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Wootten et al.

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[45] **Apr. 29, 1975**

[54] **METHOD FOR INJECTING CONTRAST MEDIA INTO THE VASCULAR SYSTEM**

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[73] Assignee: **Lear Siegler Inc.**, Elyria, Ohio

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[21] Appl. No.: **434,847**

Related U.S. Application Data

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[52] **U.S. Cl.**..... **128/2 A**; 128/218 A; 128/DIG. 1; 128/214 F

[51] **Int. Cl.**..... **A61b 6/00**; A61m 5/00; A61m 5/20

[58] **Field of Search**..... 128/218 A, DIG. 1, 2.05 R, 128/2 A, 236, 2 R, 214 R, 214 F; 222/59, 76

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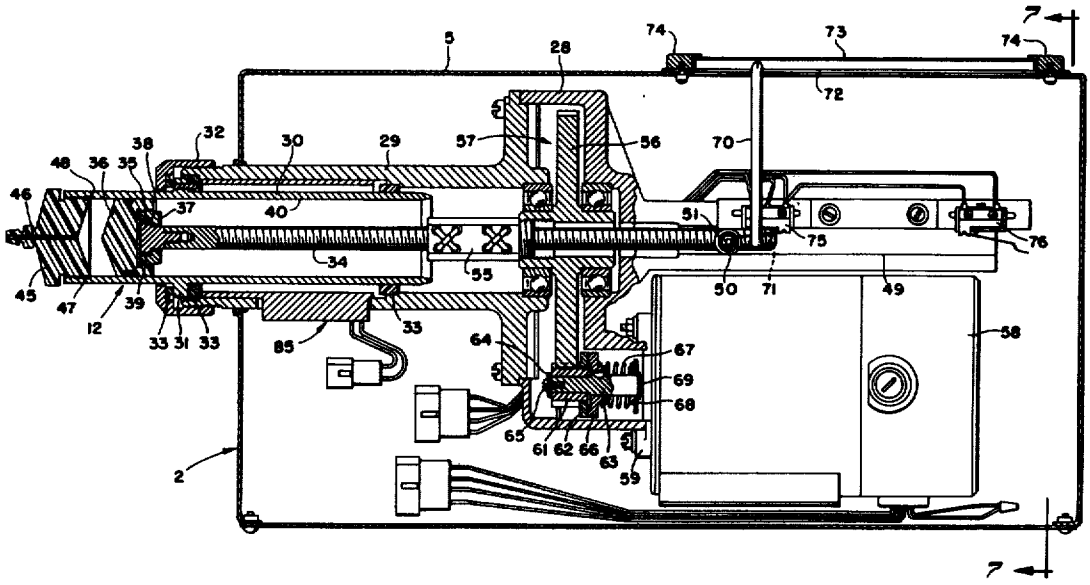
Primary Examiner—Aldrich F. Medbery

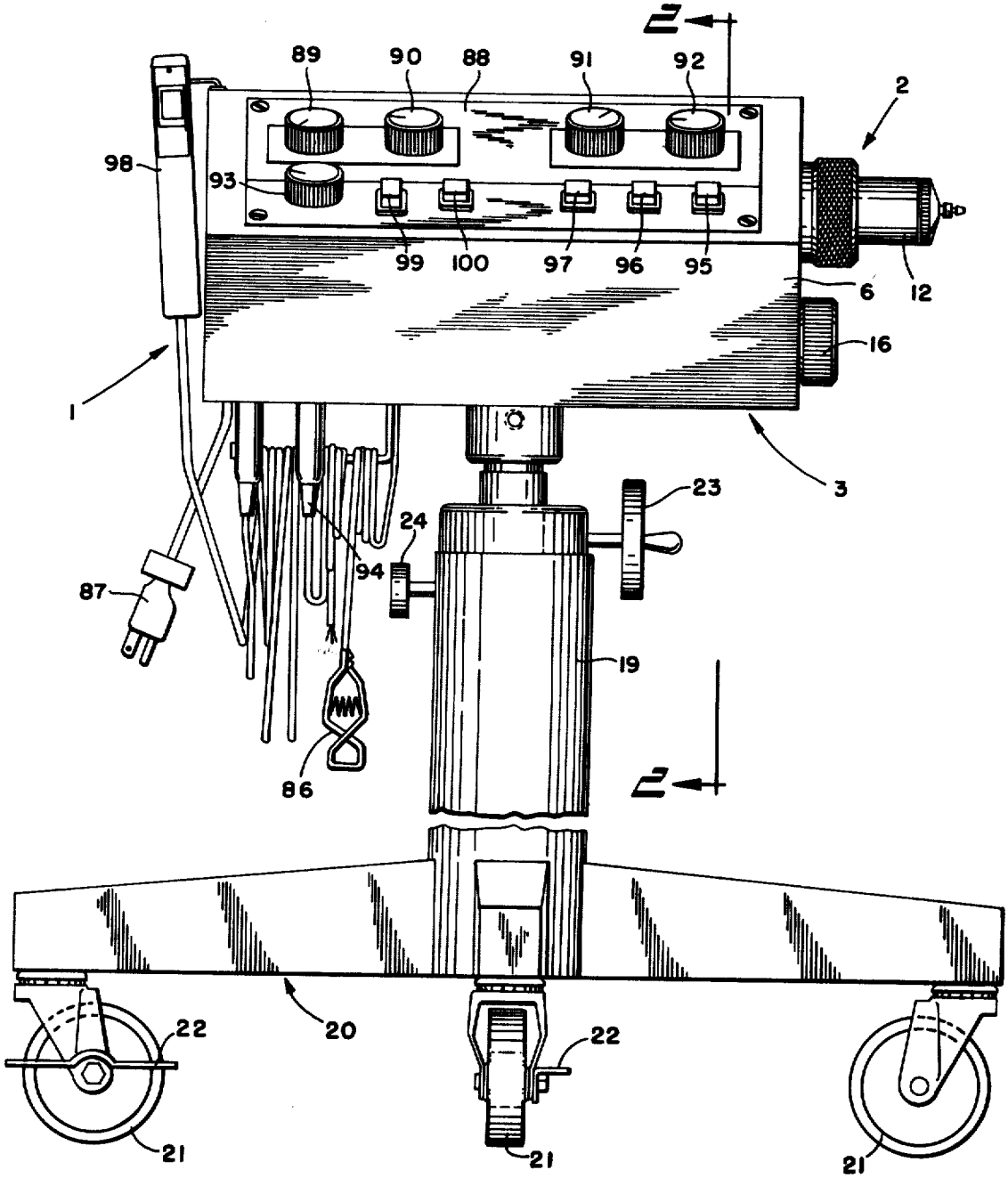
Attorney, Agent, or Firm—Donnelly, Maky, Renner & Otto

[57] **ABSTRACT**

A method by which fluid is delivered sequentially at more than one rate as desired. Such different flow rates and the duration of time of each flow rate are independently preselected, after which the piston is caused to be automatically sequentially advanced within the syringe at the preselected rates of speed for the preselected periods of time during one cycle of advancement of the piston to obtain the desired different flow rates and duration of time of each flow rate.

11 Claims, 9 Drawing Figures

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89
90
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98
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100
97
96
95
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12
16
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3
23
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94
87
19
86
2
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21
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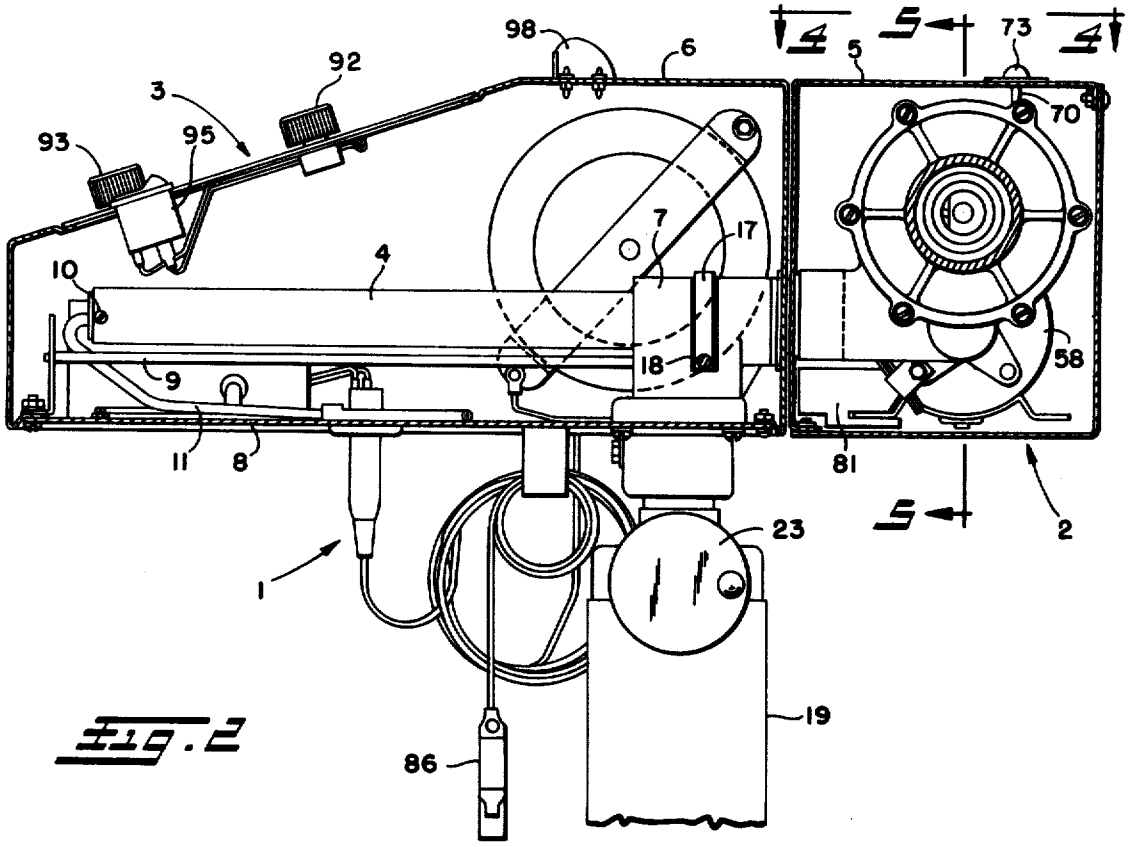
Fig. 1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6
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Fig. 2

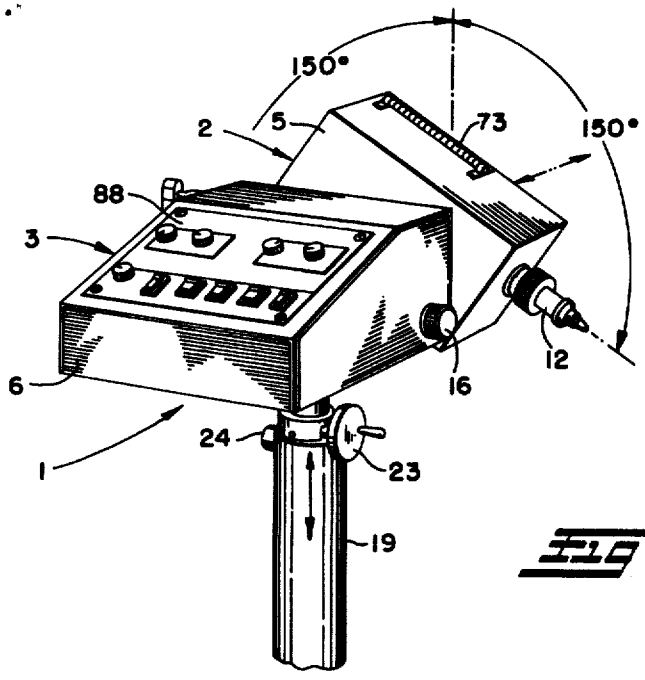
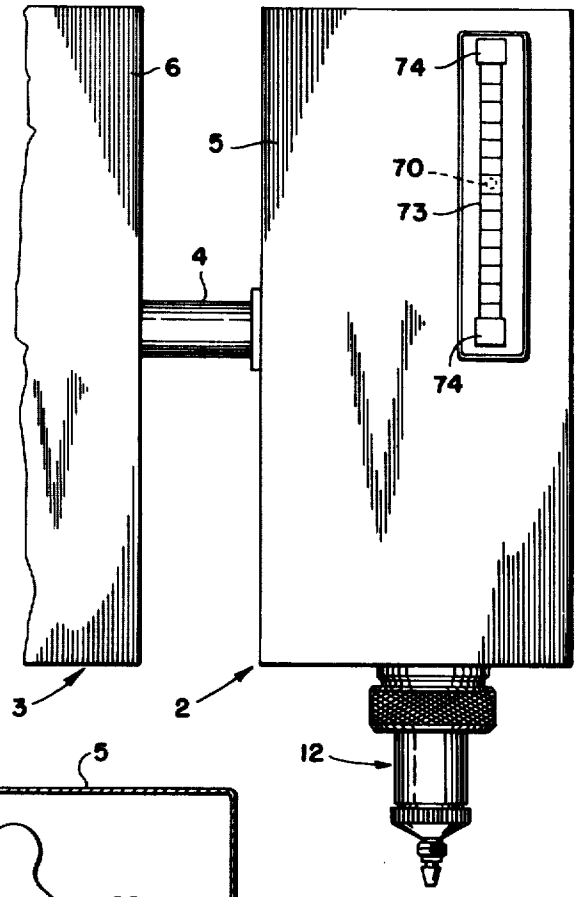

150°
2
5
73
150°
88
3
6
16
12
24
1
23
19

Fig. 3

Fig. 4



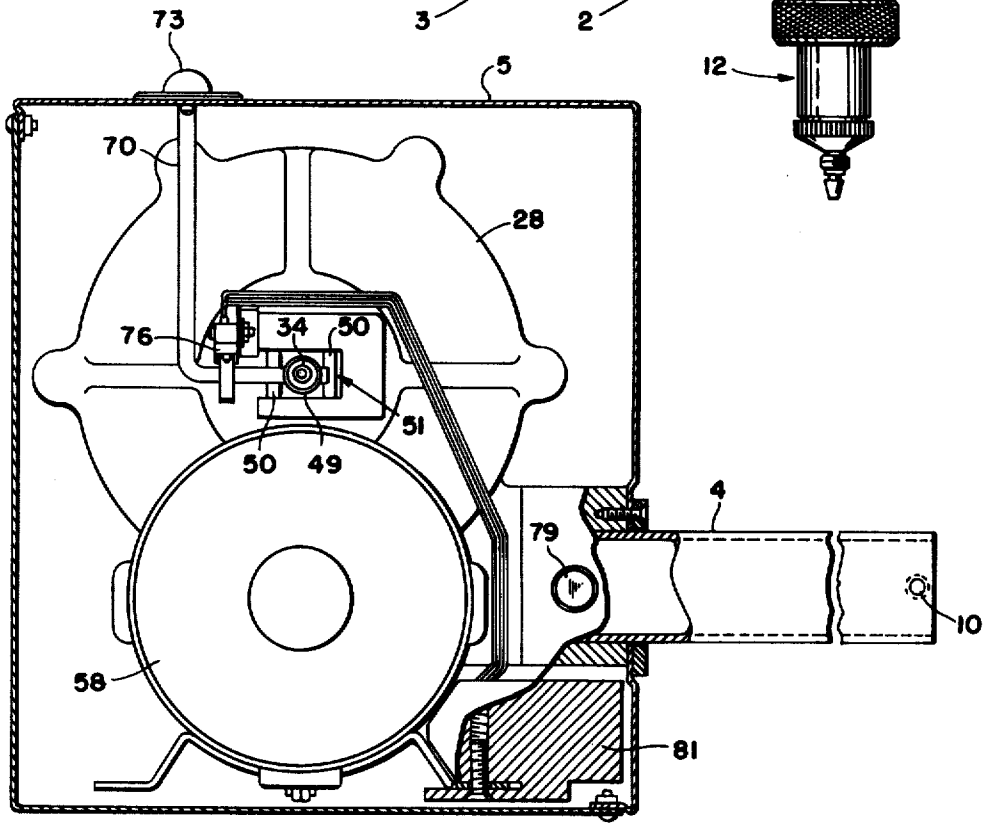
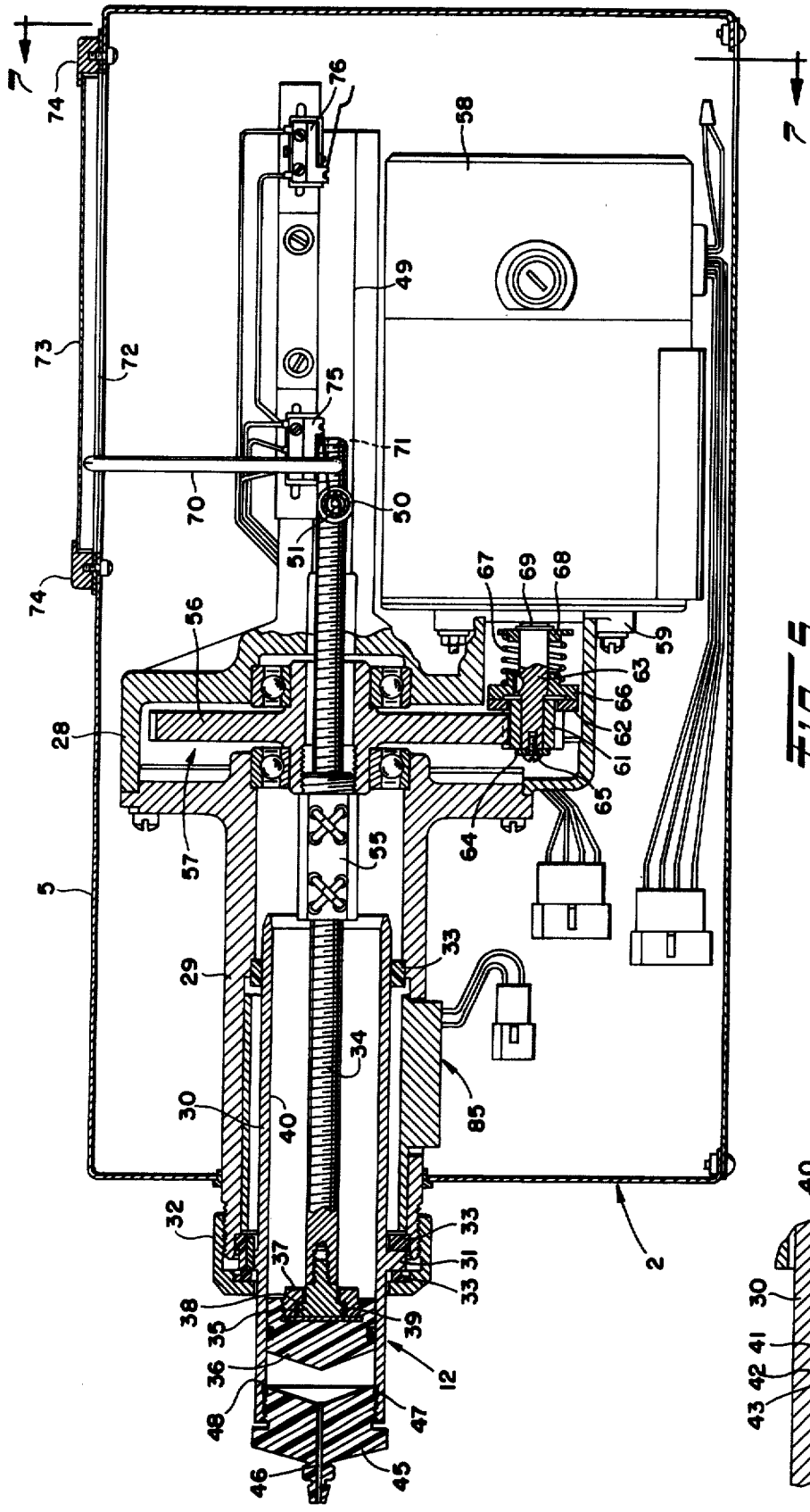


Fig 7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64
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55
5
29
33
34
85
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12
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47
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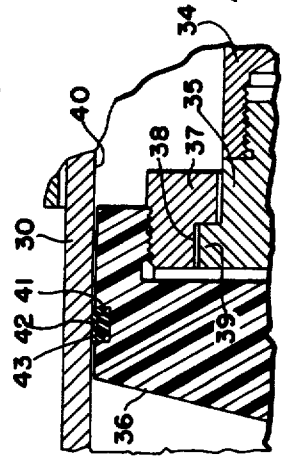
45
2

FIG. 5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36

FIG. 6

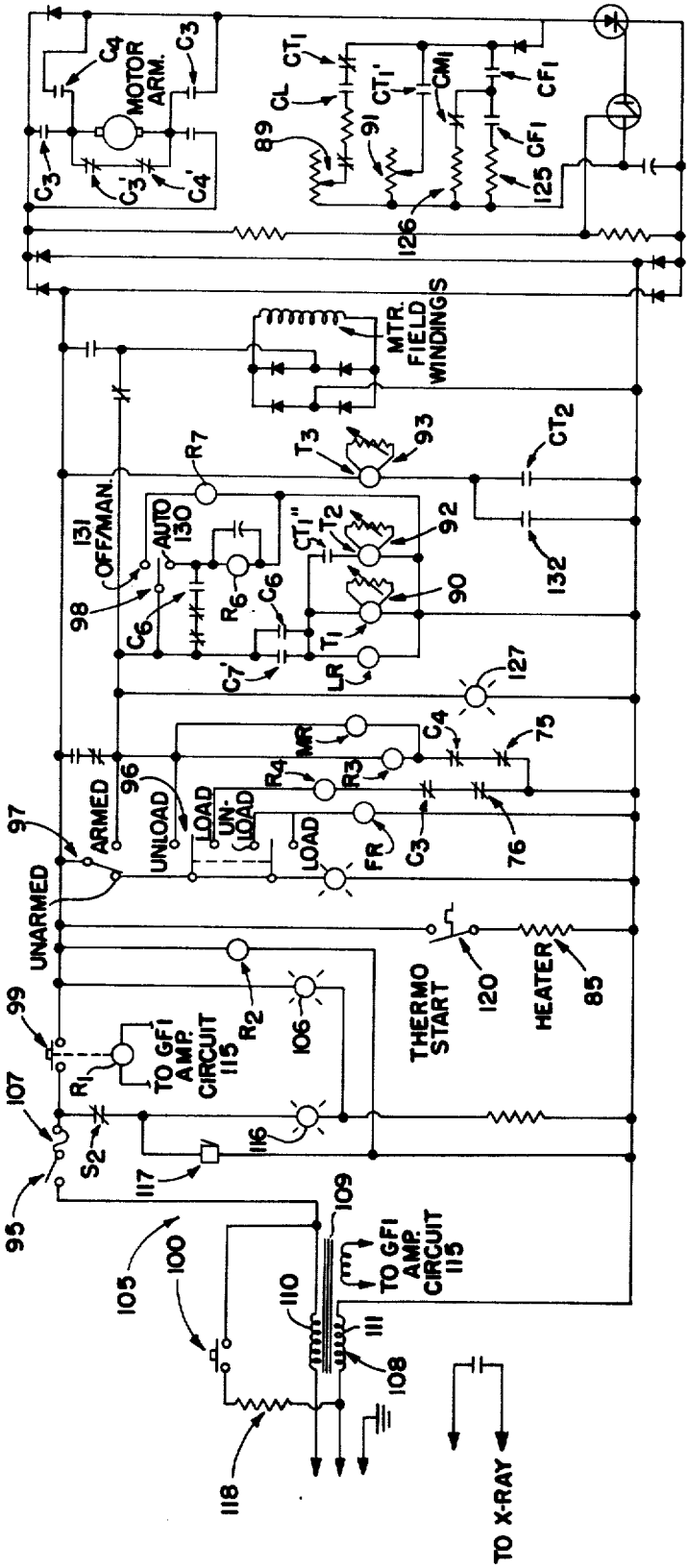
MOTOR ARM.
C4
C3
C3'
C4'
CT1
CT1'
CM1
CF1
CL
89
91
125
126
MTR. FIELD WINDINGS
T3
93
CT2
R7
131 OFF/MAN.
AUTO 130
98
CT1"
T2
92
90
132
R6
C6
T1
C7'
LR
127
MR
C4
75
R4
R3
96
ARMED
UNLOAD
LOAD
UN-LOAD
LOAD
FR
C3
76
97
UNARMED
99
107
95
R1
TO GFI AMP. CIRCUIT 115
R2
106
THERMO START
120
HEATER
85
S2
116
117
109
105
100
110
111
108
118
TO X-RAY

FIG. 5

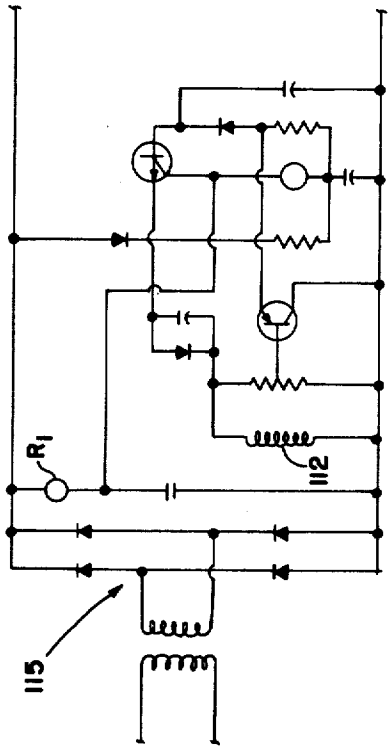
R1
112
115

FIG. 6

METHOD FOR INJECTING CONTRAST MEDIA INTO THE VASCULAR SYSTEM

CROSS-REFERENCE TO RELATED APPLICATIONS

This application is a division of applicants' copending U.S. application Ser. No. 340,226, filed Mar. 12, 1973 and now U.S. Pat. No. 3,812,843.

BACKGROUND OF THE INVENTION

This invention relates generally as indicated to an improved method for injecting a contrast media into a person's vascular system.

It has become standard procedure to inject contrast media into the vascular system to study and obtain information about the arterial tree. Conventional practice has been to make multiple injections and take a series of X-rays where visualization of a substantial portion of the arterial tree is desired, particularly the entire arterial tree of a lower extremity which is the most frequently involved site of an obstruction. The primary objection to this procedure is that it often requires the patient to be subjected to multiple injections, and also increases the patient's exposure to X-rays. The time required to carry out this procedure is also oftentimes lengthy, and it involves the use of relatively expensive equipment such as rapid film changers, moving table, and special X-ray source.

Another objection to the procedure described above is that visualization of the critical span is not always adequate, necessitating a repeat of the procedure at another time after the contrast media has disappeared from the system.

An improved arteriographic technique has been devised which provides simultaneous visualization of the entire arterial tree of a lower extremity during a single injection without the use of a film changer. By this technique, a slow prolonged infusion, typically 2 ml per second for 20 seconds, is made into the femoral artery at the groin, immediately followed by a rapidly delivered bolus, typically 20 ml per second for 2 seconds. On completion of the injection, the low flow injection has reached the digital vessels and the final bolus is localized in the distal aorta with all vessels between being opacified, whereby a single X-ray exposure may be taken from the aorta to the foot with the film positioned under the area of interest.

Using this latter technique, peripheral arteriography of the lower extremities can be accomplished without multiple X-ray exposures, and without the need for such expensive equipment as rapid flim changers, moving table top, or tedious flow measurement methods. A single puncture is made in the femoral artery, followed by low flow injection down the extremity, high flow retrograde into the aorta, and a single X-ray exposure from the aorta to the foot. This not only minimizes the time required for angiography of the extremities, but also substantially contributes to more complete opacification and renders exceptionally good filling and visualization of the critical area.

This biphasic technique has previously been carried out on a limited scale using hand injections. However, it has been found that the results obtained by such hand injections were not always consistent, and the final bolus could not always be delivered retrograde into the aorta.

SUMMARY OF THE INVENTION

With the foregoing in mind, it is a principal object of this invention to provide a method for obtaining much more consistent results using the biphasic technique previously described.

Another object is to provide such a method by which fluid may be delivered from the injector sequentially at two different rates or at one rate as desired.

Still another object is to provide such a method which permits independent selection of both the flow rates and duration of time of each.

Yet another object is to provide such a method which provides for sequential injection of fluid at such different flow rates and times utilizing either manual or automatic controls.

To the accomplishment of the foregoing and related ends, the invention, then, comprises the features hereinafter fully described and particularly pointed out in the claims, the following description and the annexed drawings setting forth in detail a certain illustrative embodiment of the invention, this being indicative, however, of but one of the various ways in which the principles of the invention may be employed.

BRIEF DESCRIPTION OF THE DRAWINGS

In the annexed drawings:

FIG. 1 is a front elevation view of a preferred form of injection apparatus constructed in accordance with this invention;

FIG. 2 is a fragmentary transverse section through the control cabinet and syringe assembly of the apparatus of FIG. 1, taken on the plane of the line 2—2 thereof;

FIG. 3 is a fragmentary isometric view on a somewhat reduced scale of the control cabinet and syringe assembly illustrating the range of movements of the syringe assembly relative to the control cabinet;

FIG. 4 is a top plan view of the syringe assembly of FIG. 2 as seen from the plane of the line 4—4 thereof;

FIG. 5 is a fragmentary enlarged longitudinal section through the syringe assembly of FIG. 2, taken on the plane of the line 5—5;

FIG. 6 is an enlarged sectional view of the syringe piston seal of FIG. 5;

FIG. 7 is a fragmentary transverse section through the syringe assembly of FIG. 5 taken on the plane of the line 7—7;

FIG. 8 is a schematic diagram showing a control circuit for controlling the operation of the injector apparatus of FIGS. 1 through 7; and

FIG. 9 is a schematic diagram showing a ground fault interrupter circuit for providing protection against current leaks to ground.

DESCRIPTION OF THE PREFERRED EMBODIMENT

Referring now in detail to the drawings and initially to FIGS. 1 and 2 thereof, for carrying out the method of the present invention, there is shown a preferred form of injection apparatus 1 in accordance with this invention including a syringe assembly 2 and control assembly 3 for controlling the operation thereof in a manner to be subsequently described. The syringe assembly 2 is desirably connected to the control assembly by an elongated tube 4 which extends from one side of

the syringe assembly box 5 into the control cabinet 6 as clearly illustrated in FIG. 2.

Within the control cabinet 6 is a support 7 suitably attached to the base plate 8 and having an opening therethrough in which the tube 4 is slidably received, permitting both longitudinal and rotational movement of the syringe assembly 2 relative to the control assembly 3. A pair of spaced apart stop rods 9 paralleling the tube 4 limits the extent to which the syringe assembly 2 may be rotated in either direction for all longitudinal adjusted positions of the syringe assembly, there being provided a stop screw 10 on the distal end of the tube 4 which engages one or the other of the stop rods 9 during rotation of the syringe assembly in opposite directions to limit such rotation and protect the wiring harness 11 leading from the control assembly to the syringe assembly through the hollow tube 4 against breakage. The stop screw 10 also limits the maximum extent to which the syringe assembly 2 may be extended relative to the control assembly 3 by engagement with the fixed support 7. Preferably, the disposition of the stop rods 9, only one of which is shown, is such that the syringe 12 of the syringe assembly 2 may be tilted a maximum of +150° and −150° from the vertical as illustrated in FIG. 3, and the syringe assembly may also be extended from 0 to approximately 18 inches from the control cabinet 6.

To secure the syringe assembly 2 in the desired longitudinal and rotational adjusted positions, a lock knob 16 is provided on the control cabinet 6. Tightening of the lock knob 16 causes the tube 4 to be clamped by a flexible collar 17 on the stationary support 7, the lock knob being connected to the collar 17 by a threaded rod 18. Further adjustments of the position of the syringe assembly 2 will be permitted upon loosening the lock knob 16 and subsequently retightening the same after the syringe assembly has been moved to the desired adjusted position.

For ease of portability of the injector apparatus 1, the control assembly 3 may be mounted on a mobile support stand 19 with a triangular base 20 on which are mounted swivel casters 21 as shown in FIG. 1 to permit the unit to be wheeled about. Each caster 21 desirably includes a separate lock 22 which when turned in one direction locks the caster against rotation and when turned in the opposite direction unlocks the caster.

Adjacent the upper end of the stand column 19 may be provided a column adjustment handle 23 for raising and lowering of the control assembly 3 and syringe assembly 2 attached thereto. The height of the injector 1 is desirably adjustable from approximately 38 to 57 inches by rotation of the column adjustment handle 23 in opposite directions, and a column lock nut 24 is desirably provided for locking the control assembly and syringe assembly in the desired vertical adjusted position.

As best seen in FIGS. 5 and 7, the syringe assembly 2 includes a main support housing 28 to which is bolted a syringe housing 29 for receipt of the barrel 30 of the syringe 12. The syringe barrel 30 has a radial outwardly projecting flange 31 intermediate the ends of the barrel for accurately locating and clamping the barrel within the syringe housing 29. A syringe hold-on nut 32 having threaded engagement with the OD of the syringe housing 29 releasably retains the syringe barrel 30 within the syringe housing 29, and suitable plastic insulators 33 interposed between the hold-on nut 32 and syringe barrel 30 and syringe barrel and syringe housing 29 electrically isolate the syringe barrel from the various other parts of the apparatus.

Axially extending into the syringe barrel 30 is a ball screw shaft 34 which has a push-pull screw 35 threaded into the forward end thereof to facilitate positive attachment of a syringe piston 36 to the ball screw shaft. The syringe piston 36 is shown screwed onto a screw lock-on nut 37 which has a polygonal shaped recess 38 therein of a shape corresponding to but slightly larger than the head 39 of the push-pull screw 35 for receipt of such head within the recess. The enlarged recess 38 within the screw lock-on nut 37 provides a radial clearance with the push-pull screw 35 to accommodate any misalignment between the syringe piston 36 and ball screw shaft 34 while still permitting positive pushing and pulling of the syringe piston within the syringe barrel 30 during axial inward and outward movement of the ball screw shaft. Making the nut recess 38 and screw head 39 of a corresponding polygonal shape also permits unscrewing of the syringe piston assembly 36 from the ball screw shaft 34 for sterilization of the syringe piston assembly as described hereafter.

To maintain a fluid-tight sliding seal between the syringe piston 35 and wall 40 of the syringe barrel 30, the syringe piston may be provided with an annular external groove 41 containing a Teflon slipper seal 42, with an O-ring 43 between the slipper seal 42 and bottom of the groove 41 which acts as a spring for maintaining the slipper seal in sealing contact with the syringe barrel wall as clearly shown in FIG. 6.

Threadedly received in the outer end of the syringe barrel 30 is a see-through syringe cap 45 having a central longitudinal passage 46 therethrough permitting expulsion of the fluid from the syringe during longitudinal movement of the syringe piston 36 within the syringe barrel 30 in the direction of the syringe cap. An O-ring 47 is confined between the syringe cap 46 and an internal shoulder 48 on the syringe barrel to provide a fluid seal therebetween.

The inner end of the ball screw shaft 34 is received in a longitudinally extending generally channel-shape raceway 49 in the main housing 28 and is retained against rotation by a pair of ball bearing assemblies 500 disposed on opposite sides of the screw shaft and connected thereto by a dowel pin 51 extending through the center of the ball screw shaft and ball bearings. Such ball bearings 50 absorb any rotational forces applied to the ball screw shaft 34 and support the inner end of the ball screw shaft for axial movement in either direction along the raceway 49.

Axial movement of the ball screw shaft 34 is obtained by rotation of a ball screw nut 55 having threaded engagement with the ball screw shaft and driven by a gear 56 suitably journaled within a gear box 57 between the main support housing 28 and the syringe housing 29 which provides a cover for the gear box.

Rotation of the main gear 56 may be accurately controlled by an electric motor 58, preferably a DC motor, with suitable motor mounts 59 being provided for direct attachment of the motor 58 to the main support housing 28. A suitable clutch mechanism 60 is desirably used to transmit power from the drive motor 58 to the main gear 56 to protect the motor against overload and the various other parts of the syringe against damage in the event that the syringe piston 36 bottoms out with the motor still running or limits the pressure build

up within the syringe barrel 30 due to fluid blockage or other reason.

As seen in FIG. 5, the clutch mechanism 60 may comprise a drive pinion 61 with driven clutch face 62 freely rotatable on the outer end of the motor shaft 63 and retained in place by a thrust washer 64 and screw 65 attached to the free end of the motor shaft. A clutch disc 66 keyed to the motor shaft 63 for rotation therewith is maintained in driving engagement with the driven clutch face 62 by a clutch spring 67 as long as the force required to transmit axial motion to the ball screw shaft 34 and syringe piston 36 does not exceed a predetermined level. The clutch spring 67 is confined between the clutch disc 66 and a clutch spring retainer 68 retained on the motor shaft by a snap ring 69 or the like.

The axial location of the syringe piston 36 within the syringe barrel 30 is indicated by a syringe piston position indicating rod 70 attached to the inner end of the ball screw shaft 34. The position indicating rod 70 may be secured in place by a set screw 71 threaded into a recess in the inner end of the ball screw shaft. The sheet metal cover 5 which surrounds the syringe assembly 2 has a longitudinally extending slot 72 in the top panel thereof for receipt of the upper end of the position indicator rod making it visible to the operator. A piston position indicator sight glass 73 is shown covering the longitudinally extending slot 72 and retained in place by a pair of mounting brackets 74 suitably fastened to the cover 5 at opposite ends of the slot. As clearly shown in FIGS. 3 and 4, the sight glass 73 may have suitable indicia thereon and the sides of the longitudinal slot may have a calibrated scale to indicate the actual volume of contrast agent in the syringe 12 from 0 to 120cc indicated by the position of the indicator rod 70 with respect to the calibrated scale. A pair of limit switches 75, 76 mounted in spaced apart relation on the main support housing 28 adjacent the raceway 49 are engaged by the position indicator rod 70 when the syringe piston 36 reaches either end of its stroke to shut off the motor 58.

The main support housing 28, in addition to providing a gear box 57 and raceway 49 for the ball screw shaft 34 and support for the syringe drive motor 58 and limit switches 75, 76 therefor, also contains a recess 78 for receipt of one end of the tube 4 which connects the syringe assembly 2 to the control assembly 3. As cleary shown in FIG. 7, the connecting tube 4 is retained in place within the recess 78 in the main support housing 28 by a bolt 79. A mounting ring 80 surrounding the connecting tube 4 is attached to the main support housing 28 by suitable fasteners to secure the sheet metal cover 5 to the main support housing. A weight 81 is also suitably attached to the main support housing 28 or motor 58 to locate the center of gravity of the syringe assembly 2 closely adjacent the axis of the tube 4 to facilitate tilting of the syringe assembly to any desired position as previously described.

Surrounding the syringe barrel 30 is a thermostatically controlled syringe blanket 85 for heating the contrast media from room temperature to 96° to 100°F and maintaining such temperature within twenty minutes after filling the syringe and turning on the main power. Both the blanket and thermostat 85 are desirably molded in rubber and insulated from the syringe 12.

The syringe is also electrically insulated from the syringe housing 29 by the plastic spacers 33 previously described, and the injector apparatus 1 has a ground clip 86 which is connected to the ground pin on the power cord 87. A ground fault interrupter circuit to be later described is also desirably provided to remove the power from the motor and controls and provide a signal or alarm whenever there is a current leakage to ground exceeding 0.5 milliamps.

Both the main support housing 28 and syringe housing 29 are desirably made of aluminum for reduced weight, whereas the syringe barrel 30 is desirably made of a non-corrosive high strength material such as stainless steel. The see-through syringe cap 45 is desirably made of polycarbonate and the syringe piston 36 of delrin, both autoclavable to 250°F for sterilization.

The various parts of the syringe 12 are disassembled to permit sterilization thereof. Before disassembling the syringe, the syringe piston 36 is desirably moved to the 0cc position as indicated by the volume indicator rod 70. Then the large nut 32 holding the syringe to the syringe housing 29 may be removed to permit the see-through syringe cap 45 and syringe barrel 30 to be pulled out of the syringe housing. Next the see-through syringe cap 45 may be unscrewed from the syringe barrel 30 and the O-ring 47 removed, after which the syringe piston assembly 36 may be unscrewed from the ball screw shaft 34, leaving the cap seal 42, 43 on the syringe piston.

After the various syringe parts have been sterilized, the syringe piston 36 is screwed back onto the ball screw shaft 34 and the syringe barrel 30 is pushed into place and retained therein by screwing the large nut 32 back on to firmly clamp the radial flange 31 on the syringe barrel in place adjacent the end of the syringe housing 29.

Next the syringe piston 36 is retracted until the indicator reading corresponds to the desired volume of contrast media with which the syringe is to be filled. Then the lock knob 16 on the control cabinet 6 is loosened to permit the syringe assembly 2 to be rotated until the syringe 12 is pointing vertically upward so that the contrast media may be poured directly into the syringe barrel, keeping the fluid level below the O-ring groove 48.

Before filling the syringe barrel, the O-ring 47 is inserted into the O-ring groove 48 and afterwards the see-through cap 45 is screwed into the barrel until it bottoms against the O-ring. Next one end of a catheter may be connected to the luer loc fitting on the see-through syringe cap 45 and the other end inserted into an empty contrast media bottle to permit the syringe piston 36 to be moved slightly forward to express any trapped air from the syringe or catheter. Finally, the lock knob 16 is loosened and the syringe assembly 2 rotated until the tip of the syringe 12 is pointing down from the horizontal at a maximum angle from the horizontal of approximately 60°.

Suitable controls are provided on the control panel 88 which permit selection of two different flow rates for two different periods of time. Separate control knobs are provided for selecting each rate of flow in cubic centimeters per second and the time of each flow rate in seconds. The first slow inject flow control knob 89 permits a selection of a flow rate of anywhere from 0.3 to 10cc per second for a period of time anywhere from off to 25 seconds as determined by the setting of a second control knob or dial 90. The first rapid inject flow control knob 91 permits the selection of a flow

control rate of anywhere from 5 to 40cc per second for a period of time anywhere from off to 6 seconds as determined by still another control knob **92.** The product of the flow rate and time for each of the slow and rapid inject phases will determine the volume of fluid injected during each phase of injection.

An additional control knob **93** may also be provided on the control panel **88** for selecting a delay period, for example, from **0** to **2** seconds after completion of the entire injection phase for triggering the X-ray exposure. An X-ray cable connector **94** is shown for connecting the control box to an X-ray machine.

Also provided on the control panel **88** are a lighted on-off power switch **95** which includes a **20** amp circuit breaker, a manual loading and unloading switch **96,** and a lighted armed/unarmed selector switch **97.** The manual loading or unloading switch **96** is used to fill or empty the syringe **12** when the armed/unarmed switch **97** is in the unarmed position. When the armed/unarmed switch **97** is in the armed position, the unit may be operated by a remote control or hand trigger switch **98** to inject contrast media into a patient either manually or automatically as described hereafter.

A lighted safe/unsafe ground fault interrupter switch **99** and associated circuit detects current leaks to ground above .5 milliamps, and automatically moves from the safe to unsafe position when the power switch **95** is on to remove power from the control and syringe assemblies. A ground fault interrupter push to test switch **100** is also provided for checking the operation of the ground fault interrupter circuit. Correct operation of the ground fault interrupter circuit is indicated during a test when the unsafe light comes on and an audible alarm sounds. To turn the unsafe light off and stop the audible alarm after completion of a test merely requires pushing the safe/unsafe switch **99** to the safe position.

With the armed/unarmed switch **97** in the armed position, depressing and releasing the automatic position on the hand trigger switch **98** will cause the injector apparatus **1** to automatically sequentially inject the two different flow rates selected on the flow and rapid inject flow rate and time control dials **89, 90** and **91, 92,** respectively. However, the injection may be stopped at any time during the automatic injection phase by depressing and releasing the manual position on the hand trigger switch **98.** Alternatively, the entire injection phase will remain under the direct control of the operator by pressing the manual position on the hand trigger switch. Releasing the manual position on the hand trigger switch at any time will immediately stop the injection.

Having thus described the various parts of the injector apparatus, a brief description of its operation will be set forth.

OPERATION

To operate the injector apparatus **1,** the control assembly **3** should first be raised to the desired height by loosening the stand lock knob **24** and rotating the stand adjustment handle **23** to raise or lower the control and syringe assemblies **3, 2** to the desired height, after which the lock knob may be tightened to hold such assemblies in the desired vertical adjusted position. The power cord **87** should then be plugged into a suitable power source and the lighted main power switch **95** turned on, followed by a testing of the ground fault interrupter circuit as previously described. If the ground fault interrupter circuit checks out properly, the safe/unsafe switch **99** should be pushed to the safe position to turn off the unsafe light and stop the audible alarm which should have gone on when the test switch **100** was depressed to indicate a correct operation of the ground fault interrupter circuit.

The load/unload switch **96** should then be held in the unload position until the syringe piston **36** is at the 0cc position to facilitate disassembly and sterilization of the syringe as previously described. After sterilization, the syringe piston **36** and syringe barrel **30** should be reassembled and with the armed/unarmed switch **97** in the unarmed position the load/unload switch **96** moved to the load position to retract the syringe piston to the desired volume of contrast media as shown on the indicator rod **70.** Then the cabinet lock knob **16** should be loosened to permit the syringe assembly **2** to be rotated until the syringe **12** extends vertically upward and with O-ring **47** in place the contrast media may be poured into the syringe barrel, keeping the fluid level below the O-ring groove **48.** After filling, the syringe cap **45** should be threaded into position in the upper end of the syringe barrel **30.**

Next one end of a catheter may be connected to the syringe cap **45** and the other end inserted into an empty contrast media bottle so that the unload switch **96** may be depressed to express any trapped air in the syringe or catheter.

Thereafter the cabinet lock knob **16** should be loosened to permit the syringe **12** to be rotated until its tip is pointing down from the horizontal. The syringe assembly **2** may also be extended horizontally from the control assembly **3** to the extent desired, followed by a tightening of the cabinet lock knob to lock the syringe in the desired position.

Next both the slow inject control knobs **89** and **90** and rapid inject control knobs **91** and **92** should be set to the desired flow rates and periods of time for each flow rate, and the X-ray delay control knob **93** should also be set to the desired time delay for the X-ray exposure after completion of the entire injection phase. The X-ray cable **94** should also be properly connected both to the control assembly **3** and to the X-ray machine.

The injector apparatus **1** is now ready to be used to inject contrast media or other fluid into the patient after the catheter needle has been properly inserted. The injection phase is under the control of the hand trigger switch **98** as soon as the armed/unarmed selector switch **97** is moved to the armed position, whereby movement of the hand trigger switch either to the automatic or manual positions will cause the contrast media to be injected into the patient. When the hand trigger switch **98** is depressed in the automatic direction, the switch may be released and the injector apparatus will still continue to inject the fluid into the patient in accordance with the programmed flow rates and times. However, such procedure may be interrupted at any time by depressing the hand trigger switch **98** in the manual direction and releasing it. Moving the hand trigger switch **98** in the manual direction requires the operator to continue to press the switch during manual injection since releasing the trigger switch after pushing it in the manual direction will immediately stop the injection.

On completion of the injection, the X-ray machine will be automatically triggered after a time delay of

from 0 to 2 seconds as determined by the setting of the X-ray delay control knob **93.** By then the earliest delivered contrast media has reached the digital vessels, while the final bolus is in the distal aorta with all vessels in between opacified. The X-ray source is desirably elevated maximally, preferably to 6 feet, and the X-ray film is positioned along the entire length under study, with appropriate filters. A single, long film holder is preferred, but multiple, overlapping film holders may also be used.

THE CONTROL CIRCUIT

FIG. **8** is a schematic diagram of the primary control circuit **105** for controlling the operation of the injection apparatus **1** previously described. Included in the circuit is the circuit breaker and on-off switch **95** which must be depressed to energize the circuit. A light **106** signals that the power is on, and the circuit breaker **107** protects the circuit against an overload. The power to the circuit passes through a differential transformer **108** which produces a signal in the transformer core **109** whenever the current through the two coils **110, 111** is different, as when there is a current leakage to ground. This signal is picked up by the output coil **112** of a ground fault interrupter amplifier circuit **115,** schematically illustrated in FIG. **9,** which amplifies the signal to energize a relay **R1,** causing the safe/unsafe switch **99** to open thereby removing the power from the motor and controls. When this occurs, a second relay **R2** is deenergized causing the associated switch **S2** to close which lights the unsafe light **116** and sounds a buzzer or alarm **117.** Such a ground fault interrupter circuit **115** is desirably sufficiently sensitive to detect current leaks to ground above 0.5 milliamps.

The ground fault interrupter test switch **100** is connected to a suitable resistor **118** for simulating a current leakage when the test switch **100** is depressed to check the operation of the fault interrupter circuit **115.** Correct operation of the ground fault interrupter circuit **115** is indicated when, upon pushing the test switch **100,** the unsafe light **116** goes on and the buzzer or alarm **117** sounds.

To reactivate the primary control circuit **105** upon release of the test switch **100,** the operator need only depress the ground fault interrupter switch **99** to energize the relay **R2** which opens the portion of the circuit including the unsafe light **116** and buzzer **117** causing them to be turned off.

When the primary control circuit **105** is energized, power is supplied to the heater **85** surrounding the syringe barrel **30** which is controlled by the thermostat **120** to heat the contrast media from room temperature to approximately 96° to 100°F and maintain the contrast media at that temperature.

The armed/unarmed selector switch **97** may be moved between the unarmed position shown in FIG. **6** in which operation of the syringe drive motor **58** may be manually controlled by the loading and unloading switch **96** and the armed position in which such motor may be controlled by the hand trigger switch **98.** When the armed/unarmed selector switch **97** is in the unarmed position shown, the hand trigger switch **98** is taken out of the primary control circuit and the load-/unload switch **96** is in the circuit permitting manual operation of the syringe drive motor **58** in opposite directions by moving the load/unload switch to the load and unload positions for respectively filling or emptying the syringe **12.**

When the load/unload switch **96** is moved to the unload position, the relay **R3** is activated which closes the associated motor contacts **C3** causing the motor to extend the syringe piston **36** for unloading the syringe. Movement of the load/unload switch **96** to the load position activates another relay **R4** which closes its respective motor contacts **C4** causing the direction of rotation of the motor **58** to be reversed to retract the syringe piston **36** for loading the syringe.

The speed of the drive motor **58** when under the control of the load/unload switch **96** is desirably greater during operation in the loading direction than in the unloading direction and is controlled by the amount of resistance in the SCR firing circuit. A field relay FR in the load/unload circuit activates its associated contacts **CF1** when the load/unload switch is moved either to the load or unload positions to supply current to the motor field circuit. A manual relay MR switches between the two motor speeds for loading and unloading the syringe. When the switch **96** is moved to the unload position, the manual relay MR is energized, causing the associated contact **CM1** to be opened, whereby the speed of the motor **58** is controlled by the resistor **125** for unloading the syringe, whereas when the switch **96** is moved to the load position, the manual relay MR is not energized, causing the associated contact **CM1** to be closed, whereby the speed of the motor is controlled by the resistor **126** for loading the syringe.

Since the speed of the syringe piston **36** need not be adjustable during the manual load and unload modes, fixed resistors **125, 126** may be used to control the speed of the motor during such modes. Preferably, such resistors **125, 126** are selected so that when the load-/unload switch **96** is moved to the load position the syringe piston will be retracted to fill the syringe at a rate of approximately **6cc** per second and when the switch **96** is moved to the unload position the syringe will be extended to empty the syringe at a rate of approximately 1.3cc per second. Separate limit switches **75** and **76** are provided in the unload and load circuits, respectively, for opening their respective contacts when the syringe piston **36** reaches the respective ends of its stroke.

Movement of the armed/unarmed switch **97** to the armed position removes the load/unload switch **96** from the primary control circuit and readies the circuit for the injection phase through actuation of the hand trigger or remote control switch **98.** The position of the armed/unarmed switch **97** may readily be indicated by providing indicator lights **127** and **128** in the respective armed and unarmed circuits. Current is continuously supplied to the motor field windings when the injector apparatus is in the armed mode to avoid any time lag in building up the magnetic field during the normal injection phase, whereas during the unarmed mode, the motor field is only turned on when the field relay FR is energized by movement of the load/unload switch **96** to either of the load or unload positions.

During the armed mode, the two manual motor speed resistors **125** and **126** are removed from the primary control circuit and the hand trigger or remote control switch **98** is operative to control the movement of the syringe piston **36** in the injection direction only. The hand trigger switch **98** desirably includes both an automatic position **130** and an off/manual position **131.**

When the switch **98** is moved to the automatic position **130**, the relay R6 is activated causing the associated contacts C6, C6 to close, and such contacts C6, C6 will remain closed even though the hand trigger switch **98** is released to cause automatic sequential injection of the fluid as determined by the settings of the slow and rapid inject control knobs **89, 90** and **91, 92**. However, the injection may be stopped at any time during the automatic injection phase by moving the switch **98** to the off/manual position **131** and releasing the switch. When the switch **98** is moved to the off/manual position, it activates the jog relay R7 which opens the contact C7 in the automatic control circuit, deenergizing the relay R6 and opening the associated contacts C6, C6 whereby when the switch **98** is then released, the injector motor will stop. Movement of the switch **98** to the off or manual position also causes the jog relay R7 to close another contact C7' for manual operation of the injector during the armed mode. Releasing the switch **98** from the manual position will automatically stop the injection.

When the hand trigger switch **98** is moved either to the automatic or manual positions **130** or **131**, a relay LR is energized which closes its associated contact CL for controlling the speed of the drive motor during slow injection as determined by the setting of the potentiometer control knob **89**. A time delay relay T1 is energized at the end of its timing cycle as set by the slow inject time potentiometer control knob **90** to open the contact CT1 associated with the slow inject potentiometer control knob **89** and close the contact CT1' associated with the rapid inject potentiometer control knob **91** for automatically switching from slow inject to rapid inject at the end of the slow inject time. The time delay relay T1 also closes a switch CT1'' for actuating a second time delay relay T2 at the end of its timing as set by the rapid inject time control knob **92**. When the time delay relay T2 is energized, it closes the contact CT2 for activating the X-ray time delay relay T3 after a delay of from 0 to 2 seconds as set on the X-ray delay control knob **93**. If the syringe piston **36** reaches the end of its stroke during the armed mode before the relay T3 is activated, the limit switch **132** will be tripped, stopping the drive motor **58** and activating the X-ray time delay relay T3 as previously described. The relay contacts C3', C4' on the motor provide dynamic braking when both contacts are closed by creating a magnetic field which brakes the motor, as well known in the art. the art.

Although a single drive motor **58** is shown, it will be apparent that two different speed drive motors may be used for the slow and rapid modes of injection, respectively. Alternatively, two different gear boxes may be used in conjunction with a single drive motor, with clutches to switch the motor from one gear box to the other for slow and rapid injection.

Conventional feedback controls such as disclosed in U.S. Pat. Nos. 3,623,474 and 3,631,847 may also be provided for measuring and controlling the speed of the syringe piston throughout the period of injection to obtain predictable, controlled flow rates under varying conditions. Alternatively, various other control systems may be used to accomplish substantially the same results, including, for example, an optical feedback to monitor the motor speed; a highly regulated DC power supply wherein the voltage supplied to the motor is monitored and fed back to control the power supply; or an open loop frequency control system utilizing an RC circuit with a variable resistance and a unijunction transistor to create a variable frequency pulse to operate the motor.

From the foregoing, it will now be apparent that the method and apparatus of the present invention minimize the time required for angiography of the extremities, reduce the amount of apparatus, and substantially contribute to more complete opacification and visualization. Such a method and apparatus also make X-ray exposure minimal with fewer injections and smaller volumes of contrast media. The injector apparatus may also be used for other arteriographic procedures as well, including conventional angiography, by using either the slow inject or rapid inject modes separately. The controls for the mode not used are simply set at "0".

The embodiments of the invention in which an exclusive property or privelege is claimed are defined as follows:

1. A method of injecting a fluid into the vascular system of a mammal comprising the steps of filling a syringe with the desired quantity of fluid to be injected, providing a bolus of said fluid in the vascular system during one cycle by moving a motor driven piston mounted for axial movement within the syringe for expelling such bolus of fluid therefrom, and controlling the movements of such piston to cause the piston to automatically sequentially advance at more than one rate of speed of advance movement within the syringe for different periods of time during such one cycle of advance movement of such piston.

2. The method of claim **1** wherein controls are provided for independently preselecting more than one rate of speed of advancement of the piston within the syringe and the periods of time of each advancement during such one cycle of advancement prior to such advancement, further comprising the step of presetting such controls to control the movements of such piston as aforesaid.

3. The method of claim **1** further comprising the step of stopping and restarting the piston at selected times during such advancement.

4. The method of claim **2** further comprising the step of automatically actuating an X-ray machine after a time delay upon completion of such sequential advancement of such piston.

5. The method of claim **4** further comprising the step of activating the time delay for the X-ray machine whenever the piston reaches the end of its stroke before the preselected time.

6. The method of claim **1** wherein there is a syringe cap and associated seal on the outer end of the syringe, and prior to the step of filling the syringe with the desired quantity of fluid the piston is extended to expel any fluid therefrom and the syringe is disassembled and sterilized, then reassembled except for the syringe cap and associated seal, and the piston is retracted to the desired fluid volume and the syringe is then pointed vertically upwardly to permit the fluid to be poured into the syringe.

7. The method of claim **6** wherein after the syringe has been filled with the desired quantity of fluid, the syringe cap and associated seal are assembled on the outer end of the syringe.

8. The method of claim 1 wherein prior to filling the syringe with the desired quantity of fluid the syringe is checked for current leaks to ground.

9. The method of claim 1 wherein the piston is caused to automatically sequentially advance first at a relatively slow rate for a relatively long period of time and then at a relatively faster rate for a much shorter period of time during such one cycle of advancement of such piston, followed by automatic actuation of an X-ray machine.

10. The method of claim 1 further comprising the step of interrupting such automatic sequential advancement of the piston during such one cycle of advancement of the piston, and controlling the movements of the piston for the remaining portion of the injection cycle.

11. A method of injecting a fluid into the vascular system of a mammal comprising the steps of filling a syringe with the desired quantity of fluid to be injected, such syringe including a motor driven piston mounted for axial movement within the syringe for expelling such fluid therefrom, and controlling the movements of such piston to cause the piston to automatically sequentially advance at more than one rate of speed of advance movement within the syringe barrel for different volumes of each advancement during one cycle of advance movement of such piston and providing controls for independently preselecting more than one rate of speed of advance movement of the piston within the syringe and volumes of each advancement prior to such advancement, further comprising the step of presetting such controls to control the movements of such piston as aforesaid, such piston being caused to automatically sequentially advance first at a relatively slow rate for a relatively long period of time and then at a much faster rate for a much shorter period of time, followed by actuation of an X-ray machine.

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