

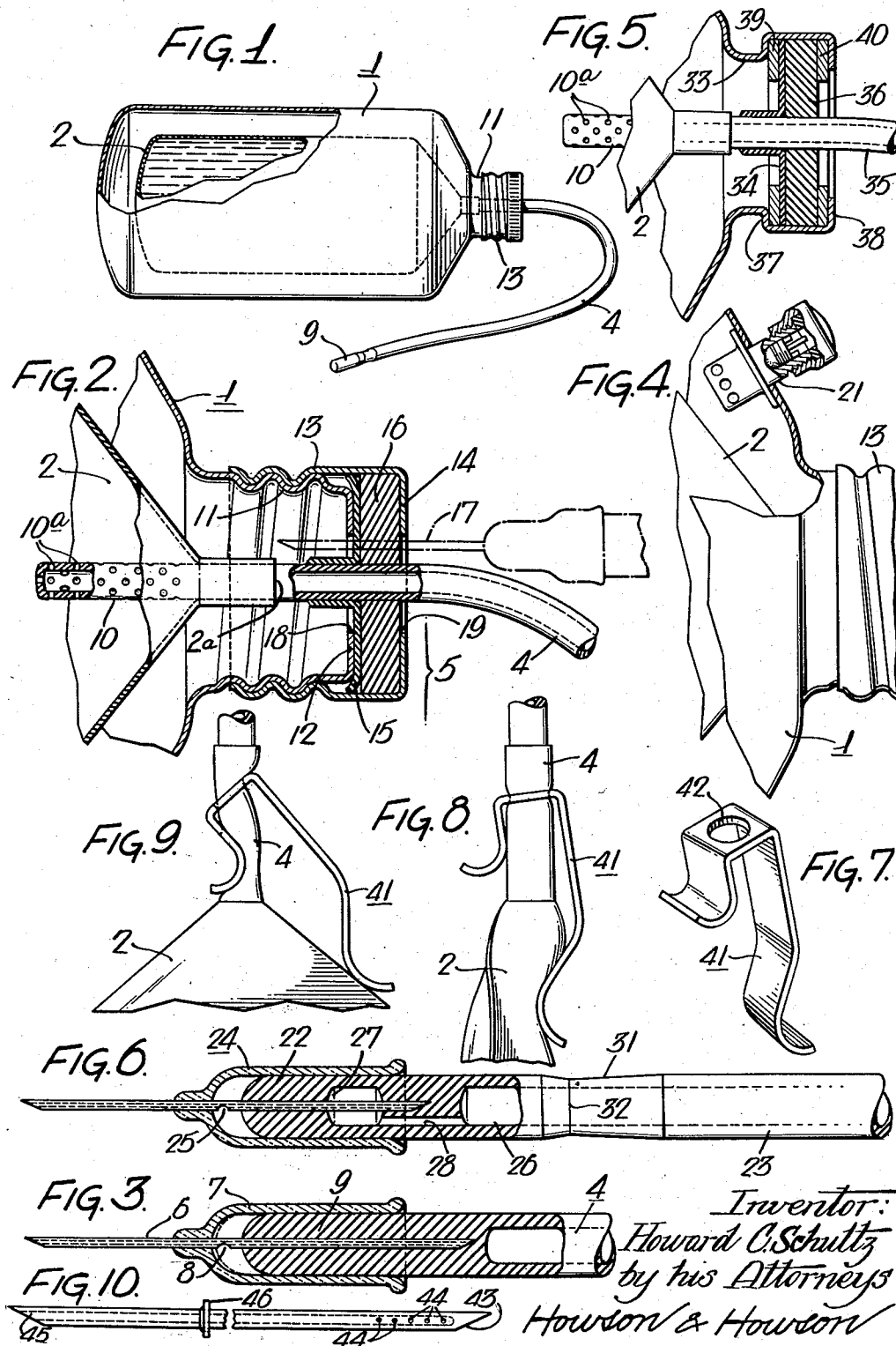
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PRESSURE-VACUUM CLYSIS UNIT

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PRESSURE-VACUUM CLYSIS UNIT

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23 Claims. (Cl. 128—214)

This application is a continuation-in-part of my co-pending application Serial Number 128,628, now abandoned.

A principal object of the invention is to provide a practical pressure-vacuum clysis unit including an adaptable clysis or intravascular needle, said unit being in the form of a compact light weight package capable of being utilized under substantially all conditions for infusion and transfusion purposes or for taking and storing citrated or non coagulating bloods for subsequent transfusion or other purposes.

To this general end the invention contemplates provision of a unit of the stated type containing the blood or other medium together with suitable pressure means for forcing the said medium under controlled pressure into the blood vessel or other tissues.

Another object of the invention is to provide a unit of the aforesaid type wherein fluid pressure is utilized for discharge of the infusion or transfusion medium.

Still another object is to provide a unit of the character set forth above including means for automatically maintaining a substantially constant rate of discharge from the unit of the transfusion medium.

A further object of the invention is to provide a unit of the stated type employing a fluid-pressure medium capable of affording and maintaining a substantially constant actuating pressure within the unit throughout the discharge operation.

Another object of the invention is to provide a unit of the stated character wherein the chamber which is occupied by the fluid pressure medium when the device is to be used for infusion or transfusion purposes, may be evacuated, and the vacuum thus produced employed for withdrawing blood from a blood vessel for subsequent transfusion or other purpose.

Still another object of the invention is to provide a unit of the character set forth comprising an outer and an inner container of which the inner is composed of a suitable flexible material adapting the container for contraction or expansion, as the case may be, under pressure or vacuum imposed upon the interior of the outer container, said inner container being provided with means for connection through the medium of a suitable intravascular needle with a blood vessel or tissue for transfusion or infusion purposes or for withdrawal of blood as previously set forth.

A further object of the invention is to provide a unit of the character set forth above wherein the outer container is mechanically strong and rigid and practically unbreakable; and either translucent or opaque as desired.

A still further object is to provide a unit of the character set forth wherein the outer container is provided with means for injecting a pressure fluid such as air or gas, either inert or active, into the container, or for evacuating said container, the resulting pressure or vacuum being imposed upon the inner flexible container for the purposes set forth.

Another object of the invention is to provide a unit

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of the stated character which may be readily sterilized by autoclaving or by other suitable means, and so packaged without contamination.

The invention further contemplates, in conjunction with the container unit described above and in connection with the inner flexible container of said unit, an intravascular or clysis needle adaptable for infusion or transfusion purposes or for withdrawing blood as the case may be.

Still another object of the invention is to provide a needle of improved design incorporating readily operable test means for determining whether or not the terminal end of the needle is accurately positioned within the blood vessel wherein the transfusion medium is to be injected.

In addition, the invention contemplates provision of an infusion or transfusion unit, including all of the equipment required for performing the operation, in immediately available form, said unit being light in weight and highly mobile and incorporating means for forcing the infusion or transfusion medium into the blood vessel or tissue to which the unit may be connected, whereby the device, after connection to said blood vessel or tissue, may operate automatically and in any position to complete the operation.

The invention resides also in certain structural features and details hereinafter described and illustrated in the attached drawings, wherein:

Figure 1 is a side elevational and partial sectional view of a pressure-vacuum clysis unit in accordance with the invention;

Figure 2 is an enlarged fragmentary sectional view showing a detail of construction;

Figure 3 is an enlarged longitudinal sectional view of the needle element;

Figure 4 is a sectional view illustrating a modification within the scope of the invention;

Figure 5 is a fragmentary sectional view similar to Figure 2 illustrating another modification;

Figure 6 is a sectional view similar to Figure 3 illustrating a modification of the needle element;

Figure 7 is a view in perspective of a flow regulating element detached from the unit;

Figures 8 and 9 are fragmentary side views showing the mode of operation of the device; and

Figure 10 is a side view of a modified form of needle including a built-in flow regulating means.

With reference to the drawings, a unit assembly made in accordance with my invention comprises an outer container 1, and an inner container 2, the latter container being composed of rubber, plastic, or other flexible material impervious to air and liquids and having a tubular extension 4 which passes through the wall of the container 1. Preferably, the tube 4 is integral with the container 2, but in any event the joint 5 where the tube passes through the wall of the container 1 is hermetically sealed to preclude leakage. In effect the inner end of the tube 4 where it joins the container proper defines a port 2^a in the container to which the tube affords access from the outside of the outer container or casing 1.

To the tube 4 is connected an intravascular or clysis needle 6. In the present instance the needle is of double-end type and has connected thereto a transparent hub 7 which tightly embraces a mid-section of the needle and forms a sleeve surrounding one end portion of the latter. In this portion the needle 6 is provided with an aperture 8 which opens into the bottom of the sleeve 7 as illustrated. The tube 4 is provided with a solid end portion 9 of cylindrical form which neatly fits within the sleeve 7, said end portion 9 being slidable in the sleeve and functioning as a plunger within the cylindrical bore of the latter. Thus, when the terminal portion 9 of the tube is withdrawn slightly in the

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sleeve suction will be applied to the outer end of the needle through the aperture 8.

As shown in Figure 3 the inner end of the needle 6 is imbedded in the solid end portion 9 of the tube, and the said inner end of the needle and the solid end portion 5 are of such relative length that when the end portion 9 is fully inserted in the sleeve the terminal end of the needle will project beyond the inner end of the solid portion into the interior of the tube 4. When, however, the plunger is slightly retracted the inner end of the 10 needle will be embedded in the solid material of said end portion and the tube 4 will be operatively disconnected from the needle.

When the aforescribed assembly is to be used for infusion or transfusion purposes it will be provided 15 as a unit with the blood or other medium filling the inner container 2 which will thus be in the expanded condition within the container 1, said medium also filling the tube 4 down to the inner end of the solid end portion 9. The blood or other medium is thus contained in a 20 sealed impermeable envelope in sterile condition entirely segregated from any source of contamination. The outer container 1 will contain air or other gas under pressure. The needle connected to the end of the tube 4 will be in the condition illustrated in Figure 3, the terminal end 9 of the tube being slightly retracted in the sleeve 7.

The needle is inserted in the blood vessel or subcutaneous tissues in the usual manner, and the plunger then slightly retracted so as to impose suction at the aperture 8. If the needle is positioned in a blood vessel this suction will cause blood to appear in the aperture. If no blood appears assurance is had to the opposite effect. The plunger is now advanced into the sleeve 7 so as to cause the inner end of the needle to enter the interior of the tube 4. The pressure within the container 1 now operates to compress the inner container 2 and to force the contents of the latter through the tube 4 and through the needle 6 into the blood vessel or other tissue. The fluid pressure in the container 1 is sufficient to insure a complete collapse of the flexible container with consequent complete discharge of the contents into the blood vessel or other tissues with exception of the small volume of the material left within the short length of the tube 4. After completion of the operation, the needle is removed, and the entire unit may then be discarded or may be cleaned and sterilized for re-use. It is contemplated, however, that this unit may be made sufficiently inexpensively to render it economically expendable.

It is preferred to form the outer container 1 of metal or other rigid material of light weight and sufficient strength to contain the fluid pressure imposed thereon as described above. Obviously, the pressure will vary with the capacities and relative sizes of the inner and outer containers. Where the inner container has a capacity of one litre and the outside container a capacity one-third larger, positive pressures of approximately 40 lbs. per square inch have been found suitable for ordinary infusion and transfusion purposes. For a one-half litre inner container and an outer container one-third larger a positive pressure of approximately 25 lbs. per square inch might be used. Negative pressures for such containers will correspond to the positive. Visibility is not essential but may be desirable. The inner container 2 may be made of any suitable flexible material such, for example, as rubber or plastic, although the latter material is considered desirable. Vinyl resin plastics such as Koroseal, tygon, and polyethylene (polythene), are well suited for the purpose.

Various devices may be employed for sealing the joint between the wall of the container 1 and the inner container 2 or tube 4 and one such means is illustrated in Figure 2. As therein illustrated, the container 1 has a threaded neck 11 which terminates at its outer end in

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an inturned flange 12. A threaded sleeve 13 is provided for the neck, and this sleeve also has an inturned flange 14 at its outer end. The tube 4 also has a flange 15, preferably integral with the tube but, otherwise, joined to the wall of the tube in integral leakproof manner. The flange 15 has an outside diameter corresponding approximately to the inside diameter of the sleeve 13, so that the flange may be clamped between the flanges 12 and 14 to form an hermetically sealed joint where the tube 4 passes to the outside of the container. The flange 15 and the joint as a whole may be reinforced and strengthened by use of a washer 16 or of rubber or other suitable material the inner periphery of which closely embraces the tube 4 and the outer peripheral portion of which is confined between the flanges 12 inwardly and 14 outwardly of the flange 15.

Where the material of the flange 15 is self-sealing in the sense that after penetration, as by a needle, the material will act automatically to close the aperture; or where the flange 15 and washer 16 conjointly display such self-sealing characteristics, the fluid pressure medium may be introduced into the container 1 by way of a needle 17, shown in broken lines in Figure 2, introduced through apertures 18 and 19 in flanges 12 and 14 and through the penetrable elements 15 and 16. As an alternative the container 1 may be provided with a stem 21, see Figure 4, equipped with a suitable check valve for admission of the pressure medium.

It will be noted by reference to Figures 1 and 2 that the tube 4 extends inwardly of the container 2, the inner projecting end portion 10 of the tube having a plurality of small apertures 10a through which the contents of the container must pass in discharging to the tube. By thus providing a plurality of ports, danger of stoppage due to clotting, where the said contents is blood, is reduced to a minimum, and the apertured tube has a desirable filtering effect.

In the needle device described above the sleeve 7 may be made of glass or transparent plastic so that blood withdrawn through the aperture 8, as described above, may be visible. As previously stated, the tube 4 may be integral with the inner container 2 and the solid terminal end 9 may be an integral part of the tube. Since the device may occupy any position during the transfusion or infusion operation, due to the use of pressure, the tube 4 may be short and preferably will not exceed 12". Thus, during the operation the container 1 may be strapped to the arms of the patient in close proximity to the point of injection so that no necessity arises for an elongated connection tube.

As previously set forth the device may be utilized for withdrawing blood from the body for citration and storage for subsequent transfusion purposes. When the device is used for this purpose the inner container 2 is first evacuated within the outer container and is then sealed off. A vacuum is then drawn on the outer container 1 by way of a hollow needle inserted through the flanges 12 and 14 as described above, or by way of the stem 21 which in this case would be equipped with a reverse check valve to maintain the vacuum. When, under these conditions, a needle is inserted in a blood vessel in the manner previously described, the negative pressure in the container 1 will cause expansion of the inner container with resultant suction on the tube 4 and upon the needle and consequent withdrawal of blood from the blood vessel into the container 2, the latter having previously been provided with the necessary citrating material. After the container 2 has been fully expanded the needle may be withdrawn, the tube 4 sealed, and the containers stored under suitable conditions for subsequent transfusion or other purposes. The fluid pressure necessary for the transfusion operation may be applied to the container 1 either before storage or at the time the transfusion operation is to be performed. Where valves are used in applying negative and posi-

tive pressures to the outer container for the sequence of operations described above, separate valves may be employed, or a single valve with a suitable adaptor.

The device is subject to considerable modification without departure from the invention and in Figure 6 I have illustrated a modified form of needle unit wherein a continuous retractive movement of the plunger 22 at the end of the tube 23 in the needle sleeve 24 will result first in an application of suction at the needle aperture 25, and, after presence or absence of blood at that aperture indicates that the needle is in the right place, will subsequently connect the needle with the interior of the tube 26 for the infusion or transfusion operation. In this case the terminal end portion 22 of the tube is provided intermediate its ends with a chamber 27, this chamber being connected to the interior 26 of the tube 23 by a channel 28. Originally the inner end of the needle will be embedded in the material of the solid end portion 22, as illustrated in the drawings, so that it has no connection with the interior 26 of the tube 23, and when the plunger 22 is retracted in the sleeve 24 suction will first be imposed in the needle aperture 25, and with continued retraction the end of the needle will be caused to enter the chamber 27.

The rate of flow of the blood or other fluid medium into or from the inner container may be regulated as required by the size of the needle or by control of the tube passage in well known manner. Further adaptability at the delivery (or take) end to meet the requirements of particular conditions may be achieved by means of the device shown at 31 in Figures 1 and 6. At this point, in proximity to the closed end of the tube, the latter will be molded or otherwise fabricated with a beveled circumferential recess, the bevel being such that when the tube has been severed on the line 32 the resulting beveled terminal end will fit the hub socket of any standard needle or will receive an adaptor to which may be attached other delivery or take instruments designed for special purposes involving the use of positive or negative pressures as described.

In Figure 5 I have illustrated a type of construction wherein the inner container is permanently sealed within the outer casing. The said casing in this instance is provided with a neck 33 in which the sealing elements, including in the present instance a plastic disc 34, integral with or integrally attached to the tube 35 of the inner container, and a self-sealing rubber backing disc 36, are clamped between the intumed flange portions 37 and 38 of the neck. Discs 39 and 40 of metal or like semi-rigid material are placed respectively outside of the rubber disc 36 and inside the disc 34 to form solid abutments for the clamping flanges 37 and 38 of the casing. In the primary functional respects this construction corresponds to the embodiment illustrated in Figure 2 and described above.

In Figures 7, 8 and 9 I have illustrated a device for automatic regulation of rate of flow from the inner container. The regulating element 41, shown in Figure 7, may be composed of any suitable rigid material. This element, applied to the neck of the container 2, as illustrated in Figures 8 and 9, with the tube 4 passing through the aperture 42, assumes the position shown in Figure 8 when the container is full, and thereby distorts the tube and restricts the tube passage. Thus, when the effective pressure in the casing is at a maximum i. e., when the container is full and the pressure space in the casing is at a minimum, the passage through the tube is also at a minimum. As the contents of the container discharge and the container gradually collapses, the element 41 moves toward the position shown in Figure 8, and in the course of this movement the restriction of the tube is gradually reduced. The effective flow passage is thus increased as the effective pressure on the container is reduced, so that there is a tendency to maintain a uniform rate of discharge. Obviously, the device

works in reverse to regulate flow into the container from without under the effects of negative pressure in the casing, tending also in this case to maintain uniform rate of flow.

The needle shown in Figure 10, which may be used in place of needles of the type shown in Figures 3 and 6, differs in part from the latter type of needle in the lack of a hub element, and also in the fact that the hubless needle has one end 43 sealed and is provided near that end with a longitudinally arranged series of small apertures 44, the combined port area of which will equal or approximately equal the effective area of the needle bore. In practice the needle will occupy originally a position in the solid end of the tube 4 corresponding to the position of the needle 6 in Figure 3, and the exposed end 45 may be inserted in the tissues by manipulation of the solid end portion of the tube in which the one end of the needle is embedded. Either before or after insertion the inner end of the needle may be caused to penetrate the tube end so as to enter the hollow interior of the tube and to an extent establishing communication between said interior and at least one of the apertures 44. The rate of flow through the needle will be in part a function of the number of the apertures 44 exposed in the interior passage of the tube, so that the apertures afford a means for regulating the flow rate through the needle either to or from the inner container. If desired, a small projection or hub 46 may be provided on the exterior of the needle to aid in the operations of insertion in the tube end and in the tissues, and of penetration to the interior of the tube.

It is apparent that the unit may be readily tested for leakage in the inner container before use by holding the unit upright, that is tube end up, and opening the needle as described above. Any air or bubbles in the tube and discharging from the needle would indicate leakage.

I have found that there are certain advantages in employing in the unit a fluid pressure medium of the low boiling point type, such for example as Freon, which assumes a liquid state at relatively low temperatures and which volatilizes to the gaseous state when the temperature exceeds the stated boiling point. One advantage of the use of a fluid pressure medium of this type is the fact that it will afford, when used in properly calculated quantity and under controlled conditions, a substantially constant pressure within the unit regardless of the degree of inflation or deflation of the inner container. This insures a correspondingly substantially constant rate of flow to or from the inner container as the case may be. Another advantage resides in the fact that the unit may be kept, preparatory to use, in a state wherein the transfusion medium in the inner container is free from pressure of the fluid medium. Thus, the medium may be placed in the unit in the liquid state, the unit then being kept at a temperature below the boiling point of the medium until ready for use. When the temperature of the unit is brought to the operating temperature, which will exceed the boiling point of the medium, the vapor pressure of the medium places the inner container with its blood, plasma, or other content under the desired pressure for the infusion or transfusion operation. The pressure is a function in part of the temperature at which the operation is to be performed, the size of the containers and the quantity of the pressure medium available for conversion to the gaseous state, and the quantity of the medium required to maintain a desired substantially constant pressure during contraction of the inner container at the given temperature may be readily determined. To insure adequate pressure, an excess of the medium may be used.

In using this type of pressure propellant, only sufficient space may be provided between the inner and outer container walls to accommodate the required amount of liquid propellant. For expelling the contents of a one liter unit, for example, 50 cubic centimeters of propellant

may be used; and for one half liter, 25 cubic centimeters will be sufficient with substantial excess of the medium.

The reverse operation for charging the inner container may be conducted by starting with a deflated inner container and with the medium in gaseous state. By then reducing the temperature of the unit, the gas may be condensed to the liquid state with resultant formation within the outer container of a semi-vacuum which tends to expand the inner container and to draw into the latter fluid from the source with which it may be connected.

Of the available low boiling point substances I have found Freon to possess the desirable over-all properties for the purpose. Freon has a desirably low boiling point, in the neighborhood of 3.6° C. (Freon 114) and 8.9° C. (Freon 21), for example, as compared with ethyl chloride which has a boiling point of 12.5° C. Unlike the latter, Freon is neither inflammable nor poisonous. Either of the above mentioned Freons may be used, or they may be combined to afford an intermediate boiling point. With these propellants, the operating temperature range may be from around 10° C. to 40° C., which range embraces the normal room temperatures as well as the temperatures under which operations of this nature would ordinarily be conducted. Propellants of higher or lower boiling points may be used to extend this range if desired.

Where Freon is used as the pressure medium I prefer to form the inner plastic container of a high polymer of trifluorochloroethylene (Kel-F). This plastic is impervious to moisture and vapor transmission and is readily heat sealable. Polyethylene and polyvinyl chloride may also be employed, but the latter should be used only where the units are to be used within a short period after introduction of the Freon since Freon tends to lose its ability to volatilize readily after a limited period, say twelve hours, of contact with these plastics.

I have found it desirable also, where possible, to provide the interior surface of the inner container with a coating of silicone which makes the surface hemorepellent or non-wetting to blood, so that any tendency of the blood to adhere to or to clot on the surface is avoided.

The clysis unit described above has certain material advantages over the devices previously used for like purposes. It requires no support standard, for example, and can be placed in any position on any available support, or may be strapped to the body of the patient if desired. It is entirely free from possibility of airborne contamination since the container and tube provide an hermetically sealed envelope which excludes air both before and during use of the unit, a feature of material advantage over the prior devices. The high degree of mobility, compactness, and immediate availability of the unit also contribute materially to its utility.

In view of the adaptability of the unit for use with both positive and negative casing pressures and described above, the term "extra atmospheric" has been used in the broad sense to embrace pressures both above and below atmospheric.

I claim:

1. A clysis unit comprising in combination a casing, and a flexible container hermetically sealed within and having access to the exterior of the casing, said casing having a wall section composed of self-sealing needle-penetrable material capable of maintaining its self-sealing property when exposed at the opposite sides thereof to a substantial pressure differential.

2. A clysis unit comprising in combination an outer casing having a port, an inner flexible container having a tubular extension extending through said port, and needle-penetrable self-sealing means capable of maintaining its self-sealing property when exposed at the opposite sides thereof to a substantial pressure differential, said means being secured in and sealing the port around the tubular extension.

3. A clysis unit comprising in combination an outer

hermetically sealed casing, an inner flexible container having a port and means affording access to said port from outside of the casing, means responsive to changes in the volume of the fluid content of said container for controlling said port, and means for establishment of extra-atmospheric pressure in the space within said casing surrounding the container.

4. A unit according to claim 3 wherein the control means includes a flexible tube extending between the container wall and the port, together with an element engaged with the wall of the container and embracing the said tube and being movable with said wall between extreme positions corresponding respectively to the conditions of the container when full and empty of a fluid medium, said element constricting the tube when in the first of said positions and progressively reducing said constriction as it moves toward the other position.

5. A unit of the character described comprising an outer hermetically sealed casing, an inner flexible container having a port and means affording access to said port from the outside of the casing, means for establishment of extra-atmospheric pressure in the space within the casing surrounding the container, and a foraminous tube extending inwardly from the said port into the container and constituting a strainer for solid particles entrained in fluid passing to or from the container through said access means.

6. A unit of the character described comprising an outer casing, an inner flexible container having a port and means affording access to said port from the outside of the casing, the space within the casing surrounding the container forming an hermetically sealed pressure chamber, said access means comprising a normally closed flexible tube on the outside of the casing, said tube being shaped at its outer end for reception of a hypodermic needle assembly and being provided adjacent said outer end with a beveled circumferential recess which when the tube is severed will form a beveled terminal end for reception of a correspondingly socketed needle assembly.

7. Clysis apparatus comprising in combination an hermetically sealed casing, a flexible container within said casing, means for sealing the container with respect to the interior of the casing, means affording access to the casing for establishment of extra-atmospheric pressure in the space around the container and means for access to the container independently of the casing, the latter said means comprising a readily penetrable resilient element in sealing relation to the container and accessible for penetration from the exterior of the casing.

8. Clysis apparatus according to claim 7 wherein the penetrable element constitutes an integral part of the container.

9. Clysis apparatus according to claim 7 wherein the penetrable element is self-sealing after penetration.

10. Clysis apparatus according to claim 7 wherein the penetrable element is adapted for penetration by a hollow needle.

11. Clysis apparatus according to claim 7 wherein the said penetrable element is composed of rubber like material.

12. Clysis apparatus comprising in combination an hermetically sealed casing, an hermetically sealed flexible container within said casing and sealed from the interior of the latter, means affording access to the container from the exterior of the casing, and means affording access to the casing for establishment of extra-atmospheric pressures in the space around the container, the latter said means including an element in sealing relation to the casing and adapted for penetration by a hollow needle, and accessible for said penetration from the exterior of the casing.

13. Clysis apparatus according to claim 12 wherein the needle penetrable element is self-sealing.

14. Clysis apparatus comprising in combination an hermetically sealed casing, a flexible container within said casing having a resilient tubular extension, means affording access through said extension to the exterior of the casing, means of access to the interior of the casing for establishing extra-atmospheric pressures in the space around the container tending to distort the latter, and means responsive to said distortion of the container for regulating the rate of fluid movement to and from the container resulting from said distortion.

15. A clysis unit comprising in combination a sealed casing, a flexible container within the casing having a resilient tubular extension extending through the wall of the casing to the exterior of the latter, means for establishing extra-atmospheric pressure within the casing around the container and means responsive to distortion of the container for regulating the flow of fluid through said extension, said regulating means comprising an element engaged with the wall of the container and embracing the said resilient extension and being movable with said container wall between extreme positions corresponding respectively to the conditions of the container when full and empty of fluid, said element constricting the tube when in a first of said positions and progressively reducing said constriction as it moves toward the other position.

16. A clysis unit comprising an hermetically sealed casing, a flexible container in said casing also hermetically sealed, pressure means tending to distort the container in the casing to change the cubic content of the container, and means for access to the container independently of the casing, the latter said means comprising a readily penetrable element in sealing relation to the container and accessible for penetration from the exterior of the casing.

17. A clysis unit according to claim 16 wherein the pressure means consists of extra-atmospheric pressure within the casing around the container.

18. A clysis unit according to claim 17 including means for variably restricting the flow of fluid to and from the container in direct relation with the quantity of said fluid in the container.

19. A clysis unit according to claim 16 wherein the penetrable element is adapted for penetration by a hollow needle.

20. A clysis unit consisting of a casing, an hermetically sealed flexible container within the casing, means for applying distorting pressure to the container to change the cubic content thereof, and means for connecting a hypodermic needle to the container in communication with the interior of the latter.

21. A clysis unit according to claim 20 wherein the casing is hermetically sealed and comprises access means for establishing extra-atmospheric pressures in the space surrounding the container as the said pressure applying means.

22. A clysis unit according to claim 20 including a strainer interposed between the interior of the container and the point of needle connection.

23. A clysis unit consisting of an hermetically sealed casing, an hermetically sealed flexible container within the casing and means for connecting a hypodermic needle to and in communication with the interior of the container exterior to the casing, said casing having therein and within the space around said container extra-atmospheric pressure tending to distort said container.

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