Aug. 12, 1958 S. L. FOX 2,847,007

FLUID HANDLING UNIT AND APPARATUS

Filed July 19, 1954

FIG. 1.

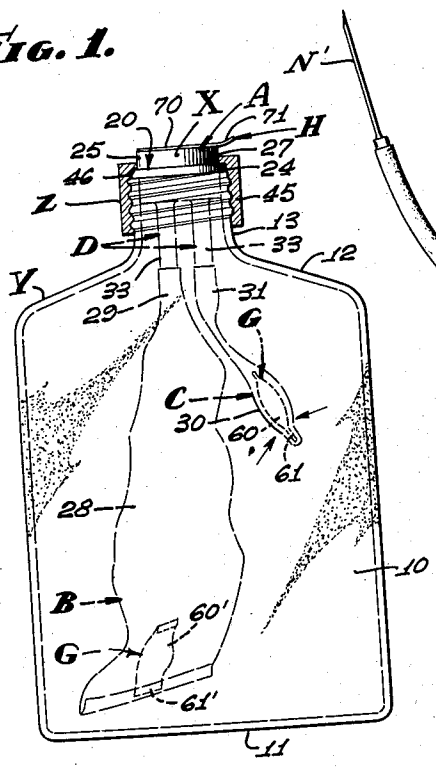


FIG. 2.

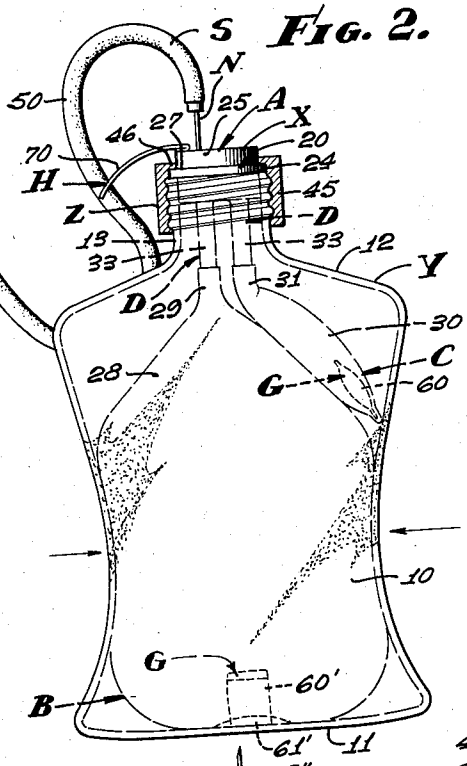


FIG. 3.

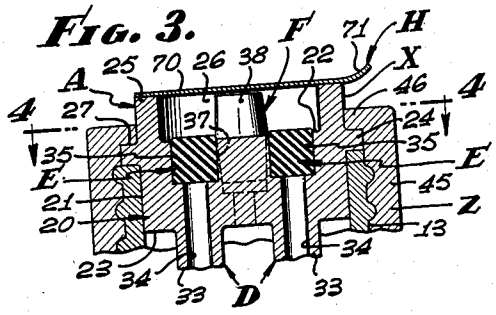


FIG. 6.

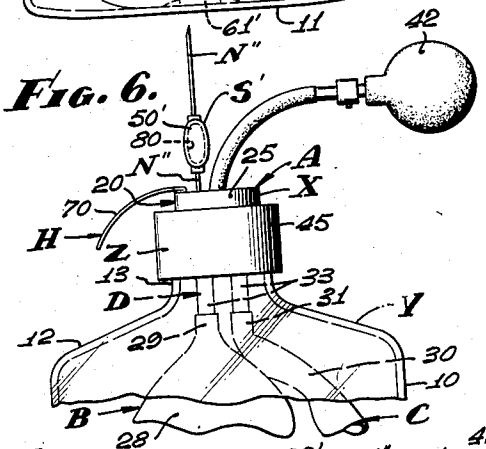


FIG. 4.

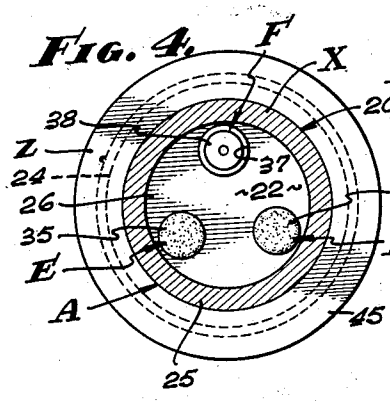


FIG. 5.

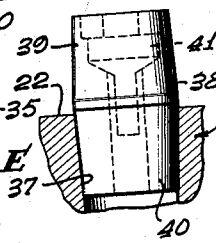
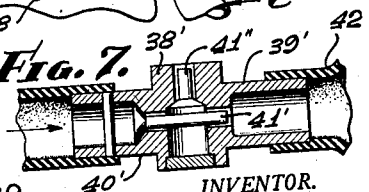


FIG. 7.



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FLUID HANDLING UNIT AND APPARATUS

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Application July 19, 1954, Serial No. 444,066

11 Claims. (Cl. 128—214)

This invention has to do with a fluid handling unit and apparatus, and is particularly concerned with a unit for collecting, storing, transporting and administering fluids, such as whole blood or plasma, or the like, in a safe, efficient and sterile manner that eliminates the danger of contamination, breakage and other handling problems.

In hospitals, laboratories, doctors' offices or like places, it is common practice to extract and to administer whole blood or plasma from or to persons being treated. In the handling of such fluids it is not only necessary to handle a supply thereof, but it is also necessary to take separate samples of the fluid being handled so that various tests such as those for cross-matching of blood can be made in order to determine the nature or type of fluid being handled. Therefore, it is necessary to associate or identify the test sample with the supply of fluid handled so that the proper sample is always associated and identified with the supply of fluid taken.

It is an object of this invention to provide a fluid handling unit and apparatus particularly useful for handling whole blood so that it can be stored in a container that is integrally associated with a sample container of the same whole blood, to the end that the storage container and the sampling container are never separated thus avoiding danger of loss or confusion as to the type of blood when cross-matching the blood samples.

It is also an object of this invention to provide a unit and apparatus of the character referred to which includes supplemental fluid containers in the form of fracturable or rupturable capsules, or the like, which contain anticoagulants, preservatives, or other saline solutions adapted to act upon the fluid in the container which is provided.

It is also an object of this invention to provide a unit and apparatus of the character referred to which provides an easily manipulated means which is adapted to be used particularly in cases of emergency when pressure infusion is desired, and the infusion or withdrawal of fluid from a person may be expedited without subjecting the person to the danger of air embolism.

It is another object of this invention to provide a unit and apparatus of the character referred to which provides a simple and easily manipulated means for pumping the containers, either to fill or to exhaust fluid therefrom.

A further object of this invention is to provide a unit of the character referred to which is convertible in its use, to be useful either as a pressure apparatus or a vacuum apparatus. With the structure of the present invention the infusion or withdrawal of blood may be forced by a simple and easily manipulated means for pumping the containers or the administering or withdrawing of blood may be done under pressure.

It is still another object of this invention to provide a unit and apparatus to be used in the collecting, storing, transporting and administering of whole blood or plasma and which is adapted to be used in connection with a needle or a conventional or standard "blood donor set," comprising a pair of tubular needles connected by a flexible hose or tube, which unit and apparatus is adapted to handle a large quantity of whole blood or plasma, as well as a small sample quantity thereof.

It is still a further object of this invention to provide a unit and apparatus as above referred to, which seals the containers handling the whole blood or plasma after the tubular needle of the "blood donor set" or the like, has been removed from the unit.

It is also an object of this invention to provide a unit and apparatus of the character referred to which is completely sterile and can be assembled as a unit and sterilized at the place of manufacture, which unit is cheap and inexpensive of manufacture so that it is expendable.

The various objects and features of the invention will be fully understood from the following detailed description of typical preferred forms and applications of the invention, throughout which description reference is made to the accompanying drawings, in which:

Figs. 1 and 2 are elevational sectional views of the apparatus as provided by the invention, Fig. 1 showing the unit of the present invention before it is filled with fluid, and Fig. 2 showing the unit of the present invention after it has been filled with fluid. Fig. 3 is an enlarged detailed sectional view of the upper portion of the unit as shown in Fig. 1. Fig. 4 is a plan section taken as indicated by line 4—4 on Fig. 3. Fig. 5 is an enlarged detailed view of a portion of the device, and Figs. 6 and 7 are views of another form of the present invention, Fig. 6 being a view of a portion of the structure similar to a portion of Fig. 2 of the drawings, and Fig. 7 being an enlarged detailed sectional view of a part of the structure shown in Fig. 6.

This invention involves, generally, an integral unitary structure or fluid handling unit X adapted to be inserted into a carrier or vessel Y, such as a jar or bottle which is adapted to be pressurized or vacuumized, and a coupling means Z. In accordance with the present invention the several parts of the unit X are integrally joined, that is, the several parts are permanently fastened together so that they cannot become separated. It will be apparent from the drawings that the several parts of fluid handling unit X, formed and related as shown, are such that they can be easily and practically molded or otherwise suitably formed from a suitable plastic material, such as polyethylene or modifications thereof such as fluorinated polyethylene or chlorinated polyethylene, or various polyvinyl compounds may be used, either acetates, alcohols or chlorides, etc. The particular material or composition used in any particular case may be selected in accordance with the conditions to be met. The materials mentioned are thermo-plastics and are essentially inert at the temperatures required for the class of use indicated. Further, they are capable of being worked or formed by extrusion, injection or compression molding or by deposition on forms from dispersions known as "plastisols" or from solutions in some instances. Furthermore, it is practical to employ a material which can be molded hot so that the formation of the unit X serves to sterilize the elements thereof and may, in practice, supplement initial sterilization which may be resorted to as circumstances require.

It is to be understood, of course, that although material such as polyethylene or polyvinyl is referred to as the material out of which to form the several parts of the unit X, it is not to be implied that the invention is limited to the use of this or any other particular material, and when the term "plastic" is used all other materials or combinations of materials are meant to be included within such term that may serve to carry out the inventive concept herein set forth.

The carrier or vessel Y to which the unit X is to be

applied or to be inserted into may be a plunger operated syringe-type container but is preferably a simple jar or bottle shaped vessel. As shown in the drawings, the vessel Y has a cylindrical outer wall **10**, a circular bottom **11** joining the outer wall at the lower end of the vessel, a top **12** joining the outer wall at the upper end of the vessel, and a neck portion **13** projecting upwardly from the top **12** and terminating in an upwardly faced opening.

The neck portion **13** has a threaded exterior as commonly employed in vessels of the type under consideration. In the preferred form of the invention the vessel Y is made of flexible resilient material such as polyethylene and may be termed a "squeeze bottle." The vessel Y or "squeeze bottle" is such that it can be deformed or compressed by suitable manipulation after which it will return to its original shape. It is to be understood, however, that the vessel Y may be of any material. That is, it may be a rigid vessel of glass or the like of any desirable shape.

The fluid handling unit X provided by this invention is a medical or surgical device to be employed in hospitals, doctors' offices, and laboratories, or the like, for the transfer of fluid such as whole blood from or to a donor or patient as the case may be. Referring to the drawings, the unit X includes a head A, a fluid storing container B carried by the head, a fluid sampling container C carried by the head adjacent the container B, a plurality of connectors D permanently joining the containers B and C to the head A, a plurality of seals E at the head A and closing the connectors D, means F for checking flow of air through the head A, supplemental fluid supplies G carried within the containers B and C, and a protector H provided to cover the active portions of the unit X. The unit X is a complete and usable structure and may be used by itself or, as shown throughout the drawings, it may be inserted into a vessel Y for protection and ease of handling and manipulation.

The head A forms a body-like part to which the other elements of the unit X are permanently attached. That is, the containers B and C, the connectors D, the seals E and the supplemental fluid supplies G are all integrally fastened together through the head A. In order to adapt the unit X to a vessel Y in the nature of a jar or bottle, the head A is in the form of a stopper or cap **20** and has a cylindrical exterior **21** proportioned to be frictionally received in the neck portion **13** of the vessel Y, a flat top **22** and a flat bottom **23**. A laterally projecting flange **24** is provided at the top **22** which overlies and stops against the top of the neck portion **13**. In addition to the above mentioned parts, the head A is provided with a tubular extension **25** that projects upwardly from the top **22** forming a chamber **26**. As clearly illustrated in the drawings, the extension **25** is smaller in diameter than the fiange **24** leaving an annular shoulder **27** that faces upwardly.

The coupling means Z that is provided is adapted to secure the fluid handling unit X to the vessel Y and involves a threaded collar **45** adapted to be threadedly engaged with the neck portion **13** of the vessel Y. The collar **45** has an inwardly turned flange **46** at the upper end thereof which overlies and clamps the flange **24**, above referred to, into sealed engagement with the upper end of the neck portion **13** of the vessel Y.

The fluid storing container B is a cell-like structure or bag and is characterized by a continuous imperforate wall **28** of supple inert film-like material, such as a vinyl plastic material. As shown in Figs. 1 and 2 of the drawings, the container B is a closed cell having an extension **29** in the form of a tube integrally formed with the cell and provided to handle fluid as the fluid flows to and from the container B. In preferred practice the fluid storing container B is initially collapsed as shown in Fig. 1 of the drawings and is inflatable as shown in Fig. 2 and, for example, may be of a size or capacity to hold 500 cubic centimeters of fluid.

The fluid sampling container C, which may be referred to as a "pilot," is a cell-like structure or bag, like the container B, and is also characterized by a continuous imperforate wall **30** of supple inert film-like material, such as a vinyl plastic material. It is to be understood that there may be one or more fluid sampling containers C as circumstances require. The container C is a closed cell having an extension **31** in the form of a tube integrally formed with the cell and provided to handle fluid as it flows to and from the container C. As shown in Fig. 1 of the drawings, the container C is initially collapsed and is inflatable as shown in Fig. 2 and, in practice, may be of a size to hold only a small amount of fluid, say, for example, 5 to 10 cubic centimeters.

There is a plurality of connectors D joining the containers B and C to the head A, and each connector is a simple tube **33** preferably molded integrally with the head A to depend from the bottom **33** thereof. For each container B and C there is a passage **34** entering the top **22** of the head A and in communication with a tube **33**, there being a tube **33** joined to the extension projecting from each container. As shown in the drawings, a tube **33** is joined to the extension **29** of the fluid storing container B, while a tube **33** is joined to the extension **31** of the fluid sampling container C. It is preferred that the fluid containers B and C be separate parts or elements permanently secured to the connectors D as by heat or adhesives as circumstances require.

The seals E are provided to close the passages **34** so that the interiors of the containers B and C are closed to the atmosphere surrounding the unit X and each seal may be a body or plug **35** of soft yielding material, such as rubber or the like, that is easily punctured as by a needle N and which will close together by the self-sealing action of the rubber or like material when the needle N is withdrawn therefrom. The plugs **35** may be secured in the passages **34** by suitable adhesives or the like permanently sealing them with the head A.

In order to fill or empty the containers B and C, a conventional or standard "blood donor set" S may be employed comprising a pair of tubular needles N and N' connected by a flexible fluid conduit or tubing **50**. When it is desired to fill or empty a container B or C, as the case may be, air is exhausted from the donor set and the needle N is manipulated to puncture the seal E closing the container so that the container is in communication with the other needle N' which may be inserted into the flesh of the donor or patient. When the needle N is removed from the seal E, the seal yieldingly closes behind the needle shutting off the interior of the container from the atmosphere surrounding the unit X.

It is a feature of this invention that a supplemental fluid supply G, for instance, a secondary fluid supply of anti-coagulants, preservatives or other reagents or salines is provided. Suitable materials such as powders or fluids are provided in the supply G ready to be mixed either immediately before, during, or after use of the device. The supply G may contain anti-coagulants, preservatives or other reagents or any desired saline solution. In the case illustrated I have shown a secondary or supplemental fluid container **60** carried by the container C, and a secondary or supplemental fluid container **60'** carried by the container B. The containers **60** and **60'** are in the form of thin-walled or fracturable elements filled with suitable material and located within the containers B and C. In the case illustrated the fracturable containers **60** and **60'** are anchored in the container walls at the lower ends thereof where portions **61** and **61'** of the containers **60** and **60'** are held between the sealed or joined ends of the containers. With such an arrangement and relationship of parts, initial application of pressure to the cell, say at the rear end thereof, as indicated by the arrows in Fig. 1, will break the containers and liberate

the contents thereof so that it mixes or co-mingles with the contents of the containers. It will be apparent, however, that by suitable handling of the device the secondary containers **60** and **60'**, when employed, need not be fractured or ruptured but can be fractured at any desired time, as circumstances require.

The means F provided for checking the flow of atmosphere to or from the vessel Y involves, generally, a simple check valve adapted to control the flow of atmosphere through the head A into or out of the interior of the vessel Y as circumstances require. In the preferred form of the invention where a flexible vessel or "squeeze bottle" is employed a vent or port **37** is provided that extends through the head A from the top **22** to the bottom **23** thereof, which port is somewhat tapered. When gravity and/or venous pressure of the patient is employed to fill a container the port **37** is left open to allow for free flow of atmosphere from the vessel Y. Or, when blood is being given to a patient the vessel Y may be elevated and inverted so that gravity acts to aid the flow of fluid whereupon the port **37** allows for free flow of atmosphere into the vessel Y.

A reversible valve body **38** is provided which has like tapered end portions **39** and **40** engageable in the port **37**. Either end of the valve body **38** may be engaged in the port **37** so that the valve is carried in sealed engagement with the head A. The valve body **38** has a seat, and a valve element **41** engages the seat checking the flow through the valve body so that the flow can occur in one direction only. It will be readily understood that when it is desired to exhaust the atmosphere from the vessel Y, it is merely necessary to arrange the valve body **38** so that flow will occur therethrough in a direction to permit air to be removed from the vessel and so that it cannot re-enter the vessel. When it is desired to pressurize the interior of the vessel Y, it is merely necessary to reverse the valve so that it is in a position opposite to that above referred to. When a flexible vessel Y is employed it is a simple matter to gain the desired pumping action by manipulation of the cylindrical wall **10** of the vessel, as illustrated by the arrows in Fig. 2 of the drawings.

In the form of the invention shown in Figs. 6 and 7 of the drawings, a rigid vessel or substantially rigid vessel Y is employed and a separate pumping means is provided in the form of a bulb **42** for pressurizing atmosphere within the vessel. The bulb may be connected with the interior of the vessel Y through a flexible tubing or hose, which hose may be provided with a tapered end portion engageable in the port **37**. A valve body **38'** is provided, which body has like end portions **39'** and **40'** engageable in the bulb and the hose respectively. The body **38'** has a seat, and a valve element **41'** engages the seat checking the flow through the body **38'** so that flow occurs in one direction only. In this form of the invention the valve body **38'** is also provided with another seat and a valve element **41''** which checks flow from the flow passage that extends through the valve body. The valve element **41''** checks flow from the valve body at one end thereof as shown, so that a pumping action is obtained when the bulb **42** is manipulated to force air into the vessel Y as desired. It will be understood that the valve body **38'** and the elements therein may be made to be reversed or arranged in an opposite manner in order to vacuumize the vessel, if so desired.

In accordance with the present invention, a protector H is provided which closes the chamber **26** to the end that the fluid handling elements of the unit X are prevented from coming into contact with foreign objects. That is, the seals E are enclosed in the chamber **26** and are covered by the protector H which may be a simple sheet-like element **70** joined to the end of the tubular extension **25**. In practice, the element **70** is releasably joined to the extension **25** by means of an adhesive and may be removed by lifting a tab **71** with the fingers and may be re-applied to the extension **25** when desired.

In Fig. 6 of the drawings there is illustrated a modified form of "blood donor set" or unit S' that involves generally a pair of oppositely disposed needles N'' and a tubular body **50'**. The tubular body **50'** is closed at its ends and is preferably a rigid member forming a fluid handling chamber **80**. The needles N'' are tubular parts and are rigidly fastened to the ends of the body **50'** to project therefrom and are both in direct communication with the interior of the chamber **80**. In order to use the "blood donor set" S' it is merely necessary to insert one of the needles N'' into the sealing means E, above described, whereupon the other needle N'' is adapted to be directly engaged with the patient. As shown, the chamber **80** is filled with a pack of suitable filtering material so that the fluid passing through the device is cleaned of any blood clots or foreign particles.

From the foregoing it will be apparent that the fluid handling unit X is a simple, inexpensive, sterile structure that can be easily applied to a vessel Y and which can be utilized to aid in the extraction or administering of fluid, such as whole blood or plasma to or from a patient. The "pilot" or sample container C, which is permanently attached to the storing container B, is always adjacent the said storing container so that cross matching or other testing of the "pilot" or sample is always associated or identified with the fluid carried in the storing container.

It will also be understood from the foregoing, that the apparatus provided can be inverted and held in an elevated position by means of a bail secured to the vessel Y to administer blood by force of gravity, and it will also be apparent that in emergencies or when it is otherwise desired, it is a simple matter to speed up the flow of blood by manual manipulation of the apparatus provided.

Having described only typical preferred forms and applications of the invention, applicant does not wish to be limited or restricted to the specific details herein set forth, but wishes to reserve any variations or modifications that may appear to those skilled in the art and fall within the scope of the following claims.

Having described the invention, applicant claims:

1. A fluid handling apparatus of the character described, comprising, a flexible vessel of resilient material and adapted to be deformed as by manipulation and having a neck with an opening therein, and a unitary device adapted to be carried by the vessel and including, a head to be secured in the neck to close the opening in the vessel, a fluid handling container permanently joined to the head, and a tubular connector projecting from the head and in communication with said container.

2. A fluid handling apparatus of the character described, comprising, a flexible vessel of resilient material and adapted to be deformed as by manipulation and having a neck with an opening therein, and a unitary device adapted to be carried by the vessel and including, a head to be secured in the neck to close the opening in the vessel, a plurality of fluid handling containers permanently joined to the head, and a plurality of tubular connectors projecting from the head and each in communication with a container.

3. A unitary fluid handling device of the character described, including, a single head, a plurality of fluid handling containers permanently joined to the head, there being tubular connectors projecting from the head and in communication with the containers, seals at each connector closing the connector and container in communication therewith, and a supplementary fracturable container within one of the said containers and adapted to release material into the said container.

4. A fluid handling apparatus of the character described, comprising, a vessel having a neck with an opening therein, and a unitary device adapted to be carried by the vessel and including, a head secured in the neck to close the opening in the vessel, and a plurality of collapsible fluid handling containers permanently joined to the head to be carried and supported within the vessel, and

a plurality of seals in the head associated with the containers and each closing the container associated therewith.

5. A fluid handling apparatus of the character described, comprising, a vessel having a neck with on opening therein, and a unitary device adapted to be carried by the vessel and including, a head secured in the neck to close the opening in the vessel, a collapsible container for storing fluid and permanently joined to the head, a second collapsible container adjacent the first mentioned container and for sampling fluid and permanently joined to the head, and tubular connectors projecting from the head and into the vessel and in communication with the containers, said containers being carried and supported within the vessel.

6. A fluid handling apparatus of the character described, comprising, a vessel having a neck with an opening therein, and a unitary device adapted to be carried by the vessel and including, a head secured in the neck to close the opening in the vessel, a collapsible container for storing fluid and permanently joined to the head, a second collapsible container adjacent the first mentioned container and for sampling fluid and permanently joined to the head, tubular connectors projecting from the head and into the vessel and in communication with the containers, seals at each connector closing the connectors and the containers in communication therewith, and means checking flow of atmosphere through the head and in communication with the interior of the vessel surrounding the said containers, including a passage through the head, and a check valve engaging and closing the passage against flow in one direction, said containers being carried and supported within the vessel.

7. A fluid handling apparatus of the character described, comprising, a flexible resilient vessel having a neck with an opening therein, and a unitary device adapted to be carried by the vessel and including, a head secured in the neck to close the opening in the vessel, a collapsible container for storing fluid and permanently joined to the head, a second collapsible container adjacent the first mentioned container and for sampling fluid and permanently joined to the head, tubular connectors projecting from the head and into the vessel and in communication with the said containers, seals at each connector closing the connector and the containers in communication therewith, and means checking flow of atmosphere through the head and in communication with the interior of the vessel, including a passage through the head, and a check valve engaging and closing the passage against flow in one direction, said containers being carried and supported within the vessel.

8. A fluid handling apparatus of the character described, comprising, a vessel having a neck with an opening therein, and a unitary device adapted to be carried by the vessel and including, a head secured in the neck to close the opening in the vessel and having a tubular extension forming a chamber, a plurality of collapsible fluid handling containers permanently joined to the head, tubular connectors projecting from the head and in communication with the containers and with the said chamber, and a removable protector normally secured to the extension of the head and closing the chamber.

9. A fluid handling apparatus of the character described, comprising, a vessel having a neck with an opening therein, and a unitary device adapted to be carried by the vessel and including, a head secured in the neck to close the opening in the vessel, a collapsible container for storing fluid and permanently joined to the head, a second collapsible container adjacent the first mentioned container and for sampling fluid and permanently joined to the head, and tubular connectors projecting from the head and into the vessel and in communication with the said containers, and means checking flow of atmosphere through the head and in communication with the interior of the vessel, said containers being carried and supported within the vessel.

10. A fluid handling apparatus of the character described, comprising, a vessel having a neck with an opening therein, and a unitary device adapted to be carried by the vessel and including, a head secured in the neck to close the opening in the vessel, a collapsible container for storing fluid and permanently joined to the head, a second collapsible container adjacent the first mentioned container and for sampling fluid and permanently joined to the head, and tubular connectors projecting from the head and into the vessel and in communication with the said containers, and means controlling flow of atmosphere through the head and in communication with the interior of the vessel, including, a passage through the head, a hose connected to the passage, a manually operable bulb carried by the hose, and a valve associated with the bulb and controlling the direction of flow through the hose, said containers being carried and supported within the vessel.

11. A unitary fluid handling device of the character described, including, a single head, a plurality of fluid handling containers permanently joined to the head, there being tubular connectors projecting from the head and in communication with the containers, seals at each connector closing the connector and container in communication therewith, and a blood donor unit comprising a needle adapted to pierce one of said seals to thereby be carried by the head and to be in communication with the interior of a container, a second needle in fluid connection with the first mentioned needle and adapted to be inserted into a patient, and a filter in the fluid connection between the needles.

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