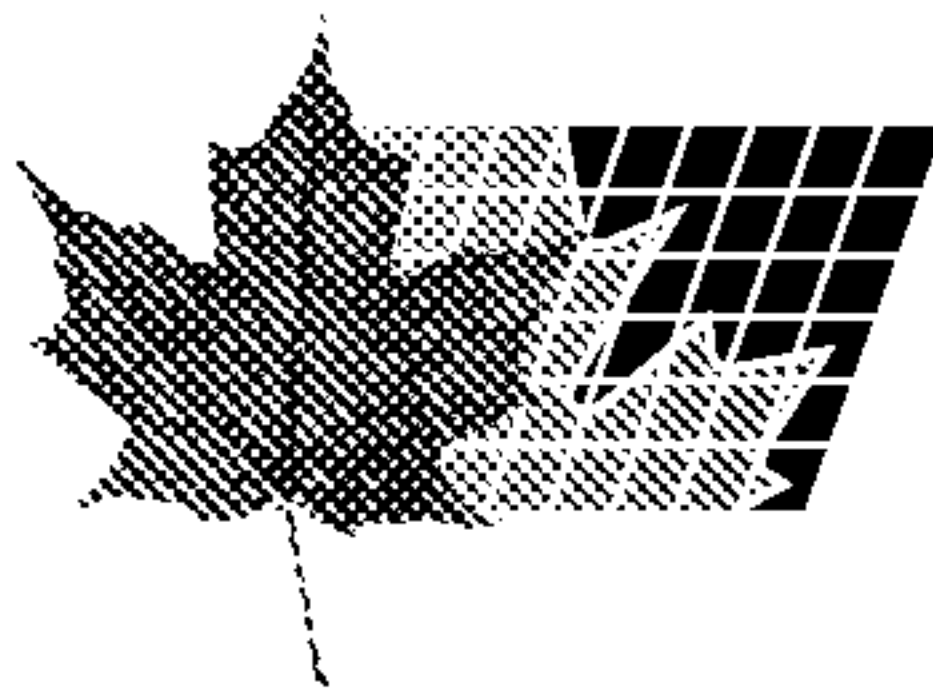




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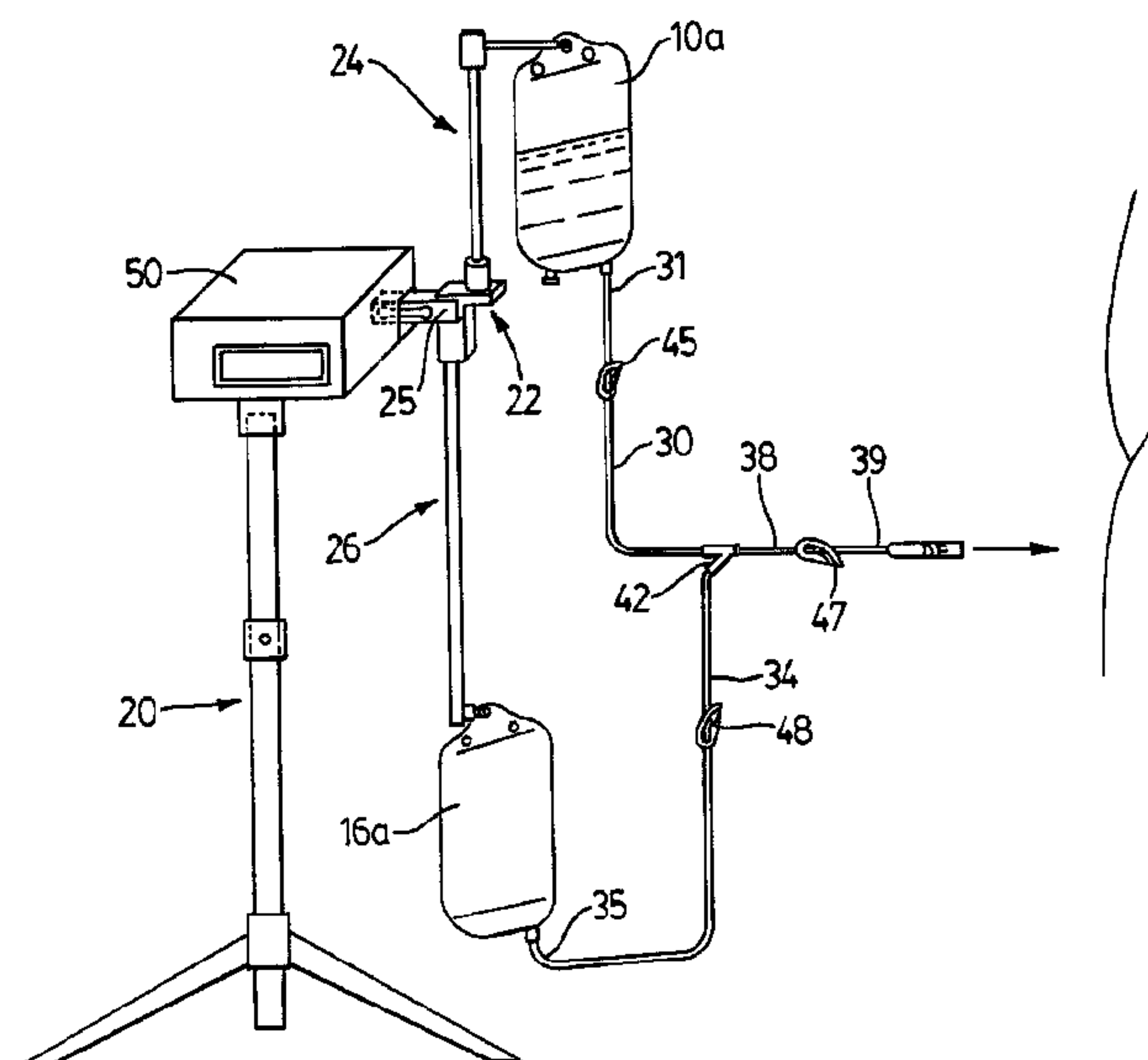
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(54) **METHODE ET APPAREIL DE DIALYSE PERITONEALE
AMBULATOIRE CONTINUE**

(54) **METHOD AND APPARATUS FOR CONTINUOUS
AMBULATORY PERITONEAL DIALYSIS**



(57) An apparatus for continuous ambulatory peritoneal dialysis includes a weighing device secured to a support frame, with a suspending structure for hanging a container of fresh dialysis solution from the weighing device. A further support structure suspends from the same weighing device a container or bag for receiving spent dialysis solution. Three conduits are connected together at respective proximal ends, with one conduit being adapted for connection at its distal end to the fresh dialysate container, a second conduit adapted for connection at its distal end to the container for receiving spent dialysis solution, and the third conduit being a patient conduit adapted for communication at its distal end with a patient catheter through which dialysis solution can both enter and leave the peritoneal cavity. Each of the conduits has its respective clamp for selectively permitting and halting fluid flow through the respective conduit. A central processor is operatively associated with the weighing device, and monitors a signal from that device, the signal representing the weight being supported at any given time by the weighing device. The central processor has data input/output capability by which it can be programmed to carry out a three-stage cycle consisting of a) a fill stage during which the drain conduit is closed, and dialysis solution passes from the container of fresh dialysate through the fill conduit, thence through the patient conduit to the peritoneal cavity of the patient; b) a dwell stage during which the dialysis solution remains in the peritoneal cavity, and c) a drain stage during which the dialysis solution flows from the peritoneal cavity through the patient conduit, thence through the drain conduit to the container for receiving spent dialysis solution. The central processor also includes a real time clock allowing the central processor to track the time taken to fill, the dwell time and the drain time.

ABSTRACT OF THE DESCRIPTION

An apparatus for continuous ambulatory peritoneal dialysis includes a weighing device secured to a support frame, with a suspending structure for hanging
5 a container of fresh dialysis solution from the weighing device. A further support structure suspends from the same weighing device a container or bag for receiving spent dialysis solution. Three conduits are connected together at respective proximal ends, with one conduit being adapted for connection at its distal end to the fresh dialysate container, a second conduit adapted for connection at its distal end to
10 the container for receiving spent dialysis solution, and the third conduit being a patient conduit adapted for communication at its distal end with a patient catheter through which dialysis solution can both enter and leave the peritoneal cavity. Each of the conduits has its respective clamp for selectively permitting and halting fluid flow through the respective conduit. A central processor is operatively associated
15 with the weighing device, and monitors a signal from that device, the signal representing the weight being supported at any given time by the weighing device. The central processor has data input/output capability by which it can be programmed to carry out a three-stage cycle consisting of a) a fill stage during which the drain conduit is closed, and dialysis solution passes from the container of
20 fresh dialysate through the fill conduit, thence through the patient conduit to the peritoneal cavity of the patient; b) a dwell stage during which the dialysis solution remains in the peritoneal cavity, and c) a drain stage during which the dialysis solution flows from the peritoneal cavity through the patient conduit, thence through the drain conduit to the container for receiving spent dialysis solution. The central
25 processor also includes a real time clock allowing the central processor to track the time taken to fill, the dwell time and the drain time.

**METHOD AND APPARATUS FOR CONTINUOUS AMBULATORY
PERITONEAL DIALYSIS**

This invention relates to a method and apparatus for performing peritoneal
5 dialysis, capable of use in both the hospital and home environment.

BACKGROUND OF THIS INVENTION

Generally, peritoneal dialysis is used to correct the following medical disorders:

- 10 1. Acute and chronic renal failure;
2. Severe water retention;
3. Electrolyte disorders; and
4. Drug intoxication (acute poisoning).

The kidneys have the normal function of excreting metabolic waste products
15 from the body. They also regulate the amount and composition of body fluids, as well as performing important endocrine functions, some of which are the regulation of blood pressure, bone marrow function, and bone composition.

In kidney failure, the above functions are affected. Mild or moderate kidney malfunction may result in abnormalities that can be corrected or ameliorated by
20 drugs or dietary measures. However, when kidney failure is severe, artificial kidney function becomes necessary to maintain life. Artificial kidney (dialysis) treatment cannot totally compensate for the patient's own kidney. Dialysis primarily substitutes for the lost excretory function and helps regulate fluid, electrolyte and acid-base balance.

25 Two types of artificial kidney treatment are recognized, namely hemodialysis and peritoneal dialysis.

In hemodialysis, the blood is treated directly by using an extra-corporeal system with an artificial membrane (kidney). Peritoneal dialysis uses the principles of osmosis and diffusion across the peritoneal membrane to indirectly remove toxic
30 substances from the blood, and thereby correct certain electrolyte and fluid imbalances.

In result, extra-corporeal hemodialysis is used when rapid and efficient dialysis is necessary to preserve the life of the patient in case of severe renal failure or drug intoxication.

Technically, hemodialysis is more demanding than peritoneal dialysis, and this along with other medical reasons has led to the increasing use of the relatively simple peritoneal operation in the event of (a) acute and chronic renal failure, (b) severe water retention, (c) electrolyte disorders and (d) drug intoxication (acute poisoning).

Prior to the 1970's, peritoneal dialysis treatment was a manual operation. Subsequently, however, further developments were made, these falling into two categories: (a) complete automatic fluid proportioning system, and (b) simple semi-automatic cyclor. The semi-automatic cyclor system required the least amount of technical operating skill, and was based upon the principles of gravity and siphon. This system allows the dialysis fluid to flow into the abdominal cavity under gravitational action, keeps it there for a period of time, and then allows the fluid to flow out. This cycle is continuously repeated until the end of the dialysis treatment.

The Prior Art

In order to improve efficiency, reliability and patient safety, we developed a peritoneal dialysis apparatus which was patented on June 27, 1978 as U.S. patent 4,096,859. This development was embodied in a complex peritoneal dialysis apparatus capable of being programmed to provide a predetermined quantity of fresh dialysis solution, passing this solution into the peritoneal cavity of a patient using gravity feed, allowing the solution to remain in the peritoneal cavity for a predetermined length of time, and draining spent dialysis solution from the peritoneal cavity into a waste solution container, again by the urging of gravity. Although this prior system functions well, certain users have found it to be unnecessarily complex and expensive.

30 GENERAL DESCRIPTION OF THIS INVENTION

Accordingly, it is an object of one aspect of this invention to provide a simple but reliable apparatus for continuous ambulatory peritoneal dialysis (CAPD), which is easy for the patient to program.

More particularly, this invention provides an apparatus for CAPD,
5 comprising:

a support frame,

a weighing means secured to the support frame,

first support means operatively associated with the weighing means for suspending from the weighing means a container of fresh dialysis solution,

10 second support means for suspending a container for receiving spent dialysis solution,

a first, a second and a third conduit each having a distal end and a proximal end,

said first conduit being a fill conduit adapted for connection at its distal end
15 to the container of fresh dialysis solution,

said second conduit being a drain conduit adapted for connection at its distal end to the container for receiving spent dialysis solution,

said third conduit being a patient conduit adapted for communication at its distal end with a patient catheter through which dialysis solution can both enter and
20 leave the peritoneal cavity of the patient,

junction means where the proximal ends of the first, second and third conduits are connected together and are in communication with each other,

clamp means for selectively permitting and halting fluid flow through each of the first, second and third conduits, and

25 central processor means operatively associated with the weighing means and receiving from the weighing means a signal representing the weight being supported at any given time by the weighing means, the central processor means also having data input/output capability by which it can be programmed to carry out a three-stage cycle consisting of :

- a) a fill stage during which the drain conduit is closed, and during which dialysis solution passes from the container of fresh dialysis solution through the fill conduit, thence through the patient conduit to the peritoneal cavity of the patient;
- 5 b) a dwell stage during which the dialysis solution remains in the peritoneal cavity of the patient; and
- c) a drain stage during which the dialysis solution flows from the peritoneal cavity of the patient through the patient conduit, thence through the drain conduit to the
- 10 container for receiving spent dialysis solution;

the central processor means including a real time clock allowing the central processor means to track the time taken to fill, the dwell time and the drain time.

Further, this invention provides a process for peritoneal dialysis utilising an apparatus comprising:

- 15 a support frame,
a weighing means secured to the support frame,
first support means operatively associated with the weighing means for suspending from the weighing means a container of fresh dialysis solution,
second support means for suspending a container for receiving spent dialysis
- 20 solution,
a first, a second and a third conduit each having a distal end and a proximal end,
said first conduit being a fill conduit adapted for connection at its distal end to the container of fresh dialysis solution,
- 25 said second conduit being a drain conduit adapted for connection at its distal end to the container for receiving spent dialysis solution,
said third conduit being a patient conduit adapted for connection at its distal end to a patient catheter through which dialysis solution can both enter and leave the peritoneal cavity of the patient,
- 30 junction means where the proximal ends of the first, second and third conduits are connected together and are in communication with each other,

clamp means for selectively permitting and halting fluid flow through each of the first, second and third conduits, and

central processor means operatively associated with the weighing means and being adapted to receive from the weighing means a signal representing the weight
5 being supported at any given time by the weighing means, the central processor means having a real time clock and also having data input/output capability by which it can be programmed;

the said process comprising the steps:

passing a signal from the weighing means to the central processor means,
10 said signal representing the weight being supported at any given time by the weighing means, and, in sequence,

closing the drain conduit and opening the other two conduits to allow dialysis solution to pass from the container of fresh dialysis solution through the fill conduit, thence through the patient conduit to the peritoneal cavity of the patient;

15 closing the patient conduit and allowing the dialysis solution to remain in the patient's peritoneal cavity for a predetermined dwell period; and

closing the fill conduit and opening the other two conduits to allow spent dialysis solution to pass from the peritoneal cavity of the patient through the patient conduit, thence through the drain conduit to the container for receiving spent
20 dialysis solution.

GENERAL DESCRIPTION OF THE DRAWINGS

Several embodiments of this invention are illustrated in the accompanying drawings, in which like numerals denote like parts throughout the several views,
25 and in which:

Figures 1 (a) and (b) represent the fill stage and the drain stage utilized in the prior art;

Figure 2 shows the main components in a complete CAPD apparatus, adapted to carry out the prior art stages illustrated in Figure 1;

30 Figure 3 is a schematic view of one embodiment of this invention;

Figure 4 is a schematic view of a further embodiment of this invention;

Figure 5 is a front view of a programming and display panel used in this invention;

Figure 6 shows the components of a quick connect cap which can be utilized
5 with this invention;

Figure 7 shows the use of the cover and cap illustrated in Figure 6; and

Figure 8 is a schematic view of a further version of this invention, similar to that shown in Figure 4.

10 **DETAILED DESCRIPTION OF THE DRAWINGS**

In Figure 1(a), representing the prior art, a container 10 of fresh dialysis solution is suspended at a level above the peritoneal cavity of the patient 12, and a conduit or line 14 allows the dialysate to flow by gravity into the peritoneal cavity. For a typical patient and a standard bag of dialysis solution, the fill stage requires an
15 average of about ten minutes.

When the fill stage is completed, the empty bag 10 may either be disconnected or simply rolled up and carried around under the clothing. After filling, the dwell stage is initiated. This takes typically from four to six hours, after which the patient is ready to drain the spent dialysis solution either into the empty
20 bag from the previous fill or into a new bag. In Figure 1(b) the bag 16 collects the spent dialysate from the peritoneal cavity of the patient, and it will be noted that the bag 16 is located below the level of the peritoneal cavity of the patient. When the drain stage is completed, the patient is ready to begin a new cycle. Typically, an IV pole is often used to suspend the bags at suitable heights. This technique of
25 treatment is often referred to as single line or straight line CAPD.

CAPD systems have evolved during the past two decades into two main types: standard systems and disconnect systems. The former implies the need to carry an empty bag and tubing during dialysate dwell, while the latter technique fully disconnects the spent bag and the tubing sets. Numerous connectors and
30 transfer sets have been designed to simplify the procedure and reduce the rate of contamination.

While the straight line system provides the most economical form of CAPD treatment, it also has many drawbacks. One of the most common problems is contamination, which often results in peritonitis or inflammation of the peritoneum. If the patient, during spiking of the new solution bag, inadvertently touches the connection site, the bacteria will flow straight into the peritoneal cavity.

A number of different CAPD sets are presently in use which address the problem of contamination. These include the Y connection type transfer sets and variations of these including double bag systems wherein the solution bags and transfer set are all manufactured as a single unit.

Figure 2 shows a typical Y tubing set 17 connected to the patient's catheter 40 via a transfer set 28. The transfer set 28, which is also known as an adapter, is a short piece of tubing with a manual clamp 46 and suitable mating connectors at both ends to provide properly sealed connections to the titanium adapter 48 of the catheter 40 and to the connector 49 of the patient line 38 of the Y set 17. The Y set comprises a Y junction 42 from which three separate tubes branch out. The first tube 30, called the fill line, is connected to a fresh sterile solution bag 10a at the time of performing the exchange. The second tube 34, called the drain line, comes attached to an empty sterile drain bag 16a. The third tube 38, called the patient line, connects to one end of the transfer set 28 as shown. Each of these three lines has a manual clamp (explained more fully below) for controlling the flow of solution through that path. There are available other variations of this standard configuration which are used to save cost. For example the drain bag need not be attached as part of the sterile Y set. Instead, the empty solution bag from the previous exchange can be saved to be used as the drain bag for the next exchange, as described in U.S.A. patent 5,053,003, October 1, 1991, Joseph E. Dadson et al.

To explain the functioning of the Y set, let us assume that the patient has been dwelling. Once the dwell period expires, the patient takes a new Y set 17, connects the fill line 30 to a fresh sterile solution bag 10a, and connects the connector end 49 of the patient line 38 to the transfer set 28. At this point the three clamps of the Y set 17 and the clamp 46 of the transfer set 28 are all closed. The patient begins by opening the transfer set clamp 46, the patient line clamp 47 of the

Y set 17, and the drain line clamp 48 of the Y set 17. This allows the patient to drain, i.e. the dialysis fluid and the toxic wastes flow via the catheter 40, the transfer set 28, the patient line 38 and via the drain line 34 to the drain bag. When the drain phase is completed, the patient closes the patient line clamp 47 and then
5 opens the fill line clamp 45 for about 10 seconds. This permits fluid to flow from the fresh solution bag 10a through the fill line 30, through the Y junction 42, and through the drain line 34 into the drain bag 16a. Lastly, the patient closes the drain line clamp 48 and opens the patient line clamp 47. This allows the fresh solution to flow from the solution bag into the peritoneal cavity via the fill line 30, the Y
10 junction 42, the patient line 38, the transfer set 28 and the catheter 40. When the fill is completed, the patient clamps the transfer set clamp 46. The patient then disconnects the Y set 17 from the transfer set 28 and discards it. At the same time the patient caps off the open end of the transfer set with a suitable connector.

This type of Y set treatment is called "Drain Before Fill" and also "Flush
15 Before Fill". As can be seen, this technique is definitely superior to the straight line technique in that a drain phase right after connection to a new Y set 17 flushes out any bacteria that might be present adjacent to the transfer set connection site and also in the catheter or the transfer set. In addition, the flushing of the fill line before filling the solution into the peritoneal cavity might flush out any bacteria acquired
20 while connecting the fill line to the new solution bag. The results obtained with the use of Y set 17 are definitely far superior to the straight line technique and have been proven to be so by experts all over the world. The Y set technique therefore has become the industry standard although slight variations of it are prevalent depending upon the economic circumstances in the individual situations. Recently,
25 the concept of the double bag system, although more expensive, is being promoted, wherein the sterile solution bag is preattached to the Y set and the whole set comes sterile in one package. This eliminates the need to connect the fill line 30 into the new sterile solution bag 10a.

As intimated previously, the cost of the treatment is a major obstacle
30 preventing rapid growth of the simpler CAPD. In CAPD the infusion volume is not controlled and the entire contents of the dialysate bag are emptied into the

peritoneum. Since most current CAPD sets are disconnect "Y" type and because the patient normally needs a minimum of from 2L exchanges per day, four "Y" sets with four solution bags or alternatively four double bag systems are needed per day. This number increases as the peritoneal cavity loses its efficiency and more exchanges per day are required. The problem becomes more severe when CAPD is done with children. Pediatric CAPD in many countries is very expensive because solution bags with smaller volumes are more costly (per unit of solution) than normal 2L bags. In addition, these special pediatric size bags are difficult to acquire and necessitate keeping stock of different sizes of bags. Moreover when extremely low fill volumes other than the standard pediatric bag sizes are required, special measuring devices like burettes are introduced in the tubing sets making the tubing sets extremely expensive and cumbersome.

Another problem with the current CAPD treatment is patient compliance. The role that compliance plays in determining the adequacy of dialysis dosage will be described later in more detail. As seen above, CAPD is done 4-6 times a day and seven days a week. This causes a lot of mental, psychological, and physical fatigue for the patients. Patients have to remember the exact sequence of opening and closing the clamps every time they perform the exchange and this can be very confusing for some of the patients. All this fatigue eventually leads to non-compliance whereby patients skip exchanges and also do not conform to all the sterility guidelines. The new CAPD system addresses the problems of (1) checking the compliance itself, and (2) reducing patient fatigue by initiating the CAPD steps at the touch of a button.

Despite the increasing use of continuous ambulatory peritoneal dialysis (CAPD), the ability of this form of dialysis to provide adequate treatment over longer periods of time remains a cause of some concern. A number of patients receiving CAPD will transfer to other forms of dialysis, particularly hemodialysis due to the inability of CAPD to provide adequate dialysis in terms of biochemical control or fluid removal. One of the major issues currently facing nephrologists caring for patients receiving long term peritoneal dialysis (PD) is the adequacy of the treatment. Dialysis adequacy has a major impact on morbidity and mortality.

Additionally if patients are to receive adequate dialysis, whether the target Kt/V is 1.7, 2.0, or higher, the patient needs to perform all prescribed exchanges. This leads to another issue of patient compliance. Compliance indicates the extent to which the patient has carried out the task as assigned.

5 Although measurement of compliance with prescribed therapy is straightforward in hemodialysis, no such method exists for continuous ambulatory peritoneal dialysis (CAPD). An indirect method based on creatinine kinetics for measuring compliance in CAPD patients has been described in the literature but subsequent reports have failed to validate this method. There is only one report of
10 compliance in CAPD patients in the literature. This was assessed by inventory checks of supplies in patients' homes over a 4-9 week period. This study revealed noncompliance in 57% of U.S.A. CAPD patients, with these patients performing a mean of 73% of prescribed exchanges. This degree of noncompliance, if verified and maintained in the longer term, would have a major deleterious effect on
15 outcome; many patients would be receiving inadequate dialysis.

 Noncompliance of treatment regimens in patients on dialysis may have adverse and possibly fatal consequences. A review of compliance literature in end stage renal disease (ESRD) patients indicates that at least 80% of patients have some form of noncompliance. Since peritoneal dialysis is performed at home, at issue is
20 whether or not the patient actually does all of the prescribed exchanges. Results of the CANUSA study demonstrated the association of decreased survival with lower Kt/V and decreased creatinine clearance. If less than the prescribed dialysis is actually delivered to a patient due to failure to perform all exchanges, then survival could clearly be affected.

25 If patients are to receive adequate dialysis, whether the target Kt/V is 1.7, 2.0, or higher, the patient needs to perform all prescribed exchanges. To illustrate the effect of noncompliance on an individual patient, one of the noncompliant patients had a weekly Kt/V of 2.09 based on a 24-hour dialysate and urine collection. The home visit supply inventory revealed the patient was performing only 74% of the
30 prescribed exchanges, thus making the Kt/V of the actual dialysis delivered only 1.55.

It is clear from this study that the measured-to-predicted creatinine ratio will not predict compliance with prescribed exchanges. Patient compliance with prescribed exchanges in PD can be determined to some accuracy with supply inventories. However, this approach of determining compliance would be very
5 costly, requiring periodic home visits and inventory checking by healthcare personnel, and would still not verify whether patient underwent specified Dwell time and other prescription parameters which play a major role in adequacy. This new invention solves the problem of checking patient compliance by storing all the treatment data in a semiconductor memory or PCMCIA card-type memory which
10 can be verified by the healthcare personnel at any time anywhere.

Bioincompatibility of the currently used dialysis solutions has been suggested as a reason for the changes of the peritoneum during long term peritoneal dialysis (PD). Studies suggest that daily exposure to currently used glucose-based PD solutions may result in functional changes in the peritoneum. The decreased fluid
15 removal, due to increased fluid reabsorption, resulting in decreased clearances for small solutes as well as increased glucose absorption, represents changes which, in clinical use, may prevent the peritoneum from withstanding long-term PD use. The results indicate that the functional studies of the peritoneal transport characteristics after daily infusion of dialysis fluid may be a useful model to assess the
20 biocompatibility of PD solutions. Continuous measurement and monitoring of the dialysate flow rates and ultrafiltrations of individual exchanges will help to determine the effect of long dwells on the functioning of the peritoneum.

Early detection of poor ultrafiltration symptoms may perhaps warn the physician of a failing peritoneum and a resulting change in prescription may allow
25 the patient to stay on PD longer. Presently, there is no mechanism for studying such parameters on a continuously on-going basis.

Referring now to Figure 3, there is illustrated one embodiment of an apparatus for continuous ambulatory peritoneal dialysis, which comprises a support frame shown generally at 20 and typically resembling an IV pole, a weighing means
30 shown generally at 22 secured to the support frame, a first support means 24 for suspending from the weighing means 22 a container 10a of fresh dialysis solution,

and a second support means 26 for suspending from the weighing means a container 16a for receiving spent dialysis solution. Both the first and the second support means 24 and 26 are in the form of vertical posts, which are mounted to a common flange 25 forming part of the weighing means 22. A first conduit 30 is provided,
 5 having a distal end 31 adapted for connection to the container 10a of fresh dialysis solution. A second conduit 34 has a distal end 35 adapted for connection to the container 16a for receiving spent dialysis solution. A third conduit 38 is a patient conduit having a distal end 39 adapted to connect with a transfer set 28, in turn connected to the patient catheter 40.

10 Each conduit has, opposite its distal end, a proximal end, the proximal ends of the conduits being connected together at a Y-junction 42. All three conduits are in communication with each other at the Y-junction 42.

In the embodiment shown in Figure 3, each conduit 30, 34 and 38 has a respective manually operable clamp 45, 48 and 47 respectively. Each clamp is
 15 capable of selectively permitting or halting fluid flow through its respective conduit.

A housing 50 is suspended at the top of the support 20 and contains a central processor means operatively associated with the weighing means 22, and receiving from the weighing means a signal representing the weight being supported at any given time by the weighing means 22. The central processor means also has data
 20 input/output capability by which it can be programmed to carry out a three-stage cycle consisting of:

- a) a fill stage during which the drain conduit is closed, and during which dialysis solution passes from the container of fresh dialysis solution through the fill conduit, thence through the patient conduit to the peritoneal cavity of the patient;
- 25 b) a dwell stage during which the dialysis solution remains in the peritoneal cavity of the patient; and
- c) a drain stage during which the dialysis solution flows along the catheter from the peritoneal cavity of the patient, thence through the transfer set 28, thence through the patient line 38, thence through the drain line 34 to the container 16a
 30 for receiving spent dialysis solution.

The central processor means further includes a real time clock allowing the central processor means to track the time taken to fill, the dwell time, and the drain time.

It will also be noted that the weight transducer 22 is suspended from and
5 supported by the housing 50.

The construction described with respect to the Figure 3 embodiment attempts to maintain the simplicity and functionality of the conventional CAPD (manual). However, the basic principle of the new system can be expanded to include other functions and add more flexibility to the control system. For example, different
10 kinds of transducers, flow meters or other devices could be used to monitor the amount of fluid infused or drained. Since the patient will never be filling and draining at the same time, a single transducer can be employed to weigh both the fill volume and the drain volume.

The patient inputs the amount of fluid to be delivered by an electronic
15 means, for example by manipulating the "up" and "down" buttons 52 and 54, shown to the right on the control panel 53 seen in Figure 5. A numerical display 56 registers the total amount as controlled by the buttons 52 and 54, and a "set" button 58 tells the central processor to use the value shown in the display at the time the set button 58 is depressed. When the patient has input the appropriate information, he
20 opens the necessary clamps 45, 46 and 47 to allow the fill stage to begin. As the patient fills, the amount infused or remaining to be infused is shown on the display 56. After a sufficient amount has been infused, the patient closes the fill line clamp 45 to prevent any more infusion of fluid. When the sufficient amount has been delivered, the scale device could generate an electronic beep or a similar alert. The
25 patient then closes the clamp 47 to initiate the dwell stage. The electronic control could then measure and display the passage of real time by showing either the true clock time or the number of minutes still to go for the dwell stage. The total time of the dwell would have been previously input by the patient.

When the dwell stage is completed, the patient opens the clamps 46, 47 and
30 48 to allow the drain phase to occur. The amount of drain fluid is again measured by the weighing means 22 and shown on the display 56. The patient then flushes

the line in the manner normally accomplished with the Y system. At this point, the patient is ready to open the necessary clamps to allow the fill phase to begin again.

Ideally, during the fill and drain phases, the scale measures flow rates, total fill volume, total drain volume, and ultrafiltration. Because the electronic control system has a real time clock, it can record all parameters, such as the actual clock time of the exchange, the time taken for infusion, the dwell time, and the drain time. This allows clinicians to determine patient compliance and to study the transport characteristics of the patient from exchange to exchange. It becomes possible to optimize the dialysis solution dosage for each patient, and to determine many other criteria for prescription CAPD. The basic weighing mechanism permits calculation of many other treatment parameters as and when desired by reprogramming the control electronics in the scale. An optical system could be inserted into the drain flow path to detect cloudiness of the fluid, thus permitting early detection of one of the symptoms of peritonitis.

In another embodiment of this invention as shown in Figure 4, in addition to the scale mechanism, the Y set lines are routed through a clamping system on the control unit which selectively mechanically occludes one line at a time. This permits the CAPD exchange to be carried out without any manual intervention. The principle of one form of cam-operated mechanical occlusion can be derived from U.S. patent 4,096,859, granted to us on June 27, 1978.

As already pointed out, Figure 5 shows a typical control panel for this invention. Ideally, the "set" button in conjunction with the "up" and "down" buttons allows the patient or the nurse-in-charge to enter a variety of treatment variables, including the fill volume, the dwell and drain times, and the number of exchanges. When the power is first turned on, the control system selects the reference position of the occlusions cams, in which all Y set lines are closed. This is the start position. Pressing the "start" button then initiates the treatment process whereby the drain, the flush, and the fill phases of the process are automatically performed. The scale keeps track of the flow rates at all times. During fill, the control system automatically clamps off the fill line when the required amount of fluid has been delivered to the patient. During drain, the control system clamps off

the patient line when the drain time has elapsed and the preselected minimum drain volume limit is exceeded. If suitable conditions are not met, an alarm will be generated. Moreover, in CAPD, the patient is not asleep but rather is fully aware of the operation taking place. Therefore safety is not an issue.

5 Storage of treatment parameters and variables is provided via electronic means such as PCMCIA memory cards or some other devices. These portable devices can be removed and taken to the hospital for examination by the physicians at regular intervals. With miniaturization in electronics, the whole control system can be assembled into a very small portable unit which is completely battery
10 powered. The illustration in Figure 5 is only one example of many possible representations. The "set", "up", and "down" buttons could be eliminated by permanently storing the treatment variables into the memory card so that the control panel is simplified and also the variables cannot be changed by the patient.

 Currently, as discussed above, CAPD cost is a very important issue. As
15 more exchanges are needed to improve adequacy, the cost of the treatment is significantly increased. A 2L infusion is considered a norm for most adults, but recently a 2.5L infusion is being suggested for improving the adequacy. This becomes a very heavy burden to the healthcare system of the country, especially in the developing world where patients do not have enough money to receive even the
20 basic minimum 4 exchanges a day and thus cannot receive adequate dialysis.

 Recently, in APD (automated peritoneal dialysis), the use of 5L solution bags is being advocated to help reduce the cost of dialysis because 5L solution bags are proportionately much cheaper in cost than the 2L or 3L bags. The CAPD system disclosed herein makes it possible to use the cost-saving 5L bags for CAPD.
25 A simply "Y" system in conjunction with a 5L bag will provide two 2.5L exchanges. At the end of the first exchange, the patient will disconnect from the system by using a unique quick connect cap 60 (U.S. patent 4,983,161, issued on January 8, 1991, to Joseph E. Dadson, et al) which is prefilled with disinfectant (see Fig. 6). The patient uses one half 62 of the quick connect cap 60 to cover the
30 transfer set connector 66, and uses the other half 64 of the quick connect cap 60 to cover the patient connector 68 of the Y set. The quick connect cap and its

application are shown in Figures 6 and 7 respectively. To start a new exchange the patient will simply remove the covers from the transfer set connector 66 and the patient connector 68 of the Y set and rejoin them. Since the two ends were covered with connectors filled with disinfectant, they will remain sterile.

5 Along the same principle, double bag systems can be manufactured with a 5L preattached solution bag instead of conventional 2L bags. The use of the present invention in conjunction with the quick connect cap 60 will permit two 2.5L exchanges from one double bag system and will significantly reduce the cost per exchange. Also possible is the manufacture of double Y/double bag systems or the
10 use of one Y set 70 in conjunction with two 5L solution bags 72 which comprise one Y set with another Y in the fill line to connect to two solution bags (Figure 8). With this variation the patient can even receive up to four 2.5L exchanges from one system. This will further reduce the cost of the treatment and make it affordable for patients around the world.

15 In dialyzing children, normally much smaller amounts of fluid are infused. Solution bags of 250 ml, 500 ml, and 1L sizes are quite common. In many cases these special bags are relatively expensive and their availability and the keeping of inventory becomes a problem in many places and many countries. The use of the present CAPD system will eliminate the requirement of special pediatric bags. For
20 example, one 2L double bag system will permit four 500 ml exchanges, or one 5L double bag system will permit five 1L exchanges which will be sufficient for most children. This will result in tremendous savings to the healthcare system. Different combinations of solution bags can be utilized to get the most optimum dialysis and cost savings.

25 It is clearly seen from the above description that the addition of the scale device and the occlusion mechanism tremendously improves the flexibility and simplicity of CAPD treatment and opens a large number of new options. Some of the advantages of the new device are:

- 1) Precise delivery and monitoring of the fluids in all phases of the CAPD
30 exchange;

- 2) Complete automation of all CAPD steps by the touch of a single button;
- 3) For children, there will be no need to use special pediatric bags. With this device, it will be possible to use standard 2L or 3L bags and do 4 or 5 exchanges with a single bag.
- 5 4) It will be possible to do CAPD with 5L bags or with any other size bags. The cost of healthcare is a very critical issue these days and it is especially so in development countries. By reducing the cost of treatment or of each exchange, they will be able to perform adequate exchanges and get sufficient dialysis. 5L commercial bags are cheaper than the equivalent amount of solution in 2L bags.
- 10 One "Y" set in conjunction with one 5L bag and one quick connect cap will provide 2 CAPD exchanges, or a double "Y" system will provide all 4 exchanges. Twin bags or ultra bags or double bag systems can in future be built in 5L solution bags.
- 5) The device will store all the treatment parameters to determine patient
- 15 compliance and decide whether the patient is getting sufficient dialysis dosage.
- 6) The device will allow the clinicians to obtain exact patient ultrafiltration characteristics from one exchange to another over an extended period of time. This will aid them in determining the transport characteristics of the peritoneal cavity, and in making many other observations which otherwise would not be
- 20 obtainable.

While several embodiments of this invention have been illustrated in the attached drawings and described hereinabove, it will be evident to those skilled in the art that changes and modifications may be made therein without departing from the essence of this invention, as set forth in the appended claims.

**THE EMBODIMENTS OF THE INVENTION IN WHICH AN EXCLUSIVE
PROPERTY OR PRIVILEGE IS CLAIMED ARE DEFINED AS FOLLOWS:**

- 5 1. An apparatus for CAPD (Continuous Ambulatory Peritoneal Dialysis),
comprising:
- a support frame,
 - a weighing means secured to the support frame,
 - first support means operatively associated with the weighing means for
 - 10 suspending from the weighing means a container of fresh dialysis solution,
 - second support means for suspending a container for receiving spent dialysis
solution,
 - a first, a second and a third conduit each having a distal end and a proximal
end,
 - 15 said first conduit being a fill conduit adapted for connection at its distal end
to the container of fresh dialysis solution,
 - said second conduit being a drain conduit adapted for connection at its distal
end to the container for receiving spent dialysis solution,
 - said third conduit being a patient conduit adapted for communication at its
 - 20 distal end with a patient catheter through which dialysis solution can both enter and
leave the peritoneal cavity of the patient,
 - junction means where the proximal ends of the first, second and third
conduits are connected together and are in communication with each other,
 - clamp means for selectively permitting and halting fluid flow through each of
 - 25 the first, second and third conduits, and
 - central processor means operatively associated with the weighing means and
receiving from the weighing means a signal representing the weight being supported
at any given time by the weighing means, the central processor means also having
data input/output capability by which it can be programmed to carry out a three-
 - 30 stage cycle consisting of :

- a) a fill stage during which the drain conduit is closed, and during which dialysis solution passes from the container of fresh dialysis solution through the fill conduit, thence through the patient conduit to the peritoneal cavity of the patient;
- 5 b) a dwell stage during which the dialysis solution remains in the peritoneal cavity of the patient; and
- c) a drain stage during which the dialysis solution flows from the peritoneal cavity of the patient through the patient conduit, thence through the drain conduit to the
- 10 container for receiving spent dialysis solution;

the central processor means including a real time clock allowing the central processor means to track the time taken to fill, the dwell time and the drain time.

- 15 2. The apparatus claimed in claim 1, in which the central processor means is adapted to emit a signal when a pre-programmed quantity of fresh dialysis solution has entered the patient's peritoneal cavity during the fill stage.
3. The apparatus claimed in claim 1, in which the central processor means is
- 20 adapted to emit a signal when a pre-programmed quantity of spent dialysis solution fails to collect in the said container during the drain stage, the latter being of predetermined length.
4. The apparatus claimed in claim 1, claim 2 or claim 3, in which the central
- 25 processor means has an internally set program controlling the quantity of fresh dialysis solution to be infused into the patient's peritoneal cavity during the fill stage and the minimum quantity of spent dialysis solution to be collected during the drain stage.
- 30 5. The apparatus claimed in claim 1, claim 2 or claim 3, in which the central processor means has set means by which the patient can preset the quantity of fresh

dialysis solution for the fill stage, and the quantity of minimum spent dialysis solution in the drain stage.

6. The apparatus claimed in claim 1, claim 2 or claim 3, in which said clamp
5 means includes a separate, patient-operable clamp for each conduit.

7. The apparatus claimed in claim 1, claim 2 or claim 3, in which said clamp
means comprises a mechanism controllable by the central processor means, the
mechanism being adapted to occlude and open each of the conduits as called for
10 during the various stages of peritoneal dialysis.

8. The apparatus claimed in claim 1, claim 2 or claim 3, in which the second
support means is operatively associated with the weighing means, and in which the
container for receiving spent dialysis solution is suspended from the weighing
15 means.

9. A process for peritoneal dialysis utilising an apparatus comprising:
a support frame,
a weighing means secured to the support frame,
20 first support means operatively associated with the weighing means for
suspending from the weighing means a container of fresh dialysis solution,
second support means for suspending a container for receiving spent dialysis
solution,
a first, a second and a third conduit each having a distal end and a proximal
25 end,
said first conduit being a fill conduit adapted for connection at its distal end
to the container of fresh dialysis solution,
said second conduit being a drain conduit adapted for connection at its distal
end to the container for receiving spent dialysis solution,

said third conduit being a patient conduit adapted for connection at its distal end to a patient catheter through which dialysis solution can both enter and leave the peritoneal cavity of the patient,

5 junction means where the proximal ends of the first, second and third conduits are connected together and are in communication with each other,

clamp means for selectively permitting and halting fluid flow through each of the first, second and third conduits, and

central processor means operatively associated with the weighing means and being adapted to receive from the weighing means a signal representing the weight
10 being supported at any given time by the weighing means, the central processor means having a real time clock and also having data input/output capability by which it can be programmed;

the said process comprising the steps:

passing a signal from the weighing means to the central processor means,
15 said signal representing the weight being supported at any given time by the weighing means, and, in sequence,

closing the drain conduit and opening the other two conduits to allow dialysis solution to pass from the container of fresh dialysis solution through the fill conduit,
20 thence through the patient conduit to the peritoneal cavity of the patient;

closing the patient conduit and allowing the dialysis solution to remain in the patient's peritoneal cavity for a predetermined dwell period; and

25 closing the fill conduit and opening the other two conduits to allow spent dialysis solution to pass from the peritoneal cavity of the patient through the patient conduit, thence through the drain conduit to the container for receiving spent dialysis solution.

10. The process claimed in claim 9, in which the central processor means emits a signal when a pre-programmed quantity of fresh dialysis solution has entered the patient's peritoneal cavity during the fill stage.

5 11. The process claimed in claim 9, in which said central processor means is programmed to measure and remember any ultrafiltration, permitting evaluation of the performance of the peritoneal cavity.

12. The process claimed in claim 9, in which the central processor means is
10 programmed to measure patient compliance, by retaining a record of all exchanges and all parameters.

13 The process claimed in claim 9, in which the second support means is
operatively associated with the weighing means, and in which the container for
15 receiving spent dialysis solution is suspended from the weighing means.

14. The process claimed in claim 13, in which the central processor means emits a signal when a pre-programmed quantity of spent dialysis solution fails to collect in the said container for receiving spent dialysis solution during the drain stage.

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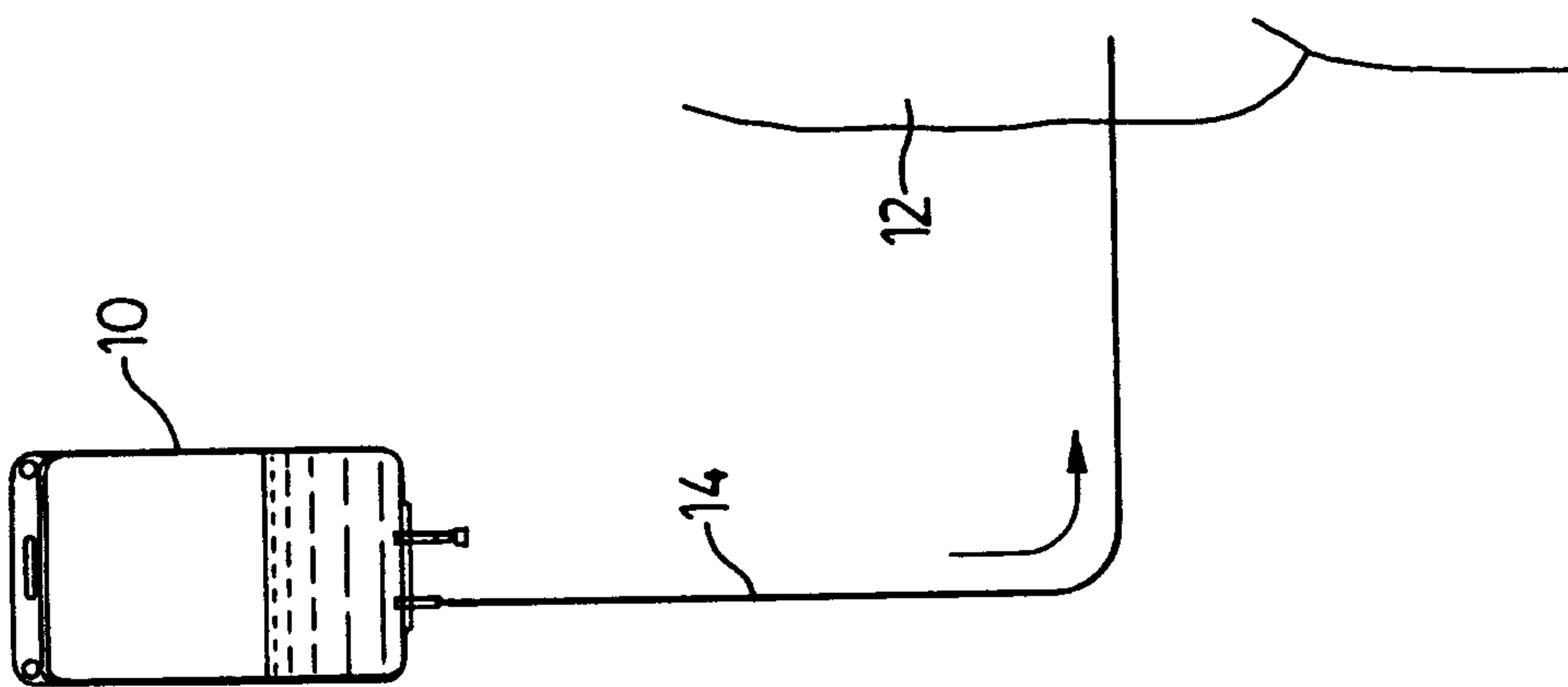


FIG. 1a
(PRIOR ART)

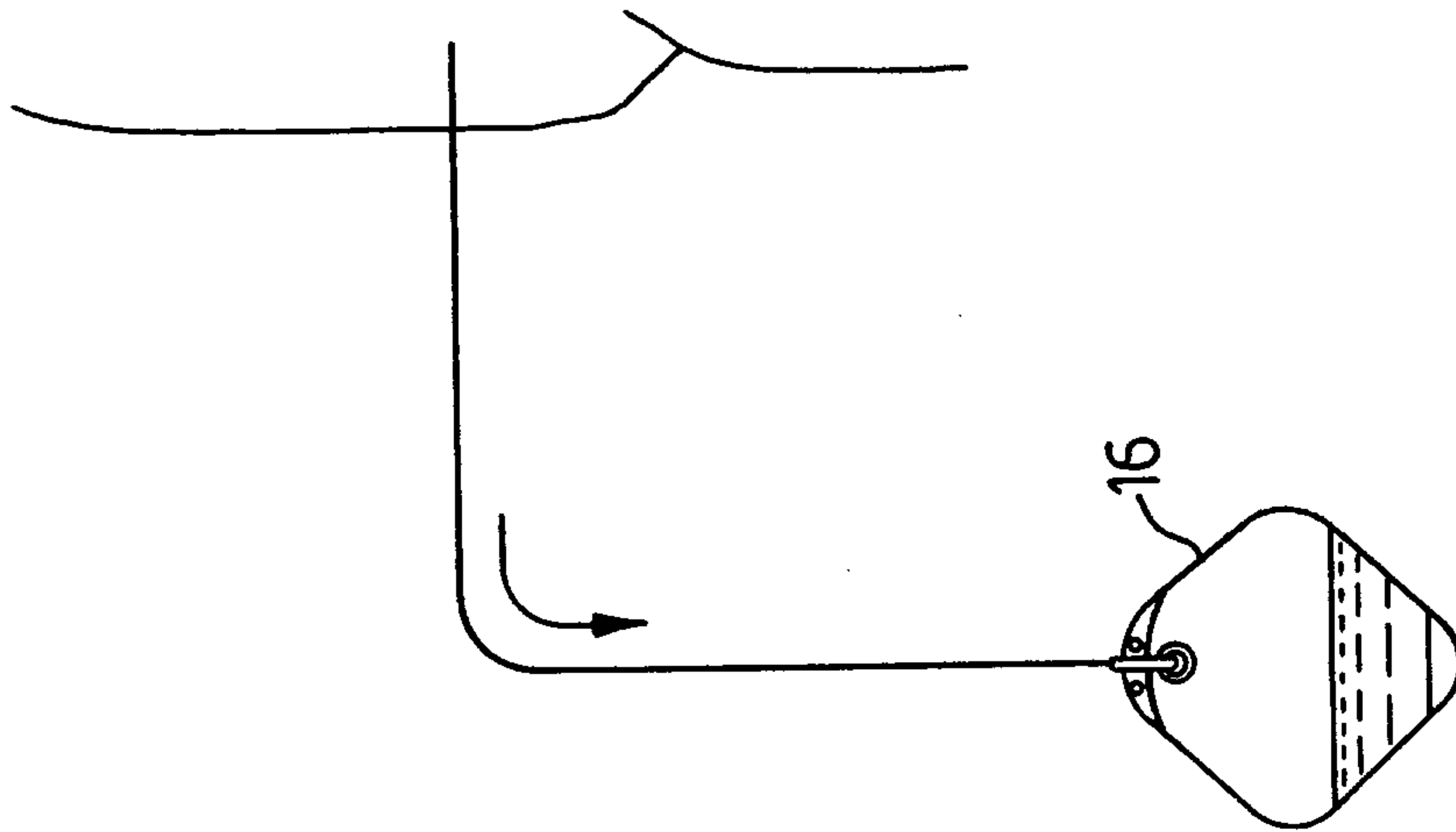


FIG. 1b
(PRIOR ART)

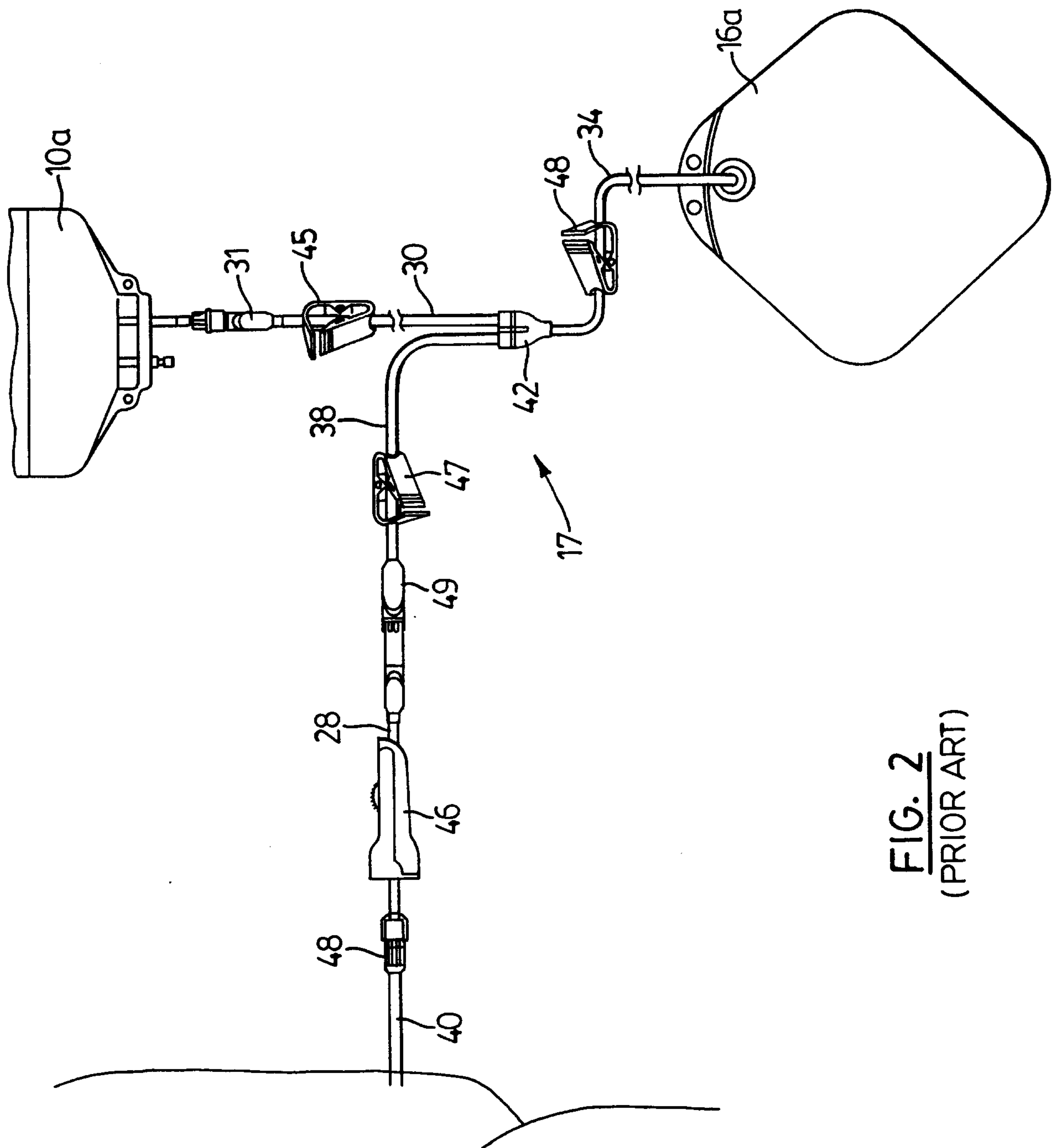


FIG. 2
(PRIOR ART)

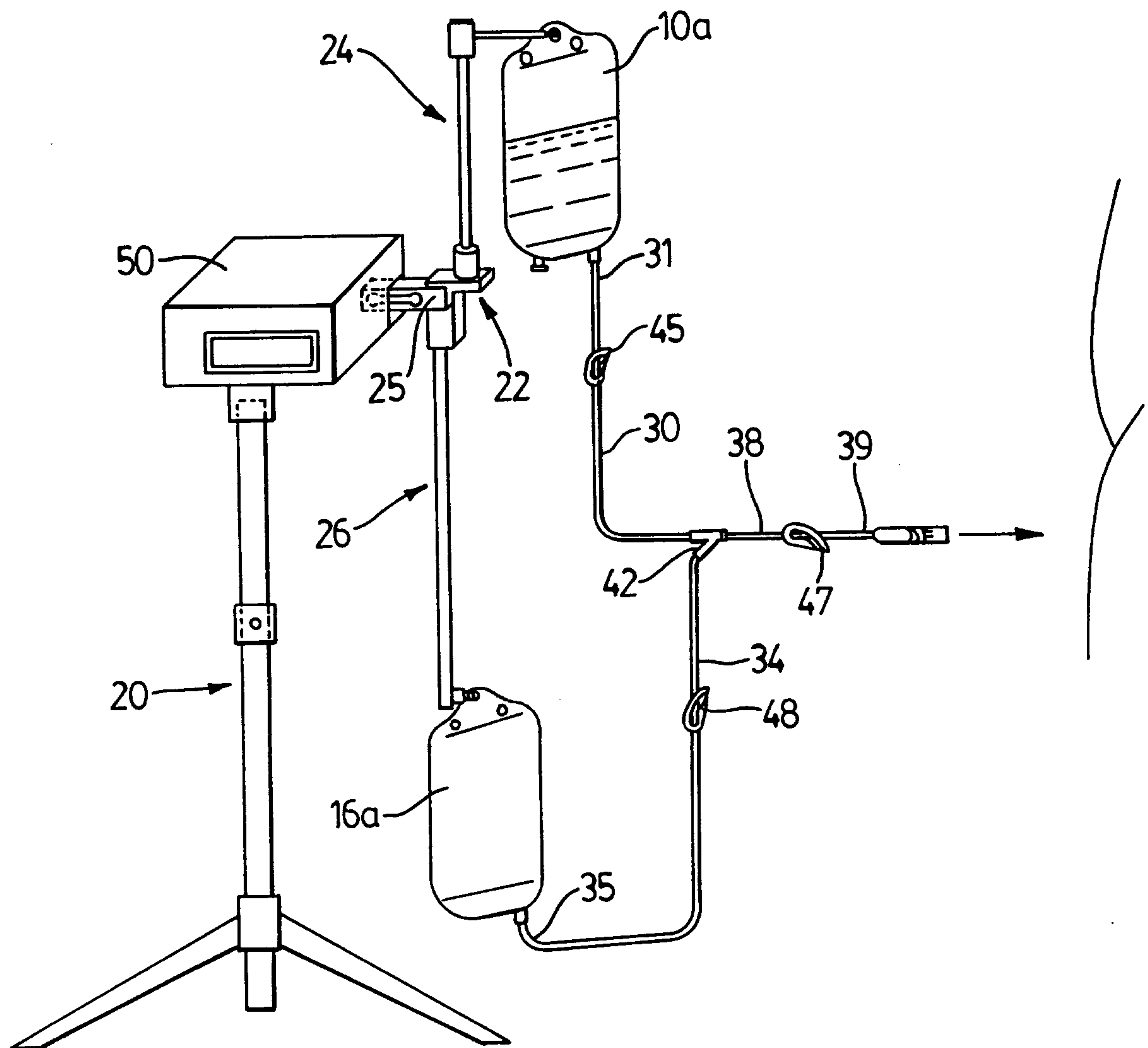


FIG. 3

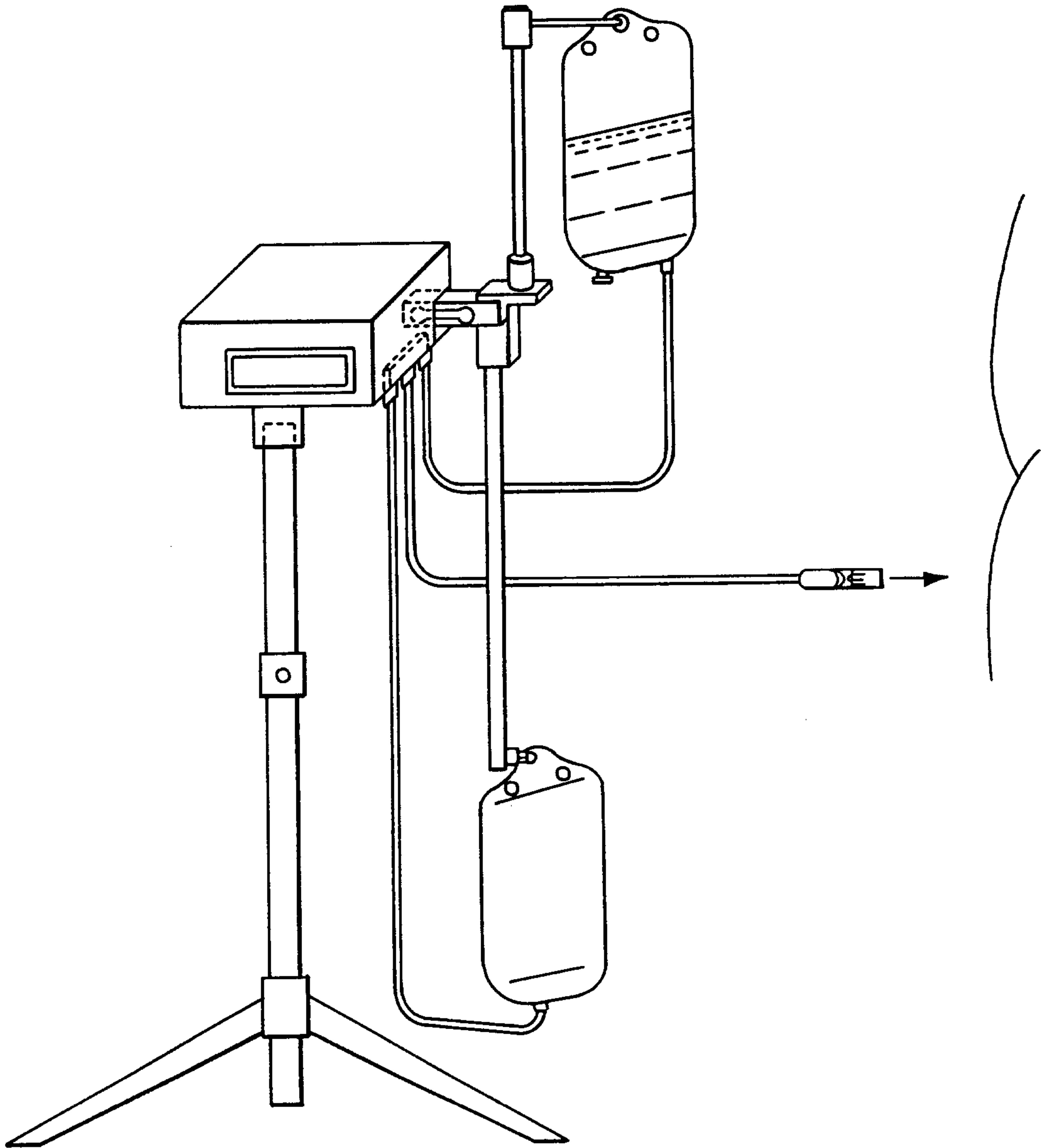


FIG. 4

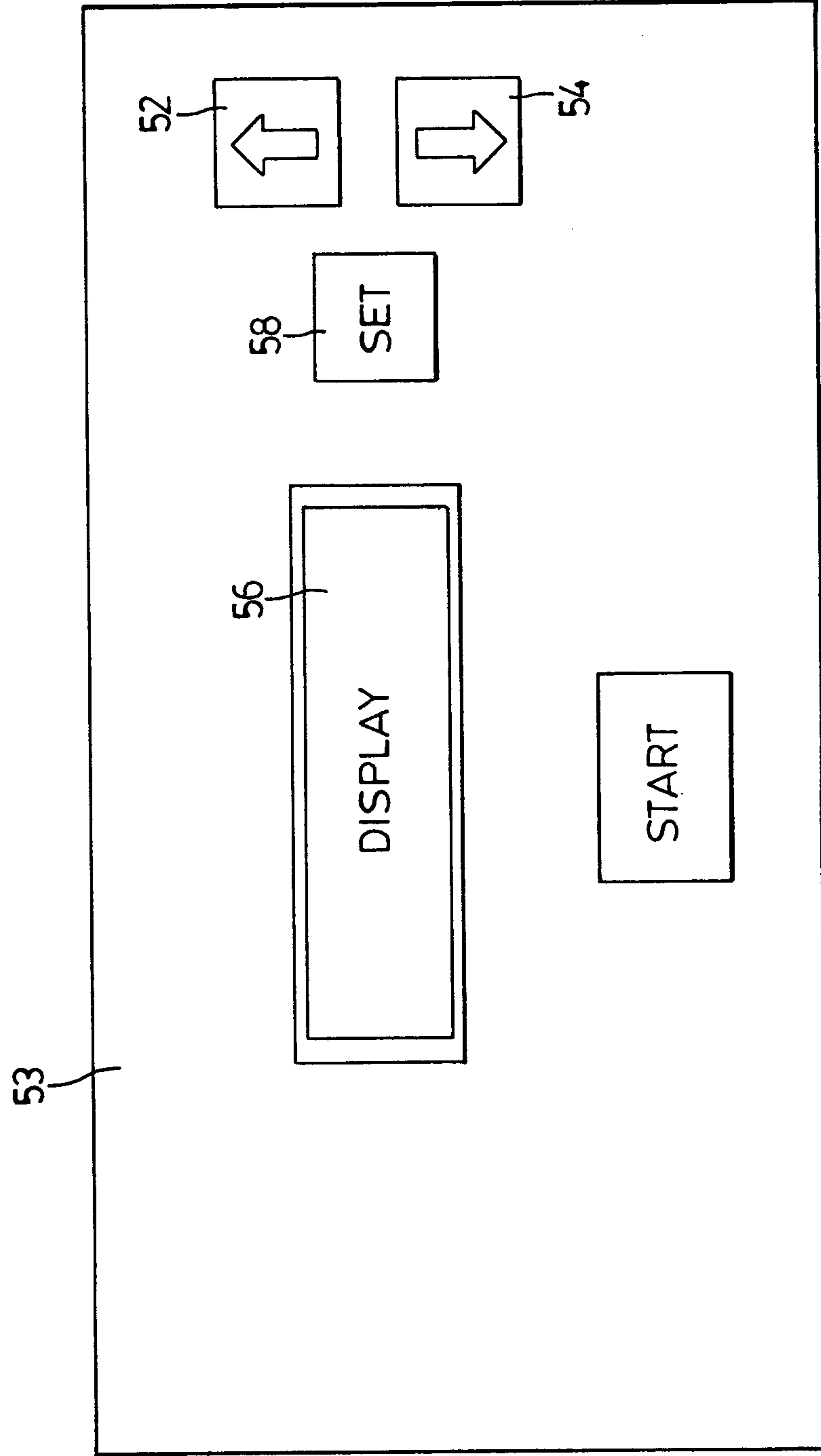
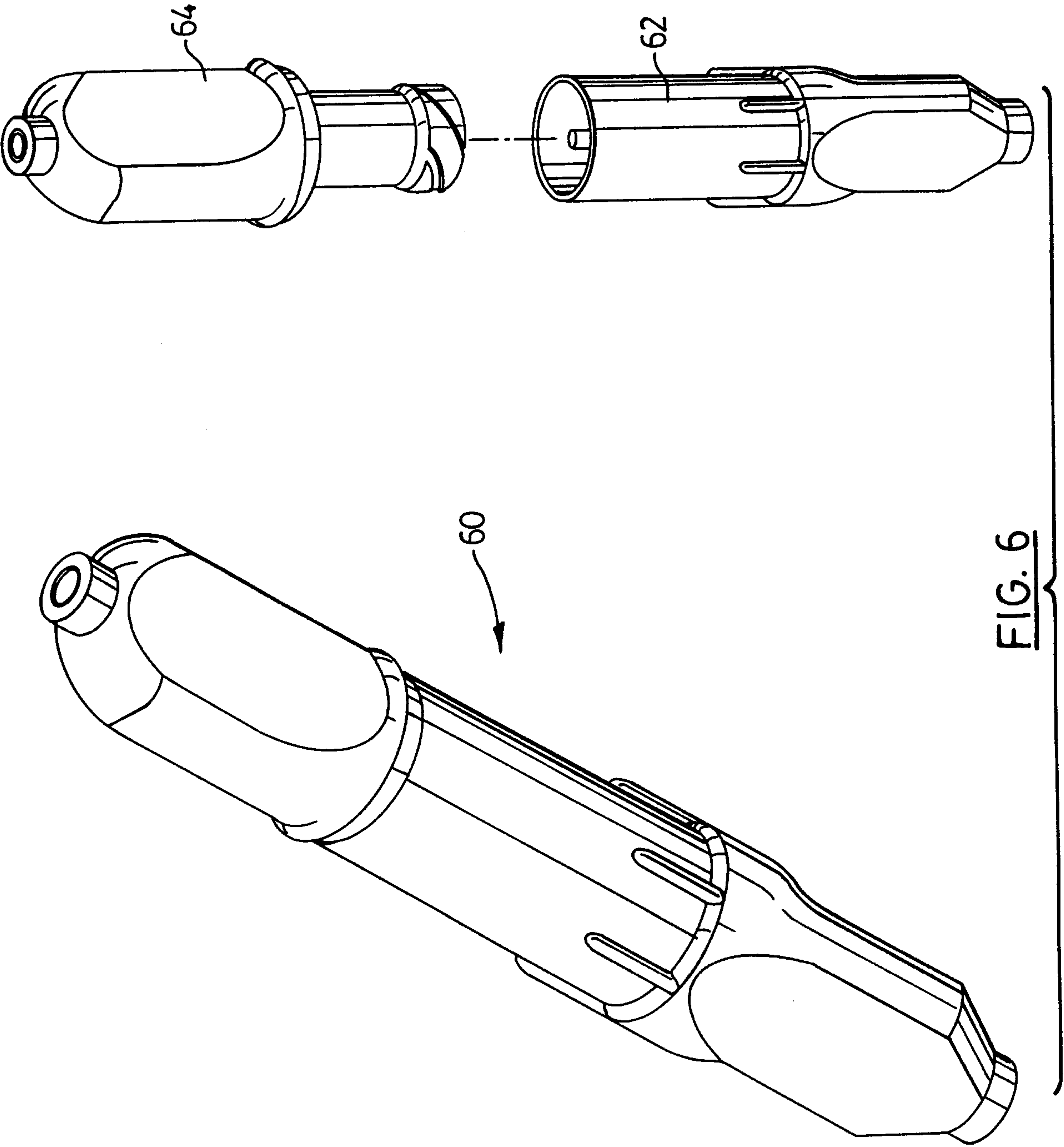
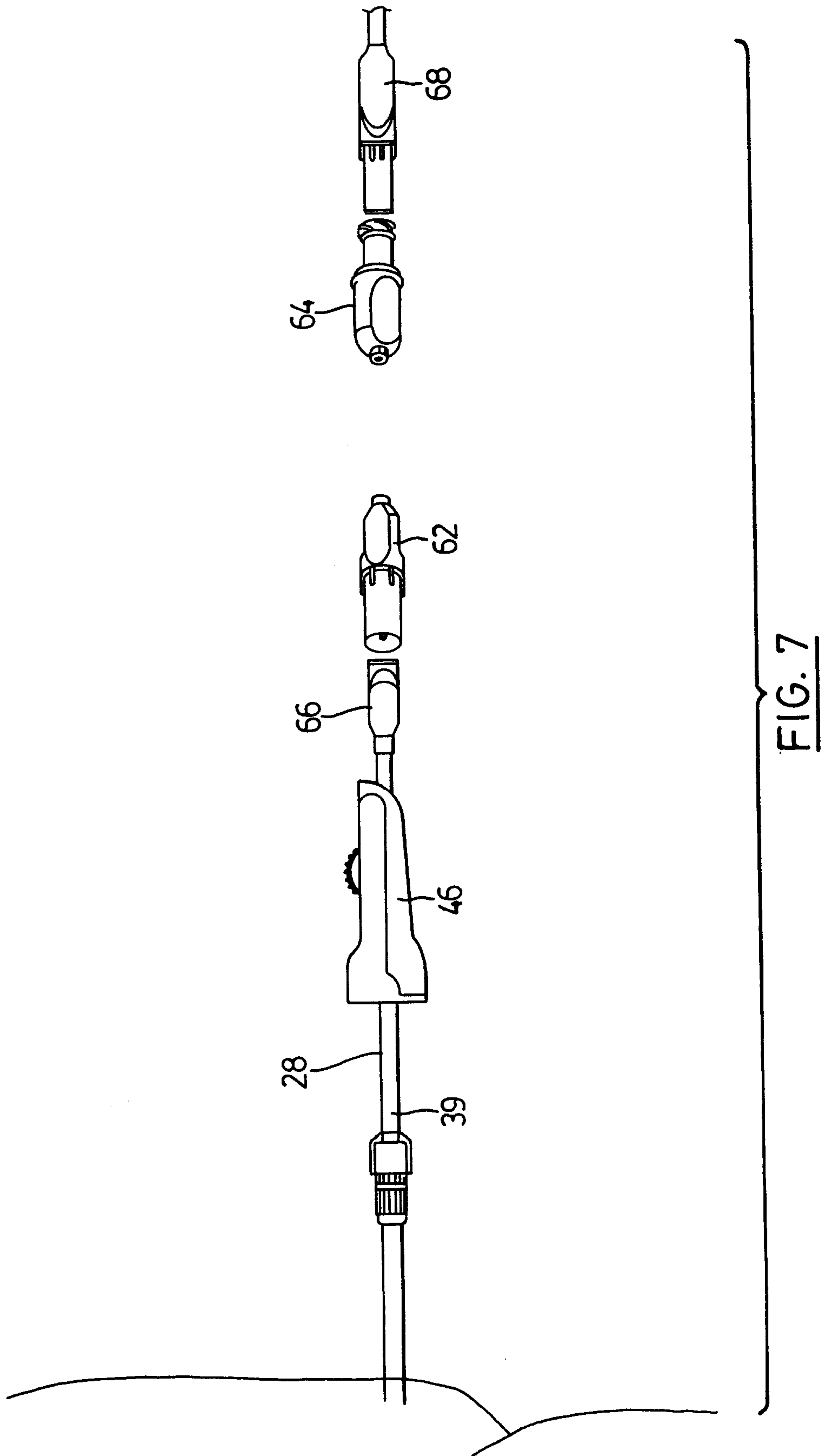
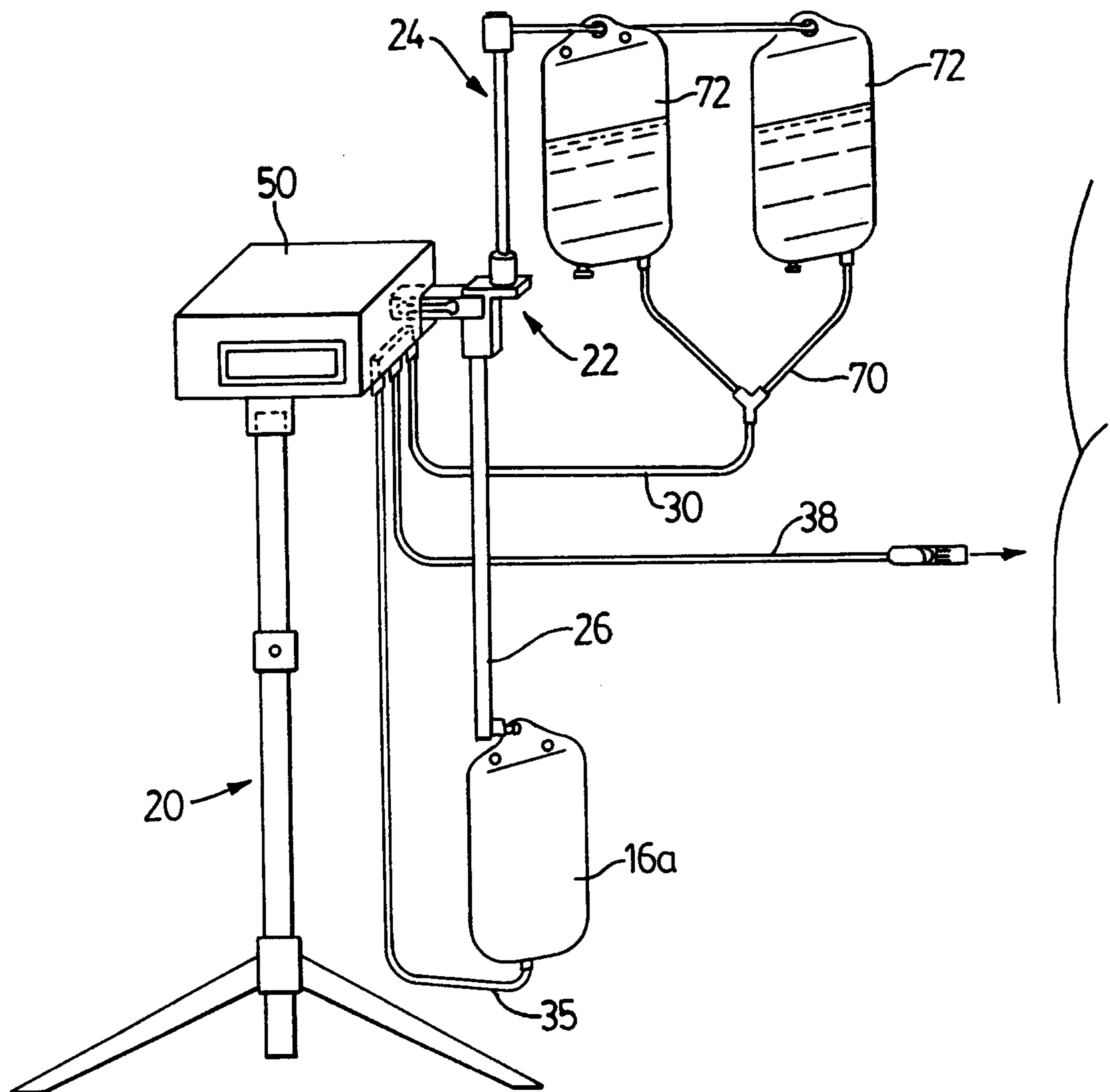


FIG. 5





FIG. 8

