump fluid load pressure;
   b. first means responsive to said sensing means for increasing said pressure when it falls below a first predetermined level; and
   c. second means responsive to said sensing means for venting said pressure to ambient pressure when the load pressure exceeds a second predetermined level.

2. The combination as defined in claim 1 and further including third means responsive to said sensing means for venting said pressure to ambient pressure when said pressure falls below a third predetermined level.

3. The combination as defined in claim 2 and further including first timing means responsive to said first means for measuring a first predetermined time interval and further including fourth means responsive to said first timing means and said sensing means for venting said pressure to ambient pressure when said pressure increasing to a fourth predetermined level does not occur within a first predetermined interval.

4. The combination as defined in claim 3 and further including a second timing means responsive to said sensing means for measuring a second predetermined time interval and further including fifth means responsive to said second timing means and said means for venting said pressure to ambient pressure when said pressure falls from above a fourth predetermined level to below said first predetermined level within a second predetermined interval.

5. The combination as defined in claim 4 wherein said fourth predetermined level is greater than said first predetermined level and is less than said second predetermined level.

6. The combination as defined in claim 2 wherein said third predetermined level is less than said first predetermined level which is less than said second predetermined level.

7. The combination as defined in claim 4 wherein the first predetermined interval is longer than the second predetermined interval.

8. The combination as defined in claim 4 and including further means responsive to said sensing means for changing pressure when it deviates from a normal level within a predetermined pressure range lying between said first predetermined level and a fifth predetermined level.

9. The combination as defined in claim 8 wherein said last mentioned pressure change in response to load pressure exceeding the normal level within the predetermined pressure range is accomplished by relatively slowly venting to ambient as compared to the rate of venting when load pressure exceeds the second predetermined level.

10. The combination as defined in claim 8 wherein said fifth predetermined level is greater than said first predetermined level and is less than said second predetermined level.

11. The combination as defined in claim 2 wherein said first means includes a slow fill valve whose rate is not substantially in excess of in vivo blood to absorb the fluid utilized.

12. A circulatory assist system comprising:
   a. Fluid driven pump means for pumping blood;
   b. means for sensing pump fluid load pressure;
   c. means for venting said load pressure to ambient;
   d. means for increasing said load pressure; and
   e. a plurality of means responsive to said sensing means including, first means for controlling said venting means within a predetermined load pressure range, second means for controlling said pressure increase means within said same predetermined load pressure range, and third means for controlling said pressure venting means above and below said predetermined load pressure range.

13. A system as defined in claim 12 wherein, the venting means includes a relatively slow vent and a relatively fast vent, the latter serving to vent above and below the predetermined load pressure range.

14. A system as defined in claim 13 further including fourth means coupling the first and second controlling means to said low pressure venting and to said increasing means, thereby causing pressure to vent when the pressure falls below said predetermined range within a first predetermined interval.

15. A system as defined in claim 14 and further including fifth means coupling said first and second controlling means to said low pressure venting for said increasing means, thereby causing pressure to vent when the time required to increase pressure to said predetermined range exceeds a second predetermined interval.

16. A system as defined in claim 15 wherein the first predetermined interval is longer than the second.

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