US 20010018937A1

(19) United States

(12) Patent Application Publication (10) Pub. No.: US 2001/0018937 A1

Nemoto (43) Pub. Date: Sep. 6, 2001

(54) METHOD AND DEVICE FOR PRE-FILLING A SYRINGE WITH A CONTRAST AGENT

(76) Inventor: **Shigeru Nemoto**, Tokyo (JP)

Correspondence Address:
Robert C. Beck
Suite 100
2900 Thomas Avenue South
Minneapolis, MN 55416-4477 (US)

(21) Appl. No.: **09/813,063**

(22) Filed: **Mar. 20, 2001**

Related U.S. Application Data

(63) Continuation-in-part of application No. 09/471,464, filed on Dec. 22, 1999, now abandoned.

(30) **Foreign Application Priority Data**

Dec. 28, 1998 (JP) 10-373095

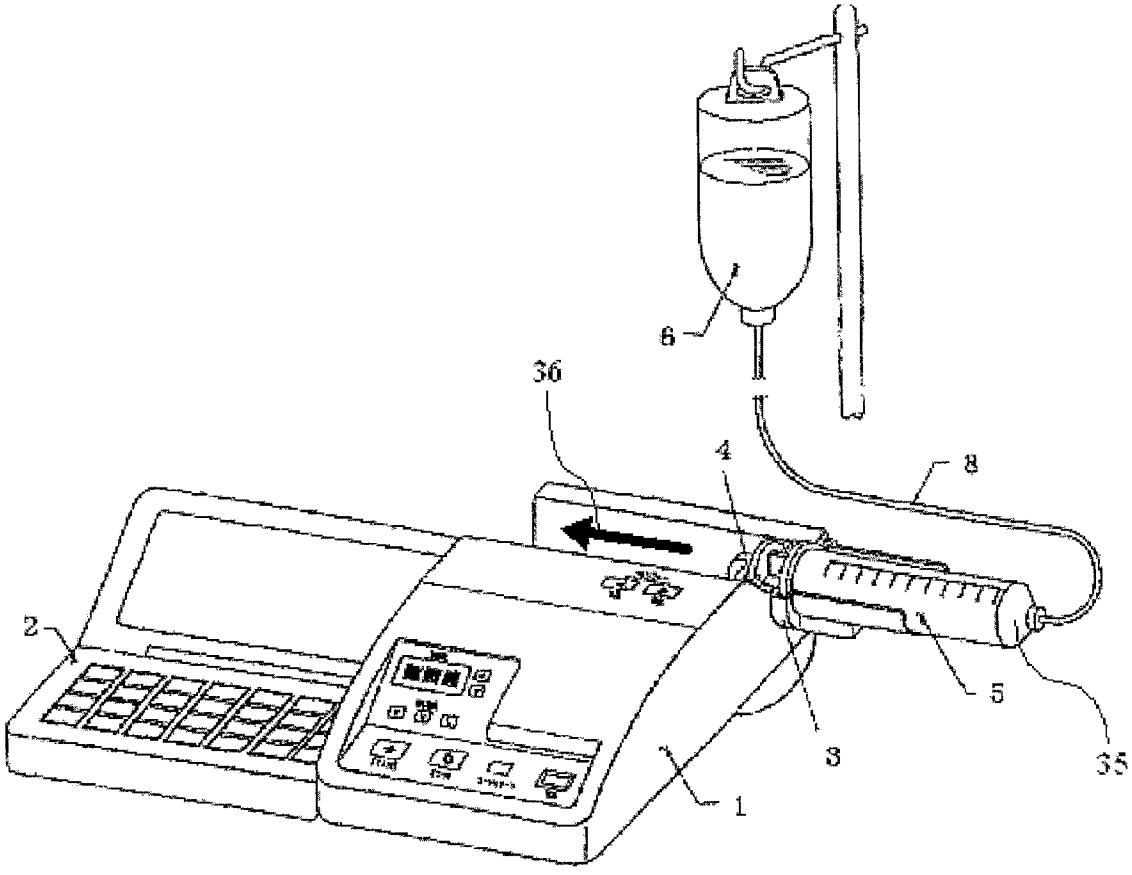
Publication Classification

(51) **Int. Cl.**[7] **B65B 1/04**

(52) **U.S. Cl.** **141/27**; 141/18; 604/416

(57) **ABSTRACT**

A method and device for filling a syringe with a chemical solution such as a contrast agent is disclosed. The device has a cylinder holder, a piston holder, a driving mechanism to move the piston holder relative to the cylinder holder, a keyboard to input test conditions, and a computer. Based on the test conditions, the computer calculates the volume of the chemical solution necessary for a patient. The piston holder is allowed to aspirate the precise volume necessary for the patient from a bottle where the chemical solution is stored. Thus the correct and necessary volume of the chemical solution is transferred from the bottle to the syringe, which minimizes the waste of the chemical solution.



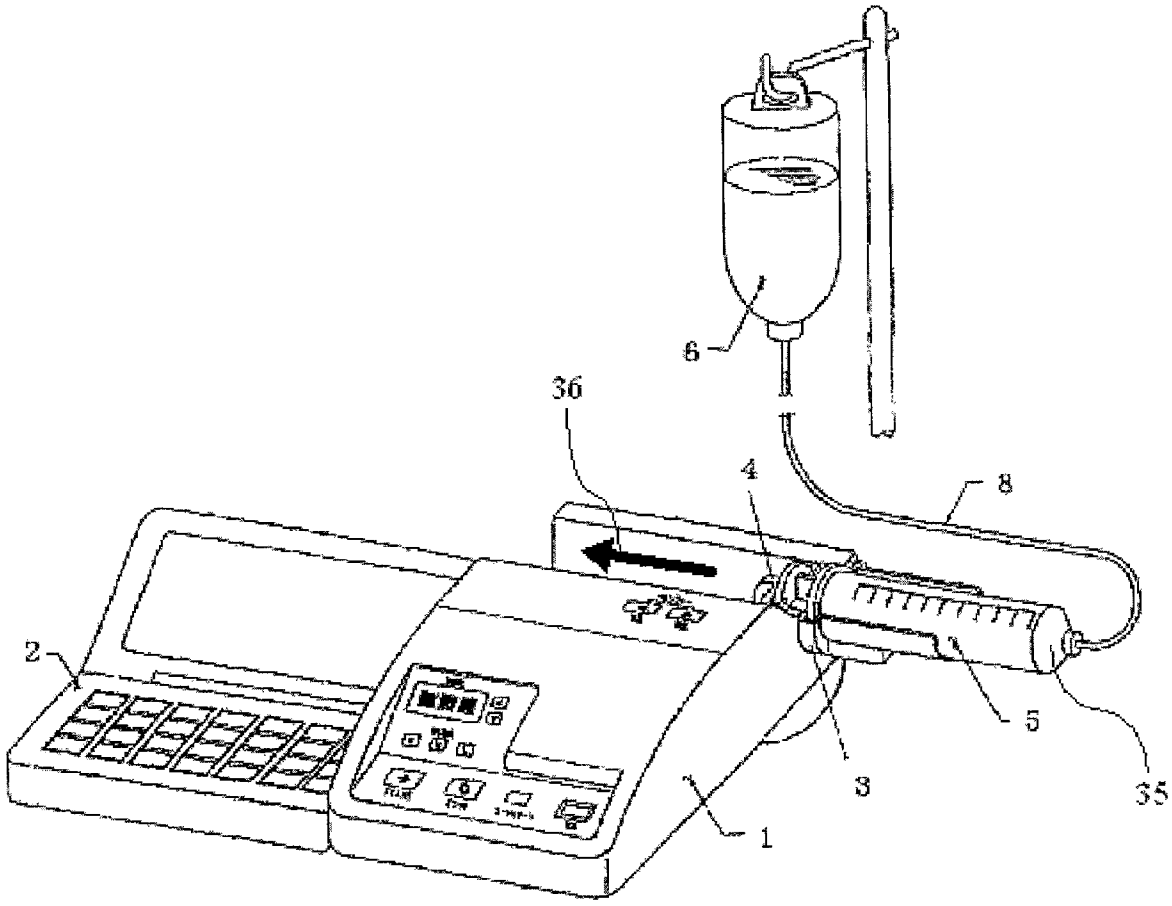


FIG. 1

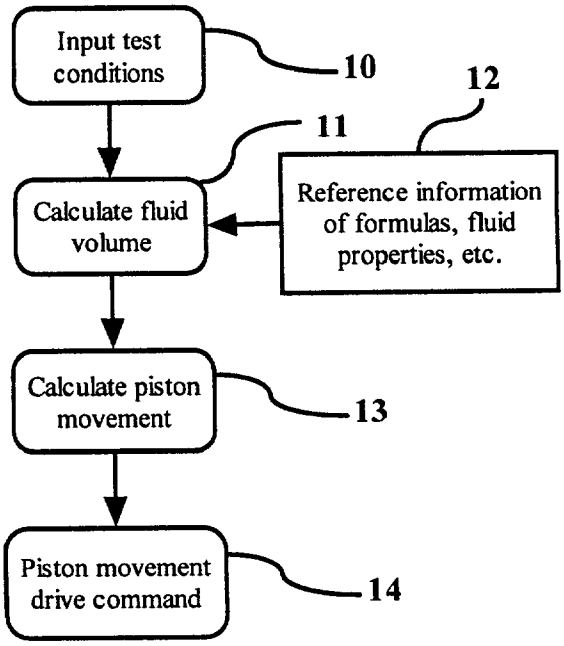


Figure 2

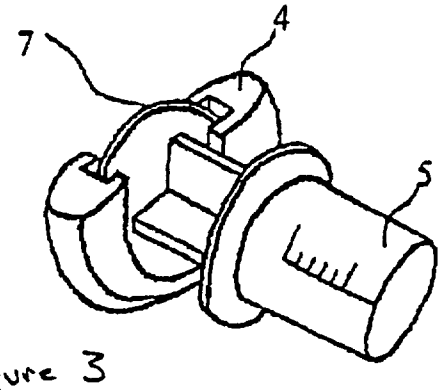


Figure 3

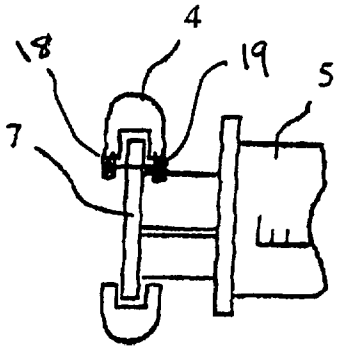


Figure 4

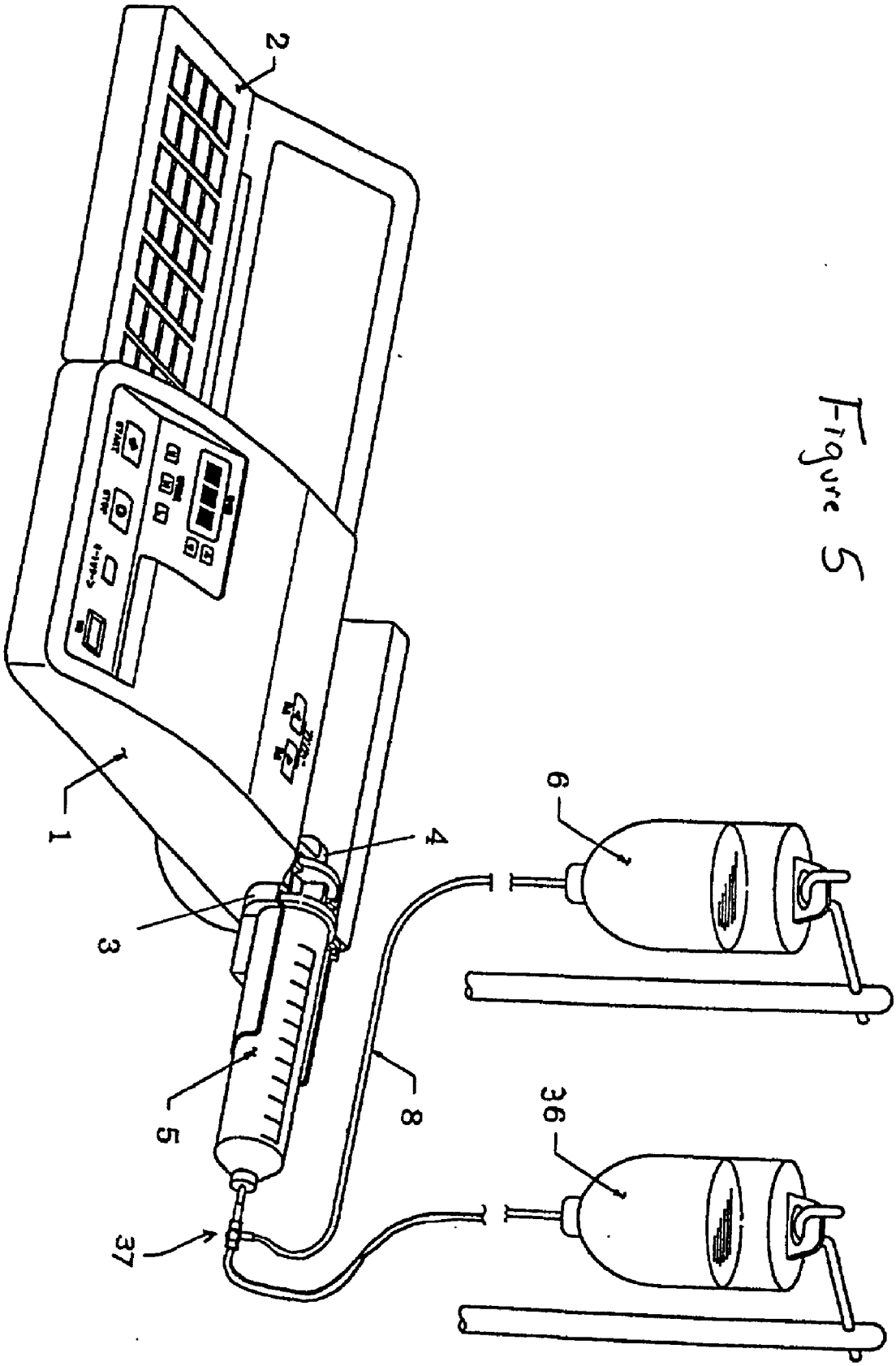


Figure 5

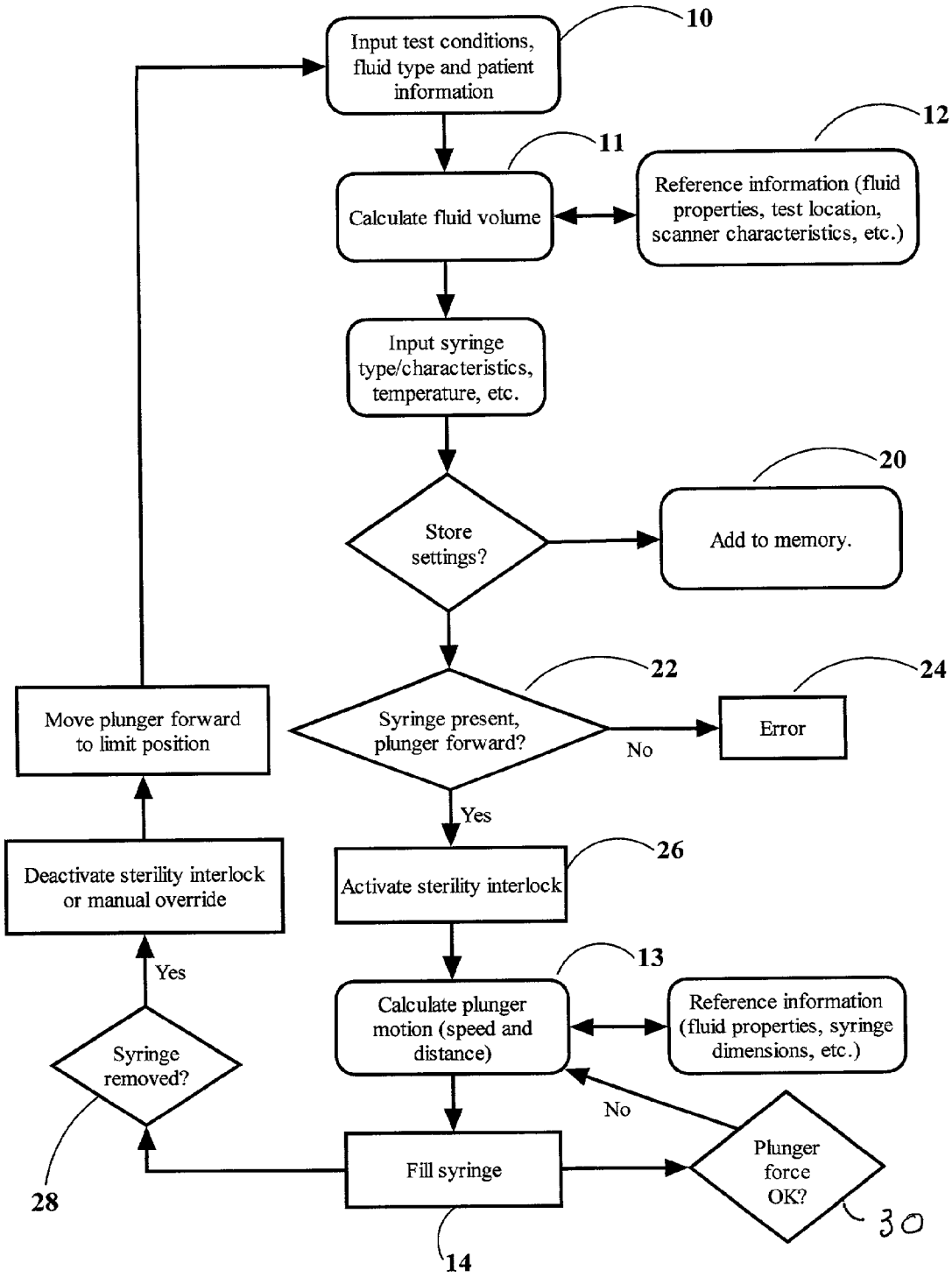

Input test conditions, fluid type and patient information
10
Calculate fluid volume
11
Reference information (fluid properties, test location, scanner characteristics, etc.)
12
Input syringe type/characteristics, temperature, etc.
Store settings?
Add to memory.
20
Syringe present, plunger forward?
22
No
Error
24
Yes
Move plunger forward to limit position
Deactivate sterility interlock or manual override
Activate sterility interlock
26
Calculate plunger motion (speed and distance)
13
Reference information (fluid properties, syringe dimensions, etc.)
Yes
Syringe removed?
No
Plunger force OK?
30
Fill syringe
28
14

Figure 6

METHOD AND DEVICE FOR PRE-FILLING A SYRINGE WITH A CONTRAST AGENT

CROSS REFERENCE

[0001] The present case is a continuation in part of U.S. Ser. No. 09/471,464 filed Dec. 22, 1999 entitled A METHOD AND DEVICE FOR FILLING A SYRINGE WITH A CHEMICAL SOLUTION now abandoned.

TECHNICAL FIELD

[0002] The present invention relates to a device and a method for transferring a fluid (such as a chemical solution or contrast agent used for magnetic resonance imaging, X-ray CT, angiography, urography and the like) from a container (such as a bottle) to a syringe so as to fill the syringe with the fluid.

BACKGROUND OF THE INVENTION

[0003] Contrast agents, such as those used for magnetic resonance imaging ("MRI") and X-ray CT imaging, are often used in liquid form having a high viscosity. These contrast agents are generally sold and provided to hospitals or other testing facilities in a bottle or syringe. When the contrast agent is provided in a syringe, it can be directly attached to an automatic injector designed for the contrast agent and can be used at once. In this way, filled syringes allow for easy and simple administration to the patient. However, if the contrast agent is not supplied in syringe form, the agent must be transferred from the bottle to the syringe prior to administration to the patient.

[0004] Unfortunately, it takes a long time and much effort to aspirate a viscous fluid into the syringe, by hand. Although it is possible to aspirate the contrast agent into a syringe using an automatic injector, this causes difficulties. For instance, loading a syringe is not possible while the injector is being used to deliver contrast agent to the patient.

[0005] In addition, the volume of the contrast agent used during a procedure depends upon the patient's weight and the type of diagnostic study.

[0006] In conventional practice all or most of the chemical solution in the bottle is transferred to the syringe. Only a portion of the contents of the syringe may be required for the study. Since the necessary volume is then administered there can be substantial waste.

SUMMARY OF THE INVENTION

[0007] The present invention overcomes the problems of the prior art technology. The objective of the present invention is to provide a filling device and a filling method which are used for slowly filling the syringe with the correct and necessary volume of a viscous chemical solution. This filling device and method thus transfers the contrast agent from the container to the syringe while minimizing the waste of the contrast agent remaining in the syringe after the procedure.

[0008] Accordingly, the present invention is directed to a filling device for filling a syringe with a chemical solution. This is accomplished by transferring the chemical solution stored in a container to the syringe. The device includes a cylinder holder to hold the syringe barrel, a piston holder to hold the syringe piston and a driving mechanism to move the piston holder relative to the cylinder holder. An input mechanism to input test conditions is provided. This device is implemented with a microprocessor system that can calculate the volume of the chemical solution based on the test conditions. The calculated volume is used to generate a control signal to drive a motor whereby the piston holder is allowed to move according to the volume calculated with the calculation mechanism.

[0009] Another aspect of the present invention is directed to a method for filling a syringe with a chemical solution by transferring the chemical solution stored in a container to the syringe, comprising the steps of: mounting a syringe barrel and a piston to a cylinder holder and a piston holder, respectively, connecting the tip of the syringe to the connecting tube attached to the container storing the chemical solution, inputting test conditions with an input mechanism in the filling device, calculating the necessary volume of the chemical solution for administration with a calculating means in the filling device, moving the piston holder based on the calculated chemical solution volume, thereby the necessary volume of the chemical solution is aspirated from the container and fills the syringe.

[0010] In one embodiment of the present invention, the filling device may be deigned for exclusive use as a filling device. In this embodiment the filling device detects the presence of a syringe for pre-filling and locks out "forward" syringe plunger motion which could contaminate the source of contrast agent. This safety feature may be subject to a manual override, which will not commonly be used. The interlock feature may rely on a detector for detecting the physical presence of the syringe or a software interlock may be used which simply requires the user to confirm that the syringe has been removed from the machine before allowing plunger motion that may potentially contaminate the container of contrast. Also, the use of a monitor for motor current can be used to detect the presence of a syringe for interlock functions.

BRIEF DESCRIPTION OF THE DRAWINGS

[0011] **FIG. 1** shows an embodiment of the chemical solution-filling device of this invention.

[0012] **FIG. 2** is a flow chart showing the chemical solution filling method of this invention.

[0013] **FIG. 3** is an enlarged view (perspective view) to show an example of the chemical solution-filling device of this invention.

[0014] **FIG. 4** is an enlarged view (top view) to show an example of chemical solution filling device of this invention.

[0015] **FIG. 5** shows an embodiment of the chemical solution-filling device of this invention.

[0016] **FIG. 6** is an alternate flow chart showing the chemical solution filling method of this invention.

DETAILED DESCRIPTION OF THE INVENTION

[0017] **FIG. 1** shows an embodiment of a chemical solution-filling device of the present invention. The filling device shown in this embodiment comprises a main body **1** and a calculator portion **2**. Equipped with the main body **1** are a cylinder holder **3** to a hold the barrel of a syringe **5**, a piston holder **4** which holds the piston of the syringe **5** and can

move relative to the cylinder holder, and a driving portion, not shown in this figure, which includes a motor, also not shown, to move the piston holder **4**. In general, the structures required to drive the piston holder **4** include a leadscrew and stepper motor. These devices are well known in this field and further description is not required. The stepper motor is under the digital control of the calculation portion **2**. The calculation portion may also monitor the amount of current required to drive the stepper motor and in this fashion acquire information used for filing the syringe. The calculation portion **2** contains an input interface, such as a keyboard, to input diagnostic test conditions, a display and a computer or other processing unit as a calculation and data storage means inside of the calculation portion **2**.

[**0018**] As shown in **FIG. 1**, the barrel and the piston of the syringe **5** are attached to the cylinder holder **3** and the piston holder **4**, respectively. The syringe **5** is connected to the chemical solution bottle **6** through the connecting tube **8**. The tube set and bottle may be coupled with a conventional Luer or septum-piercing "spike". Every effort is made to minimize the dead volume in the tube set.

[**0019**] A sensor may be provided to detect the presence of a syringe in the filling device. For example an optical transmitter **18** may project light to an optical receiver **19**, located in the coupler or piston holder **4**. In this instance the presence of the flange of the syringe plunger will interrupt the beam and notify the software that the syringe is present. Barrel detection is also an alternative approach to detection of the syringe.

[**0020**] The method of using the present invention is shown in the flowchart in **FIG. 2**. First the test conditions are input into the calculation portion **2** through the keyboard as shown in step **10**. The test conditions used in a diagnostic X-ray CT, for instance, would include the scanning condition of X-ray CT, the test region, the patient's weight, and a description of the contrast agent. These actual input conditions should be sufficient to calculate the correct amount of contrast agent used for the procedure. The test conditions actually inputted in step **10** can be changed as necessary to be appropriate for the particular test. The calculation portion **2** may be menu driven and queries may be presented to the user which include the type of study to be performed.

[**0021**] In step **11**, the computer in the calculation portion **2** then calculates the volume of the contrast agent to be used. This calculation is based on the test conditions inputted in step **10**. The necessary standard volume of contrast agent or calculation coefficient for each input item can be stored in database in advance and used to calculate the volume according to the test conditions. For example, the necessary injection volume for a patient based on his weight is stored. This information is represented by box **12** in the flow chart of **FIG. 2**. The correct and precise volume is then calculated based on this information as altered by the test conditions of step **10**. In the instances where a menu is used to interrogate a user a lookup table maybe used to supply the information represented by **12**.

[**0022**] Once step **11** determines the injection volume of the chemical solution, the moving distance of the syringe piston is calculated in step **13**. The moving distance is based upon the volume calculated in step **11** and the known cross-sectional area of the barrel of the syringe **5**. If syringes **5** of varying cross-sectional area are to be used in the present invention, then it is possible to determine which syringe **5** is being used by requiring that the type of syringe being used be inputted with the other test conditions in step **10**. Alternately, a simple mechanical device (not shown in the figures) could be moved into contact with the syringe **5** to determine which of the possible syringes are being utilized. In addition to merely calculating the piston moving distance required to create the volume calculated in step **11**, step **13** may also take into consideration the required moving distance of the piston to compensate for the dead space in the connecting tube **8**.

[**0023**] Once the piston moving distance is determined, a signal is sent to the motor in the main body **1** to move the piston holder **4** (and hence the piston of syringe **5**) the required distance in step **14**. By so instructing the motor, the piston is moved and the required amount of chemical solution is aspirated into the syringe **5**. This is defined as the "filling" direction labeled in **FIG. 1** with the arrow **36**.

[**0024**] If the aspiration speed is too fast, leakage of air from connectors or damage of the syringe occurs frequently. Therefore, it is also preferable that the aspirating condition of the filling device, such as aspirating speed or aspirating pressure, can be altered. Since the aspirating condition differs depending on the properties of the chemical solution, solution temperature and the type of the syringe and the like, it is specifically preferred that the aspirating condition should be calculated by the computer based on these data. Stepper motor current draw or torque can also be used to modify the withdrawal speed of the piston.

[**0025**] As mentioned previously, the filling device of the present invention may be designed for exclusive use as the filling device or may also serve as an injector for injecting the chemical solution to the patient. In cases where the device is designed for exclusive use as a filling device, the syringe filled with a chemical solution by this filling device will be used with, but separately from, an injector. The chemical solution will be injected to a patient through a delivery extension tube attached to the tip of the syringe. When the filling device also serves as an injector, injection is conducted through a delivery extension tube attached to the tip of the syringe in place of the connecting tube **8**. Alternatively, injection may also be conducted by changing the path using a three-way valve from a connecting tube to a delivery extension tube. Attached to the end of the delivery tube would be a suitable apparatus for injection, such as a butterfly needle and the like or catheters depending on the test regions.

[**0026**] When the injection of the chemical solution is conducted, the path though the syringes tip to the test region in the patient's body may constitute a dead space. This dead space may also preferably be taken into consideration in determining the moving distance of the piston. The dead space is labeled **35** in **FIG. 1**.

[**0027**] Using the filling device of this invention, the optimum volume of the chemical solution fills the syringe **5** with no need to recalculate or control the volume when the chemical solution is injected to the patient. Therefore, the present invention allows the use of an injection device with a relatively simple mechanism as a device for the administration of chemical solution to the patient. Also, there is no waste of chemical solution since only the necessary volume of chemical solution is transferred from the bottle **6** to the

syringe **5**. It is especially effective when expensive chemical solutions are used or the chemical solution is stored in a bottle **6** of large capacity.

[**0028**] The embodiment explained so far is the case where only one kind of chemical solution is used. However, a chemical solution may be used after being diluted with physiological saline solution or pure water in order to obtain a suitable concentration of iodide, for example for X-ray CT, or a suitable viscosity of the fluid. In such cases, the dilution ratio of the chemical solution is calculated by the computer to give the volume of the chemical solution and the diluent, thereby the moving distance of the piston is determined. The aspiration of the chemical solution and the diluent is achieved, for example, using the system shown in **FIG. 5**. In this system the path of the chemical solution from chemical solution bottle **8** and the diluent bottle **36** may be switched using a three-way valve **37**. The switching may be operated manually or automatically synchronous to the movement of the piston. In some instances, where mixing is required, the computer may instruct the piston to aspirate from each container and then to refill and re-aspirate from a container to provide very good mixing.

[**0029**] The example of a contrast agent for X-ray CT was used above, although this device can be used to transfer other chemical solutions, both viscous and non-viscous. The main purpose is to transfer other viscous solutions, however, such as contrast agents for MRI, angiography or urography.

[**0030**] The only requirement for the cylinder holder **3** and the piston holder **4** is that they are adapted to the barrel and piston, respectively, of the syringe **5** being used. For example, **FIG. 1** shows cylinder holder **3** and piston holder **4** that fit closely with the brim of the syringe barrel and the syringe piston. **FIGS. 3 and 4** show enlarged views of the flange of the piston **7** being held by the piston holder **4**. In the preferred embodiment, the channel of the piston holder **4** is wider by about 1 mm than the thickness of the piston flange **7** in order to make it easier to put in and take out the piston **5**. Although the piston holder **4** is shown in the figures with a semi-circular shape having an interior groove slightly larger the thickness of a circular piston flange **7**, nothing in the present invention is intended to limit the piston holder **4** to such shapes. For instance, those with standard skill in the art would be aware of numerous other configurations of piston flange **7**, and could develop corresponding piston holders **4** to hold such flange **7**. These other configurations are well within the scope of the present invention.

[**0031**] There is also no particular limitation for the mechanism used to move the piston holder **4** the distance calculated in step **13**. For instance, the mechanism might utilize a stepping motor, a ball screw shaft and a ball screw nut that is engaged with the ball screw shaft and supports the piston holder **4**. In this case, the stepping motor would drive the rotation of the ball screw shaft based upon the signal transmitted from the calculating mechanism as described in connection with step **14**. This causes the movement of the ball screw nut together with the piston holder in the longitudinal direction of the ball screw shaft axis. The necessary interface to drive the stepping motor the calculated distance is well known in the prior art. It is also well known that the current or force required to drive the stepper motor can be monitored electrically by software. In **FIG. 6** process **30** monitors the force or a proxy for force.

[**0032**] Although not described above in connection with **FIG. 2**, it is also possible to include a preliminary step in the aspiration process to remove air from the syringe **5** and connecting tube **8**. This step would involve programming the aspirator to aspirate the necessary volume of chemical solution after confirming that the syringe piston is pushed automatically all the way to the end. This would result in all air being removed from the system prior to aspiration of the chemical solution.

[**0033**] Although the embodiment illustrated in **FIG. 1** shows the example of single-piece construction in which the calculating portion **2** and the piston driving main body **1** are accommodated in one housing, separate-type construction can also be used. It is desirable that the motion of forward, backward and stop, and aspiration speed (moving speed) and the like can be set or controlled not only at the calculating portion **2**, but also at the main body **1** of the aspiration device. Controls for doing so are shown on the main body **1** in **FIG. 2**. This enables both manual operation and automatic operation. While these controls are present on the preferred embodiment shown in the figures, such controls are not necessary and it is possible that controls are located within the calculating portion **2**.

[**0034**] Turning to **FIG. 6** there is shown an alternate flow chart for operating the syringe-filling device. This version makes use of the syringe sensor. As stated above it is possible for air to enter the system and purging of the air from the filled syringe is an important safety step. However, it is undesirable to clear air from the syringe while connected to the container **6**. Any reverse flow may contaminate the contrast agent in the container **6**, which is very undesirable. In this alternate system once a syringe is placed in the machine only a drawing motion is permitted for the plunger. Once again the plunger speed is optimized for the viscosity of the contrast agent. The possibility of contamination is eliminated by restricting the motion of the syringe.

[**0035**] When a syringe is in the device the motor current required to drive the plunger rises to a nominal fixed value. Operation at this current may be used as a proxy for the presence of a syringe in the machine. This may augment or supplant the photoelectric syringe detection system for the interlock function.

[**0036**] A software interlock function can be applied as well. For example the device could interrogate the user to confirm that a syringe has been removed before plunger motion is unrestricted.

[**0037**] In **FIG. 6**, the input test conditions are keyed into the device through the keyboard on the computer **2**. This process permits the calculation of the appropriate amount of contrast agent to be pulled into the syringe. This data is passed to memory in process **20** if desired by the user. With the preliminary calculations completed the filling device interrogates the holder to determine if a syringe is present in process **2**. If no syringe is present, then an error condition is detected and the user is notified. It is likely that this message will prompt the user to install the correct syringe in process **24**. Next, the device activates a sterility interlock function in step **26** that creates error conditions and messages if the syringe is removed before it is completely filled according to the volume computed in step **13**. Next, the device issues the motor drive instruction to the plunger in process **14**. At the completion of the fill cycle the user removes the syringe at

process **28**. The remaining processes return the plunger to the start position for the next operating cycle. In this preferred implementation the syringe detection is part of the interlock process to eliminate operator error. A simpler, software solution can be implemented as well. In this version the syringe plunger motion aspirates contrast agent into the syringe and the cycle will not resume until the operator has confirmed through a keystroke on the console that the completed syringe has been removed from the filling machine device.

[**0038**] In the embodiment shown in the figures, the input means of the calculating portion **2** is shown as a keyboard. However, it is within the scope of the present invention to use any other input interface known in the art. For instance, it may be preferred in some cases to transmit the data of the patient directly from the host computer of the hospital into the calculating portion **2**. Alternatively, the interface of the calculating portion may be simple selection switches.

[**0039**] Although it is not the main objective of the present invention, the filling device of the present invention may be used as an injector for pre-filled type syringes. In this case, although a quantity of the chemical solution may be wasted, the injection can be conducted easily.

[**0040**] The invention is not to be taken as limited to all of the details set forth above, as modifications and variations to these details may be made without departing from the spirit or scope of the invention.

What is claimed is:

1. A filling device for filling a syringe with a chemical solution stored in a container, the syringe having a barrel and a piston, the filling device comprising:

a cylinder holder adapted to hold the syringe barrel;

a piston holder adapted to hold the syringe piston;

a syringe detector for detecting the presence of a syringe in the device;

a driving mechanism attached to the piston holder, the driving mechanism being capable of moving the piston holder relative to the cylinder holder in a forward and a reverse direction;

an input mechanism adapted to receive inputted test conditions;

a calculation portion to calculate an appropriate volume of the chemical solution based on the test conditions;

whereby the driving mechanism moves the piston holder according to the volume calculated by the calculation portion in the filling direction if and only if the syringe is present in the device.

2. The filling device according to claim 1, wherein the syringe detector is a photoelectric monitor that detects the presence of a syringe component.

3. The filling device according to claim 1, wherein the syringe detector is a current monitor that detects the level of current used to operate the driving motor.

4. The filling device according to claim 1, wherein the chemical solution is a contrast agent for X-ray CT, magnetic resonance imaging, angiography or urography.

5. The filling device according to claim 1, wherein the device further comprises a data storage mechanism.

6. The filling device according to claim 1, wherein the input mechanism is a keyboard.

7. The filling device according to claim 1, wherein the calculation portion is a computer.

8. The filling device according to claim 4, wherein the data storage mechanism is a data storage system in a computer.

9. The filling device according to claim 1, wherein the driving mechanism comprises a stepping motor, a ball screw shaft, and a ball screw nut engaged with the ball screw shaft.

10. The filling device according to claim 1, wherein the driving mechanism and the calculation mechanism are accommodated in one housing.

11. The filling device according to claim 1, wherein the test conditions are selected from the group consisting of:

scanning condition, test region, patient's weight, and contrast agent description.

12. The filling device according to claim 1, wherein the test conditions include an indication of the cross-sectional area of the syringe.

13. A syringe filling system comprising:

a) a syringe having a piston with a piston flange and a barrel of a known cross-sectional area;

b) a barrel holder adapted for holding the piston barrel;

c) a piston holder adapted for receiving the piston flange, the piston holder capable of movement relative to the barrel holder;

d) a driving mechanism attached to the piston holder, the driving mechanism moving in response to a driving signal;

e) a data receiving interface for receiving test conditions;

f) a processing unit for calculating a volume in response to test conditions; and

g) a signal generator that generates a driving signal to instruct the driving mechanism to move the piston holder solely in the reverse direction to aspirate and sufficiently fill the syringe according to the calculated volume.

14. The syringe filling system of claim 13, further comprising a bottle containing a fluid, and a connecting tube connecting the bottle to the syringe, wherein the driving signal compensates for the dead space in the connecting tube.

15. The syringe filling system of claim 13, further comprising a means for determining the cross-sectional area of the syringe.

16. The syringe filling system of claim 13, wherein the data receiving interface is a computer to computer interface for receiving data from a separate computer containing patient data.

17. The syringe filling system of claim 13, further comprising a data storage media containing standard usage information regarding the use of at least one contrast agent, wherein the processing unit uses the information in the data storage media along with the test conditions to calculate the volume.

18. A method for filling a syringe with a chemical solution by transferring the chemical solution stored in a container to the syringe, comprising the steps of:

a) mounting a syringe barrel and a piston to a cylinder holder and a piston holder, respectively, equipped in a filling device,

b) connecting the tip of the syringe to a connecting tube attached to the container storing the chemical solution,

c) inputting test conditions with an input means in the filling device,

d) calculating necessary volume of the chemical solution for administration with a calculating means in the filling device,

e) detecting the presence of the syringe within the filling device;

f) moving the piston holder based on the calculated chemical solution volume, if and only if the syringe presence is detected, whereby the necessary volume of the chemical solution is aspirated from the container and fills the syringe.

19. The method of claim 18, wherein the process of inputting the test conditions includes inputting an indication of the size of the syringe barrel.

20. The method of claim 18, further comprising the step of determining the cross-sectional area of the syringe.

* * * * *