

[54] PULSATILE PUMPING SYSTEM

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Primary Examiner—William L. Freeh

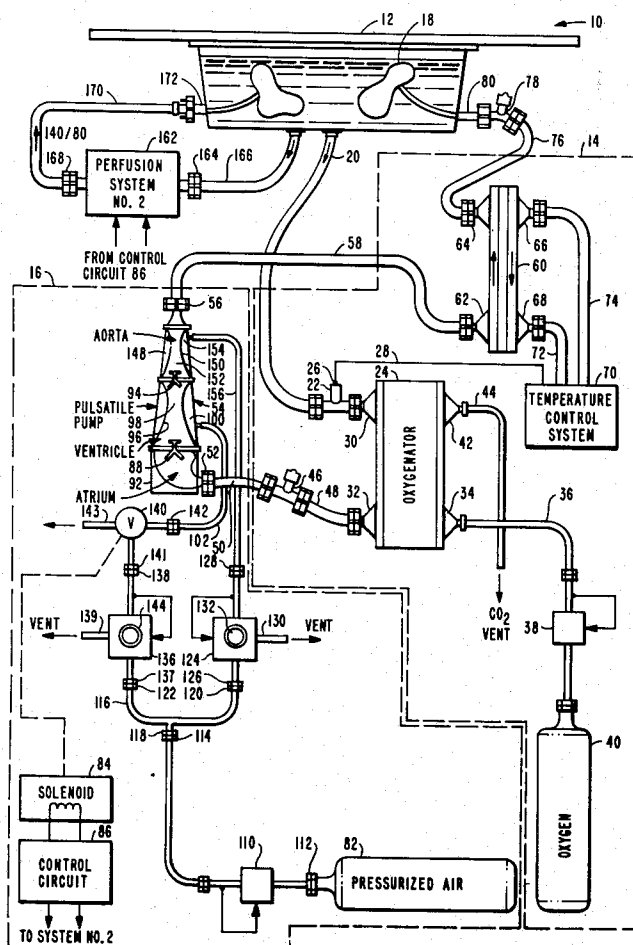
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[57]

ABSTRACT

A portable pulsatile pumping system simulates the pumping mechanism of a human heart in pumping fluid for such applications as organ perfusion systems. The pumping system includes a regulated source of pressurized gas, a pulsatile pump having an aorta chamber providing a sustained minimum diastolic pressure and a ventricle chamber providing a higher systolic pressure during a selectively variable part (1 to 99 percent) of each cyclic pumping action, the periodicity of which may be varied from 5 to 150 cycles per minute. The gas source is connected to the pump by a first adjustable pressure regulator to maintain the chosen diastolic pressure in the aorta chamber. The ventricle chamber is alternately coupled to gas pressure taken through a second pressure regulator and vented by a solenoid mechanism operated by a digital electronic timing control circuit. The digital electronic control system employs digital counters and selector switches to generate square wave pulses of varying duration and periodicity in a manner which provides both conservation of electrical battery energy and high reliability. At the same time, an optimum pumping system is achieved because the elasticity of the gas and connecting tubing are employed to smooth the sharp signal transitions.

10 Claims, 4 Drawing Figures

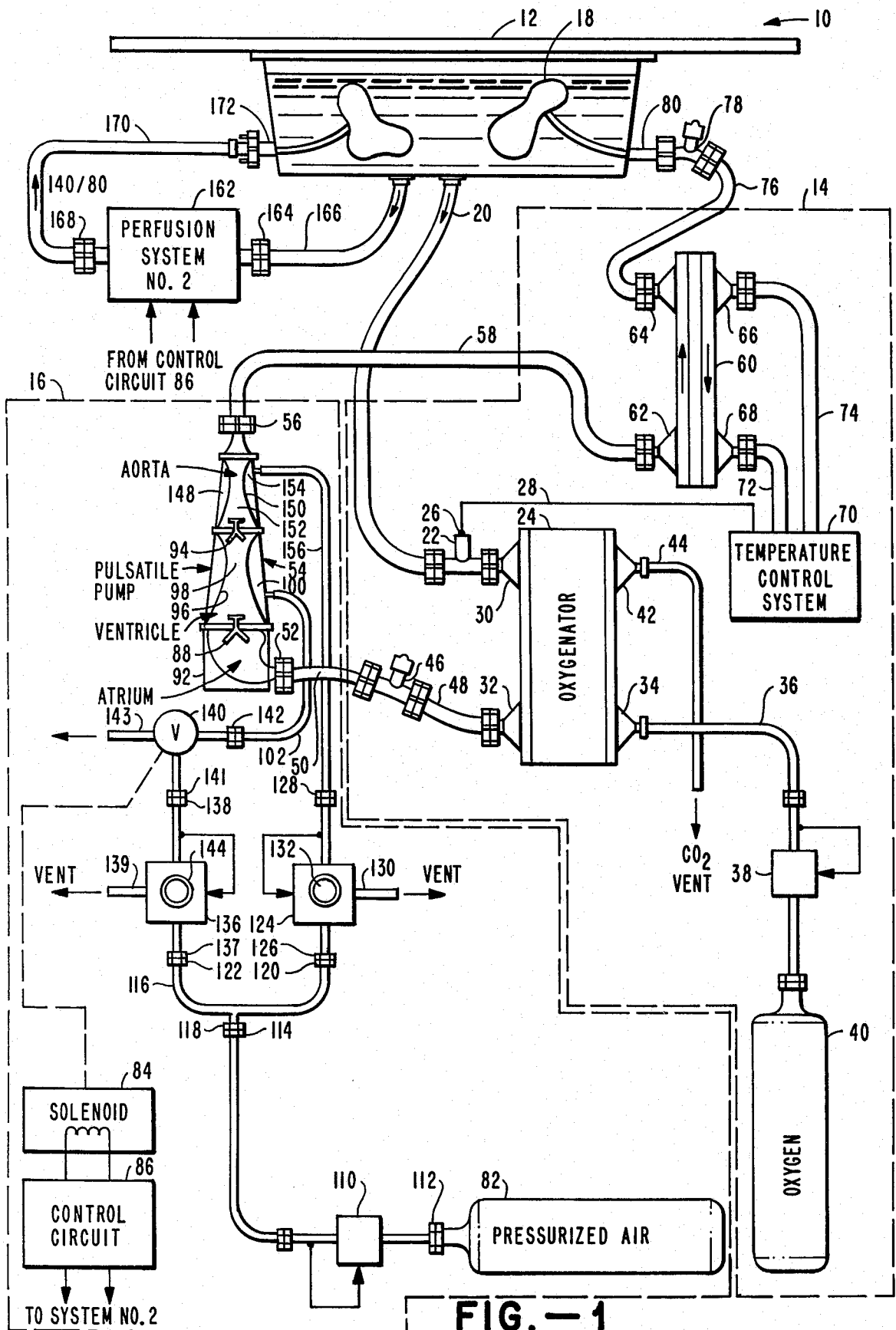


FIG.—1

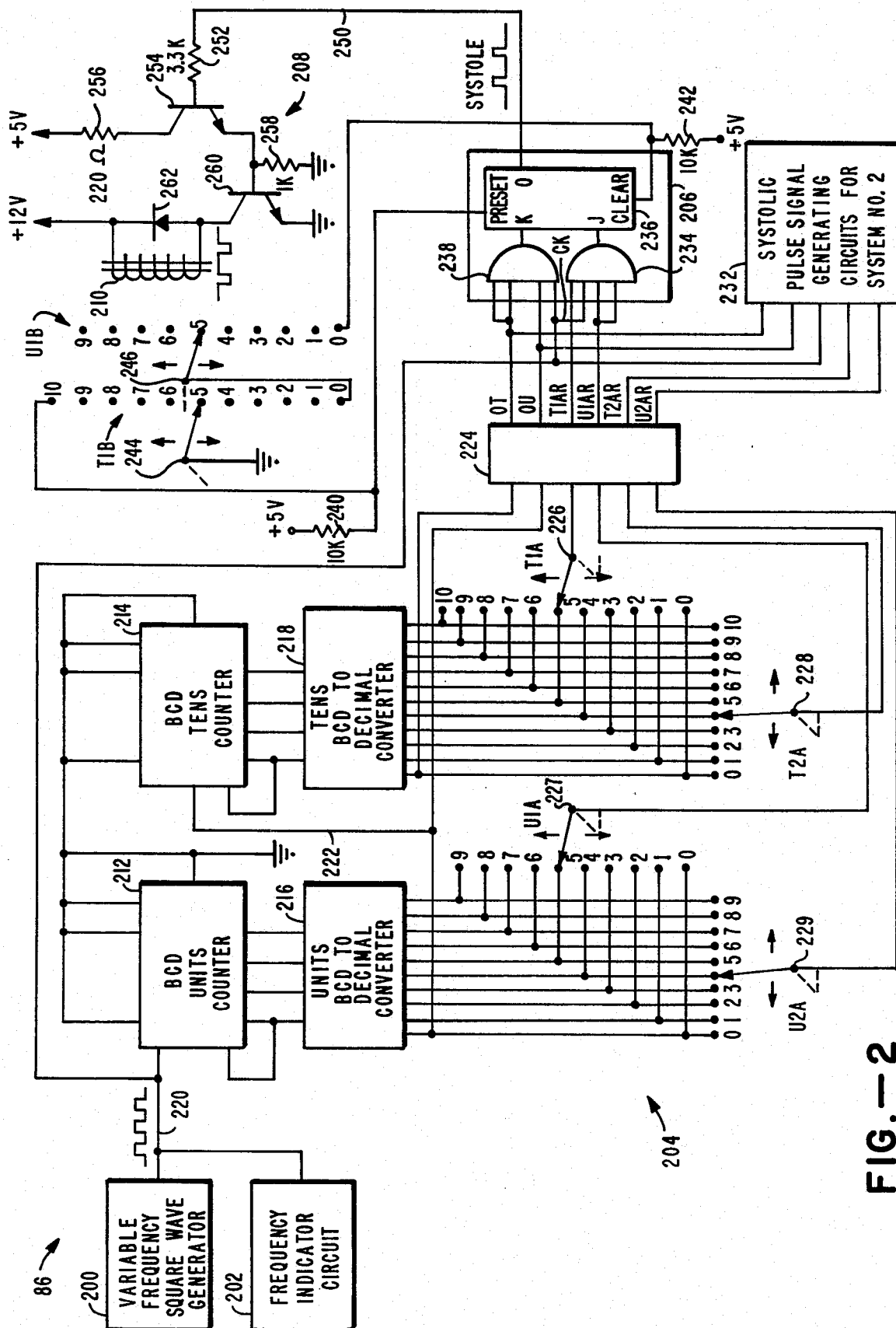


FIG.—2

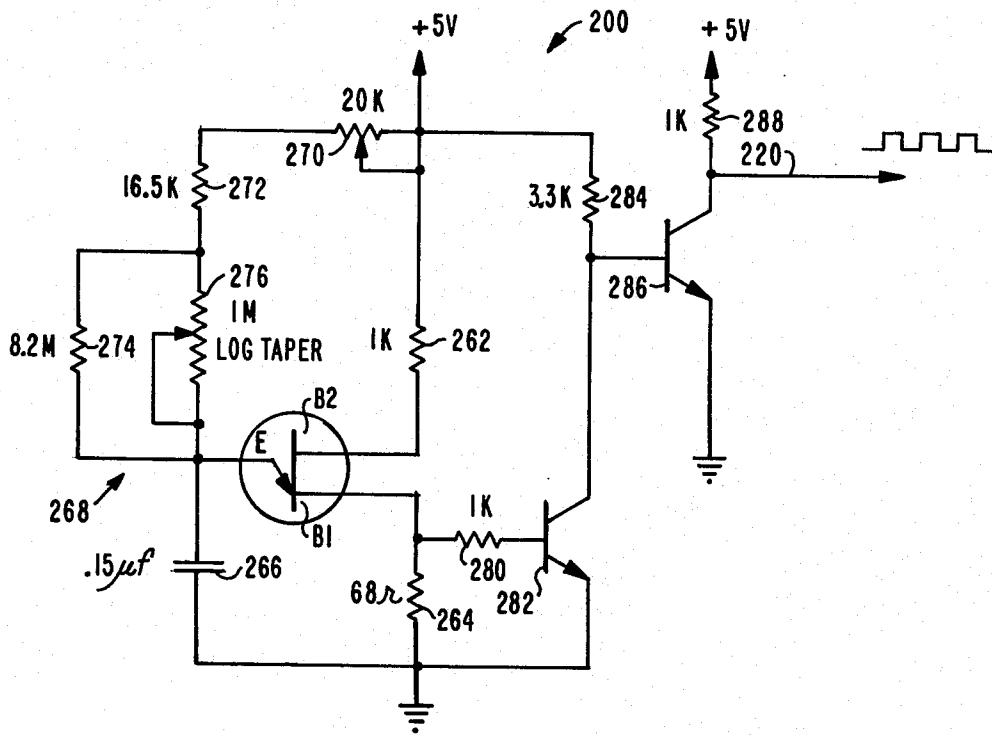


FIG.—3

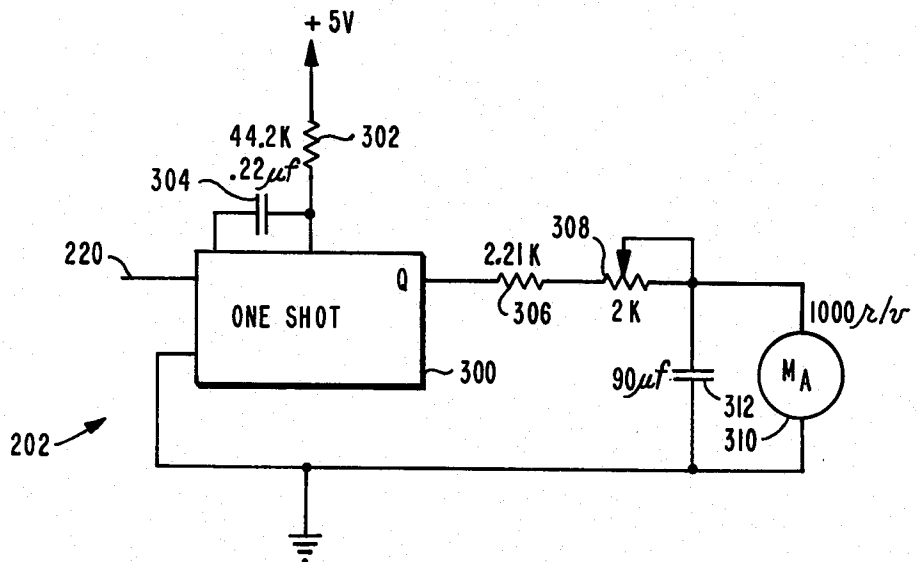


FIG.—4

PULSATILE PUMPING SYSTEM

BACKGROUND OF THE INVENTION

1. Field of the Invention

This invention relates to a system providing gentle, pulsatile pumping for life sustaining fluids, and more particularly to pulsatile pumping systems for organ perfusion systems whose cyclic characteristics may be varied within wide ranges.

2. History of the Prior Art

There are many biomedical systems in which it is desirable to pump life sustaining fluids in a pulsatile manner closely simulating cardiac action. One such application is in an organ perfusion system for preserving an organ such as a kidney from the time it is removed from a donor until it is feasible to transplant it in a recipient.

An organ perfusion system typically recirculates a perfusate containing oxygen and nutrients under control of a pump. Perfusate is drawn from a pool in which the kidney rests, passed through an oxygenator which adds oxygen and removes carbon dioxide, adjusted in temperature, typically by cooling to 5°-10° C., and returned to the kidney. Incoming perfusate is connected to the renal artery of the kidney and passes through the kidney to the pool of perfusate in which the kidney rests, from which pool it is again recirculated. While the reasons are not fully understood at present, a pulsatile pumping action is preferred because it appears to aid the distribution of perfusate through an organ and the performance of life sustaining functions.

Because of the difficulty of getting donors and recipients at the same place at the same time it is desirable that an organ perfusion system be portable and be able to maintain the organ viable, for at least several days. At the same time it must provide smooth, gentle handling of the perfusate under controlled conditions so as not to shock the life sustaining fluid. An advantageous pulsatile pump that closely simulates cardiac pumping action when properly energized is described in U.S. Pat. No. 3,639,084 and incorporates distensible ventricle and aorta chambers connected in series by one-way valves. An atrium chamber collects perfusate under gravity flow and the adjacent ventricle chamber responds to applied periodic systolic pressures to pump perfusate into the aorta chamber which is under constant bias to provide a sustained minimum diastolic pressure. As described in the referenced patent, the systolic and diastolic pressures may be supplied by a regulated source of pressurized air and a fluid logic control circuit may control the periodic repetition of systolic pressure in the ventricle chamber. However, the fluid timing and logic control requires large amounts of compressed air, which militates against portability, and such controls do not adequately permit adjustability over wide operation ranges.

SUMMARY OF THE INVENTION

A pulsatile pumping system for life sustaining fluids in accordance with the invention is portable and economical but yet provides the high reliability, versatility and gentle handling needed for organ perfusion. A pulsatile pump is driven by a highly portable pressurized gas source under control of an accurate, low energy digital electronic circuit. The digital circuit provides accurate control of the pumping action over a wide range of pumping rates and pressure proportions while

the elasticity of the gas and connecting tubing smooth sharp transitions resulting from digital control.

A particular example of the system includes a pump of the distensible chamber type having ventricle and aorta chambers responsive to applied fluid pressures, a source of pressurized fluid providing driving energy for the pump, a diastolic pressure regulator valve coupling the pressurized fluid to the aorta chamber to maintain a constant diastolic pressure therein, a systolic pressure regulator valve coupling the pressurized fluid to the ventricle chamber to provide alternate atmospheric and systolic pressures therein under control of an electronic control circuit, and an electronic digital control circuit connected to control the systolic pressure regulator valve. The control circuit includes a transducer which is responsive to square wave signals and a digital circuit providing square wave signals at a selected variable frequency with the systolic portion of each cycle having a selectively variable proportion. The elasticity of the driving fluid and connecting conduits smooth the sharp actuating signal transitions provided by the digital electronic control to attain a gentle but precise pumping action.

The control circuit includes a variable frequency square wave clock signal generator and two series connected stages of a binary coded decimal (BCD) counter which recycles after each 100 cycles of the clock signal. BCD to decimal decoders are connected to provide a decimal output indicating the state of the units and tens portions of the counter respectively. A pair of two rotor multiple contact rotary switches is connected to the decimal outputs of each of the units and tens decoders so that the rotatable wiper arms are energized when the counters have counted to the decimal outputs which are connected to the contacts at which the rotors are set. A flip flop providing the systolic pressure control signal is connected to reset when the counters recycle and set when the advancing count causes the rotors of both the units and tens switches to become simultaneously activated. As the flip flop sets and resets it provides a square wave pump control signal demarcating alternate diastolic and systolic time intervals with adjustably selectable proportions and the frequency.

BRIEF DESCRIPTION OF THE DRAWINGS

A better understanding of the invention may be had from a consideration of the following detailed description taken in conjunction with the accompanying drawings in which:

FIG. 1 is a schematic diagram of an organ perfusion system utilizing a pulsatile pumping system in accordance with the invention;

FIG. 2 is a partly block diagram and partly schematic representation of a digital electronic control circuit controlling the operation of the pulsatile pumping system shown in FIG. 1;

FIG. 3 is a schematic diagram representation of a variable frequency square wave clock signal generator used in the electronic control circuit shown in FIG. 2; and

FIG. 4 is a schematic diagram representation of a square wave clock signal frequency indicator used in the electronic control circuit shown in FIG. 2.

DETAILED DESCRIPTION

Referring to FIG. 1, there is shown a portable organ

perfusion system 10 for preserving living organs over an extended period of time. The system 10 includes a container or organ chamber 12, in which an organ is to be maintained, a perfusate conditioning system 14 and a pulsatile pumping system 16 which controls the recirculation of life sustaining perfusate from a pool in the container 12, through the conditioning system 14 and through an organ 18 in the container 12 back to the pool in the container 12.

Perfusate moves under gravity flow from the pool in the container 12 through a conduit 20 and T section 22 to an oxygenator 24 of conventional construction. The T section 22 contains a thermistor probe 26 which is in thermal communication with perfusate passing there-through and generates an electrical temperature signal indicative of perfusate temperature on a conductor 28. Perfusate enters the oxygenator at an inlet 30 and passes through the oxygenator 24 under gravity flow to an outlet 32. The oxygenator 24 has an oxygen inlet 34 connected by a conduit 36 to a pressure regulating valve 38 which is in turn connected to a source of pressurized oxygen 40. The pressure regulator valve 38 maintains the oxygen pressure within the oxygenator 24 at a proper level for dissolving a desired amount of oxygen in the perfusate as it passes through the oxygenator 24. An outlet 42 is connected to a conduit 44 to vent carbon dioxide which is removed from the perfusate as it passes through the oxygenator. Thus, as perfusate reaches the outlet 32 it has been resupplied with oxygen and unwanted carbon dioxide has been removed. An access T coupling 46 is connected by conduits 48 and 50 between the outlet 32 of the oxygenator 24 and an inlet 52 of a pulsatile pump 54 within the pumping system 16.

The pump 54, which is of the distensible chamber type described in U.S. Pat. No. 3,639,084, delivers the perfusate at an outlet 56 from which it passes through a conduit 58 to a heat exchanger 60 having perfusate inlet 62 connected to the conduit 58 and a perfusate outlet 64. The heat exchanger 60 has an inlet 66 and outlet 68 through which a heat carrying fluid passes to provide thermal compensation for the perfusate to tend to maintain it at a selected constant temperature. A temperature control system 70 receives the heat carrying fluid through a conduit 72 which is connected to the outlet 68 and delivers heat carrying fluid through a conduit 74 to the inlet 66.

The temperature control system 70 is connected to operate in response to the temperature control signal on conductor 28 to maintain the perfusate at a desired temperature. The temperature control system removes heat from the heat carrying fluid as it is recirculated through the heat exchanger 60 in a typical situation where a perfusate temperature of 5°-10° C. is desired. As the heat carrying fluid is circulated through the heat exchanger 60 it is in thermal communication with the perfusate, thereby tending to maintain perfusate leaving the heat exchanger at outlet 64 at the same temperature as heat carrying fluid entering the heat exchanger through inlet 66. In other arrangements it may be desirable to maintain the perfusate at or near normal body temperature control and in this case it may be necessary for the temperature control system 70 to add heat to the heat carrying fluid as it is recirculated through the heat exchanger 60 in order to maintain the perfusate at the desired temperature.

As perfusate leaves the outlet 64 of heat exchanger 60 it flows through conduit 76 to access T coupling 78 and then through conduit 80 back to the container 12 where the conduit 80 is connected to an organ 18 which is being preserved. For instance in the case of a kidney, the conduit 80 would be connected to the renal artery thereof. The access T couplings 46 and 78 permit perfusate to be periodically drawn off by hypodermic needles for laboratory analysis. Similarly, substances can be added to the perfusate by injection through the access T couplings 48, 78.

In addition to the pump 54, the pumping system 16 includes a source of pressurized driving fluid 82 in the form of a high pressure air bottle which is easily and efficiently coupled to the pump 54, a pressure regulating and conduit system connecting the driving fluid with the pump 54, a solenoid transducer 84 controlling a systolic pressure valve in the pressure regulating and conduit system and a digital electronic control system 86 providing a periodic square wave pulse control signal for actuating solenoid 84. The source of pressurized fluid may alternatively be provided by a battery driven electric motor driving a compressor. The pulse control signal has a selectively variable frequency with systolic and diastolic time intervals of adjustably selectable duration within each cycle. The pump 54 is designed to provide a gentle pulsatile pumping action closely resembling the pumping action of a human heart which alternates a relatively low diastolic pressure with a relatively high systolic pressure during each pumping cycle. The pump 54 contains three chambers which are connected in series through one-way valves 88 and 94 which permit perfusate to flow only in a forward direction through the pump 54. An atrium chamber 92 collects perfusate as it passes under gravity flow through the inlet 52. A ventricle chamber is divided by a flexible membrane 96 into two portions. An interior or perfusate portion 98 of the ventricle chamber is interior to the membrane 96 and receives perfusate through one-way valve 88 from the atrium 92 under gravity flow when the external or driving fluid portion 100 of the ventricle is at atmospheric pressure. The external portion 100 of the ventricle chamber is connected to the pressure regulating system through a small flexible, elastically expandable energy absorbing conduit 102 of a resilient material such as silicone rubber having an inside diameter of about ¼ inch.

The pressure regulating system includes a high pressure regulating valve 110 having an inlet orifice 112 connected to the high pressure source 82 and an outlet orifice 114. The pressure regulating valve 110 maintains a constant pressure of about 20 psi at the outlet 114. A Y connection 116 has an inlet connected to the regulated pressure outlet 114 and separate outlets 120, 122. A fourway diastolic pressure regulator valve 124 has an inlet orifice 126 connected to outlet 120, an outlet orifice 128 and a vent orifice 130. The diastolic pressure regulator valve 124 provides a selectable constant output pressure of 0-500 millimeters of mercury at the outlet 128. This diastolic pressure is set at a desired level by varying the position of a control knob 132 which is typically set to provide a diastolic pressure of about 80 millimeters of mercury. The valve 124 can either supply the outlet 128 with driving fluid from source 82 or vent driving fluid from the outlet 128 to the atmosphere through vent 130 as necessary to maintain the diastolic pressure constant.

A systolic pressure regulator 136 similar to diastolic pressure regulator 124 has an inlet 137 connected to the outlet 122 of Y connector 116, an outlet 138, and a vent 139. A four-way valve 140 has an inlet orifice 141 coupled to outlet 138, an outlet orifice 142, an atmospheric vent orifice 143 and is mechanically coupled to solenoid 84 to connect the outlet 142 to atmospheric pressure through vent 143 when solenoid 84 is inactive and to provide a desired systolic pressure at outlet 142 when solenoid 84 is activated. A desired systolic pressure between 0 and 500 millimeters of mercury may be selected by rotating a control knob 144 on control valve 136 to a desired position. The control knob 144 is typically set to provide a systolic pressure of 240 millimeters of mercury. The conduit 102 is connected to the regulating system at the outlet 142 of solenoid actuated valve 140.

An optional aorta chamber 148 of pump 54 provides a low diastolic pressure which may be greater than atmospheric pressure and has a construction very similar to that of the ventricle chamber. The aorta chamber 148 has a flexible membrane or diaphragm 150 which divides an interior portion of the chamber 152 from an exterior portion 154. The exterior portion 154 is connected by a conduit 156 to the outlet 128 of diastolic pressure regulator valve 124 which causes the predetermined diastolic pressure to be constantly maintained in the external portion 154 of aorta chamber 148.

During a diastolic portion of a pumping cycle, the solenoid 84 is inactive and the external portion 100 of ventricle chamber is vented to atmospheric pressure. This allows membrane 96 to expand as perfusate flows by reason of a gravity head through one-way valves 88 from the atrium 92 into the interior portion 98 of ventricle chamber. Then, as solenoid 84 receives an activating signal from control circuits 86, systolic control valve 140 is driven to a systolic pressure condition to provide the systolic pressure through outlet 142 and conduit 102 to the exterior 100 of ventricle chamber. This relatively high systolic pressure drives perfusate from the interior portion 98 of ventricle chamber through one-way valve 94 to the aorta chamber 148 which is somewhat smaller than ventricle chamber. As perfusate is forced through one-way valve 94 during this systolic portion of the cycle, the flexible membrane 96 collapses, the interior portion 98 decreases in volume, and the exterior portion 100 increases in volume. At the beginning of a systole portion of a pumping cycle, the pump 54 continues to provide perfusate at the diastole pressure. However, the aorta membrane 150 rapidly expands to maximum capacity, permitting the systolic pressure to then be passed through the aorta chamber to the kidney 18. The cycle is then repeated as the solenoid 84 is deactivated, causing systolic control valve 140 to again vent the exterior portion 100 of ventricle chamber to the atmosphere.

After the systolic portion of a pumping cycle is terminated by control circuit 86 the membrane 150 begins to collapse under the constant pressure in the external portion 154 of the aorta chamber 148 to force perfusate out through the outlet 56 at the constant, sustained, minimum diastolic pressure. Before the membrane 150 is completely collapsed a new systolic portion of a pumping cycle must be commenced to force more fluid into the aorta chamber. In this way the pulsatile pump 54 provides alternating diastolic and sys-

tolic pressures at the outlet 56 with a pumping characteristic very closely following that of a human heart.

The small internal diameter of conduit 102 and the elastic energy absorbing properties of the driving fluid and conduit 102 combine to provide an energy absorbing fluid impedance which acts as a hydraulic filter to smooth sharp pressure transitions in the ventricle chamber. Some life sustaining fluids such as whole blood are easily damaged by shock and must therefore be treated extremely smoothly and gently. This hydraulic impedance or filtering characteristic permits the hydraulic control system to be controlled by a square wave pulse signal having sharp transitions (for example 5 millisecond rise — 30 millisecond decay) without damaging the life sustaining fluid. By the time the digital pulse control signals reach the external portion 100 of the ventricle chamber sharp transitions have been filtered out. Thus, the pulsatile pump 54 is able to handle a life sustaining fluid gently and without shock, whether it be whole blood, perfusate or some other fluid, even though control is provided by a digital electronic signal having sharp transitions.

A second organ perfusion system represented by a hollow rectangle 162 and labeled Perfusion System No. 2 is connected to receive perfusate at an inlet 164 through a conduit 166 from the pool in container 12 and provide perfusate through outlet 168 and conduit 170 to a conduit 172 which connects to a second organ to be preserved within the container 12. Organ Perfusion System No. 2 shares the container 12 and certain components in the control circuit 82 with Perfusion System No. 1 and may be assumed to be substantially identical to Perfusion System No. 1 even though it is not described in detail.

The electronic digital control circuit 86 includes a variable frequency square wave generator 200 which generates a digital square wave clock signal at a frequency selected by an operator, a frequency indicator circuit 202 which indicates to an operator the frequency of the square wave clock signal, a proportioning control circuit 204, a gated flip flop 206, a power amplifier 208 and a solenoid coil 210 which controls the activation of solenoid 84 (FIG. 1).

The proportion control circuit 204 includes a century counter having a BCD units counter 212, a BCD tens counter 214 connected to count cycles of the counter 212, a BCD to decimal converter 216 responsive to the outputs from the unit counter 212 and a BCD to decimal converter 218 responsive to outputs from the BCD tens counter 214. The BCD counters 212, 214 may be implemented with MC 7490P integrated circuits manufactured by Motorola and the BCD to decimal converters 216, 218 may be implemented with MC 7442P integrated circuits, also manufactured by Motorola. The decoded decimal units and decimal tens outputs of the century counter indicate the successive counts of the century counter as it counts clock pulses from 0 to 99 and then recycles back to 0 at count 100. For instance when the counter reaches the count of 55 the number 5 outputs of both the units converter 216 and tens converter 218 will have a high voltage thereat and each of the other decoded decimal outputs will have a low or ground potential thereat. The counter 212 and converter 216 together with the counter 214 and converter 218 form first and second decade counting systems providing discrete decimal outputs indicative of instantaneous counts therein.

Four switches are provided to permit operator control of the proportion of each pumping cycle during which systolic pressure is desired, two for system No. 1 and two for system No. 2. Each switch contains two completely insulated portions designated part A and part B having mechanically coupled rotors which are simultaneously and synchronously positioned by a single control knob. Switch U1 is a ten position rotary switch in which an A portion has the fixed contacts thereof connected to the ten decimal outputs of the units converter 216 in sequence. Similarly, switch T1 is a 11 position rotary switch having ten of its 11 contacts connected to the ten decimal outputs of tens converter 218 in sequence. The eleventh contact is not connected. The two switches U2 and T2 of the second perfusion system are connected in similar manner with the ten A contacts of switch U2 connected to the ten decimal outputs of units converter 216 and ten of the eleven A contacts of switch T2 connected to the ten decimal outputs of tens converter 218 with the eleventh A contact left open. The BCD units counter 212 receives the variable frequency clock signal as an input on conductor 220 and BCD tens counter 214 receives its counting input from decimal output zero from units converter 216 on conductor 222. The integrated circuits 212, 214, 216 and 218 may otherwise be connected, biased and compensated in a conventional manner. An isolator 224 which may be implemented with an MC 836P integrated circuit manufactured by Motorola is connected to receive inputs from the decimal zero output of tens converter 218, the decimal zero output of units converter 216, the rotary wiper contact 226 of switch T1A, the rotary wiper contact 227 of switch U1A, the rotary wiper contact 228 of switch T2A and the rotary wiper contact 229 of switch U2A and provide outputs designated OT, OU, T1AR, U1AR, T2, AR, and U2AR respectively in response thereto.

These six signals are used by systolic pulse generating circuits for both systems No. 1 and No. 2 to generate the systolic pulse signals which actually control the activation of solenoid coil 110. Since this portion of the system is identical for both system No. 1 and system No. 2, the systolic pulse generating circuits for system No. 2 is indicated merely by a hollow rectangle 132 and it will be understood that the same description applies as given hereafter for system No. 1.

As illustrated with respect to system No. 1, the wiper arm signals TLAR and ULAR for the digit and for the decimal and unit switches respectively are received by an AND gate 234 controlling the J input to a JK flip flop 236 within an integrated circuit gated flip flop 216. The TLAR and ULAR signals operate in combination with the clock signal to activate AND gate 234 at the selected variable count, causing AND gate 234 to generate an intermediate control signal which activates the J input to flip flop 236. An AND gate 238 generates an intermediate control signal which activates the K input to flip flop 236 in response to the OT, OU and clock signals which occur as the century counter resets. The AND gates 234 and 238 are connected to be enabled by the clock signal from the square wave generator 200. An inverting preset input to flip flop 236 is connected through a 10 K resistor 240 to a 5 volt source. It is also connected to the number 10 contact of the B portion of switch TL. The number 10 contact of the A portion of switch TL is not implemented. A movable

rotor 244 of switch TLB is connected to ground. An inverting clear input to flip flop 236 is connected through a 10 K resistor 242 to a 5 volt source and to the number 0 contact of the B portion of the switch UL. The wiper arm 245 of switch ULB is connected to the number 0 fixed contact of switch TLB. Thus, whenever both of the system No. 1 proportioning system switches are set to zero, flip flop 236 is constrained to the clear state. Similarly, whenever switch TLB is set to the number 10 position, flip flop 236 is constrained to remain in the one or true state. The Q output of flip flop 236 provides the square wave systolic pulse control signal on conductor 250 which drives the coil 210 through power switching amplifier 208.

Conductor 250 is connected through a 3.3 K resistor 252 to the base of an npn transistor 254. The collector of transistor 254 is connected through a 220 ohm resistor 256 to a +5 volt source and the emitter of transistor 254 is connected through a 1 K resistor 258 to ground and also to the base input of an npn transistor 260. The emitter of transistor 260 is connected to ground and the collector is connected both to the anode of a diode 262 and to a negative terminal of solenoid coil 210 in solenoid 84. The solenoid coil 210 and diode 262 are connected in parallel with the positive terminal of coil 210 being connected to a +12 volt source and the cathode of diode 262 connected to the same +12 volt source.

The power switching amplifier 208 responds to a systolic pulse control signal on conductor 250 by activating the coil 210 when the control signal is high or true and inactivating the coil 210 when the control signal is at ground potential or false. Whenever the systolic pulse control signal is true, transistor 254 is turned on permitting current to flow through the collector and emitter thereof to in turn cause transistor 260 to be turned on. As transistor 260 is turned on activating current is permitted to flow from the +12 volt source through coil 210 to the collector of transistor 260 and then out through the emitter of transistor 260 to ground. This activation of coil 210 causes solenoid 84 to switch four-way pressure regulator valve 136 to the systolic pressure state wherein systolic pressure is applied to external cavity 100. As the systolic pulse control signal returns to ground potential, transistors 254 and 260 are switched off and the continued flow of current through the coil 210 is blocked. As coil 210 is deactivated solenoid 84 causes pressure regulator valve 136 to return to a state wherein atmospheric pressure is communicated to external chamber portion 100. Energy which may be stored by solenoid coil 210 at the time transistor 260 is switched off may be dissipated through diode 262.

The variable frequency square wave generator 200 is illustrated in greater detail in FIG. 3. The generator 200 includes a type 2N2840 variable frequency oscillator 260 having a B2 terminal connected through a 1 K resistor 262 to a +5 volt source and a BL terminal connected through a 68 ohm resistor 264 to ground. The control terminal E of oscillator 260 is connected through a 15 μ farad capacitor 266 to ground and also through a frequency control circuit 268 to the +5 volt source. The frequency control circuit 268 includes a 20 K potentiometer 270 having one terminal and the wiper contact connected to the +5 volt source and the other terminal connected to a 16.5 K resistor 272. The other terminal of resistor 272 is connected to one terminal of

an 8.2 megohm resistor 274 and one terminal of a 1 megohm potentiometer 276 having a logarithmically varying resistance. The opposite terminal of resistor 274, the wiper arm of potentiometer 276, and the opposite terminal of potentiometer 276 are connected to the gate or control input E to oscillator 260. The output from the oscillator 260 is taken from a BL terminal which is connected through a 1 K resistor 280 to the base of an npn amplifying transistor 282. Transistor 282 has its emitter connected to ground and its collector connected through a 3.3 K resistor 284 to a +5 volt potential. The collector of transistor 282 is connected to the base of a second amplifying transistor 286 having its emitter connected to ground and its collector connected through a 1 K resistor 288 to the +5 volt potential. The square wave clock signal is provided on conductor 220 which is connected to the collector of amplifying transistor 286.

The variable square wave generator 200 provides a square wave clock signal at a frequency variable between 8.33 and 250 hertz in accordance with the setting of potentiometer 276. This frequency range corresponds to a frequency range of 500 to 15,000 cycles per minute which is divided by 100 by the century counter 204 to provide a frequency range of 5 to 150 pulses per minute for the systolic pulse control signal on conductor 250.

The frequency indicator circuit 202 is illustrated in greater detail in FIG. 4. The frequency indicator 202 includes a one shot 300 which receives the clock signal from square wave generator 200 on conductor 220 and generates a positive output for a selected time interval in response to each positive going transition of the clock input. The one shot 300 may be a type MC 8601P integrated circuit manufactured by Motorola and has a 44.2 K resistor 302 and a 0.22 μ farad capacitor 304 connected in a conventional manner to control the time interval of the output. The output is taken from the key terminal and connected through a 2.21 K resistor 306 and a 2 K trim pot 308 to a positive terminal of a milliammeter 310 which has its negative terminal connected to ground. A 90 μ farad filter capacitor 312 is connected in shunt across the terminals of milliammeter 310 to smooth changes in voltage across the terminals of the meter 310. The resistor 306 and potentiometer 308 operate in conjunction with a fixed voltage at the Q output of one shot 300 to provide in effect a constant current source which provides meter 310 with a fixed amount of charge for each fixed firing interval of one shot 300. The total charge per unit of time reaching milliammeter 310 is thus directly proportional to the frequency at which the one shot is fired under control of clock signal on conductor 220. This charge must pass through milliammeter 310 in the form of a current which drives the pointer to a rotational position directly proportional to the frequency of the clock signal. Milliammeter 310 may be calibrated to indicate the frequency of the systolic pulse control signal directly.

The electronic digital control circuit 86 provides precise, highly reliable, low cost control of the pulsatile pumping system with the consumption of very little electrical power. A highly portable, conventional 12 volt battery (not shown) easily provides the required source of electrical energy. A conventional voltage regulator such as a LM309K manufactured by National Semiconductor may be connected to the 12 volt battery to provide the +5 voltage source required at many

points in the control circuit 86. While an easily portable battery provides the electrical power, an easily portable bottle of pressurized air may be used to provide the pneumatic power. Since the pressurized air driving fluid is used only to drive the pulsatile pump 54, much less driving fluid is consumed by the perfusion system 10 than would be required if the driving fluid were also used to energize a pneumatic timing control system. Since a 25-pound bottle of pressurized air will operate the perfusion system 10 for 8-12 hours, the complete perfusion system including energy sources is relatively light in weight and highly portable. This arrangement makes optimum use of both electrical and pneumatic elements and energy sources to provide an economical, highly reliable, portable perfusion system 10 which can be used to preserve an organ for several days while transporting it from one place to another.

The electrical control system permits the systolic portion of each cycle of the pulsatile pump 54 to be varied under automatic control between 1 and 99 percent, fixed at 0 percent, fixed at 100 percent or completely controlled by hand. For instance, by setting the units and tens control switches to number 55, diastolic pressure will be provided during the first 55 percent of each pumping cycle and systolic pressure will be provided during the last 45 percent of each pumping cycle. As the century counter recycles the 0 outputs of both the units and tens BCD to decimal converters 216, 218 will go true causing the OT and OU signals to go true to activate the K input to flip flop 236. The K input causes flip flop 236 to reset and produce a ground potential output signal which turns off power amplifier 208 to deactivate solenoid coil 210 and connect the exterior portion 100 of ventricle chamber 94 to atmospheric pressure. As soon as the century counter reaches the count of 55 the "5" outputs of the units and tens BCD to decimal converters 216, 218 go true causing the TLAR and ULAR signals to go true, thereby activating the J input to flip flop 236. As the J input is activated flip flop 236 switches to the true state to provide a high voltage systolic signal which turns on power switching amplifier 208 to activate the coil 210 in solenoid 84 and connect the external portion 100 of ventricle chamber to the selected systolic pressure. This systolic pressure is maintained throughout the last 45 counts of the pumping cycle until the century counter 204 recycles to again switch the systolic pulse control signal to the low state. By setting the proportion switches TL and UL at any desired count between 99 and 1 the systolic or high pressure portion of each pumping cycle can be varied from 1 to 99 percent.

When both the units and tens proportioning switches are set to the zero position, the B portion of the switch causes flip flop 236 to be constrained to the zero state and the exterior portion 100 of ventricle chamber is continuously vented to atmospheric pressure. Similarly, when the tens switch is set to the number 10 position the preset input of flip flop 236 is continuously activated causing the flip flop to provide a continuous systole signal as a pulse control signal to cause a systole pressure to be continuously provided to the exterior portion 100 of ventricle chamber. Since pulsatile pump 54 requires alternating systolic and atmospheric pressures in the ventricle chamber to maintain pumping action, no fluid will be pumped so long as the proportion switches are set to provide continuous systolic or diastolic pressures at the ventricle chamber. However, by

setting the tens unit switch in the zero position and manually alternating the ten switch between the zero and ten position, both the frequency of the pumping cycle and the relative proportions of systolic and diastolic pressure can be controlled manually over any desired range.

Although there has been described above a particular arrangement of a pulsatile pumping system in accordance with the invention, it will be appreciated that the scope of the invention is not limited thereto. Accordingly, any modification, variation or equivalent arrangement within the scope of the appended claims should be considered to be within the scope of the invention.

What is claimed is:

1. A system for providing a selectively controllable pulsatile flow of a perfusate to simulate cardiac action comprising: a pulsatile perfusate pump which comprises flexible chamber means, said means being collapsible in response to applied fluid pressure, to pump perfusate in said chamber means through a flow line in pulsatile manner;

at least one fluid pressure means;

adjustable systolic pressure regulator means coupled to said fluid pressure means;

first conduit means including control signal responsive valving means coupling said systolic pressure regulator means to said ventricle chamber means; and

electronic control means including adjustable means for generating square wave control signals of adjustable duration and repetition rate, the square waves having sharp rise and fall times, wherein said valving means comprises a two output valve having a venting output and an output communicating with said perfusate pump, wherein said fluid pressure means comprises a pressure storage vessel, and wherein said electronic control means comprises counter means adjustable to provide valving means controlling outputs at selected counts, said counter means being adapted to count said square wave control signals.

2. The invention as set forth in claim 1 above, wherein said first and second conduit means comprise small diameter resilient tubing, and wherein the applied fluid under pressure is air.

3. A combination electronic pneumatic pump control system for gently controlling a pulsatile pump maintaining a first output pressure and producing a periodically occurring systolic output pressure greater than the first pressure in response to a periodically occurring fluid drive pressure comprising:

a selectively venting pressure control valve having an input connectable to a drive fluid pressure source under control of a transducer;

a conduit connected to the outlet of the pressure control valve to a fluid operated pulsatile pump for providing operating fluid to said pump, said conduit restricting the flow of drive fluid therethrough;

a transducer connected to control said pressure control valve to selectively connect the outlet to said pressure source in response to first and second states respectively of an electronic digital control signal having sharp transitions between states; and

an electronic digital control circuit providing an electronic digital control signal to the transducer, said control circuit including a recycling counter,

means responsive to the counter for switching the electronic digital control signal to a first state when the counter reaches a first selected count, and means for switching the electronic digital control signal to a second state when the counter reaches a second selected count, each state being present during a selected variable proportion of each control signal.

4. The pump control system as set forth in claim 3 above, wherein the conduit includes at least one elastically expandable portion which absorbs energy as it expands in response to a pressurized drive fluid therein.

5. The pump control system as set forth in claim 4 above, wherein the drive fluid is an expandable gas.

6. The pump control system as set forth in claim 5 above, wherein the drive fluid is compressed air.

7. The pump control system as set forth in claim 3 above, wherein at least one of said first and second counts is selectively variable under operator control.

8. The pump control system as set forth in claim 5 above, wherein the electronic digital control circuit includes an oscillator generating a clock signal at a selectively variable frequency; a recycling counter connected to count cycles of the clock signal; means responsive to the counter for generating first and second intermediate control signals in response to first and second counts of the counter respectively, said control signal generating means including means for selectively varying the count at which at least the first intermediate control signal is generated; and means connected to switch the electronic digital control signal to the first and second states in response to the first and second intermediate control signals respectively.

9. A system for providing a selectively controllable pulsatile flow of a perfusate to simulate cardiac action, the flow having selectable diastolic and systolic intervals and pressures comprising:

a pulsatile perfusate pump having at least a pair of pump chamber means responsive to applied fluid pressures;

means providing diastolic and systolic fluid pressures; conduit means providing substantial impedance to fluid flow and coupling each of said diastolic and systolic pressure means to a different chamber of said perfusate pump;

signal responsive valving means coupled into the conduit means coupling the systolic pressure means to the perfusate pump; and

electronic control signal generating means coupled to said valving means and including means for generating a systole control signal of controllable duration and repetition rates, to provide control signals to said signal responsive valving means, said systole control signal means comprising an electronic digital control circuit which includes an oscillator for generating a clock signal at a selectively variable frequencies; a recycling counter connected to count cycles of the clock signal; means responsive through the counter for generating first and second intermediate control signals in response to the first and second counts of the counter respectively, said control signal generating means including means for selectively varying the count in which at least the first intermediate control signal is generated; and

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means for altering the signal responsive valving means in response to the first and second intermediate control signals respectively.

10. For use in an organ perfusion system circulating a perfusate through an organ, a pulsatile pumping system comprising:
a pump connected to receive perfusate in an inlet and deliver perfusate in an outlet, said pump including first and second control fluid inlets and providing a first perfusate pressure at the outlet in response to a high control fluid pressure at the first control fluid inlet and a second perfusate pressure at the outlet in response to a low control fluid pressure at a second control fluid inlet in the absence of the high control fluid pressure at the first control fluid inlet;
means for connecting the first control fluid inlet to a high pressure control fluid source in response to a first electrical signal condition and disconnecting

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the first control fluid inlet in response to a second electrical signal condition;
a timing control circuit coupled to said means for connecting for providing a bistate electrical signal of selectable periodicity having alternate first and second electrical signal conditions, the control circuit including means responsive to operator control for selecting the relative durations of the first and second electrical signal conditions during each period, in which said timing control circuit comprises an electronic digital control circuit including a recycling counter, means responsive to the counter for assuming the first electrical signal condition when the counter reaches a first selected count, and means responsive to the counter for assuming the second electronic signal condition when the counter reaches a second selected count.
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