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HEART AUGMENTATION SYSTEM PROVIDED WITH MEANS FOR MEASURING INTRA-ARTERIAL PRESSURE

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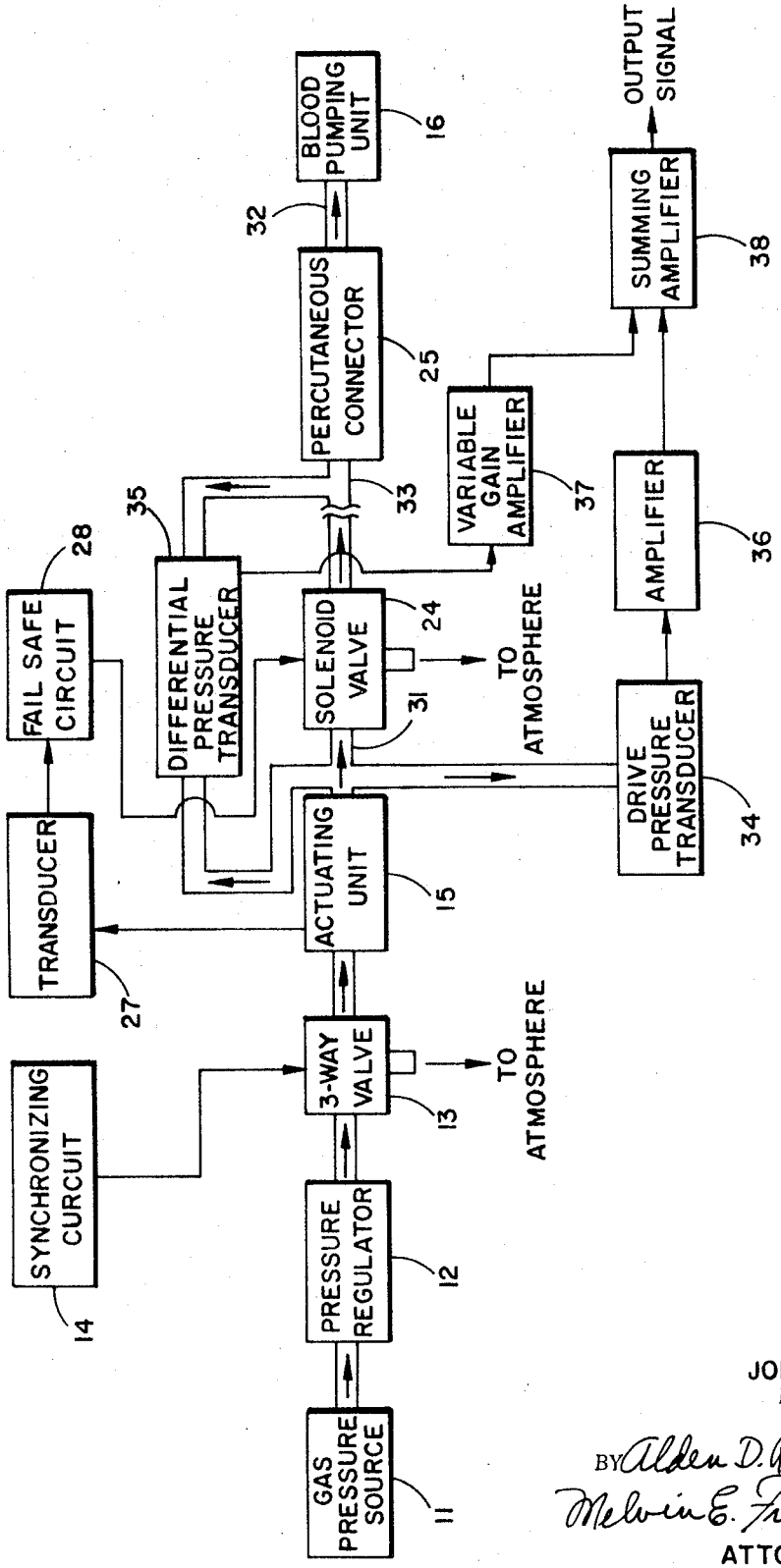

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HEART AUGMENTATION SYSTEM PROVIDED WITH MEANS FOR MEASURING INTRA-ARTERIAL PRESSURE

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ABSTRACT OF THE DISCLOSURE

Apparatus for providing an electrical signal which is representative of intra-arterial pressure. This is accomplished by providing an electrical signal proportional to the pressure drop between an actuating pump and blood pump and subtracting this signal from an electrical signal proportional to the driving pressure at the actuating pump.

This invention relates to circulatory assist systems and more particularly to apparatus for measuring pressures in circulatory assist systems.

The advent of open heart surgery has presented to the medical profession the opportunity of repairing damaged or diseased hearts of individuals and where appropriate, using circulatory assist systems in individuals who without such correction and/or systems face premature death. Many devices are involved in this type of surgery. For example, one circulatory assist system may comprise an auxiliary ventricle or valveless blood pump connected across the arch of the aorta and driven by fluid pressure in response to electronic signals (QRS wave) provided by the heart itself. By operating the blood pump or auxiliary ventricle in proper phase, the systolic pressure in the left heart can be reduced and the systemic circulation can be maintained with a substantially reduced work load on the heart muscle. In addition, the operation of the auxiliary ventricle has the effect of shifting the phase of the normal systolic pressure so that this pressure appears in the aorta at a time when the left ventricle is relaxed. Assuming competence of the normal aortic valve, one then has an increased perfusion pressure available to the coronary arteries. It is believed that such an increase in coronary perfusion, together with a reduction in the effort required from the heart, should be effective in a number of cases of cardiac insufficiency.

As may be seen from the above, one important component of circulatory assist systems is a pump that either assumes the heart's role of pumping blood or which reduces the work load of the heart muscle. By using heart pump equipment for extended periods of time, it is contemplated that the equipment may be utilized for regional perfusions in therapeutic treatment of the heart. Still other use of the equipment will be to provide circulation of blood through an artificial organ such as an external artificial kidney. In connection with this function of the apparatus, it should be noted that many research institutions at this time are concentrating their research activities on providing artificial counterparts of other organs, and whenever such application requires circulation, the present invention may be utilized.

Implantable prior art pulsatile pumps usually consist of a flexible bulb or ventricle squeezed by pressurized fluids from a pumping or actuating unit and is coupled to one or more blood vessels such as arteries or veins. Generally, arterial graft sections connect the bulb to the circulatory system. These arterial graft sections are generally of the woven Teflon-type or Dacron-type employed in the insertion of arterial grafts and the replacement of

damaged sections of an artery. Edwards Seamless Arterial Graft manufactured by the United States Catheter and Instrument Company have been found to be satisfactory.

In most, if not all, circulatory assist systems, it is necessary that the flexible bulb be synchronized with the patient's heart. A typical pneumatically driven and electrically controlled circulatory assist system is disclosed in U.S. Patent No. 3,099,260. Other systems are disclosed in patent application No. 355,273 filed Mar. 27, 1964 now abandoned, and patent application No. 531,281 filed Mar. 2, 1966, to which reference is made and which are assigned to the same assignee as this application.

In the use of circulatory assist systems, it is desirable if not necessary to be able to measure intra-arterial pressure or, which is essentially the same thing, the pressure in the auxiliary ventricle during the time it is in use. This is desirable for medical as well as operational and maintenance reasons. Accordingly, a feature of the present invention is the provision of apparatus in a circulatory assist system for measuring intra-arterial pressure.

Another feature of the present invention is the provision of apparatus in a circulatory assist system which provides an electrical signal representative of intra-arterial pressure or the pressure in an auxiliary ventricle.

A further feature of the present invention is the measurement of a part of the pressure drop along a tube connected between an actuating unit and an auxiliary ventricle which is converted to an electrical signal proportional to the total pressure drop along the tube and subtracted from an electrical signal proportional to the driving pressure at the actuating unit to provide an accurate representation of the pressure in the auxiliary ventricle.

A still further feature of the present invention is the provision of apparatus in a circulatory assist system which provides an electrical signal which is accurately representative of the pressure in the auxiliary ventricle.

A still further feature of the present invention is the provision in a circulatory assist system of apparatus for measuring intra-arterial pressures which permits a visual display accurately representative of the work done by the pumping unit.

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 additional objects and advantages thereof, will best be understood from the description of a specific embodiment when read in conjunction with the accompanying drawing which is a schematic illustration of a typical circulatory assist system incorporating apparatus in accordance with the present invention.

Directing attention now to the drawing, there is shown a schematic illustration of heart pumping or circulatory assist apparatus intended to provide intracorporeal mechanical assistance and incorporating the present invention. As shown in the drawing, in a typical system a suitable pressurized source of gas **11** feeds into a low pressure regulator **12**. Large oxygen bottles which are readily available and are a satisfactory source of oxygen are generally pressurized to a pressure of several thousand pounds and generally have a pressure regulator which, while not particularly sensitive, is satisfactory to provide a reduction in pressure approaching that required for the actuation of the blood pumping unit. A satisfactory pressure for the pumping unit has been found to be approximately 3 pounds per square inch; hence, pressure regulator **12**, while of conventional design, should permit small adjustments in the pressure range of about 10 to 3 pounds per square inch. The output of the low pressure regulator **12** is fed to a three-way solenoid actuated valve **13**. The valve **13**, which is normally open to the atmosphere, is adapted to be operated by a synchronizing circuit **14**

and allows compressed gas to be supplied to an actuating unit **15**. Thus, only when the valve **13** is actuated by the synchronizing circuit **14** does the valve **13** supply compressed gas to the actuating unit **15** which in turn controls the action of the pumping unit **16**.

Broadly, the action of both the actuating unit and the pumping unit must be capable of being synchronized with the patient's heart. The actuating unit and, hence, the pumping unit must be capable of being phased with the patient's heart while the duration of the systole and diastole strokes should be adjustable. The synchronizing circuit **14** performs the function of properly synchronizing the operation of the solenoid in valve **13** for admitting the pressurized gas into the actuating unit **15** in accordance with the demands of the patient. Typically, the synchronizing circuit is actuated by the patient's electrocardiogram or the R-wave taken directly from his heart. By way of example, the output of an EKG unit may be fed into an amplifier and synchronizer pulse circuit that is adapted to amplify the sync pulse or electrical signal used for synchronizing purposes. The amplifier and synchronizing pulse shaper if provided may be designed not only to limit the magnitude of the sync pulse but also to shape it. Since the actuating unit is designed to be synchronized with the R-wave of the sync pulse, all other portions of the wave may be either reduced or removed, thereby leaving only the R-wave. Since the hydraulic events in the patient's heart are not simultaneous with the EKG unit or the R-wave and, furthermore, since the hydraulic events in the patient's circulartory system are delayed behind the systolic pulse of the heart by varying amounts depending on the distance of the artery or vein from the left ventricle of the heart, it is desirable to provide means for phasing the systolic pulse of the pumping unit with the systolic pulse of the heart in order to accommodate these time delays and provide the desired time delay. For this purpose, a systole delay network triggered by the R-wave may be provided to create a sync pulse delayed behind the R-wave by a controlled amount to enable the systolic pulse of the pumping unit to be delayed behind the systolic pulse of the patient's heart by an appropriate time interval. By providing this time delay interval, the pumping unit may be adjusted so that the pressure reflections from the systolic pulse of the pumping unit will be properly phased with the pressure reflections from the systolic pulse of the patient's heart and in such a way as to physiologically aid the patient's heart.

The synch pulse produced by the aforementioned systolic delay network may be utilized to actuate a trigger circuit which may include a systole duration control circuit which is provided for controlling the duration of the tripped condition of the trigger circuit. The output of the trigger circuit may be fed directly into an amplifier, the function of which is to create a signal for firing a thyratron switching circuit or the like, which controls the operation of the three-way solenoid valve **13**. For a further discussion of suitable synchronizing circuits for different applications, reference is made to the aforementioned U.S. Patent No. 3,099,260, and patent application Ser. No. 355,273.

Directing attention now to the actuating unit **15**, it may be of the type disclosed in the aforementioned patent but is preferably of the type comprising a low inertial diaphragm separating the unit into an input compartment and an output compartment, the pressurized gas from valve **13** being admitted into the input compartment and the gas in the output compartment being in communication with the pumping unit **16** through a second three-way solenoid valve **24** and a percutaneous connector **25**. The actuating unit preferably is provided with stops to prevent the diaphragm from providing a volumetric displacement substantially greater than about 60 cc. which is in the range of the average volumetric displacement of the left ventricle of the human heart. Further, the actuating unit should have a low resistance to maintain the load on the heart as low as possible since the heart must move the diaphragm unless the input compartment is coupled at the appropriate time to a partial vacuum through valve **13** during diastole.

Mounted or affixed to the actuating unit is a transducer **27** actuated by the movement of the diaphragm in the actuating unit **15**. This may be accomplished in conventional fashion for example by providing a mechanical connection such as a rod between the transducer **27** and the aforementioned diaphragm in the actuating unit **15**. While the particular type of transducer used is not critical, it should preferably provide a direct current signal, the magnitude of which is proportional to the movement of the diaphragm. Thus, if the diaphragm is moving, the output signal of the transducer **27** will be a varying signal and if the diaphragm stops in any particular place, the output signal will be a direct current voltage.

The actuating unit **15** is coupled to the pumping unit **16** through a solenoid actuated valve **24**. The output signal of the transducer **27** is fed to fail-safe circuitry **28** which controls the solenoid valve **24**. The solenoid valve **24** is normally open, i.e., if the diaphragm is inoperative, the environment surrounding the collapsible bulb of the pumping unit is vented to the atmosphere. A typical pumping unit comprises a rigid container containing a collapsible bulb, the outer surface of which is in communication with a pressurized gas (the output compartment of the pumping unit **15**) and the inner surface of which is in communication with the circulatory system of the body. A typical extracorporeal ventricle is disclosed in the aforementioned U.S. Patent No. 3,099,260, and a typical intercorporeal ventricle is disclosed in the aforementioned patent application Ser. No. 355,273.

All of the foregoing components with, of course, the exception of the percutaneous connector and pumping unit may be located in a bedside control panel. Tube **31** connects the actuating unit **15** to the valve **24**, both of which are in the control panel. Tube **33** connects the pneumatic portion of the system to the patient in which is implanted the percutaneous connector **25** and the pumping unit **16**. Tube **32** which is disposed interior of the body connects the percutaneous connector to the pumping unit.

Having now described a typical circulatory assist system, attention is directed to the apparatus in accordance with the invention comprising drive pressure transducer **34**, differential pressure transducer **35**, amplifier **36**, variable gain amplifier **37** and summing amplifier **38**. The drive pressure transducer **34**, which may comprise a typical strain gauge pressure transducer providing an output voltage proportional to pressure is pneumatically coupled to tube **31** at the outlet of the actuating unit. The electrical output signal of the drive pressure transducer **34** is supplied to the input of a conventional linear amplifier **36** having zero phase shift from DC to about 50 cycles per second and the output of the amplifier **36** is coupled to one of two input terminals of a conventional summing amplifier **38** which will provide an output signal proportional to either the difference or sum of the signals supplied to its input terminals. In the present case, as will be more fully described, the polarity of the input signals to the summing amplifier should be such that the output signal of the summing amplifier is proportional to the difference of the input signals.

A conventional differential pressure transducer **35** may be connected across a length of the pressure line sufficient to provide a measurable pressure difference or drop in the line as shown by way of example in the drawing. As will be pointed out hereinbelow, the distance between the pressure connections of transducer **35** is not important. Differential pressure transducer **35** may be any conventional type which provides an electrical output signal proportional to the difference in pressures it sees through its pneumatic ports. The output signal of transducer **35** is coupled to an amplifier **37** identical to amplifier **36** except that its gain must be linearly variable over an appreciable

range. The output of amplifier **37** is coupled to the remaining input terminal of the summing amplifier **38** wherein it is subtracted from the output signal of amplifier **36**.

The flow of gases in a circulatory assist system described hereinabove may be characterized as an unsteady viscous flow. Such a flow gives rise to two effects which can influence the distribution of pressures along the pressure line which connects the actuating unit to the pumping unit. The first of these effects is simple, steady viscous pressure drop caused by the flow of gas through a relatively small caliber pipe. The second effect which in part causes the pressure difference between the pressure measured at the actuating unit and the pressure actually existing in the pumping unit is due to the unsteady nature of the flow. This second effect may be compared to the so-called "water hammer effect" and is the result of the rapidly accelerating flow in the early states of actuation of the actuating unit. Tests performed in the development of the present invention have shown that a display of uncorrected pressure (the pressure at the actuating unit) is not linearly proportional to the actual pressure within the pumping unit. It is in error by an amount which is proportional to the square of the velocity of the gas in the pressure line and also a term corresponding to the time rate of change of the velocity. Both of these effects while nonlinear functions of time are linearly proportional to the length of tubing. Thus, the losses in the pressure line are implicit functions of time and give rise to a varying correction throughout the total pressure time history. It will now be clear that drive transducer **34** cannot provide a signal accurately representative of the pressure in the pumping unit.

In accordance with the present invention, an electrical signal accurately representative of the pressure in the pumping unit is provided by measuring the pressure drop along a small fraction of the total line from the actuating unit to the pumping unit with differential pressure transducer **35** whose signal is amplified by the variable gain linear amplifier **37**. The gain amplifier **37** is adjustable in proportion to the length of pipe between the actuating unit and the pumping unit so that the output signal of this amplifier is proportional to the total pressure drop over the whole line from the actuating unit to the pumping unit. Pressure transducer **34** just downstream of the actuating unit measures the absolute pressure level in the line at the drive end and it is this pressure which must be corrected in order to infer the pressure in the pumping unit. The correct pressure in the pumping unit is inferred in accordance with the present invention by taking the adjusted output from variable amplifier **37** which is proportional to the total pressure drop in the line and subtracting it from the output of amplifier **36** (which is merely the amplified output of the drive pressure transducer **34**) in summing amplifier **38** to provide a final output voltage from summing amplifier **38** that is proportional to the actual pressure existing in the pumping unit.

The system is calibrated principally by determining the proper adjustment for variable gain amplifier **37**. The proper adjustment of amplifier **37**, which is to say the adjustment of the gain of amplifier **37**, may easily be determined in the following manner: The distal end of tube **32** which is normally connected to the pumping unit is connected to a large volume having a pressure comparable to that which would exist in the pumping unit, such as, for example, 70 to 100 millimeters pressure. It is essential that this calibration volume be large as compared to the stroke volume of the actuating unit. Since the pressure in the large calibration volume will not change significantly for significant pressure changes at the actuating unit, amplifier **37** can be adjusted to provide a substantially constant output signal from the summing amplifier. Accordingly, in the calibration procedure, the output of the summing amplifier may be connected to a scope and the variable gain linear amplifier adjusted during operation of the actuating unit to provide as closely as possible a constant output voltage from the summing amplifier. When this is achieved, the output voltage from the variable gain linear amplifier is, as has been verified by tests, accurately representative of the total pressure drop in the line connecting the actuating unit and the pumping unit.

In actual practice, that is, at an implantation of the pumping unit, the amount of line from the actuating unit to the connection on the control panel is known and will remain fixed. However, the amount of line between the percutaneous connector and the pumping unit may and probably will vary within certain limits. Therefore, the system may be calibrated at the time the pumping unit is implanted by substituting for the line which will be permanently connected to the control panel and thence to the pumping unit a second line of equal length. This line may then be connected to the aforementioned large calibration volume having the appropriate pressure as described previously and the variable gain linear amplifier adjusted for a substantially constant output voltage. At this time, the system will be calibrated and thereafter the permanent line can be used. Subsequent to implantation, the output signal of summing amplifier may, for example, be displayed on an oscilloscope to permit observation of the time history of the patient's intra-arterial pressure. Operation and/or maintenance of the entire system can be monitored by supplying the output signal to an oscilloscope in combination with the output signal of transducer **27** to provide a work diagram of the pumping unit.

While it is theoretically possible to measure the entire pressure drop from the actuating unit **15** to the pumping unit **16**, it will be appreciated that the present invention is vastly superior in that it completely eliminates the necessity of a second pressure tube which must be attached to the patient and the complications and difficulties raised thereby.

Having now described a preferred embodiment of the present invention, what is claimed is:

1. In a system for assisting blood flow within a living body comprising means for sequentially actuating a blood pumping unit including an actuating unit including a movable pressure member for providing pulsatile pressure through a tube to a blood pumping unit including a flexible bulb in communication with the blood, the combination comprising:

(a) first means for providing a first electrical signal proportional to the pressure at said actuating unit;

(b) second means for providing a second electrical signal proportional to the pressure drop between said actuating unit and said blood pumping unit; and

(c) third means for combining said first and second electrical signals and providing a third electrical signal proportional to the pressure at said blood pumping unit.

2. The combination as defined in claim **1** wherein:

(a) said first means includes pressure transducer means for measuring the pressure at said actuating unit and first amplifier means coupled to the output of said pressure transducer means for providing said first signal; and

(b) said second means includes differential pressure transducer means for measuring a portion of the pressure drop between said actuating unit and said blood pumping unit and variable gain amplifier means coupled to the output of said differential pressure for providing said second electrical signal.

3. The combination as defined in claim **2** wherein said third means includes summing amplifier means for subtracting said second electrical signal from said first electrical signal to provide said third electrical signal.

4. The combination as defined in claim **3** wherein each said amplifier means is linear and has a substantially zero phase shift from DC to at least fifty cycles per second.

5. In a system for assisting blood flow within a living body comprising means for sequentially actuating a blood pumping unit including an actuating unit including a movable pressure member for providing pulsatile pressure through a tube to a blood pumping unit including a flexible bulb in communication with the blood, the combination comprising:

(a) first means for providing a first electrical signal proportional to the pressure at said actuating unit, said first means including pressure transducer means controlled by the pressure at said actuating unit and providing an electrical signal proportional to said pressure, said first means additionally including linear amplifier means having substantially zero phase shift for receiving said electrical signal from said pressure transducer means and providing said first electrical signal;

(b) second means for providing a second electrical signal proportional to the total pressure drop between said actuating unit and said pumping unit, said second means including differential pressure transducer means controlled by the pressure drop over a portion of said tube and providing an electrical signal proportional to said portion of said total pressure drop,

said second means additionally including variable gain linear amplifier means having substantially zero phase shift for receiving said signal from said differential transducer means and providing said second electrical signal; and

(c) third means for subtracting said second electrical signal from said first electrical signal and providing an electrical output signal proportional to the pressure in said pump unit.

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