

[54] **SAFETY CONNECTOR FOR BALLOON PUMP**

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[58] Field of Search.... **128/1 R, 1 D, 214 R, 274, 273**

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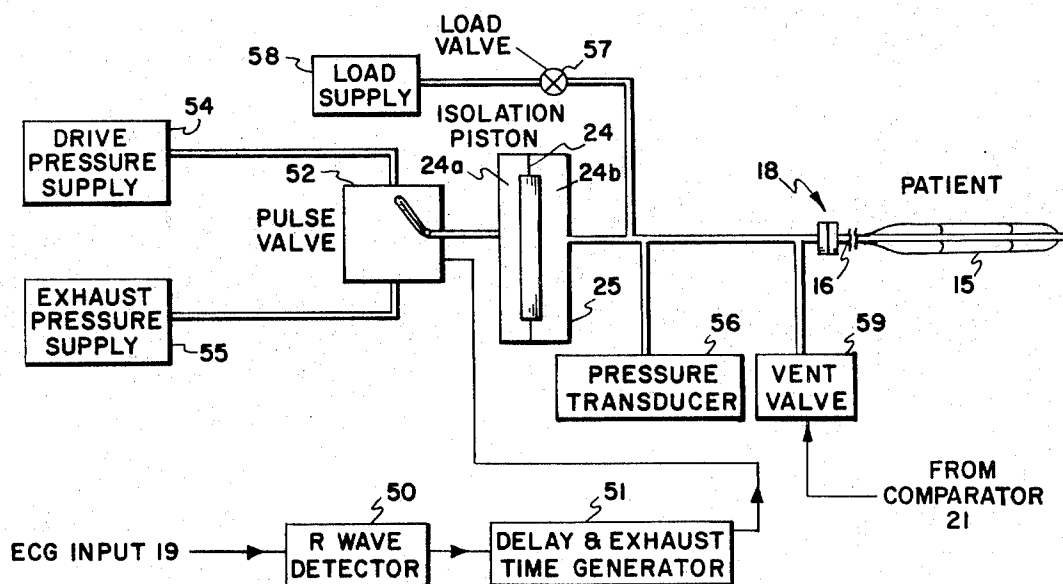
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[57]

ABSTRACT

An intra aortic balloon catheter assembly for use in a circulatory assist system which includes a special connector for joining a balloon implanted in the patient to a control console which may house both pneumatic and electronic controls. The connector is adapted to provide a signal which indicates volumetric displacement of the balloon. This volume is compared to the volume of load gas utilized and shuts the system down if an over-inflation condition exists, prevents overinflation of the balloon, inadvertent use of an incorrectly sized balloon, and allows presterilization of the whole assembly.

6 Claims, 3 Drawing Figures



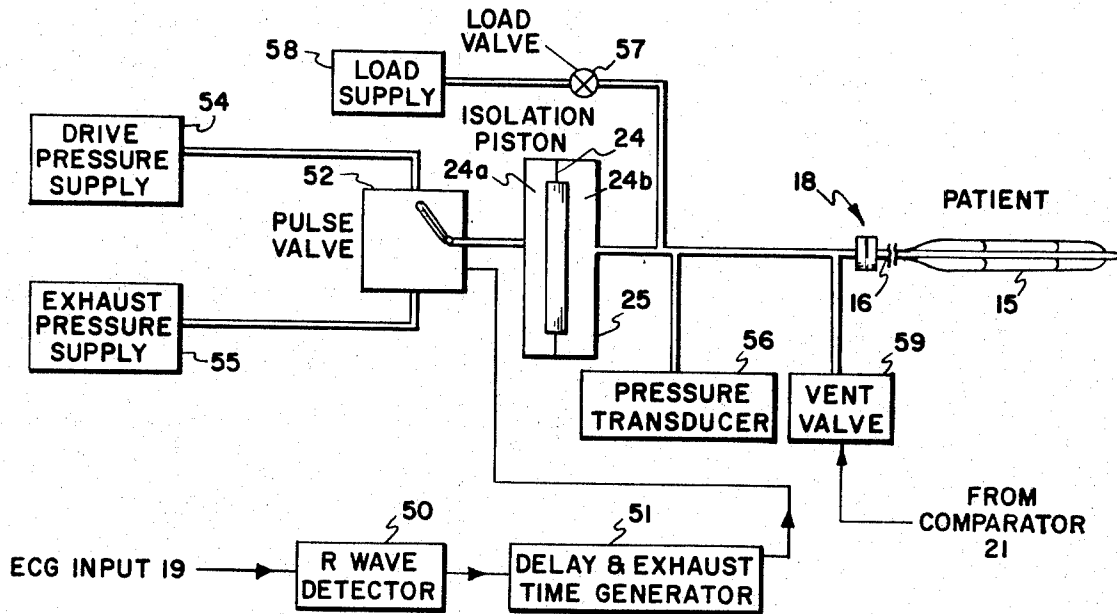


Fig. 3

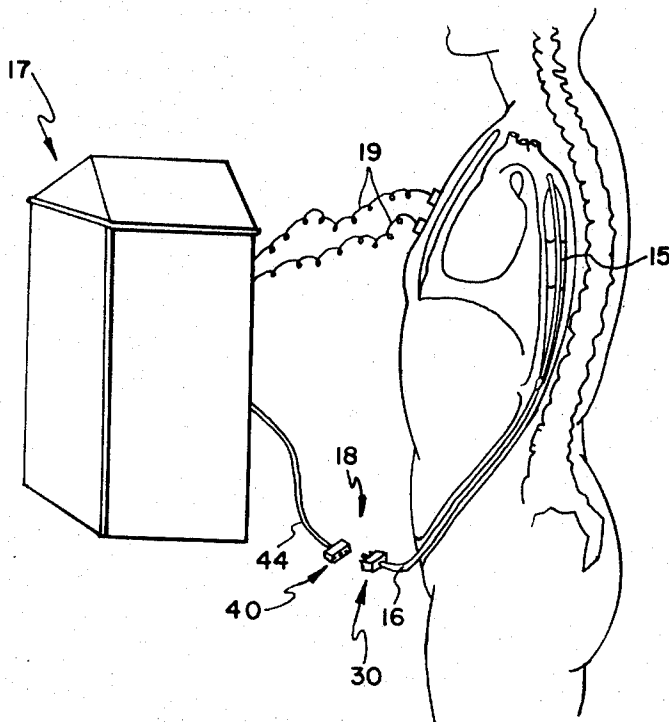
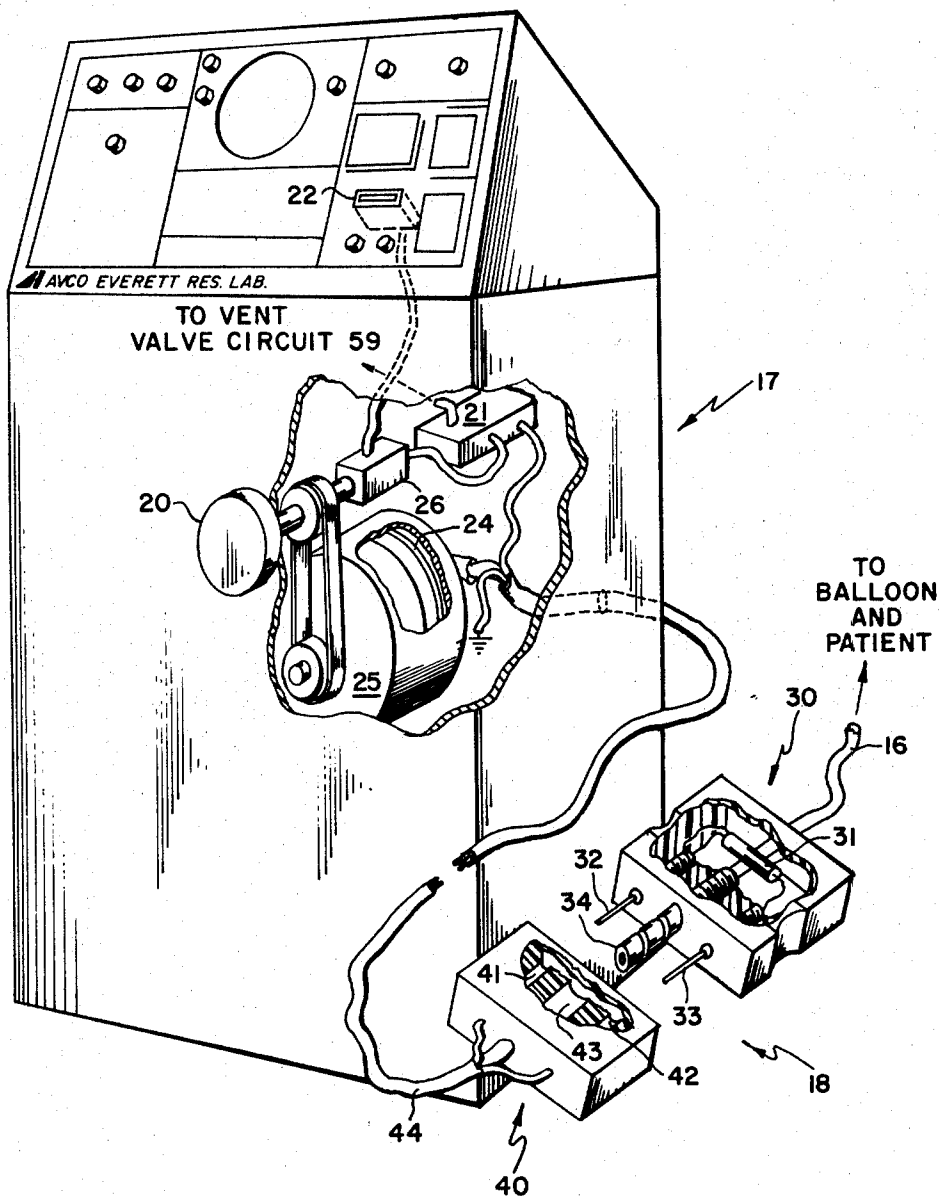


Fig. 1

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SAFETY CONNECTOR FOR BALLOON PUMP

This invention relates to circulatory assist systems and in particular to an intra aortic balloon catheter assembly. This catheter assembly increases the safety performance of circulatory assist devices and, therefore, enhances the utilization of such implantable systems in the human body.

As is well known, the systemic circulation is maintained by the action of the left ventricle in pumping blood into the aorta. Back-flow of blood into the left ventricle is prevented by the aortic valve. During its contraction (systole) the left ventricle works primarily against the elastic compliance of the aorta, raising the pressure in the aorta and distending it. As soon as contraction is complete and the ventricle relaxes, the aortic valve closes and the elastic contraction of the aorta then maintains a continuing flow of blood through the capillaries and other vessels (diastole). In addition to its function as a vessel for carrying blood to various organs, the aorta thus acts as an elastic reservoir storing some of the energy supplied by the heart.

Situations are encountered in the treatment of heart disease where the patient's heart action is simply not sufficient to supply bodily needs. For example, weakness in the heart action called heart failure may occur following a myocardial infarct. Such a heart failure will exhibit low blood pressure during the systole cycle of the normal heart rhythm. This low blood pressure in turn reduces coronary blood flow, thereby, reducing further the blood pressure, creating a deteriorating cycle. It is envisioned that a mechanical device may be used to assist the circulation. Heretofore, mechanical assistance to the systemic circulation has been attempted by veno-arterial pumping, arterio-arterio pumping, and a variety of counter-pulsation techniques including intra aortic balloon pumping.

A practical auxiliary blood pump which assists the natural heart action in a simple reliable and predictable manner should receive recognition and acceptance in the medical field. No entirely satisfactory method for long term assistance has evolved, despite the prominent need for such external assistance, substantial thought, study and work in this field over a period of years.

For one reason or another, the many proposals heretofore propounded by the medical researchers have fallen short of certain desirable requirements, thereby failing in complete acceptance. These proposals have proved too difficult, delicate and/or uncertain to maintain reliable operation, or they have proved to be partially impractical in fulfilling requirements of either proper relationship with natural heart action or volumetric response to desirable standards. Other proposals and/or related equipment have failed to respond to minimum standards of adjustability to meet adequately the requirements of the cardiac specialist.

From the foregoing discussion it will be clear then that the present invention provides an improvement over prior devices and will fill a long needed requirement in the field of circulatory assist blood systems. Intra arterial or "balloon" type pumps per se, for use, for example, in the aorta by insertion through the femoral artery, up the arterial tree and into the aorta, are well known. However, the operation of the pump is extremely critical since it must operate periodically in a transient or instantaneous pulsating manner which

must be synchronized with the patients heart. Furthermore, the stroke of such a pump must operate under various types of conditions such as at a different pressure relating to the pressure of the patient.

The present invention assists the operation of such a system by providing means which will prevent the overinflation of the balloon pump. It is absolutely essential to the operation of any medical device used within the human body, that the device must be constructed as to prevent any foreseeable hazards. Therefore, if a balloon is inserted and is overinflated because it is erroneously thought to be a larger balloon, the balloon may rupture or break in the patient's circulatory system expelling injurious if not lethal amounts of gas into the blood stream. The above situation is prevented in accordance with the present invention by means of an electronic indicator. This indicator provides a signal to the control mechanism which in turn limits the amount of pressure provided to inflate the balloon.

An object of the present invention is to provide a safety mechanism for cardiac assist devices.

Another object of the invention is to prevent overinflation of balloon pump systems.

Another object of the invention is to provide an electronic indicator which may be used to determine the size of the balloon inserted into the aorta.

Still another object of the invention is to provide an intra aortic balloon catheter assembly which is an integrated system that may be presterilized as a unit.

A further object of this invention is to provide an intra aortic balloon assembly that is electrically connected to the pneumatic systems.

Yet another object of the invention is to provide a mechanical safety connection between the balloon pump assembly and the balloon pump console.

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

FIG. 1 shows an overall view of an intra aortic balloon pump in accordance with the invention emplaced in a patient;

FIG. 2 shows an expanded break away view of the safety connector, related electronics, and the balloon pump console; and

FIG. 3 is a block diagram of the principal components of the balloon pump console.

PREFERRED EMBODIMENT

Attention is directed to FIGS. 1 and 2 which illustrate by way of example a preferred embodiment of the invention. FIG. 1 illustrates the use of a balloon pump system in accordance with the invention as used in a patient with a cardiac condition. The balloon 15 which by way of example, as that described in U.S. Pat. No. 3,504,662 is introduced through the femoral artery and positioned in the descending aorta of the patient. To facilitate the insertion, the balloon is inserted in a deflated condition. the size of the balloon used with a particular patient is determined by the patient's sex, age, size and general condition of health. Typical sizes

which are used include balloons having a 20cc, 30cc, or 40cc volumetric displacement. The balloon 15 is attached to a conventional hollow catheter 16 which provides a channel for coupling fluid such as for example, helium from the pumping console to the balloon to inflate and deflate the implanted balloon during operation. The end of the catheter 16 remote from the balloon is coupled to the electronics and pneumatics of the console 17 by the use of a special plug/socket type connection generally designated 18 which will be discussed more fully hereinafter. The balloon, catheter, and part of the connector make up an integral, replaceable unit which may be sterilized together prior to insertion into the human body. The patient's electrocardiac output (ECG) may for example, be monitored in the conventional manner via leads 19. The ECG signal is used in providing the timing sequence for the cardiac assist device so that the balloon will be inflated during the cardiac diastole period.

The basic function of a typical console is to provide inflation of the balloon following closure of the aortic valve on the next heartbeat. A typical block diagram of the principal components is shown in FIG. 3. The ECG signal is fed into a R-wave detector 50. The ECG signal consists of a scintillation pattern dependent upon the electrocardiac output, the highest positive going spiked portion of this signal occurs when the depolarization signal reaches the bundle of His in the heart prior to ventricular contraction. This positive spiked portion of the signal is known in electrocardiography as the R-wave which is sensed by the detector 50. Each R-wave signal from detector 50 is fed to delay and exhaust time generator 51 which provides electrical signal to electromechanical pulse valve 52. The R-wave starts a clock in the delay and exhaust time generator 51 from which the time of inflation and deflation is measured. These times can be adjusted as fractions of the period between heartbeats by manual adjustments. The electrical signals from generator 51 for inflation or deflation actuate a conventional pulse valve 52 which connects the console side 24a of the isolating piston 24 to the drive pressure supply 54 or the exhaust pressure supply 55 respectively.

The isolating piston is used for safety purposes. It is designed so that it does not noticeably decrease the rate of inflation or deflation of the balloon. The isolating piston 24 separates the fluid in the drive mechanism on the console side 24a from the fixed amount of fluid or load gas on the patient side 24b used to inflate the balloon 15. Thus, in the unlikely event of a violent rupture of the balloon, only a limited amount of gas will be injected into the patient. Furthermore, small leaks in the balloon can be detected by the observation of a gradual drop in pressure of gas as measured by pressure transducer 56 on the patient side 24b of the isolating piston 53. Some replacement of load gas is normally required due to permeability of the balloon membrane to helium which is normally used as a load gas. Load gas may be replaced through a load valve 57 from a load supply 58. A vent valve 59 is provided on the patient side of the isolating piston which opens automatically in case of a circuit failure or the like and leaves the balloon in a deflated position.

Attention is now again directed to FIGS. 1 and 2. On the front of the console as best shown in FIG. 2, is posi-

tioned an isolating piston control knob 20 for affecting control of the isolating piston 24 in the fixed volume pump 25 to provide a desired volume of the gas in the patient side of the pump 24b which determines the amount of load gas to be used. The position of control knob 20 also provides an electrical signal by means of a potentiometer 26 that is fed to a conventional comparator 21 and an indicator 22 on the face of the console. The control knob 20 is initially set according to a volume of less than or equal to the specified volumetric capacity of the balloon and its associated catheter. When control knob 20 is positioned correctly, the volume reading at indicator 22 should not exceed the rated capacity of the balloon by more than 2cc. Allowing too large a displacement of the fixed volume pump can overpressure the balloon. A meter reading more than about 5cc's lower than the rated balloon volume should be avoided since this indicates that part of the balloon is not inflating and is then subject to possible thrombotic complications. A balloon which does not fully inflate provides crevices which allow blood to stagnate and form clots which may impede flow and endanger the patient.

The mechanical connector 18 between the catheter and the console is shown in greater detail in FIG. 2. As shown in FIG. 2, the connector 18 comprises a male type plug 30 permanently affixed to the balloon catheter 16, and a female type socket 40 attached to the catheter leading to the console. Disposed within the plug 30 is a resistor 31. The valve of resistor 31 is chosen to reflect the volumetric displacement of the balloon 15 to which plug 30 is attached. Resistor 31 is electrically connected between pins 32 and 33 which are carried by plug 30. Catheter 16 is permanently and sealably connected to a rigid hollow tube 34 which is affixed to and protrudes a distance from the end surface of plug 30.

The female socket 40 is constructed as to receive plug 30, electrical insets 41 and 42 being adapted to receive pins 32 and 33 and recess 43 being adapted to sealably receive tube 34. Recess 43 receives tube 34 with an air tight connection when plug 30 is mated with socket 40. Recess 43 is permanently and sealably affixed to hollow tubing 44 and which is removably connected to the fixed volume pump 25. This completes the pneumatic channel between the balloon and the console. Insets 41 and 42 receive pins 32 and 33 when plug 30 is mated with socket 40. The electrical inset 42 may provide for example, an electrical connection to ground, and electrical inset 41 may be electrically connected to comparator 21 contained within the console 17.

It will now be clear, therefore, that when plug 30 is mated to socket 40 an electrical circuit is completed between the comparator 21, resistor 31, and ground. As illustrated in FIG. 2, this circuit provides in conventional manner in comparator 21 a DC level based on resistor 31 which in turn is proportional to the size of the balloon being used. The comparator in conventional manner compares the aforementioned DC level with the signal provided by the manual volume load adjusting mechanism for the isolating piston. If the volume of the load gas to be provided to the balloon exceeds the safety limits of the balloon, the comparator provides a signal operative to shut off the operation of the volume

meter and rapidly vent the system to the atmosphere. By way of example, this may be accomplished by providing a signal from comparator 21 to activate vent valve 59. This will immediately deflate the balloon and minimize the resistance to blood flow through the aorta. However, if the volume of the load gas to be provided to the balloon is within the safety limits of the balloon assembly, no shut down signal is generated to shut the operation off and the system may function safely in its normal mode.

The value of resistor 31 used in the circuit is matched to the volume of the balloon 15, thus, for example, a 30cc balloon may have a 510 ohm resistor and, a 20cc balloon may have a 300 ohm resistor. The circuit which is completed should be a low voltage (e.g., 2 volts) circuit in order to protect the patient from any electrical shock. Accordingly, only low impedance is necessary to complete the circuit through the resistor 31.

The various features and advantages of the invention are thought to be clear from the foregoing description. Various other features and advantages not specifically enumerated will undoubtedly occur to those versed in the art, as likewise will many variations and modifications of the preferred embodiment illustrated, all of which may be achieved without departing from the spirit and scope of the invention as defined by the following claims:

We claim:

1. In a circulatory assist system having pneumatic means including pneumatic pump means adapted to sequentially apply pressure to a load gas to inflate and deflate a balloon placed in an artery of a patient, means for providing a first output signal proportional to the volumetric displacement of said pneumatic pump means, and electronic timing means for controlling said pneumatic means by sequencing said inflation and deflation to the said patient's heart rhythm, the im-

provement comprising:

- a. a catheter;
- b. a balloon coupled to one end of said catheter, said balloon being adapted to be placed in an artery;
- c. first means for providing a second output signal proportional to the volumetric displacement of said balloon, said first means comprising a connector for removeably coupling said catheter to said pneumatic pump means, said connector comprising first and second separable portions, said first portion being fixedly attached to the end of said catheter remote from said balloon, and impedance means carried by said first portion;
- d. comparator means for receiving said first and second output signals and generating a third output signal when said first output signal is greater than said second output signal; and
- e. venting means actuated by said third output signal for deactivating said pneumatic means.

2. The device of claim 1 wherein said first portion includes terminal means for electrically connecting said impedance means in circuit with said comparator means, said first portion including further means for coupling said load gas to said balloon via said catheter.

3. The device of claim 2 additionally including tube means connected between said second portion and said pneumatic pump means whereby said load gas may inflate and deflate said balloon.

4. The device of claim 3 additionally including insets disposed in said second portion for receiving said terminal means.

5. The device of claim 4 additionally including conductors electrically coupled to said insets for providing electrical connection between said insets and said comparator.

6. The device of claim 1 wherein the said impedance means is a resistor.

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