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Mason

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[54] **VALVE CONTROLLED SINGLE NEEDLE BLOOD PROCESSING SYSTEMS**

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[73] Assignee: **Betamite Electronic Devices,** Culver City, Calif.

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[52] **U.S. Cl.** ..... **128/214 R;** 128/214 E; 128/221

[51] **Int. Cl.** **A61m 5/00;** A61m 1/03

[58] **Field of Search** ..... 128/214 R, 214 B, 214 E, 128/214.2, 221, 274

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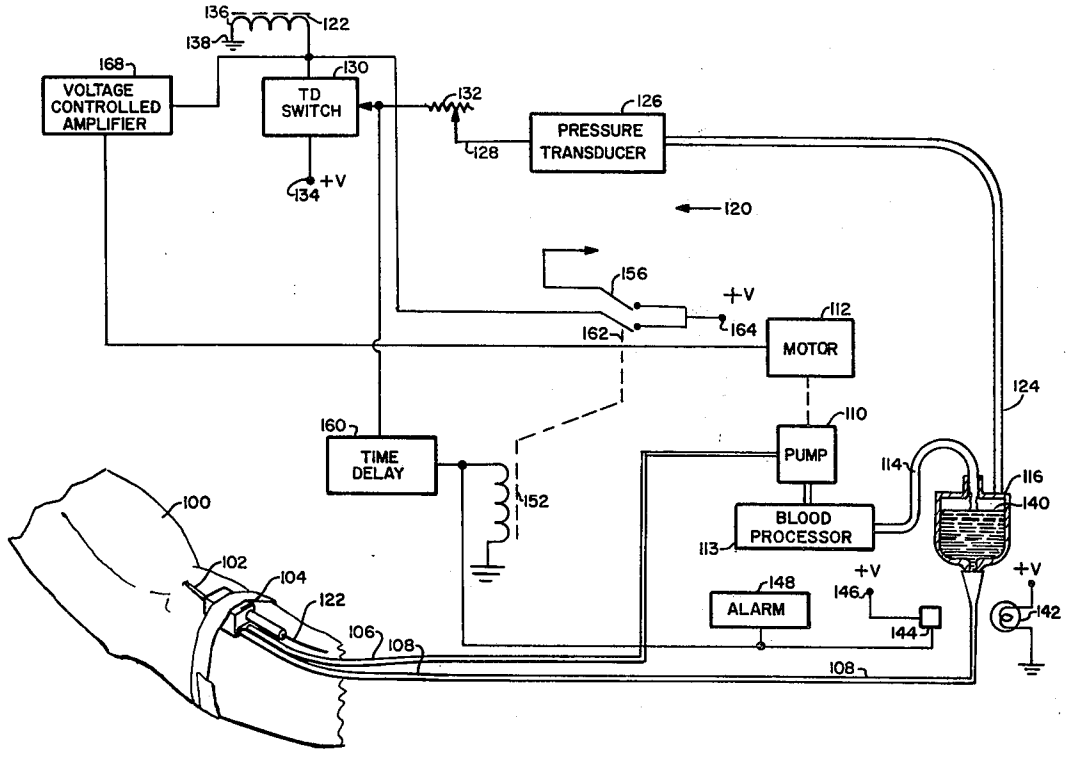
[57] **ABSTRACT**

Herein disclosed is a blood flow control system for use with a single needle for drawing blood from and returning blood to the blood channels of a patient. A needle is included which has a body with a pair of output channels leading into separate tubes. A switch is enclosed therein which provides a passage from the needle into either of the two selected channels. A switch block is attached to the needle body and is operable to cause switching from either of the two output blood channels in the needle. The switching is caused by a control circuit coupled to the switch block. The control circuit is operable depending upon the pressure of the blood in the input line of the two selected channels and causes the blood to flow from the needle to the first channel when the pressure applied to the second channel reaches a predetermined level. Upon switching, the blood is caused to flow from the processing equipment back through the needle into the patient.

7 Claims, 7 Drawing Figures



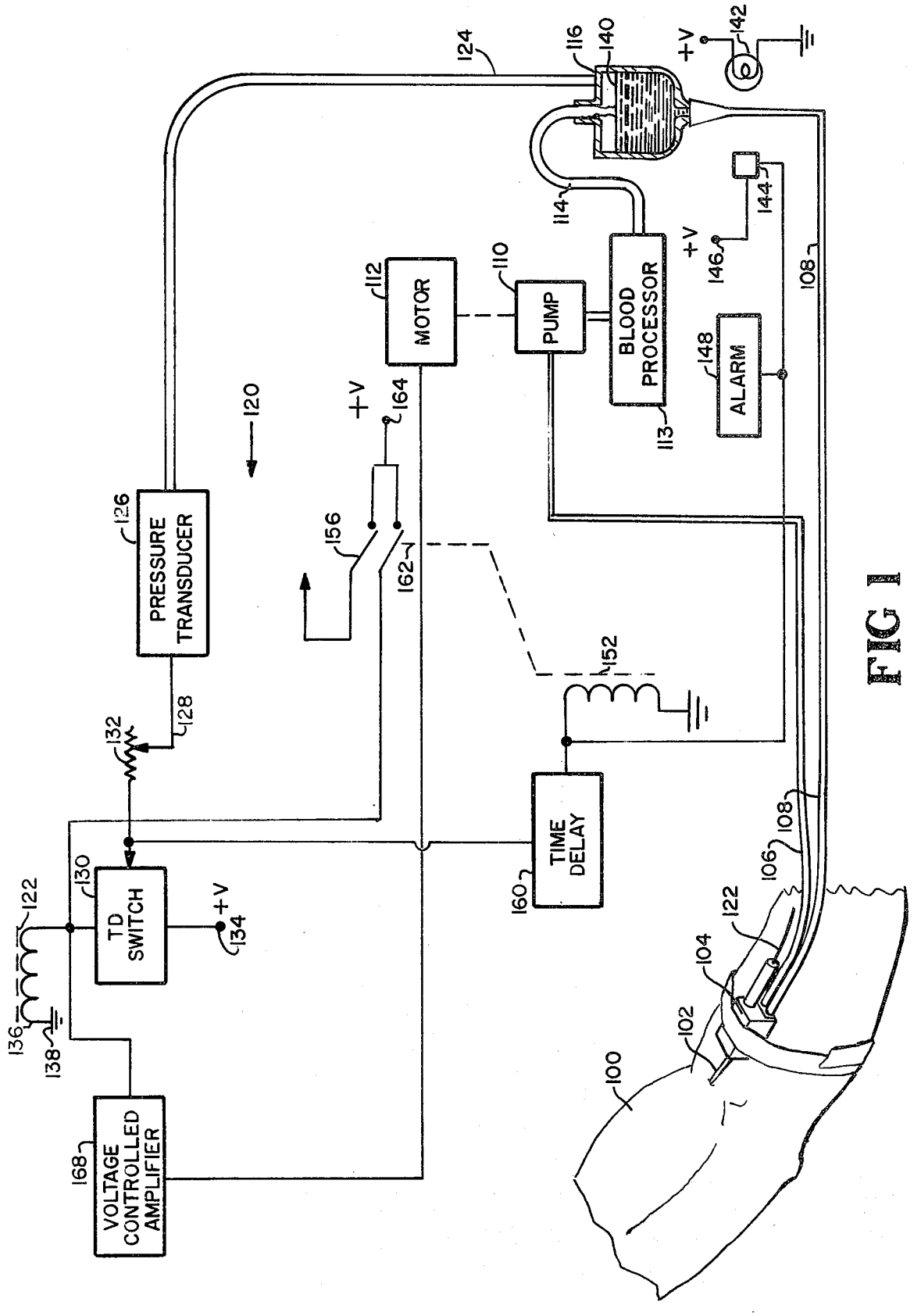
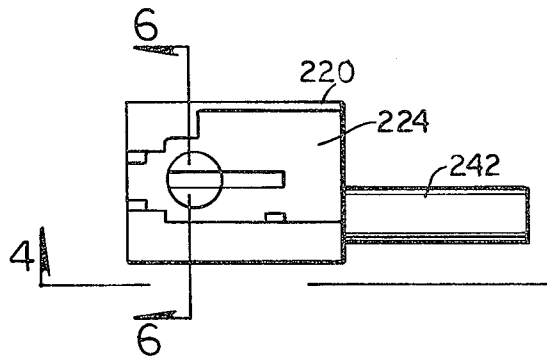

124
116
140
+V
142
114
144
+V
146
108
112
MOTOR
110
PUMP
BLOOD PROCESSOR
113
148
ALARM
120
+V
164
126
PRESSURE TRANSDUCER
156
162
152
128
132
TIME DELAY
160
108
106
122
130
TD SWITCH
+V
134
104
122
136
138
102
100
168
VOLTAGE CONTROLLED AMPLIFIER

FIG 1

FIG 3



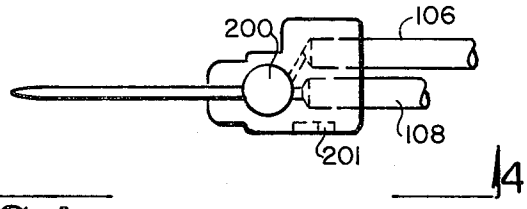
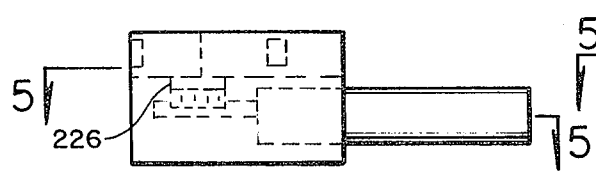


FIG 4



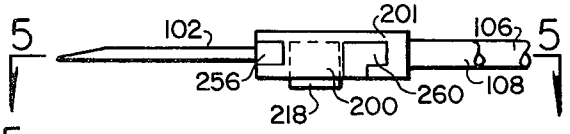
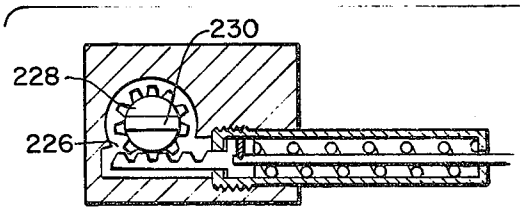
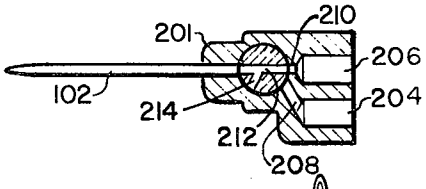


FIG 5





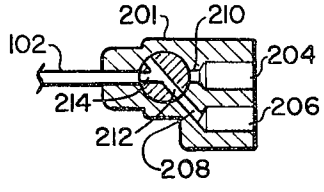


FIG 5A

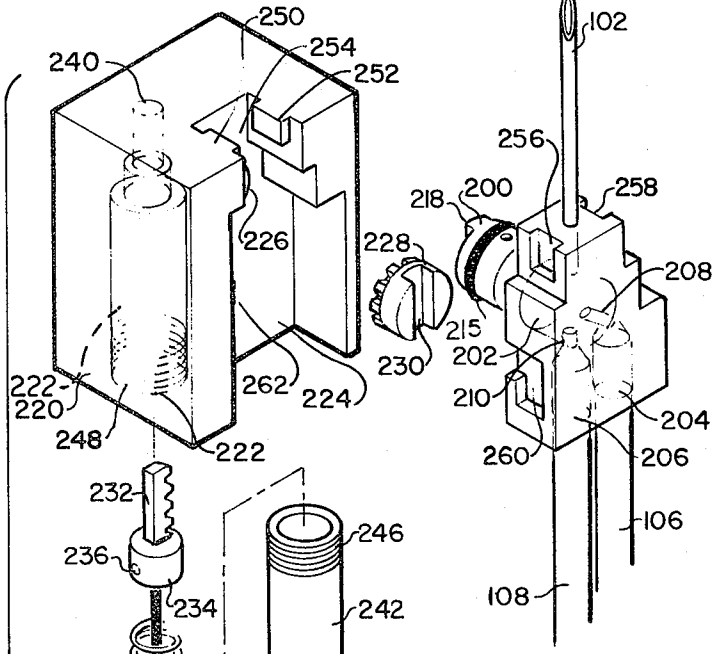


FIG 2

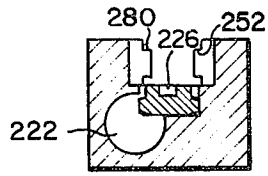


FIG 6

VALVE CONTROLLED SINGLE NEEDLE BLOOD PROCESSING SYSTEMS

BACKGROUND OF THE INVENTION

This invention relates to medical equipment and more particularly to a novel and improved single needle blood control valve system for taking blood from and returning blood to a patients blood channel for processing in blood processors or the like.

Heretofore it has been known that a patient may for one reason or the other need the blood from a blood flow channel to be removed from his system, for processing and returned to a blood flow channel. As herein used the term blood flow channels may interchangeably refer to veins or arteries. For example, in some patients there is a failure of the vital organs, such as the kidneys, and the blood must be periodically removed from the patient and processed by dialysis machines or the like and returned to the patient. Such machines for performing these processes are well known to those skilled in the art, details thereof will not be gone into in this specification but will simply be referred to herein as a blood processor.

Presently there is much equipment on the market for performing the medical processes heretofore set forth. In most cases a needle is inserted into the blood channel of a patient, to facilitate the removal of blood from a patient. A second needle is placed into the blood channel for returning the blood to the patient. This, of course, is uncomfortable for the patient to have two needles inserted into his blood channels at the same time. After continued use of such needles into the blood channels of the person, the areas become scarred, sore and very discomforted.

More recently it has been discovered that a single needle can be used on a patient to eliminate much of the discomfort, the amount of scars and injury to the patient. One method of operating this particular single needle is periodically to remove the blood and then after a certain elapsed time return the blood to the person. Prior art devices have included a method of physically clamping the flexible hoses that are used so that blood flows in one direction and then unclamping that particular hose and clamping the other hose so that blood will reverse its flow in the other direction. In this particular type of operation, certain specified materials must be used according to standards set up by law. The flexibility of the tubing that must be used according to these standards is a somewhat soft plastic and the clamping operation is very slow because of the slow memory of tubing to return to its original shape. While this system has been used to some extent, it has proved to be somewhat unsuccessful.

SUMMARY OF THE INVENTION

The present invention overcomes the disadvantages heretofore set forth specifically by the fact that it eliminates the need for more than a single needle for blood processing operation and it also eliminates the need to clamp and unclamp hoses with this slow restoration rate.

Briefly described, the present invention provides a disposable needle which has become very popular with the present medical concerns because of the fact that the need for sterilization is eliminated whereby the needles are received into the medical facilities already sterilized and thus they can be disposed of without the need for being sterilized for reuse. The needle of the present invention is coupled to a body member which has a pair of channels therefor. One channel is provided for the output flow of blood and the other is for the input flow of blood. A switching valve is constructed within the body member which includes a cylindrical member having channels therein so that when it is turned in one direction, the channel connects the needle to the output channel or when rotated again or in a different direction it connects the input channel to the needle. Operability of the switch within the body member is accomplished by a switch block which is connected directly to the body member and has facilities therein for locking the switch member to the body member.

DESCRIPTION OF THE DRAWINGS

These and other features and advantages will become more apparent to those skilled in the art when taken into consideration with the following detailed description wherein like references numeral indicate like and corresponding parts throughout the several views and wherein:

FIG. **1** is a schematic drawing of the valve control system of one embodiment of the present invention;

FIG. **2** is an exploded view of the valve and valve switch used in the system shown in FIG. **1**;

FIG. **3** is a top view of the valve and valve switch **2** with the valve and valve switch disassembled;

FIG. **4** is a side view of the valve and valve switch **3** taken along the lines **4—4** of FIG. **3**;

FIG. **5** is a section view of the valve and valve assembly taken along the lines **5—5** of FIG. **4**;

FIG. **5A** is a section view of the valve and valve assembly as shown in FIG. **5** with the valve switched to a second position; and

FIG. **6** is a section view taken along the lines **6—6** of FIG. **3**.

DESCRIPTION OF THE SHOWN EMBODIMENT

Referring now to FIG. **1** there is shown the valve control system of the present invention showing a switch **104** which is used to transfer blood flow either into or out of the arm of the patient **100** through a needle **102.** Specifically two tubes **106** and **108** leads from the switch **104** into a pump **110** which is driven by a motor **112.** Pump **110** pumps the blood from the needle **102** to the switch **104** into a blood processor **113.** The blood processor may be of the type such as an artificial kidney which is used to clean the blood from the system and return it via line **108.**

An output tube **114** from the blood processor **113** leads through a drip chamber **116** which is connected into tube **108** back into the switch **104.** The purpose of the drip chamber **116** is to give a visual indication of blood flowing in the output tube **114** and will be explained in more detail hereinafter.

The switch **104** is operated from the switch control circuit **120** by a mechanical linkage **122** therefrom. The mechanical linkage may preferrably be in the form of a cable. By manipulation of the mechanical linkage **122** blood is allowed to either flow from tube **106** with tube **108** being shut off or from tube **108** with tube **106** shut off. Thus blood may be alternately pumped from the switch **104** into the blood processor and then alternately switched so that the blood flows from the tube **108** with the tube **106** shut off. Thus, a single needle

can be used into the patient's arm and blood can be alternately pumped from and back into the patient.

The switch control circuit is operable when the pressure of the blood in the line **108** raises to a predetermined level. Specifically a pressure sensing tube **124** is connected into the drip chamber **116** in a suitable manner and connected into the pressure transducer **126.** Such pressure transducers are well known to those skilled in the art and provide an electrical signal when the pressure builds up in transducer to a predetermined level. After the predetermined level is reached, an electrical signal (of a certain level) is emitted from the lead **128** and activates a switch **130.** Specifically, a line **128** leads through an adjustment potentiometer **132** and into a suitable electrical switch **130** which has one end coupled to a voltage source **134** and the other end of which is coupled to a solenoid **136.** The other end of the solenoid **136** coupled to a ground potential **138.**

Switch **130** may be a suitable time delay switch which are well known to those skilled in the art.

Solenoid **136** operates the mechanical linkage **122** into the switch **104.** Specifically the solenoid can be coupled to a suitable cable which has one end thereof coupled directly into the switch **104** and when the switch **130** is activated, solenoid **136** pulls the cable in a suitable direction. The cable then may be suitably spring loaded so that when the switch is deactivated the cable **122** moves back into its original position. Thus switching the flow of blood through leads **106** or **108,** respectively.

To operate the pressure transducer **126** the drip chamber **116** may be comprised of a soft clear plastic enlargement in the tubing for measuring pressure in the lines and which is also the pressure in the blood processor or artificial kidney. A certain amount of air is placed into the drip chamber which lowers the blood level **140** in order that the pressure may be checked. The pressure gage may, for example, be a set of bellows or the transducer **126** as shown.

The drip chamber **116** establishes the fact that the blood is actually flowing through the lines. For example, the level of the blood **140** can be checked by visual observation that blood is actually flowing. Without the drip chamber **116,** one might observe that there is pressure in the blood flow lines **106** or **108** but not that it is actually moving.

A problem occurs in a situation where there is an air level in the drip chamber **116.** It must be essential that the blood flow level does not drop to a point whereby air enters into the patient's blood system. Thus, constant observation of the blood flow level must be made. In this shown embodiment there is a system which provides automatic detection of the level of the blood. For example, a suitable light **142** is stationed on the lower end of the chamber **116** and a photo detector **144** is positioned on the opposite side of the tubing. Thus, light will not flow through the tubing **108** as long as there is blood therein because of the dark denseness of the blood. The light will not be detected by the photo detector **144.** If the blood level **140** drops below the visual alignment of the photo detector **144** for light **142,** an electrical signal provided by the terminal **146** will be applied to a suitable alarm **148** to alarm personnel in the facilities that the blood level has dropped to an unsafe position. Also an electrical signal from photocell **144** is applied to a line **150** which energizes a solenoid **152** which de-energizes a switch **156** to cut off all power to the blood processor **113** and the motor **112** to discontinue the flow of blood into or from the patient. The solenoid **136** is activated, causing the valve to switch to closed position so air cannot go into vein. A warning light indicator goes on indicating "air" in line.

A time delay switch **160** is coupled into a solenoid **152** so that at certain time periods the solenoid **152** will open the switch **162** which leads from a voltage source on terminal **164** into a voltage controlled amplifier **168** which is used to energize motor **112.** Time delay switch **160** is automatically reset by the signal from the pressure transducer **126.**

In operation the needle **102** is placed into the patient's arm **100** and a switch **104,** which will be explained in more detail hereinafter, is switched to tube **106** so that when the pump **110** is energized by the motor **112,** blood is pumped from the patient's arm into the blood processor **113** and into tube **108** but because the tube **108** is cut off at the switch **104,** it is unable to return to the patient's arm **100.** Thus, pressure builds up in the drip chamber **116** and this pressure is applied through the tube into the pressure transducer **126.** When the pressure transducer **126** reaches a predetermined level, an electrical signal is generated in the transducer **126** and applied to the switch **130** which energizes the solenoid **136** and mechanically manipulating the mechanical linkage **122** which switches the switch **104** to cut blood flow in the tube **106** and start blood flow in the tube **108.** Blood then starts to flow from the blood processor **113** into the patient's arm to the needle **102** until such time as preset time delay is reached, causing mechanical manipulation of the mechanical linkage **122** and reversing the switch **104.** This causes periodic time onto the pressure transducer which is rhythmetic to a certain extent. As long as this same rhythm is maintained, the time delay **160** will never reach its maximum time and will be continuously reset by the signal. on lead **128** thereto. If a malfunction occurs some place in the system, for example, the needle come loose from the patient's arm, a break in the tube **106** or **108,** or a failure in the blood processor, the time delay **160** will be extended because pressure fails to raise in the pressure transducer **126.** If the set time of the time delay **160** is exceeded, solenoid **152** is engaged which will enable the solenoid **136** causing a change in the linkage reversing switch and also to an extent where the switches are cut off and the power supply to the entire unit is disconnected causing the pump to stop.

A further safety occurs in the present invention when the pump **110** is operating and the switch **104** is cut off to the tube **106.** If the pump continues to operate, a negative pressure will be built up in the blood flow line which will cause damage to the blood, specifically it will cause certain destructive damage to the blood cells themselves. Therefore, it would be desirous to reduce the speed of the motor **112** to a bare minimum. To accomplish this a voltage control amplifier **168** is coupled between the motor **112** and the output of the switch **130.** When a signal appears on the solenoid **136,** it also reduces the voltage supply to motor **112** through the voltage control amplifier **168.** The motor continues to operate but at a reduced speed eliminating the chance of any blood cell damage due to negative pressure.

Referring now to FIGS. **2–6** collectively, there is shown a disassembled view of the switch **104,** which

comprises a valve **200** and a valve body **201.** The valve body **201** secures the needle **102** therein and has a hole **202** drilled in the underside thereof as shown in FIG. **2,** and a pair of further holes **204** and **206** which communicate into the hole **202** by means of passages **208** and **210.** Note that the passage **208** from hole **204** is slanted inwardly to communicate with the hole **202** while the passage **210** in the hole **206** is straight and communicates directly into the hole **202.** The tube **106** is secured into the hole **204** and the tube **108** is secured into the hole **206** so that flow of the blood from the needle **102** can be directed into tubes **106** and **108** through the appropriate passages and holes. This is accomplished by a valve **200.**

As shown in FIG. **5** the valve **200** comprises a stragiht through hole or channel **212** which when properly aligned communicates the holes through the needle **102** into the passage **210** so that blood will flow directly to tube **108.** By turning the valve **200** the hole **212** communicates into the passage **210.** An off-shoot passage **214** from the passage **212** communicates the hole in the needle **102** into the passage **208** so that blood is now sent into the tube **106.**

Specifically the valve **200** comprises a cylindrical body which fits into the hole **202.** An O ring **215** is placed around the outside periphery of the cylindrical body valve **200** to assure a seal therein so that blood will not leak around the passage but wiil be directly communicated into its proper hole **204** and **206** and its proper tube **106** and **108** respectively. The outward side of the valve **200** has a protruding tongue which is used to manipulate the rotation of the valve **200** within the hole **202** in a manner hereinafter described.

The entire valve assembly is coupled directly to the needle **102.** The tubes **106** and **108** are manufactured specifically of an inexpensive material so that it can be disposed of after use. A switching member **220** or switching block comprises a plastic body which has a hole **222** therein so that the cable **122** can be placed therein to manipulate the valve **200.** To accomplish manipulation of the valve **200** a channel **224** is cut in one side of the block which has a specific configuration which matches the configuration of the valve body in **201** which will be explained in more detail hereinafter. A hole **226** is drilled to the top side of the channel **224** and communicates with the hole **222** drilled therein. The hole **226** communicates with the hole **222** and receives a gear **228** therein which has a groove **230** that matches the tongue **218** on the switch **200.** A rack **232** is coupled to a insert **234** by suitable pin **236** and is coupled to the cable **122** and inserted into the bore **222.** The bore **222** has smaller holes **240** therein so that the insert **234** cannot slide further than necessary to accomodate operations hereinafter explained.

The rack **232** engages the teeth on the gear **228** and when the cable is moved forward or backward it causes the gear **228** to rotate and also the switch **200.** When the switch **200** is moved for example as shown in FIG. **5** a straight through passage from the needle into tube **210** occurs. On the other hand when the gear is engaged and moves in the opposite direction passage **214** communicates the needle into passage way **208** as best shown in FIG. **5A.**

A tubular cylinder **242** has threads **246** therein which matches the threads **248** in the hole **222.** A spring **250** is placed around the cable **122** and on the outside of the insert **234.** The gear **232** and insert **236** is inserted into the hole **222.** The cable is then placed through the center of the cylinder **242.** Thereafter the spring **255** is placed within the hole **222** and the cylinder **242** is threadly mounted to the threads **248** of the hole **222** holding the spring and rack gear in place. Thus by pulling the cable in one direction and holding it there the switch switches from one direction to the other and upon release the spring action thereof changes back to its original position.

The configuration of the valve body **201** is shaped specifically as shown in FIGS. **2, 3, 5,** and **5A.** This configuration matches the configuration of the channel **224** so that the valve body **201** can be snapped into the channel **224.** A pair of locking lips **250** and **252** protrude inwardly from the small end **254** of the channel **224.** A pair of grooves **256** and **258** are provided in the matching small end of the valve body and fit the lips **250** and **252** respectfully. Thus the body **201** can be placed in the channel **224** and pushed forward to effect locking there between. This locking prevents the body from moving outwardly from the switch body.

To further facilitate locking the valve body **201** includes a second groove **260** which is L shaped. A further lip **262** protrudes inwardly from channel **224** and engages the groove **260.**

Having thus described but one preferred embodiment of this invention what is claimed is:

1. A blood access apparatus including:

a needle body portion having a pair of holes drilled in one end thereof and a round bore drilled partially through on side thereof intersecting said pair of holes;

a hollow needle in said needle body portion the end opposite said pair of holes and communicating with said round bore in said body portion;

switching needle means in said round bore in said needle body portion including direction channels for switching through access from said needle to said pair of holes;

a switching body portion having a channel therein which has a matching configuration of the needle body portion;

means in said switching body portion to switch said switching means;

said switching means including a protruding tongue;

said switching body portion including a hole in one end thereof and a round bore in said channel which intersects with said hole;

a rack and gear arrangement, said rack being disposed in said bore in said channel and engages said rack; and

a grooved member engaging said gear having a groove which engages the protruding tongue on said switching means.

2. A blood access apparatus comprising:

a needle body portion having a pair of holes in one end and a round bore through a side thereof intersecting said pair of holes;

a hollow needle mounted within said needle body portion in the end opposite said pair of holes and communicating with said round bore in said body portion, said needle having an opening therethrough;

switching means mounted within said round bore, said switching means including direction channels for switching access with said opening in said needle to either one or the other of said pair of holes;

a switching body portion having a channel therein for retaining said needle body portion in said switching body portion;

means mounted within said switching body portion to connect with and operate said switching means,

said means includes connecting means mounted upon said switching means;

said switching body portion including a hole through one end thereof and a round bore communicating with said channel which intersects with said hole;

a rack and gear arrangement, said rack being disposed through the hole and said switching body portion, said gear being disposed in said round bore and engages said rack; and

a member engaging said gear having cooperating means for engaging said connecting means of said switching means.

3. The blood access apparatus as defined in claim **2**:

wherein said switching body portion is provided with matching, adapted to connect with and support said needle body portion,

means mounted in said switching body portion to connect with and operate said switching means.

4. The blood acces apparatus as defined in claim **2** wherein:

said connecting means comprises a protruding tongue said cooperating means comprises a groove into which said tongue is to matingly cooperate.

5. The blood access apparatus as defined in claim **2** and further including:

a locking means connected between said switching body portion and said needle body portion, whereby upon said needle body portion being mounted within said channel of said switching body portion said locking means functions to prevent accidental disengagement therebetween.

6. The blood access apparatus as defined in claim **2** wherein:

said needle body portion being attached to a switching body portion;

mechanism movement means mounted within said switching body portion, said mechanism movement means connected to said switching means and also connected to activation means, upon said activation means receiving appropriate input impulses said mechanism movement means is moved to thereby move said switching means.

7. Blood access apparatus as defined in claim **6** wherein:

said mechanism movement means being movable between a first position and a second position, with said mechanism movement means in said first position said opening within said needle has access with one of said pair of holes and with said mechanism movement means in said second position said opening within said needle having access to the other of said pair of holes, a biasing means connected to said mechanism movement means, said biasing means functions to continuously bias said mechanism movement means to said first position.

* * * * *