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Jones et al.

[11] **3,737,096**

[45] **June 5, 1973**

[54] BLOOD PROCESSING CONTROL APPARATUS

[75] Inventors: **Alan L. Jones**, Endwell; **George T. Judson**, Whitney Point; **Robert M. Kellogg**, Endwell; **Victor R. Kruger**, Apalachin, all of N.Y.

[73] Assignee: **International Business Machines Corporation**, Armonk, N.Y.

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[21] Appl. No.: **211,194**

[52] **U.S. Cl.** .....**233/19 A**, 233/14 R

[51] **Int. Cl.** **B04b 11/00**

[58] **Field of Search** .....233/1 D, 1 A, 19 R, 233/19 A, 14 R, 14 A, 26, 27, 28, 20 R; 340/267

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Primary Examiner—George H. Krizmanich

Attorney—Paul M. Brannen, Elmer W. Galbi and J. Jancin, Jr.

[57] **ABSTRACT**

Apparatus for processing blood, and particularly for washing blood cells, including a centrifuge head in which is arranged a flexible blood container connected by a rotating seal to tubing which permits the entrance and exit of wash liquid and supernatant. The flow of liquid in the tubing is controlled by valve arrangements which are operable to permit the entrance of wash liquid and removal of supernatant liquid. The flexible container fits over a flexible membrane also arranged inside the centrifuge head about a solid central core. The volume defined by this membrane and the core communicates via a passage in the core with a fluid reservoir by means of a control pump which allows fluid to enter and exit from the volume defined by the membrane. During operation the unwashed blood may be entered into the container or blood bag before or after the bag is placed in the centrifuge. The centrifuge is spun until cells have settled against the outside wall at which time the valve arrangements and the control pump are activated such that fluid is pumped into the centrifuge under the volume defined by the membrane thereby forcing a supernatant to flow out to a collect container. The centrifuge is then stopped and the wash solution enters the blood container through another valve arrangement, thereby allowing the removal of fluid from the volume inside the flexible membrane. Removal of the wash liquid is accomplished by the same process of removal as the removal of supernatant previously described. Provisions are made for electrical control of all the operations including an agitate operation in which the centrifuge is spun in alternate directions for only a few revolutions or goes through alternate accelerate-decelerate cycles while rotating in the same direction to thereby agitate the material in the blood bag or flexible container during the time that a wash solution is entering. The circuit arrangements are such that a high degree of flexibility in the programming of the various operations can be obtained.

11 Claims, 12 Drawing Figures

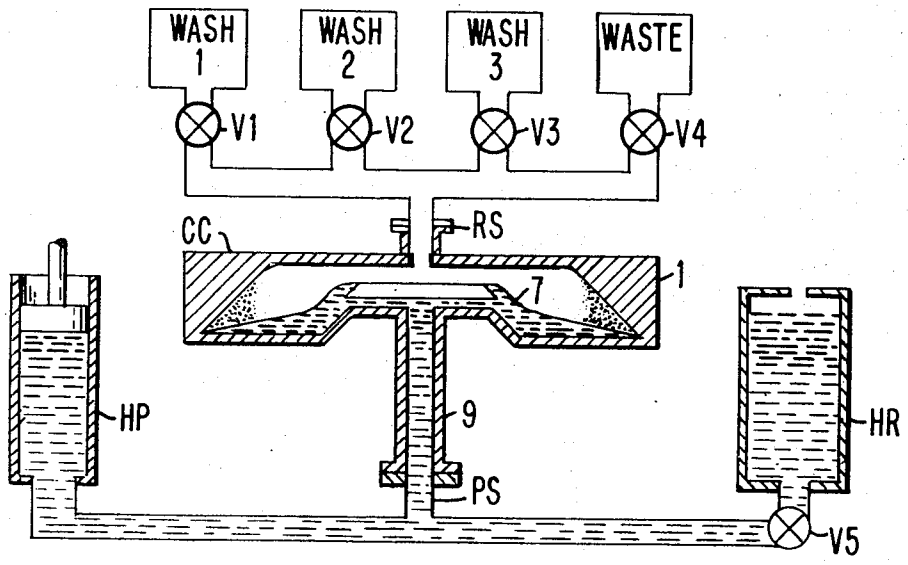


FIG. 1

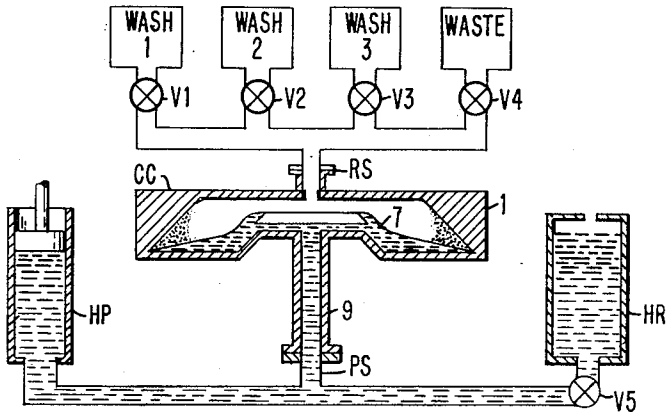
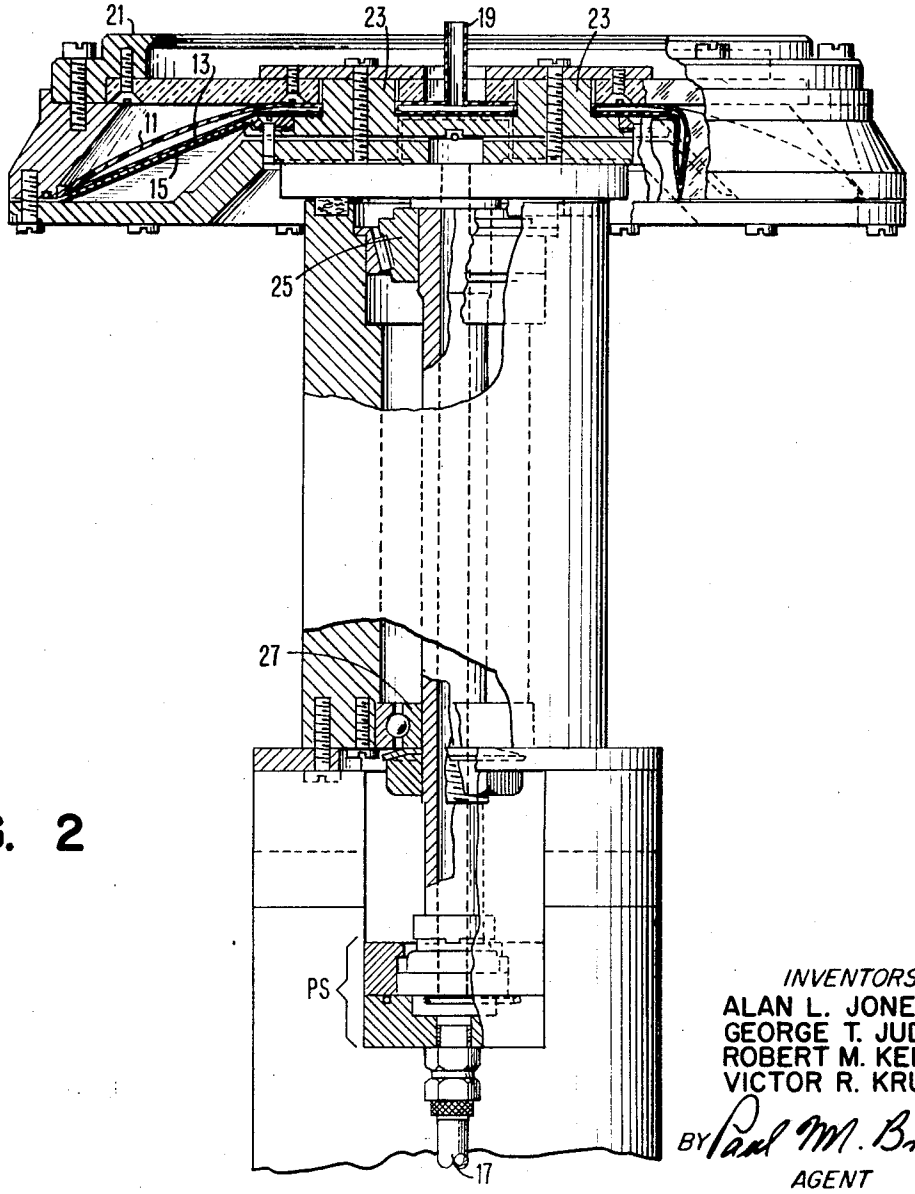


FIG. 2



INVENTORS
ALAN L. JONES
GEORGE T. JUDSON
ROBERT M. KELLOGG
VICTOR R. KRUGER
BY Paul M. Bronnew
AGENT

FIG. 3

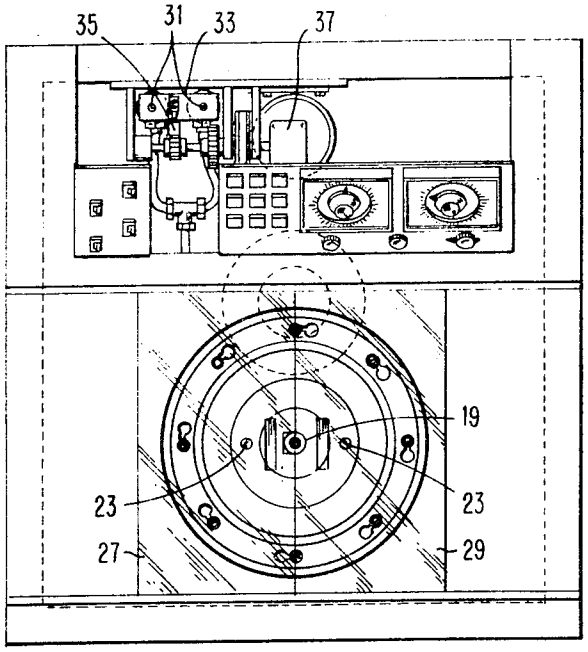


FIG. 4

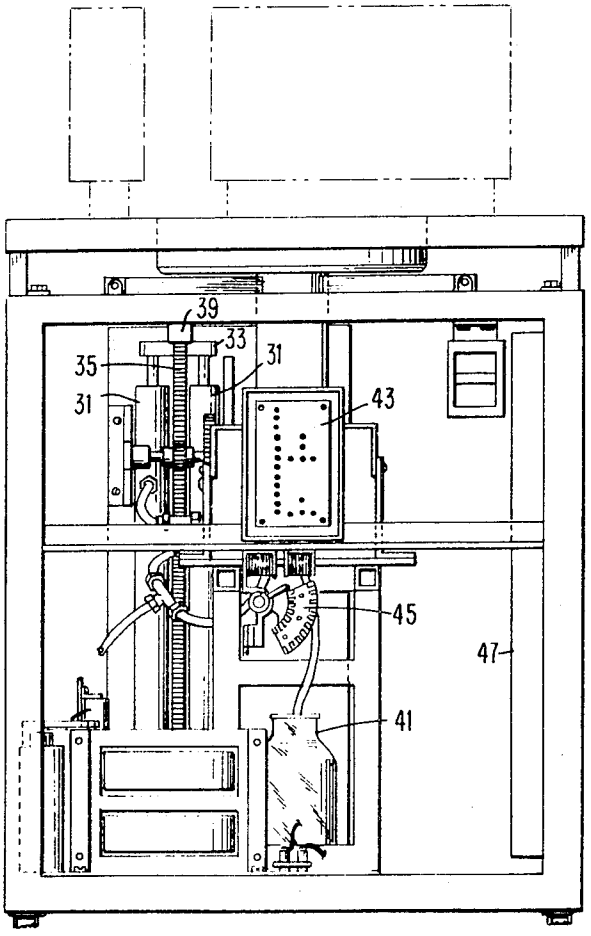


FIG. 5

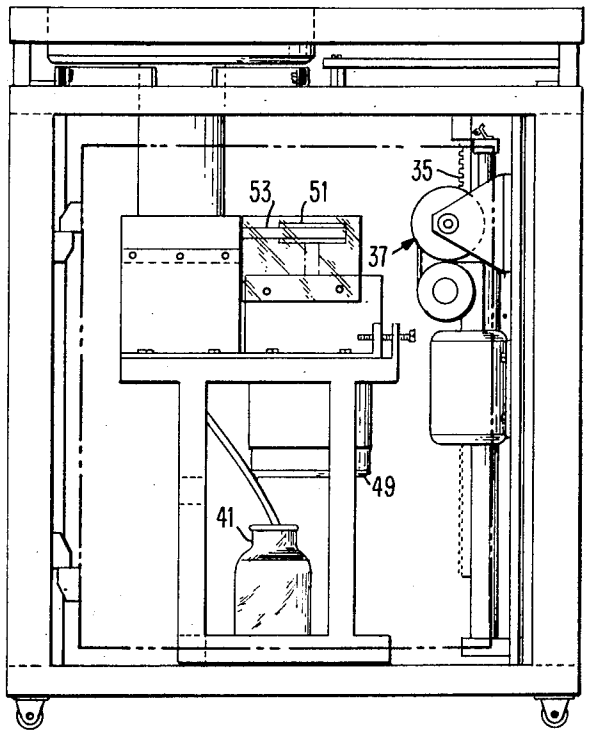
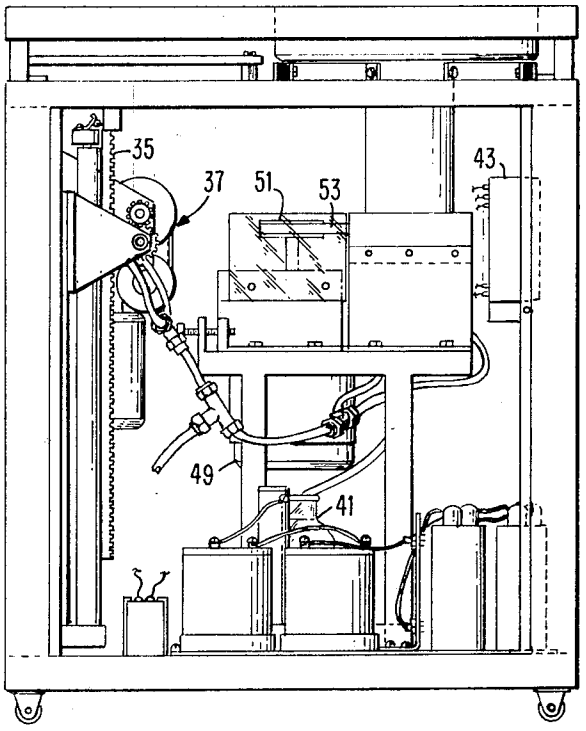


FIG. 6



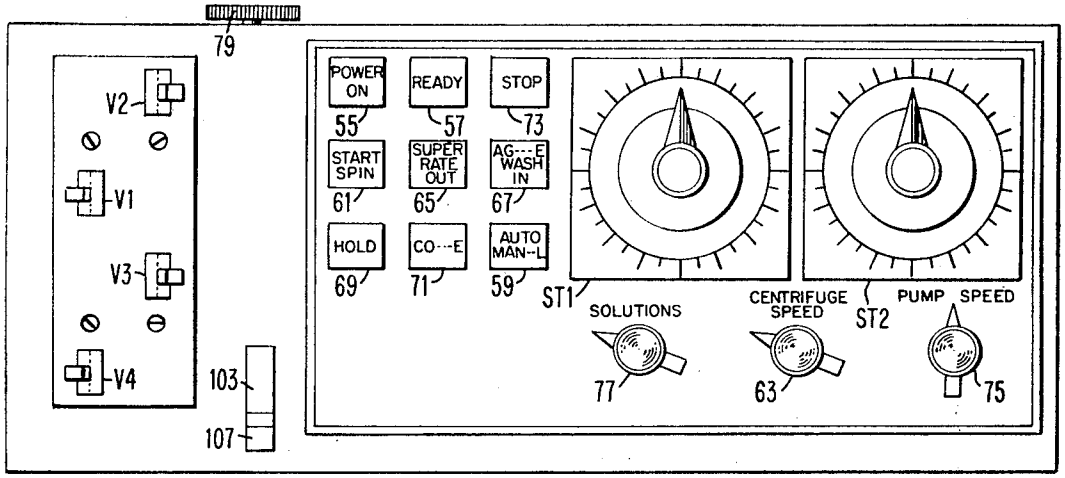
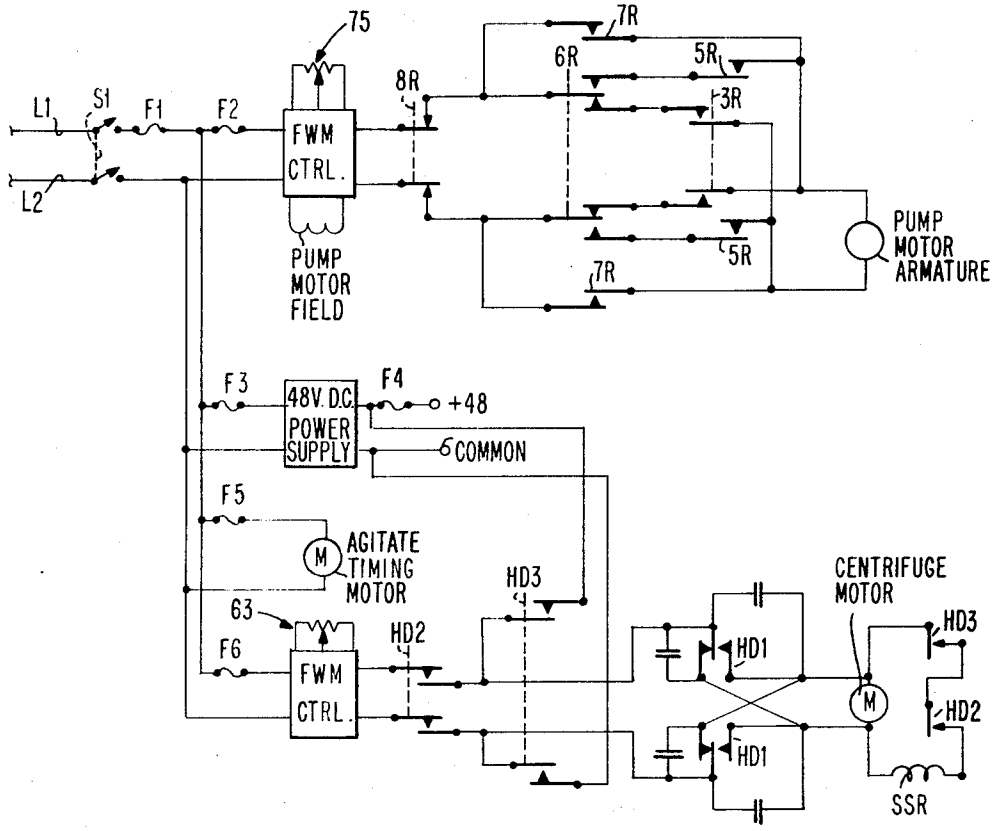

79
V2
V1
V3
V4
103
107
POWER ON
55
READY
57
STOP
73
START SPIN
61
SUPER RATE OUT
65
AG---E WASH IN
67
HOLD
69
CO---E
71
AUTO MAN--L
59
ST1
ST2
SOLUTIONS
77
CENTRIFUGE SPEED
63
PUMP SPEED
75

FIG. 7

FIG. 8


75
7R
6R
5R
3R
8R
L1
S1
F1
F2
L2
FWM CTRL.
PUMP MOTOR FIELD
5R
7R
PUMP MOTOR ARMATURE
F3
48V. D.C. POWER SUPPLY
F4
+48
COMMON
F5
AGITATE TIMING MOTOR
M
HD3
63
HD2
F6
FWM CTRL.
HD1
HD1
CENTRIFUGE MOTOR
M
HD3
HD2
SSR

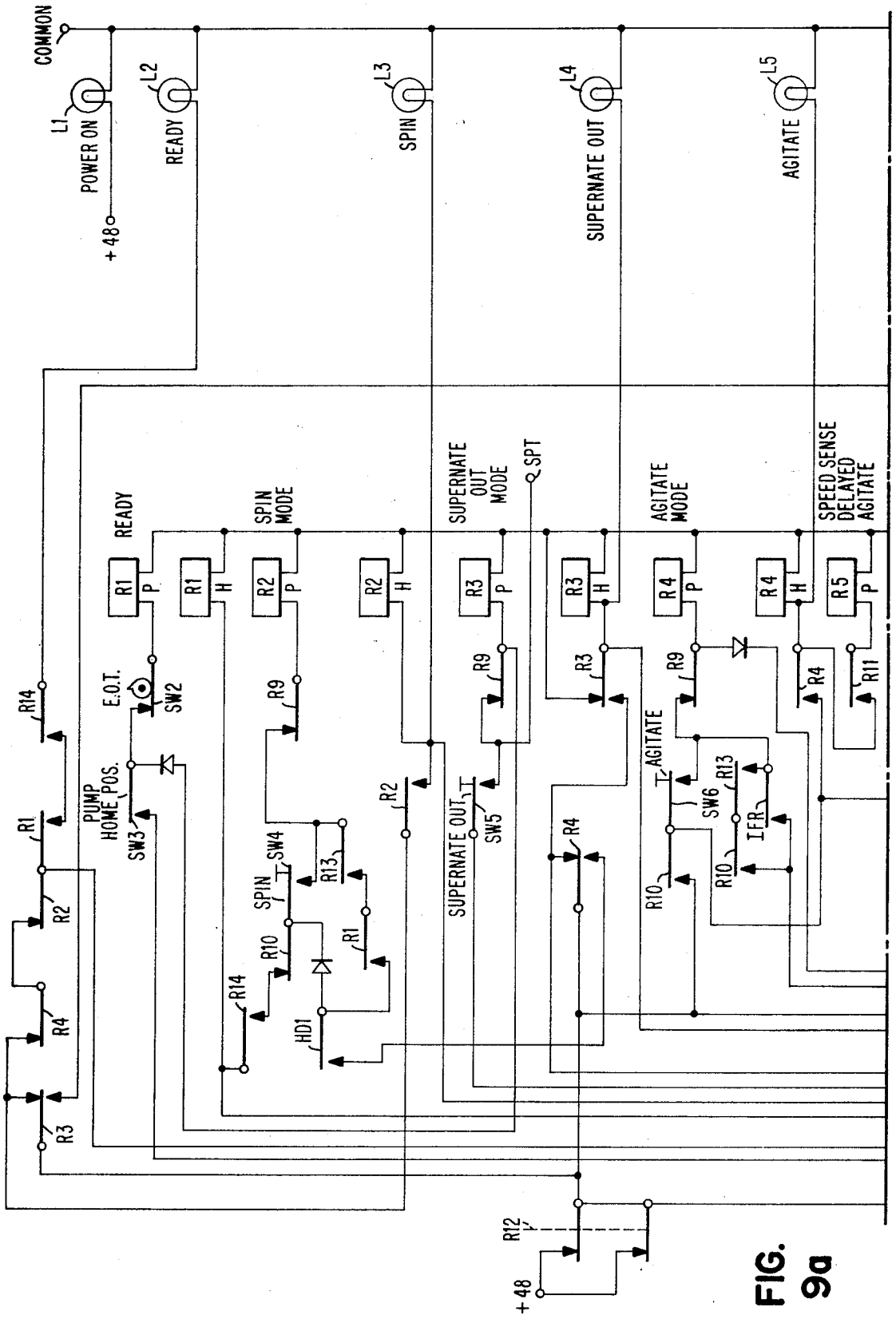

COMMON
L1
POWER ON
+48
L2
READY
L3
SPIN
L4
SUPERNATE OUT
L5
AGITATE
READY
SPIN MODE
SUPERNATE OUT MODE
SPT
AGITATE MODE
SPEED SENSE DELAYED AGITATE
R1 P
R1 H
R2 P
R2 H
R3 P
R3 H
R4 P
R4 H
R5 P
E.O.T.
SW2
PUMP HOME POS.
SW3
SPIN
SW4
SUPERNATE OUT
SW5
AGITATE
SW6
IFR
HD1
R1
R2
R3
R4
R9
R10
R11
R12
R13
R14
+48

FIG. 9a

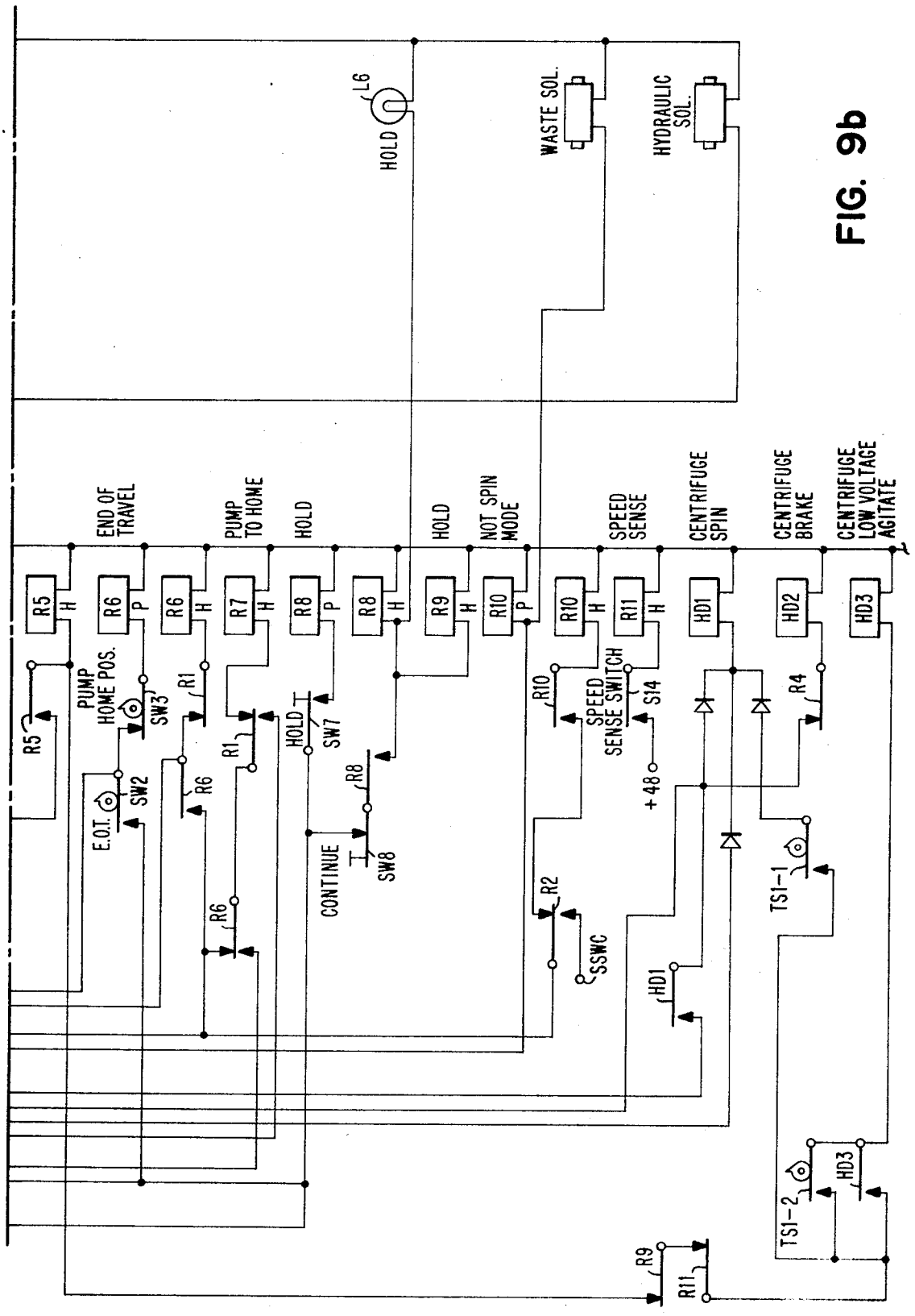

L6
HOLD
WASTE SOL.
HYDRAULIC SOL.
END OF TRAVEL
PUMP TO HOME
HOLD
HOLD
NOT SPIN MODE
SPEED SENSE
CENTRIFUGE SPIN
CENTRIFUGE BRAKE
CENTRIFUGE LOW VOLTAGE AGITATE
R5 H
R6 P
R6 H
R7 H
R8 P
R8 H
R9 H
R10 P
R10 H
R11 H
HD1
HD2
HD3
PUMP HOME POS.
SW3
E.O.T.
SW2
R1
R6
HOLD
SW7
CONTINUE
R8
SW8
R10
SPEED SENSE SWITCH
S14
+48
R4
R2
SSWC
TS1-1
TS1-2
R9
R11

FIG. 9b

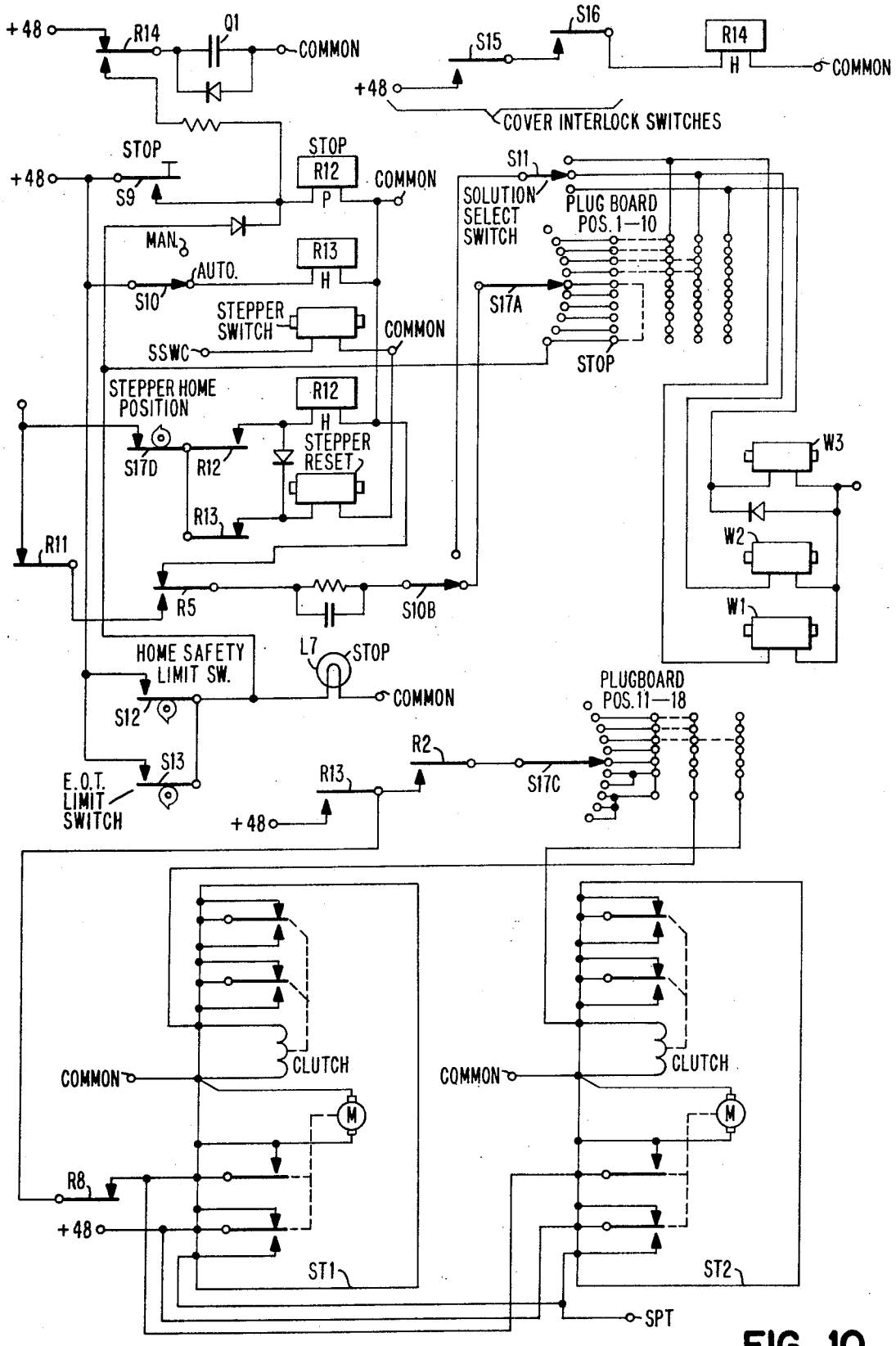

+48
R14
Q1
COMMON
S15
S16
R14
H
COMMON
+48
COVER INTERLOCK SWITCHES
STOP
+48
S9
STOP
R12
P
COMMON
S11
SOLUTION SELECT SWITCH
PLUG BOARD POS. 1—10
MAN.
AUTO.
S10
R13
H
STEPPER SWITCH
COMMON
S17A
SSWC
STOP
STEPPER HOME POSITION
R12
H
S17D
R12
STEPPER RESET
R13
W3
W2
W1
R11
R5
S10B
HOME SAFETY LIMIT SW.
L7
STOP
S12
COMMON
PLUGBOARD POS. 11—18
R2
S13
E.O.T. LIMIT SWITCH
R13
S17C
+48
CLUTCH
COMMON
M
R8
+48
ST1
CLUTCH
COMMON
M
ST2
SPT

FIG. 10

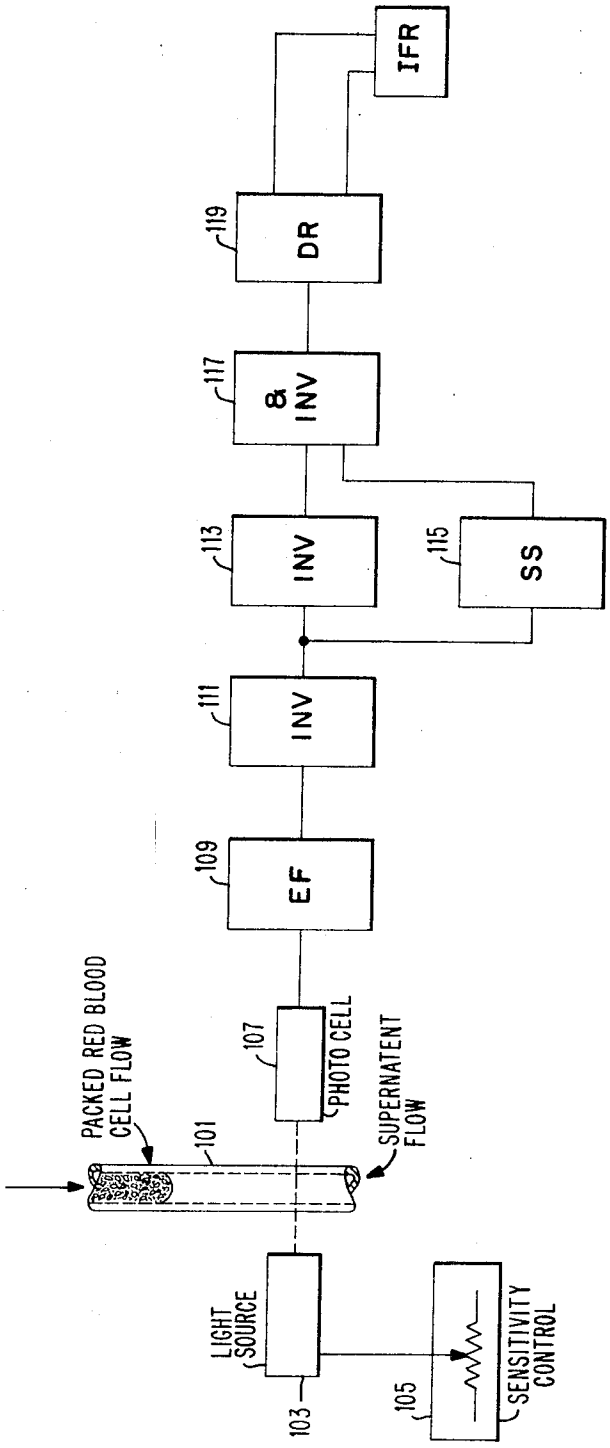

IFR
DR
119
& INV
117
INV
113
SS
115
INV
111
EF
109
PHOTO CELL
107
PACKED RED BLOOD CELL FLOW
SUPERNATENT FLOW
101
LIGHT SOURCE
103
SENSITIVITY CONTROL
105

FIG. 11

BLOOD PROCESSING CONTROL APPARATUS

FIELD OF THE INVENTION

This invention relates generally to blood processing apparatus, and in particular, to an improved arrangement for processing previously frozen blood cell volumes for transfusion.

DESCRIPTION OF THE PRIOR ART

It is known that the time of storage of red blood cells can be extended by freezing the cells prior to storage and subsequent thawing, with the addition of an appropriate additive to protect the cells during these processes. Most of these additives must be removed from the cells before they are transfused to a recipient. This washing can be done by washing the cells with various solutions and resuspending the the cells in the isotonic saline solutions, albumin, or plasma. The principal deterrent heretofore to the widespread use of frozen red blood cells is the lack of an easy-to-use, inexpensive cell washing method with all parts which come in contact with the blood being disposable and sufficiently economical that they may be disposed after a single use.

The present invention is an improvement on the configuration shown in the IBM Technical Disclosure Bulletin for December 1967 at pages 944 and 945, in that a completely designed apparatus, arranged for either manual or automatic programming is provided by the present invention.

SUMMARY OF THE INVENTION

It is a principal object of the present invention to provide an improved blood processing system, especially for the washing of preservatives from thawed red blood cells.

A more particular object of the present invention is to provide an improved blood washing system which is economical in construction and which utilizes disposable elements for those parts which come in contact with the blood.

Still another object of the present invention is to provide a blood washing system which can provide a plurality of different operations all selectable by the machine operator.

Yet another object of this invention is to provide an improved blood processing apparatus in which automatic programming of the various cycles of operation can be utilized.

Still another object of the invention is to provide a blood cell washing system of the centrifuge type, employing a disposable centrifuge container.

Other objects of the invention and features of novelty and advantages thereof will become apparent from the detailed description to follow taken in connection with the accompanying drawings.

In practicing this invention a centrifuge container or bowl is provided, having a vertical shaft, in the upper portion of which a flexible membrane is provided which can communicate with the hydraulic reservoir via the hollow core of the centrifuge shaft. The centrifuge is arranged to be rotated by an electrical motor arranged so that it can be accelerated, decelerated and reversed.

Placed within the centrifuge container is a disposable bag containing the thawed blood volume to be processed, or the thawed cells may be introduced after the empty disposable bag is placed in the centrifuge container. A centrally-located rotating seal device permits fluid to enter or leave the flexible container while the container is being rotated. By the supply of suitable hydraulic fluid to the underside of the flexible membrane, the volume of the blood container can be varied during the washing process. A plurality of valves are provided for controlling the inlet and outlet of fluids to and from the blood container, as well as controlling the flow of hydraulic fluid from the enclosed space below the flexible membrane, to the fluid reservoir. The hydraulic fluid is pressurized by a suitable control pump, preferably of the piston type driven by an appropriate drive mechanism such as, for example, a rack and pinion motion operated by a suitably controlled reversible electric motor, whereby the amount and direction of hydraulic flow can be varied. The apparatus also includes a plurality of electrical circuits including timing mechanisms which may be connected by appropriate wiring and switching means to provide a flexible programming ability so that the operator may vary the sequence and length of the steps in the washing process. The sequence and timing may be governed by manually operated switches, or by automatic sequence control circuits.

DESCRIPTION OF THE DRAWINGS

In the drawings:

FIG. **1** is a highly-schematic illustration of a blood cell washing system illustrating the broad principles of the present invention;

FIG. **2** is an elevational view of the centrifuge bowl and its supporting shaft elements;

FIG. **3** is a diagrammatic plan view of the apparatus, showing the top of the centrifuge bowl, and a view of the operator's control panel as seen from above;

FIG. **4** is a diagrammatic front elevational view, showing the hydraulic fluid control pump and reservoir, along with certain components of the electrical control system and illustrating the placement of the centrifuge and the operator's panel with respect to this portion of the machine;

FIG. **5** is a diagrammatic elevational view looking from the right-hand side of the machine, in which further detail of the hydraulic control pump drive and the centrifuge drive can be seen;

FIG. **6** is a diagrammatic elevational view of the machine from the left-hand side, showing the centrifuge drive, the rack and pinion control pump mechanism, a portion of the hydraulic apparatus and some components of the electrical power supply;

FIG. **7** is a front elevational view of the operator's control panel, which includes the pinch-off type of valve mechanisms;

FIG. **8** is a schematic illustration of the motor drive and other auxiliary circuits in the machine;

FIGS. **9***a* and **9***b*, when joined in the manner shown, form a diagrammatic illustration of a portion of the control circuits for the machine; and

FIG. **10** is a diagrammatic illustrating of additional control circuit employed in the machine.

FIG. **11** is a diagrammatic illustration of an interface detector circuit employed in the machine.

Similar reference characters refer to similar parts in each of the several views of the drawings.

DESCRIPTION OF THE PREFERRED EMBODIMENTS

Referring now to FIG. **1** of the drawings, there is shown in highly schematic form an illustration of a

blood cell washing device showing some of the elements of the present invention.

Centrifuge CC comprises a centrifuge bowl **1**, provided with a suitable cover and having a flexible membrane **7** therein, separating the bowl into upper and lower portions. The upper portion also receives a flexible blood cell container, the walls of which are coextensive with the flexible membrane and the upper portion of the centrifuge bowl. This container is connected via a rotating seal RS to a tubing system which is connected to a plurality of fluid receptacles, which can contain various types of washing fluid such as Wash **1**, Wash **2**, and Wash **3**, and also a waste receptacle designated waste. The blood container can communicate with any one of these receptacles via separate and independently operable valves **V1**, **V2**, **V3** and **V4**. The space below the flexible membrane **7** is occupied by a hydraulic fluid which is supplied to the space via the hollow central core of the centrifuge shaft **9**. Also, the permanent seal PS provides an appropriate sealable connection between the rotating portion of the centrifuge and the stationary hydraulic apparatus, which includes the hydraulic control pump HP, a hydraulic reservoir HR and one or more valves such as the valve **V5**. The pump is arranged to be reversible and it will be apparent that the volume of hydraulic fluid contained within the space defined by the flexible membrane **7** can be altered by pumping fluid in or out of the space by suitable operation of the control pump HP and the valve **V5**. Accordingly, the effective volume of the centrifuge chamber can be controllably varied. As indicated in the drawing, during centrifuging, the blood cells are forced to the wall of the blood bag or container and the centrifuge wall by a centrifugal force occurring during rotation of the centrifuge bowl.

At various times during a complete operating cycle, the wash solutions may be admitted to the bag via valves **V1**, **V2** or **V3**, and supernatant solution may be delivered to the waste receptacle via the valve **V4**. The drive mechanism connected to the centrifuge CC is arranged to either spin the centrifuge head at a constant speed or to vary the speed and/or direction of rotation of the head in an agitation cycle.

To wash blood cells, the blood bag is placed in a centrifuge either already filled with the blood cell-cryopreservative mixture or filled via the tubing and seal connections. Thereafter the centrifuge is spun until the cells have settled against the outside wall. During the spinning operation the valve **V5** which connects the volume under the flexible membrane to the fluid reservoir is open. When the centrifuge bowl begins to spin, the blood cell mixture in the flexible container will be pressed against the outside wall of the centrifuge bowl. This will result in a negative pressure in the fluid system under the flexible membrane. Therefore, since the fluid reservoir is connected to atmosphere, fluid will be forced up into the centrifuge bowl until the bowl is full, at which time the pressure at the lower rotating seal will be dictated by the difference in head between the seal and the top of the fluid in the reservoir. Hydraulic fluid in now pumped into the centrifuge by means of the control pump HP, the resulting expansion of the flexible membrane **7** forcing the supernatant solution to flow to the waste receiver through valve **V4**, which is open at this time. During this pumping operation valve **V5** is closed. The centrifuge is then stopped and put into an agitation mode in which it revolves for a few cycles in alternate directions on a continuing basis and the wash solution is entered by opening a suitable one of valves **V1**, **V2** and **V3** and pumping hydraulic fluid out of the central volume by means of hydraulic control pump HP. During the agitation mode valve **V5** is again opened. Therefore, fluid may drain from the centrifuge bowl to the reservoir faster than the hydraulic fluid pump rate. This process may be continued as many times as desired and the operation of the entire system is readily and variably controlled either by manual control or through the internal programming of the system, to be described in detail subsequently.

Referring now to FIG. **2** of the drawings, there is shown an elevational view of the centrifuge bowl and its contents, as well as the supporting structure for the rotating apparatus and the seals which permit the flow of hydraulic fluid and also of the blood and was solutions. Reference character **11** denotes the upper wall and reference character **13** denotes the lower wall of the flexible blood bag or container shown shown in a nearly-empty condition within the centrifuge structure. Beneath this bag is the flexible membrane **15**, below which hydraulic fluid is admitted from openings which communicate with the central core of the centrifuge shaft. The tubing **17** is connected to the hydraulic pumps and fluid reservoir via appropriate valves, as will be subsequently described. The tube **19** leads from the flexible blood bag to a disposable rotating seal, now shown which provides communication between the blood bag while in the centrifuge and the various reservoirs via the valve mechanisms located on the operator's panel. The centrifuge is covered by a cover **21**, which is held on by any suitable clamping means, such as a plurality of screws using a combined slot and hole technique for permitting relatively rapid removal and replacement of the cover. To hold the flexible bag in place, two or more upstanding bosses **23** are provided, from the upper surface of the centrifuge central element, and openings or holes in the blood bag, with their edges appropriately sealed, are provided to fit down over these bosses or studs. In this manner, when the cover **21** is then put in place the bag will be retained in position. A drive pulley, not shown, is located on the lower portion of the centrifuge shaft, which rides in a bearing assembly **25**, and a roller bearing **27** acts as a bearing against lateral or axial thrust. The drive pulley located on the lower end of the shaft is belted to a suitable drive motor, by which the entire centrifuge assembly may be spun at relatively high speeds. The tubing **17** communicates with the hollow interior of the centrifuge shaft via the seal connections PS, which provide for a suitable passage of hydraulic fluid into the interior of the rotating centrifuge shaft, as previously explained.

FIG. **3** of the drawings is a top plan view of a blood washing machine in accordance with the present invention. One manner of attachment of the cover plate to the bowl portion of the centrifuge is clearly illustrated in this figure, showing the plurality of hold-down screws, which cooperate with a slot and hole arrangement in the cover so that the cover may be placed down over the screws, rotated clockwise to engage the slots, and thereafter the screws may be fastened to securely hold the cover in place during the centrifuging operation. The bosses **23**, which center and align the blood container, are shown, as well as the center connection **19**, where the tubing is attached to the blood container. A pair of sliding transparent doors **27** and **29** are ar-

ranged to meet at the center of the machine with a suitable opening for the connection **19**, so that the top of the centrifuge can covered during operation. The outline of the centrifuge drive motor is shown in dotted lines in this figure. Also, to be seen in this figure is the top view of the hydraulic control pump assembly, which is here constituted, comprises a pair of cylinders **31**, with pistons tied by a yoke **33** at the top end thereof, which in turn is fastened to a rack **35**. The rack is moved up and down by a pinion driven by a motor and gear assembly **37**, so that by suitable circuit control the hydraulic control pump may be utilized to either force fluid into the centrifuge bowl or remove it therefrom. Certain of the fittings to the pump may also be seen in this view.

FIG. **4** of the drawings shows a front elevation view of the machine. In this view, the relationship between the pump cylinders, piston rods and the rack drive for the control pump may be clearly seen. At the top of the rack, as shown in FIG. **4**, a limit switch **39** is provided, which indicates the upper limit of travel of the pump pistons. This indication is used in the control circuitry to be subsequently described. FIG. **4** additionally shows the the location of the hydraulic fluid reservoir **41**, as well as certain of the electrical components. The transformers shown on the lower left portion of the figure are utilized in the power supplies for the machine. In the central portion of the figure there is shown a recessed enclosure containing a plugboard **43**, by which varying operating programs may be arranged at the convenience of the operator by connecting the various jacks with suitable jumper wires. A stepping switch **45** is also visible in this figure, this stepping switch being utilized in conjunction with the plugboard **43** for automatic program control. Reference character **47** designates a relay mounting gate, which is utilized for mounting the various relays utilized in the control of the electrical portion of the machine.

FIGS. **5** and **6** are the right-side and left-side views, respectively, of the machine. The drive motor **49** for the centrifuge is shown toward the center of the machine, driving the centrifuge by a pulley **51** and drive belt **53**, which rotates a driven pulley on the centrifuge shaft. The centrifuge drive motor is provided with suitable control circuitry which allows the speed and direction of rotation of the motor to be variably and accurately controlled. The components shown in the lower portion of FIG. **6** are electronic elements which are utilized in the power supplies of the machine and since their actual construction is not germane to the present invention, they are not described in detail.

OPERATION OF APPARATUS

As already explained, the present invention comprises apparatus for the washing of preservatives or other materials from a single unit volume of red blood cells. Under machine control, the cells are diluted with a wash solution, mixed, and then centrifuged to separate the wash solution from the cells. The supernatant is then removed and a new wash solution is entered. This is therefore a batch-oriented apparatus.

To wash a unit of cells, an empty blood bag is placed in the centrifuge bowl. The bag is connected to the cell mixture, the wash solutions and the supernate collect container via a flexible tubing harness arrangement. The cell mixture is then run into the bag by gravity. The bowl is next spun at a predetermined velocity, to provide a predetermined centrifugal force.

The cells sediment to the outside of the bag with the supernatant (or plasma) collecting at the center. After sufficient sedimentation, the waste valve is opened and the control pump is started. This forces the flexible membrane against the bottom of the blood bag, expelling supernatant. The volume of supernatant expelled is controlled by the amount of fluid pumped under the flexible membrane. Centrifuge rotation continues.

The supernatant (or plasma) is pumped to waste (or saved) until the red cells appear in the fluid line above the rotating seal at the interface detector. At this point, a first wash cycle starts as follows: the centrifuge is braked to a low speed. The machine senses this low speed, the first wash valve opens, the pump reverses, the bowl goes into an agitate cycle. Since the pump has been reversed, hydraulic fluid is now being removed from under the membrane. This in turn allows wash solution to run by gravity into the blood bag. The **37** agitate" or oscillation of the bowl serves to mix the cells and the incoming wash solution during this time. When the first wash solution is in, the machine is ready for another spin. This process can be repeated for as many cycles as desired. The cell washer can provide either packed cells or resuspended cells depending on where the process is stopped.

The operation of the blood cell washer is controlled from a console on top of the machine, illustrated in FIG. **7** of the drawings. The various controls and indication lights include:

POWER ON Light **55** — Indicates the machine power is on.

READY Light **57** — This light must be on before the machine can be started. There may be several seconds delay between "power" on and "ready" on. It indicates that the sliding covers are closed and that other functions are ready for operation.

AUTOMATIC/MANUAL Switch **59** — This two-position switch sets the machine in either a manual or automatic mode.

START/SPIN **61** — Lighted Pushbutton - At the beginning of a machine run in either automatic or manual, when the READY eight is on and with the centrifuge stopped, pressing the START/SPIN pushbutton will cause the machine to go into a SPIN mode. The centrifuge will rotate at the rate set by the setting on the centrifuge speed control **63.** The SPIN light in pushbutton **61** comes on whenever the machine is in the SPIN mode. Pressing the START/SPIN switch **61** while in the AGITATE mode will transfer the machine's operation into the SPIN pushbutton while in the SUPERNATE OUT mode will not transfer the machine into the SPIN mode. Premature pressing of the SPIN pushbutton while in AGITATE mode may not allow the full volume of wash solution to be entered.

SUPERNATE OUT **65** — Lighted Pushbutton — Initiation of this function can occur only from the SPIN mode of operation. If in the MANUAL mode, transfer into the SUPERNATE OUT mode occurs by pressing the SUPERNATE OUT button after the cells have sedimented. In the AUTOMATIC mode, transfer occurs automatically upon time out of the SPIN mode timers ST1 or ST2; but it can be

initiated manually by pressing the button at any time while in SPIN.

AGITATE/WASH IN **67** — Lighted Pushbutton — Initiation of this function can occur only from the SUPERNATE OUT mode of operation. If in the MANUAL mode, transfer into the AGITATE/WASH IN mode occurs by pressing the AGITATE/WASH IN pushbutton. In the AUTOMATIC mode, transfer occurs automatically upon activation of the end-of-travel switch on the hydraulic pump assembly or detection of the red cell interface by the photo detect assembly **103** and **107**; but it can be initiated manually by pressing the button at any time while in SUPERNATE OUT.

HOLD **69** — Lighted Pushbutton — This can be initiated during any of the machine functions:

a. In MANUAL spin, HOLD does not cause any functional change. In AUTOMATIC spin, the timers are stopped until the CONTINUE button **71** is pressed.

b. In SUPERNATE OUT, the hydraulic pump is stopped both in MANUAL and AUTOMATIC modes.

c. In AGITATE/WASH IN, the pump and the agitation are stopped for both MANUAL and AUTOMATIC modes.

Continue **71** — Pushbutton — Initiation of this function switches the Hold function off and restores the machine to the condition prior to initiation of hold.

STOP **73** — Lighted Pushbutton — Initiation of this function is at the end of a run or if it is desired to halt a run prematurely. STOP can be activated from any of the operational modes. Initiation of STOP aborts the run completely. The STOP light ON in pushbutton **73** indicates an abnormal condition. The only time the STOP light will come on is when either the home position or end-of-travel switch has failed and the control pump has driven past these switches to hit the pump over-drive safety switches. When this occurs, the machine will stop all functions.

INTERFACE DETECTOR **103, 107** — The tubing leading from the rotating seal RS to the plurality of solenoid valves passes through the interface detector. This detector determines when the blood cells are beginning to be pumped out of the flexible container during the SUPERNATE OUT mode.

CENTRIFUGE SPEED CONTROL **63** — This controls centrifuge speed.

PUMP SPEED CONTROL **75** — This controls the pumping rate for SUPERNATE OUT to WASTE. The SUPERNATE OUT pumping rate should not exceed the gravity fill rate of the WASH SOLUTIONS.

SOLUTION SELECTOR SWITCH **37** — This three-position switch selects either **V1, V2** or **V3** solenoid operated valves during AGITATE cycle in the MANUAL mode of operation. The selected solenoid valve will energize, opening a path for fluid to flow from the wash solution containers to the blood bag in the centrifuge. This is inoperative during AUTOMATIC mode.

The solenoid valves are provided with pinch levers, which extend outward through the control panel, as shown at the left-hand side of FIG. **7**, and coacting with a stationary element, selectively pinch-off tubing threaded through the structure to either permit or prevent fluid flow. The valves are accordingly, indicated as **V1, V2, V3** and **V4** in FIG. **7**.

SPIN TIMERS **ST1, ST2** — These timers are only operable in the AUTOMATIC mode of operation. They control the length of the spins. Two timers are available. SPIN TIMER **ST1** permits spins up to **15** minutes in length. SPIN TIMER **ST2** permits spins up to **4** minutes in length. The programmable plugboard **43** is jumper-wired to select the desired timer for each SPIN mode cycle.

PROGRAMMABLE PLUGBOARD **43** — The programmable plugboard allows the operator to specify the order of the wash solutions used and the length of the spins when in AUTOMATIC operation. The upper half controls the order of the washes. A jumper wire from the first column to either of the other three columns indicates which wash valve will open during that AGITATE/WASH IN cycle. The lower half of the plugboard indicates which spin timer controls each spin cycle. If the machine is in MANUAL operation, the condition of the plugboard is immaterial.

READYING MACHINE FOR OPERATION

To ready the machine for operation, the sliding covers over the centrifuge well are rolled out of the way and the cover of the centrifuge is then removed. The bag can then be placed in the bowl. The two large holes in the bag are placed snugly over the raised bosses and the edge of the bag is pressed into the bowl as far as possible. If there are too many wrinkles in the bag, it will not be possible to put the maximum amount of blood into the bag. The neck of the bag with the integrally connected seal is then threaded up through the hole in the center of the cover and the cover is then replaced. When the plastic covers are closed, they hold the seal in place. The tubing harness is placed in the valves on the console and connected to the stem from the bag after removing the cap from the bag stem. The blood can flow into the bag from a side "tee" connection or may be connected through the Wash **1** valve. In either case, this line is opened and the blood allowed to flow into the bag.

MANUAL OPERATION

All the blood will not enter the bag at first due to air in the system. Air is purged from the bag by pressing the SPIN button with the line open to the supply blood bag. As the bowl accelerates, air will pass from the bag up to the supply blood bag via the tubing harness. When the air is out of the inlet line, the STOP button is pressed. After the bowl stops, the remaining blood is allowed to flow into the bag and then the line is pinched off. If the supply blood bag is used in the WASH **1** cycle, the line is placed in valve **V1** at this point. If the supply blood bag is not used in this way, the supply line is merely pinched off.

After the blood has flowed into the machine, the SOLUTION SELECTOR **77** is placed to the appropriate position and the CENTRIFUGE SPEED CONTROL **63** and the PUMP SPEED CONTROL **75** set to their desired values. Also, the upper limit switch is set so that the desired volume of supernatant will be pumped out. The position of the upper limit switch can be changed by rotating the knob **79**. The first SPIN can then be initiated. After the cells have sedimented sufficiently, the SUPERNATE OUT button is pressed. The supernate

will continue to flow to waste until the AGITATE/-WASH IN button is pressed or the pump hits the UPPER LIMIT SWITCH or cells are detected by the INTERFACE DETECTOR. When the supernate has been removed, the AGITATE/WASH IN button is pressed. One of the wash solutions (according to the position of the SOLUTION SELECTOR SWITCH) will flow into the bag until the SPIN is pressed or the pump hits the lower limit switch. These steps are repeated until the last SUPERNATE OUT step is completed. At this time, packed cells are available. If any wash solution is either physiological saline or plasma, or any other suitable resuspending fluid, then the packed cells can be reconstituted by turning the SELECTOR SWITCH to that position and pressing the AGITATE/-WASH IN button. To shut the machine down, the STOP button is pressed. This will stop the centrifuge and send the pump to the home position. The sliding covers can then be opened and the centrifuge bowl cover removed. The tubing harness is disconnected and is removed. The bag is then removed from the machine and the cells are ready for use.

AUTOMATIC OPERATION

For AUTOMATIC operation, the machine is prepared as described above. In addition, the programmable plugboard on the front of the machine is appropriately wired. The SPIN TIMERS ST1 and ST2 must be set for the desired lengths of spin. Also, the upper limit switch on the pump is set at the desired waste volume by turning the large knob **79** on top of the console. Each turn of the knob will alter the setting by some predetermined amount. Turning this knob clockwise raises the switch and increases the volume pumped. Counterclockwise rotation of the knob decreases the volume.

After these settings have been made and the AUTOMATIC/MANUAL switch has been set to AUTOMATIC, the machine is started by pressing the START/SPIN button **61.** Form this point on, the operation is automatic. The bowl will spin until the time elapsed is that preset by the program timer. At this point, the WASTE valve will open and the pump will start. Supernatant will be pumped to WASTE until the upper limit switch is operated or cells are reused at the INTERFACE DETECTOR. At this time, the pump will reverse and the first wash solution will be allowed to flow into the bag. Also, the bowl starts agitating thereby mixing the cells with the incoming wash solution. The AGITATE mode will continue until the lower limit switch on the pump is tripped at which point the bowl goes into the second spin. This continues until the last supernatant has been removed, at which time the machine shuts down.

It should be pointed out that it is possible to go from one mode to the next ahead of time. For example, the AGITATE/WASH IN button **67** can be pressed while in SUPERNATE OUT mode. The AUTOMATIC cycling will continue. Also, it is possible to obtain a longer spin by pressing HOLD button **69.** This will stop the timer until the CONTINUE button **71** is pressed.

Prior to the start of a first run the hydraulic system is checked for adequate priming, as follows:

a. The CENTRIFUGE SPEED **63** is set to zero.
b. The upper limit switch is adjusted for maximum hydraulic pump drive travel (full clockwise rotation on the knob) and START/SPIN button **61** and the SUPERNATE OUT button **65** are depressed.
c. When the pump hits the upper limit switch, the PUMP SPEED **75** is set to zero and the STOP button **73** is pressed.
d. After the diaphragm is drawn tight against the bottom of the centrifuge cavity, the PUMP SPEED **75** is set to maximum.

The machine is ready for use when the READY light goes on.

Referring to FIG. **8** of the drawings, there is shown the details of the power supply circuitry and the motor control circuitry for control of the pump motor and the centrifuge motor. Power at the conventional line voltage and frequency is supplied over a pair of input conductors **L1** and **L2,** and through a main power switch **S1,** protected by a line fuse **F1,** from whence it is distributed to a plurality of elements each having an associated fuse bearing the references **F2** through **F6.** The pump motor control circuit includes a fullwave motor control governed by the pump speed control **75,** and supplying power to the pump motor field and also through a plurality of braking and reversing contacts to the pump motor armature. It can be seen that power to the pump motor armature is governed by the operation of contacts of relay **8R,** while the polarity of the energy supplied to the pump motor is governed by combinations of contacts on relays **3R, 5R, 6R,** and **7R.** In these circuit diagrams, as is the customary practice, the contacts of the relays are not necessarily shown with their controlling coils, but the same reference character is applied at or near the contacts as is applied to the control coil. The detailed operation of the control and braking contacts will be explained subsequently.

Power for the operation of the various control circuits is obtained by a conventional 48-volt D.C. power supply, supplying energy to the terminals designated **+48** and COMMON, which will appear at various points throughout the circuit drawings. A continuously-running motor which operates cam contacts for determining the agitation cycles is connected to the power busses through fuse **F5** as shown. The centrifuge motor is connected to a full-wave motor control governed by the operation of centrifuge speed control **63,** with direction, speed and braking being governed by contacts of relays **HD1, HD2** and **HD3.** Relays **HD2** and **HD3** also serve to connect the winding of a speed sensing relay designated SSR across the centrifuge motor at specified times.

In general, the sequence of operation of the machine is governed by a plurality of relays which are governed by circuitry shown in FIGS. **9*a*** and **9*b*,** arranged in that order from left to right, so that the corresponding circuit lines match on the drawings, as well as additional timing and stepping relay circuitry shown in FIG. **10** of the drawings.

The relay circuitry is generally arranged so that a proper sequence of steps must be followed either during automatic or manual operation of the machine, as insured by appropriate logical interlocking of the control circuits for the various relays controlling the different modes of operation. It is considered that the description of these circuits will be enhanced by describing the operation of this portion of the machine under different operating conditions.

In readying the machine for operation, the main power on switch must be turned on to energize the relay power supply, thereby supplying a 48-volt output from the power supply shown in FIG. **8.** At this time the

power on light L1, shown in FIG. 9a, lights. Also, at this time the ready light L2 will come on assuming that the pump is in its home position and the sliding covers on the centrifuge are closed. This action is obtained by the use of relays R1 and R14. Relay R1 is controlled by contacts on the pump home position switch SW3, and contact on the end of the travel switch, SW2. With the stop relay R12 de-energized, a circuit can be traced through the normally closed contacts of relay R12 and through the home position switch and the end-of-travel switch to pick the ready relay R1. With the covers closed, the cover interlocks switches S15 and S16 will be closed and relay R14 will be energized, and with relay R1 energized, a circuit is established for lighting ready light L2.

If the pump is not in its home position at the time the main power switch is on, it will go to the home position, providing the pump speed control knob is not set at zero. When it does reach the home position, the home limit switch will close and complete the circuit to energize relay R1, thereby establishing the ready condition and turning on the ready light. The machine is now ready for use either in manual or automatic mode, as determined by the setting of the manual or automatic switch.

In the manual mode, with the bag in place and the centrifuge cover locked with the sliding covers closed and locked and the ready light turned on, the desired centrifuge speed is set on the centrifuge control. Next, the desired wash solution is selected by the solution selector switch after which the spin control pushbutton is operated. This is the only function that can be activated at this time, as the first step after ready condition, because all functions are interlocked to only permit sequencing from start through the supernate out and agitate cycles.

Initiation of the spin by operation of spin pushbutton establishes a circuit to energize relay R2, which in turn energizes relays HD1 and HD2. When HD2 picks up, the dynamic brake circuit is removed from the permanent magnet centrifuge drive motor armature circuit. HD1 establishes the direction of spin and HD2 connects the output of the motor controller across the centrifuge drive armature, as shown in FIG. 8. The output of the controller is established by the setting of the centrifuge speed control knob on the operator's console. The centrifuge will then start and accelerate up to the preestablished speed and maintain its speed there until the SUPERNATE OUT switch or the STOP switch is operated.

Operating the SUPERNATE OUT switch does not alter the centrifuge spin condition, but does establish a circuit for energizing relay R3 and thereafter R2 is de-energized or released. With relay R3 picked up, the SUPERNATE OUT mode is established. Relay R3 establishes a holding circuit for itself, and also energizes relay R10, which in turn is held by its own holding circuit and the fact that relay R2 has been released. The picking up of relay R3 also opens the normally closed waste solution solenoid and closes the normally open hydraulic solution solenoid. The control pump motor will now start at the speed determined by the pump speed control knob and motor controller. The direction of operation of the pump motor is established by relay R6, which was earlier established by reaching the ready condition. These conditions are now maintained until either the pump cam trips the end-of-travel switch EOT, or the agitate/wash function is initiated or the interface detector senses the presence of red cells. When the end-of-travel switch is transferred, it will pick relay R6, which stops the pump motor and releases relay R1. The pick of relay R6 also establishes the proper direction of pump motor operation for a subsequent cycle.

The energization of relay R10, as indicated previously, establishes a "not spin" mode. In this mode the centrifuge is still spinning but is no longer under control of the START/SPIN mode logic circuitry.

Operating the AGITATE/WASH IN button, energizes relays R4 and R5 through suitable logic function circuits and causes each to hold through a holding circuit including one of their own normally open contacts. When relay R4 is picked up, it releases relays HD1 and HD2. When HD2 releases, dynamic motor braking is effected for the centrifuge motor. Current flowing in the brake circuit is sensed by the coil of the speed sense reed relay SSR, shown in FIG. 8. This will operate the reed relay which in turn energizes relay R11. Relay R11 will remain picked until the centrifuge speed reaches some predetermined low level, perhaps a few rpm, as determined by the armature back emf and the number of turns on the coil of the speed sense reed relay. When the reed relay opens because of low brake current, relay R11 is de-energized and drops out. At this time relay HD3 will be picked through position 1–2 contact of the agitate control timer. Relay HD3 will establish a holding circuit through one of its own normally open contacts and supplies energy from the 48-volt power supply to the centrifuge motor circuit via the direction reversing contacts HD1. At this time relay HD1 will be alternately picked up and released by the closing and opening of a cam-operated contact on the agitate control timer position 1–1. When the relay R11 was released, it also opened one of the wash solution solenoids. The particular wash solution selected is determined by positioning of the manual wash solution selector switch. These solenoids are energized through an RC network allowing the solenoid to pick at a value close to 48 volts, but holding through the dropping resistor at approximately 20 volts. The cycling of relay HD1 will cause the centrifuge to oscillate to thereby agitate the solution in the blood bag.

All of the cycles described above, that is the START/SPIN, SUPERNATE OUT, and AGITATE/-WASH IN can now be repeated, or the operation can be halted by operating the STOP pushbutton. If the STOP pushbutton is operated, relay R12 is picked, which removes power from all relays. Relay R12 only remains energized as long as the STOP switch is operated. Releasing of relay HD2 applies the dynamic braking circuit to the centrifuge motor while the release of relays R3 and R5 stop the pump motor, close the waste and wash solenoids and open the hydraulic drain valve. When the STOP pushbutton is released, relay R12 is de-energized and released. The normally closed point of relay R12 applies 48 volts to the pump home position switch to the end-of-travel switch and to a set of normally closed points on relay R1. If relay R1 is not operated, which means the pump is not in the home position, the normally closed relay R1 point will supply the energy to relay R7, causing the pump to return to the home position. The various controls except hold are inoperative until the pump reaches the home position. When this position is reached, the home pump switch is operated and energizes relay R1, which lights

the ready light, as previously explained and releases relay R7. At this time the machine is now ready for use again.

The hold condition can be initiated at any time, but its action will be different depending upon the particular mode of machine operation. If the machine is in the SPIN mode, there is no visual change in the machine operation except that relay R8 is energized. Under these conditions the operator cannot proceed to another step except by operating the button CONTINUE, which will drop out relay R8. If the machine is in the SUPERNATE OUT mode, operation of the HOLD button stops the pump by picking relay R8, which removes power from the pump motor. Other functions will continue, and if the CONTINUE pushbutton is operated at this time, the machine will proceed in the SUPERNATE OUT mode. If the machine is in the AGITATE mode, operation of the HOLD switch will again stop the pump as a result of relay R8 picking. Relay R9 picks when relay R8 holds. This removes power from the agitate control timer and the hold circuit of HD3. Taken together, these two events will stop the centrifuge agitation operation.

Under normal routine operating conditions the stop light L7 does not light. However, in the event of failure of the home limit switch and/or the end-of-travel switch on the hydraulic pump, emergency stop switches S12 and/or S13, which are located at the extreme ends of upper and lower travel of the pump piston, act to light the stop light and also to pick relay R12, thus, causing the machine to stop. Under these conditions the machine can only be restored to normal operation by manually turning the shaft of the pump motor by hand to move the pump piston shaft away from the emergency stop switches. At this time, of course, it would be necessary to check for and eliminate the cause of the overtravel.

To operate the machine in the AUTOMATIC mode, the timers ST1 and ST2 on the operator's console are set, the plugboard is appropriately wired and the automatic manual switch is placed in the automatic position whereupon the machine ready light is lighted. The automatic manual switch in the automatic position causes relay R13 to pick up, which in turn causes the motors and pilot lights of the timers ST1 and ST2 to be energized. The stepper switch S17 has been kept in the home position by relay R13, which energizes the step per reset magnet. At this time pushing the START/SPIN button will cause the same circuit action as encountered in the MANUAL mode. Also, it will cause the stepper switch to step one position from its home position to step 1. Upon reaching the step 1 position, the clutch of the plugboard program spin timer is energized which starts the time spin interval. The machine remains in the SPIN mode until the timer reaches the end of its preset travel. At the end of that interval that contacts in the timer operate which result in energizing relay R3, which starts the SUPERNATE OUT cycle. Energization and picking of relay R3 releases relay R2, which then resets the spin timer.

SUPERNATE OUT circuit conditions are the same as those encountered during manual operation and this cycle continues until the pump reaches the end-of-travel switch or the packed red blood cells pass the interface detector to be subsequently described. Assuming that the end-of-travel operation occurs first, the end-of-travel switch will energize relay R6 and relay R6 energizes relay R4 which establishes the AGITATE mode of operation. It should be noted that in automatic operation the solution selector switch is not operative and the wash solution is instead under control of the stepper switch. With the stepper switch at position 1, the end of speed sense reed relay will transfer and drop relay R11 thereby applying 48 volts through relay R5 to the selective wash solenoid. The machine will remain in the AGITATE mode until the pump reaches its home position at which time activation of the home limit switch will energize relay R1. Relay R1 will energize relay R2 and this relay establishes the SPIN mode and steps the stepper switch to position 2. Subsequent events are the same as those described above until the stepper switch reaches the programmed stop position. If a stop is not programmed by suitable wiring on the plugboard, the stepper will continue to advance to the final step or step 10 and then will stop at the end of the next speed sense relay operation.

A programmed stop routes the signal that otherwise would be going to one of the wash solenoids to a pick up circuit for relay R12. When R12 picks up the machine is stopped. Relay R12 also activates the stepper reset solenoid resetting the stepper to home and finishing one complete sequence.

The HOLD condition can be initiated during any step in the AUTOMATIC cycle. During spin, the HOLD circuit will stop the spin timer while the rest of the action is as described previously for manual operation. With the timer stopped, the machine will remain in spin until the CONTINUE button is pressed. This will restart the timer and the machine sequence will continue. In the SUPERNATE OUT mode, the HOLD condition acts exactly the same as in manual operation. With the pump stopped, however, the machine will remain in the SUPERNATE OUT mode because the pump cannot activate the end-of-travel switch or interface detector. Pressing the CONTINUE button will start the pump again. During the AGITATE mode, the operation of the HOLD button will act as described for manual operation again because the hydraulic pump stops and can be restarted by operation of the CONTINUE button.

The safety interlock circuit includes two magnetically-operated reed switches under the rear of the sliding covers over the centrifuge well. This is to assure that the covers are closed before the centrifuge can rotate. With the covers open, the reed switches are open and relay R14 is de-energized. Under these conditions the power is interrupted to the ready light and to the START/SPIN switch. When the covers are closed, relay R14 is energized, the ready light is lighted and the START/SPIN switch is powered. If during operation of the machine the covers are accidentally opened, relay R14 drops and momentarily picks relay R12 through the action of a charge stored on a large capacitor Q1. The momentary picking of relay R12 will initiate a stop operation and force the machine to stop.

It may be noted in FIG. 9*a* that relay R4 may be energized to initiate an AGITATE mode by the energization of a relay IFR. This relay is governed by the circuitry shown in FIG. 11 of the drawings. Referring to FIG. 11, the reference character 101 indicates the transparent flexible tubing which carries the blood cells and supernatant to and from the blood bag in the centrifuge. At a suitable location with respect to the blood bag and centrifuge, a light source 103 with a sensitivity control

of **105** is positioned on one side of the tube, and a suitable photocell or light detector **107** is located opposite the light source and arranged so that packed red blood cells pass between the light source and photocell. Interruption of the light path will cause a signal to be supplied from the photocell **107.** The photocell spectral response is chose to allow the detection of the packed red blood cell interface which is in the vicinity of 7,000 to 7,500 angstroms. This particular response area was arrived at by a spectrophotometer testing of plasma, packed red blood cells and hemolyzed samples of blood. The output of the photocell is supplied to an emitter follower stage **109** for the purpose of impedance matching, and thence to inverter **111.** From the output of inverter **111,** the signal is supplied to a second inverter **113** and the input of a single shot **115.** The purpose of the single shot is to compare, at the input of the next following stage which constitutes an and-invert circuit **117,** at the end of the single shot time-out the single shot output and signal through the inverter. If the signals are the same, then the circuit **17** will supply an output to a relay driver circuit **119** which in turn will energize the winding of relay IFR. If the signals are different at the inputs to circuit **117,** then no signal is fed to the reed relay driver. Accordingly, the circuit blanks out the effect of small slugs or packed red blood cells which interrupt the light to the photocell and prevents these minor interruptions from energizing the relay IFR and advancing the machine to AGITATE mode. Only when a relatively continuous amount of packed red blood cells interrupt the light beam, for a period longer than the time out period of the single shot, will the relay IFR be operated.

From the foregoing, it will be apparent that the present invention provides a highly improved, compact blood processing system for processing blood portions which have been frozen so as to remove the glycerol or other agents preparatory to use of blood in transfusions. The system is arranged so that it cannot only be manually operated, but by suitable programming may be run automatically. Various safety features are provided which insure the proper operation of the equipment to safeguard the operation, as well as to insure the proper sequencing in the processing of the blood.

While the invention has been particularly shown and described with reference to a preferred embodiment thereof, it will be understood by those skilled in the art that the foregoing and other changes in form and details may be made therein without departing from the spirit and scope of the invention.

What is claimed is:

1. In a blood processing apparatus including a motor-driven centrifuge having a flexible membrane therein under which fluid may be forced to alter the volume above the membrane, a collapsible blood bag adapted to fit in the centrifuge over said flexible membrane, rotatable seal means for connecting said blood bag to a tubing manifold, valve means for controlling the flow of fluids to and from said blood bag, and motor-driven control pump means for supplying or removing fluid from the space below said membrane, said system having a plurality of possible modes of operation during a cycle of operation, the combination with foregoing of control means for governing the operation of said apparatus comprising,

a plurality of manually operated switches, one for each mode of operation of said system,

electrically interlocked control means for providing a sequence of output control signals corresponding to said modes of operation,

automatic programming means effective to supply inputs to said interlocked control means in a predetermined sequence corresponding to the sequential operations of said manually operated switches,

and selection means for selectively connecting said interlocked control means to said manually operated switches or to said automatic programming means.

2. In a blood processing system as claimed in claim **1,** the further improvement comprising,

at least one timing means settable to a plurality of different time intervals and providing an output signal at the end of the settable time interval following energization of the timing means,

first circuit means connecting said timing means to said automatic programming means to energize said timing means at least one preselected point in the operating cycle of said system, and

second circuit means connecting said timing means to said interlocked control means to supply output signals to said control means to thereby initiate the next step in the operating cycle of said system.

3. In a blood processing system as claimed in claim **3,** the further improvement comprising,

first and second manually-settable motor speed control means for said centrifuge and said control pump respectively, whereby the speeds of said centrifuge and said pump may be set individually and variably by the operator.

4. In a blood processing system as claimed in claim **3,** the further improvement comprising a low voltage power source, and

motor control switching means for selectively connecting the motor for said centrifuge to said first motor speed control means or to said low voltage source.

5. In a blood processing system as claimed in claim **3,** the further improvement comprising,

motor speed sensing means connected to the motor of said centrifuge, and

circuit means governed by said speed sensing means for advancing the sequence of operation of said system in response to said centrifuge reaching a predetermined speed.

6. In a blood processing system as claimed in claim **5,** the further improvement comprising,

said speed sensing means comprising a relay selectively connected to the drive circuit of the motor of said centrifuge during dynamic braking of said motor.

7. In a blood processing system as claimed in claim **1,** the further improvement comprising,

packed blood cell detection means for detecting the presence of packed red blood cells in the tubing connected to said blood bag, and means governed by said detector for advancing the control means to the next successive mode of operation when and only when packed red blood cells are detected in said tubing.

8. In a blood processing system as claimed in claim **7,** the improvement comprising,

said packed blood cell detection means comprising means responsive only to the presence of a predetermined quantity of packed red blood cells in said

tubing for a time interval greater than a predetermined minimum time interval.

9. In a blood processing system as claimed in claim 1, the improvement comprising,

status hold means connected to said interlocked control means and effective to selectively hold said control means in any mode of operation in which said status hold means is operative.

10. In a blood processing system as claimed in claim 9, the further improvement comprising,

said status hold means comprising manually operated hold switch means connected to said control means to maintain it in the status effective when said hold switch is operated, and manually operated continue switch means effective to negate said hold switch means.

11. In a blood processing system as claimed in claim 1, the further improvement comprising,

a first fluid reservoir for maintaining fluid pressure near atmospheric pressure in the fluid system during spin operation, and

a second fluid reservoir to allow the system to accommodate different size wash solutions at each step in said blood washing procedure.

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