United States Patent [19]

McPhee

[11] **3,921,630**

[45] **Nov. 25, 1975**

[54] **THERMOPLASTIC BOTTLE WITH CONTROLLED LATERAL COLLAPSE AND METHOD OF DISPENSING LIQUID THEREFROM**

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[73] Assignee: **American Hospital Supply Corporation,** Evanston, Ill.

[22] Filed: **Feb. 26, 1974**

[21] Appl. No.: **445,836**

[52] **U.S. Cl.**... **128/214 R;** 128/DIG. 24; 128/214 D; 128/272; 215/1 C; 215/231; 222/107

[51] **Int. Cl.²**..... **A61M 5/14**

[58] **Field of Search**..... 128/214 R, 214 D, 214.2, 128/272, DIG. 24; 222/92, 107; 53/22; 215/1 C, 100 A, 231

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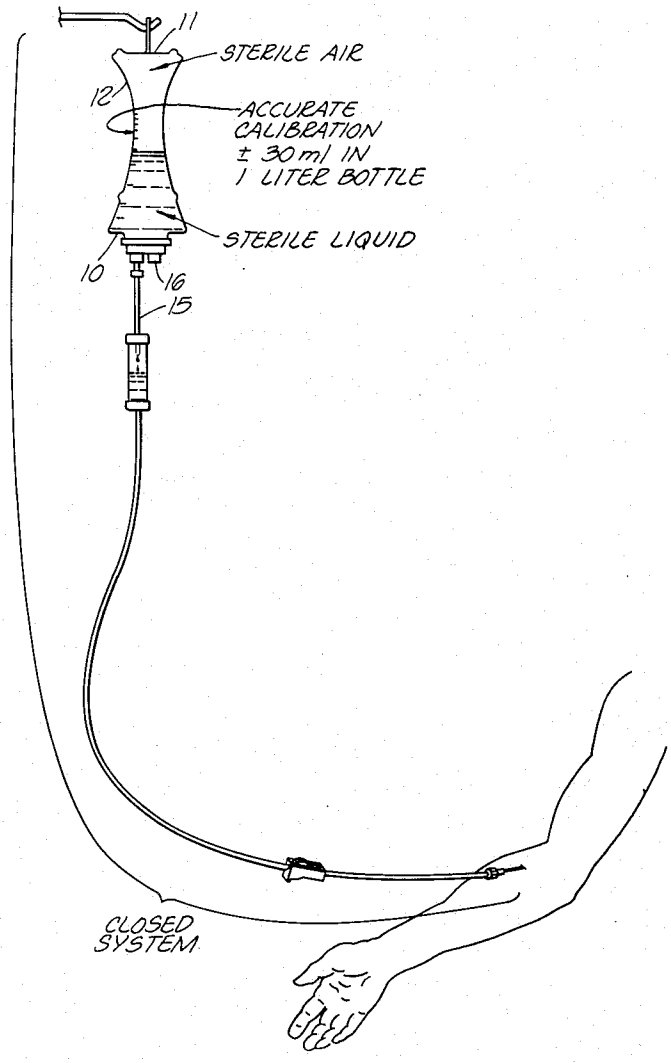
Primary Examiner—Dalton L. Truluck

Attorney, Agent, or Firm—Dawson, Tilton, Fallon & Lungmus

[57] **ABSTRACT**

A collapsible oval thermoplastic bottle that accurately measures the volume of sterile medical liquid dispensed without inletting air into the bottle. The bottle contains a sterile liquid and a constant mass of sterile gas above the liquid. A rigid oval base and a rigid oval shoulder of the bottle cooperate with a flexible oval side wall of the bottle to "control the lateral collapse" of the bottle. This "controlled collapse" redistributes the constant mass of gas within the bottle to maintain portions of the side wall at the liquid level in space relationship for accurate volumetric readings against calibrations on the bottle. A 1 liter collapsible bottle has an accuracy of ±30 ml., which accuracy is equivalent to that of a rigid glass bottle of the same size.

24 Claims, 31 Drawing Figures



FLEXIBLE THERMOPLASTIC BAG (PRIOR ART)

STORING

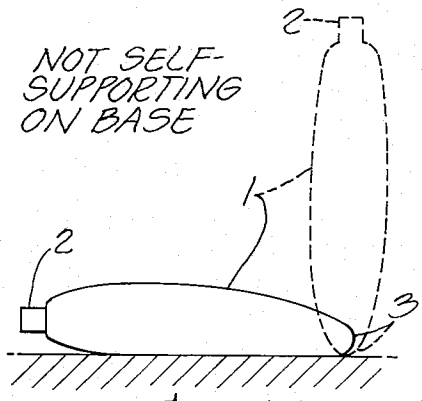


FIG. 1A.

DISPENSING

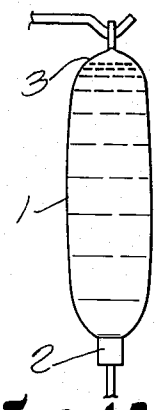


FIG. 1B.

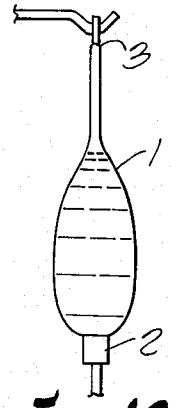


FIG. 1C.

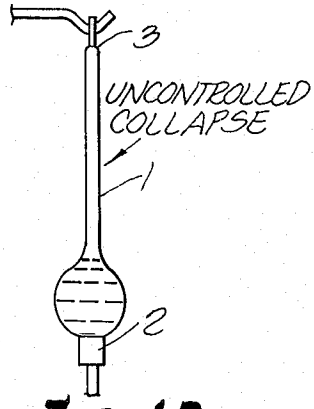


FIG. 1D.

RIGID GLASS BOTTLE (PRIOR ART)

STORING

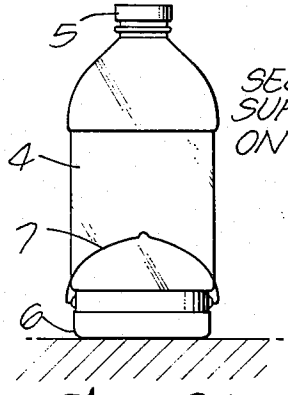


FIG. 2A.

DISPENSING

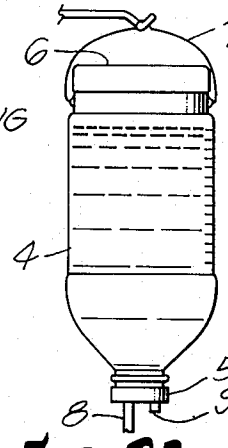


FIG. 2B.

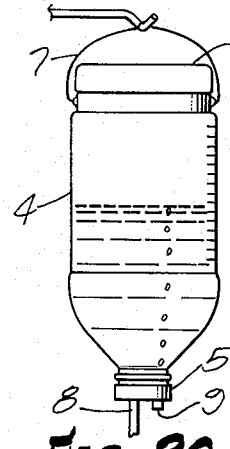


FIG. 2C.

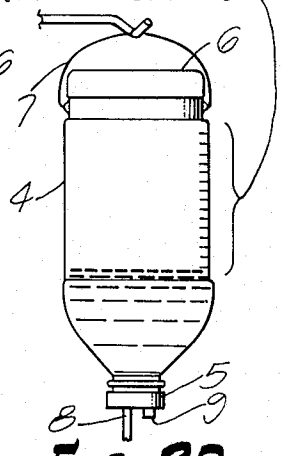


FIG. 2D.

APPLICANT'S "CONTROLLED COLLAPSE" BOTTLE

STORING

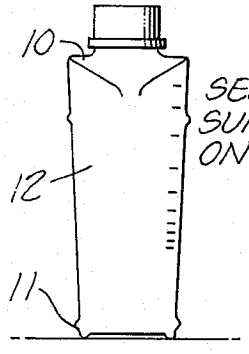


FIG. 3A.

DISPENSING

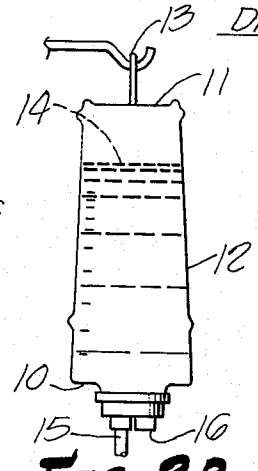


FIG. 3B.

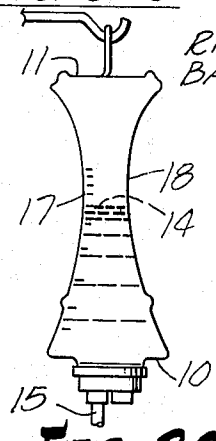


FIG. 3C.

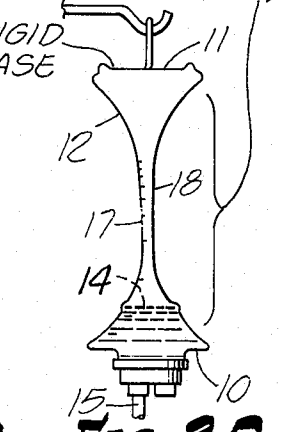


FIG. 3D.

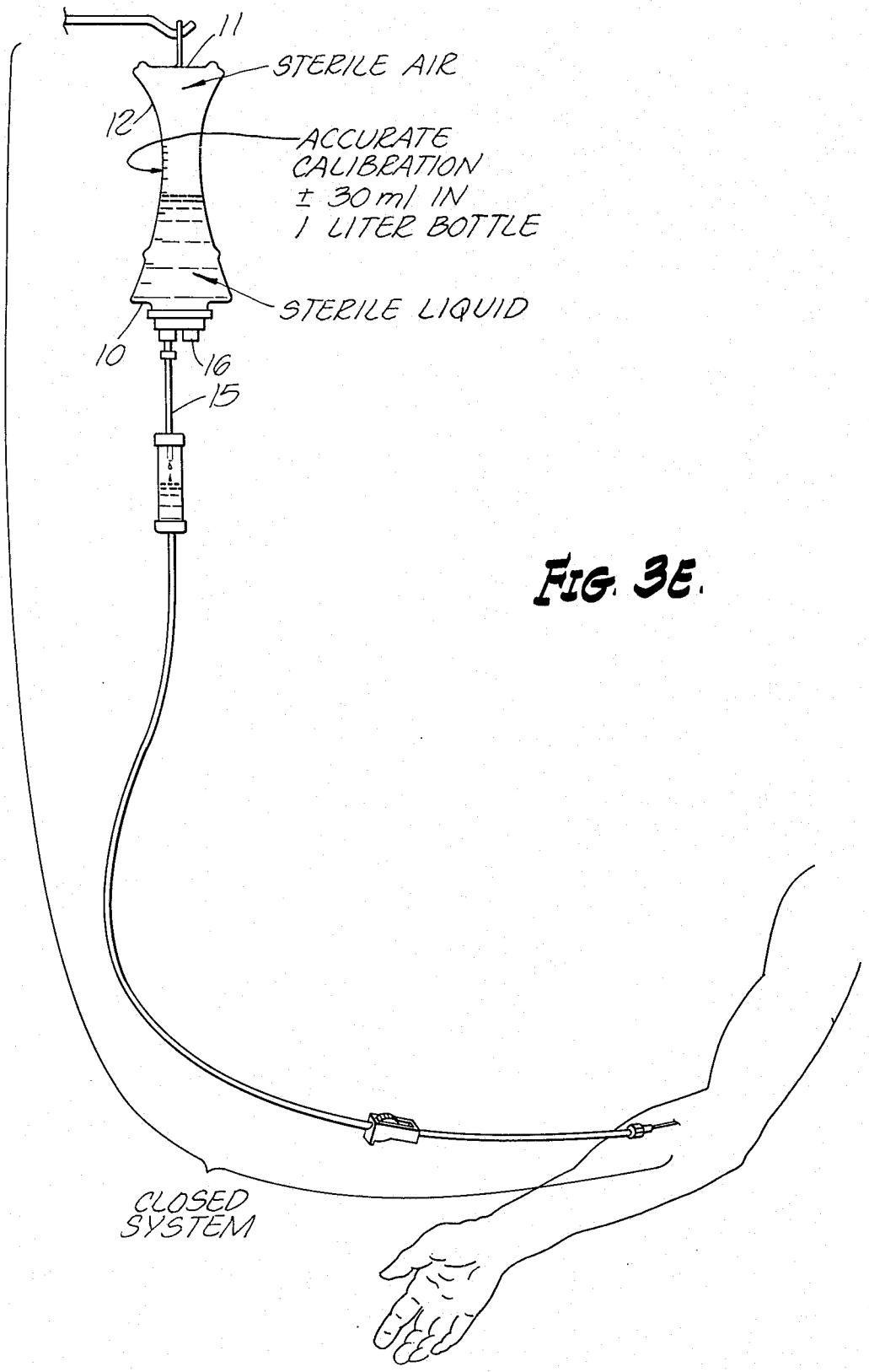

11
STERILE AIR
12
ACCURATE
CALIBRATION
± 30 ml IN
1 LITER BOTTLE
STERILE LIQUID
10
16
15
CLOSED
SYSTEM

FIG. 3E.

FIG. 4.

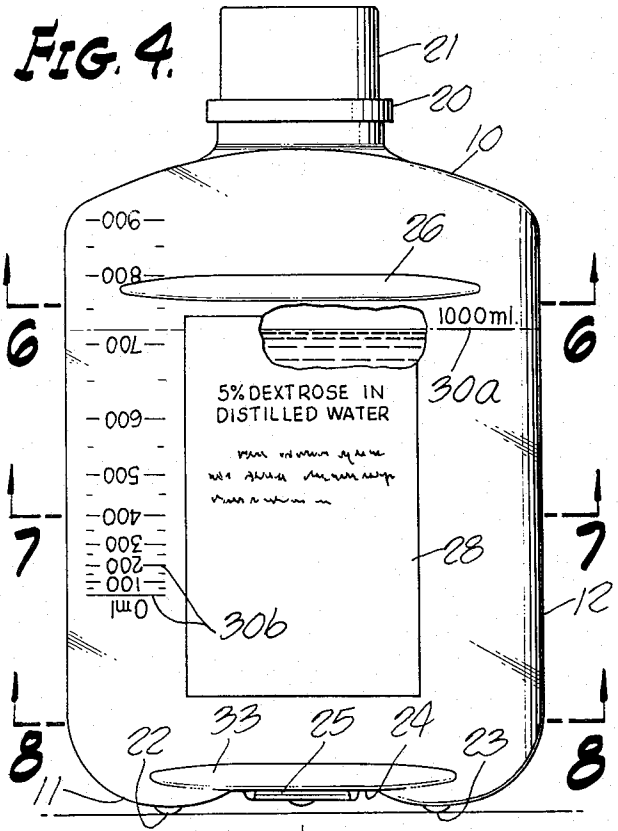


FIG. 5.

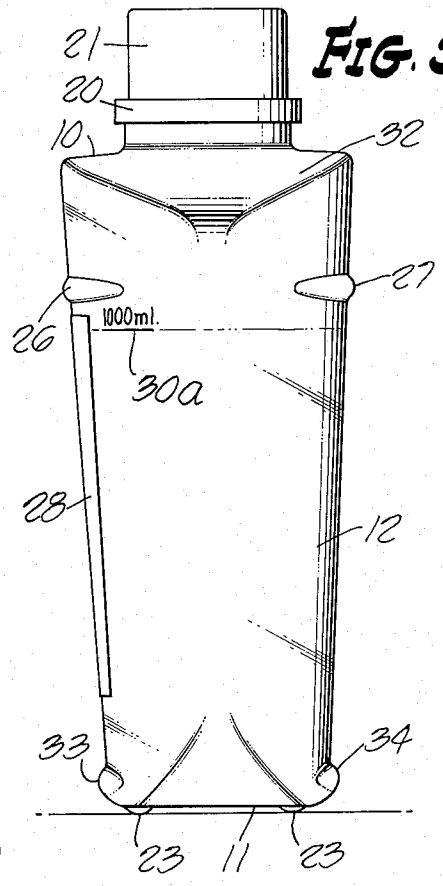


FIG. 6.

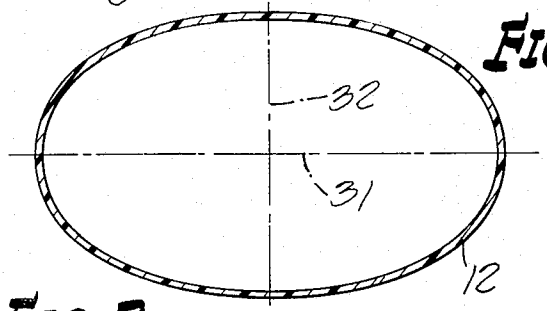
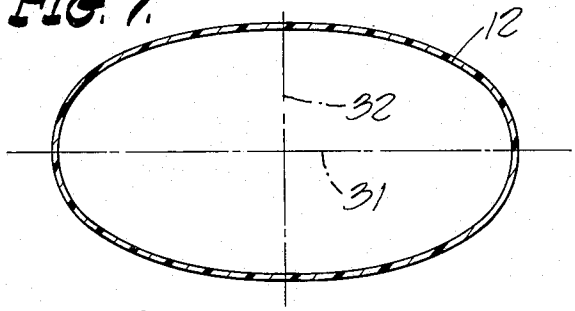


FIG. 7.



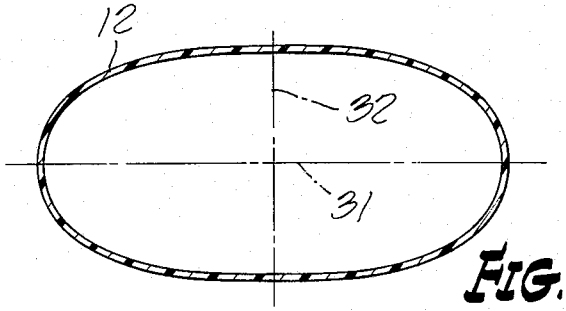
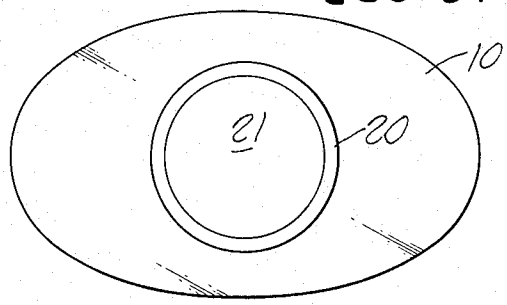


FIG. 8.

FIG. 9.



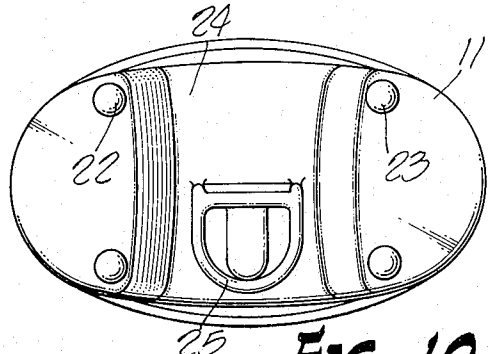


FIG. 10.

FIG. 11.

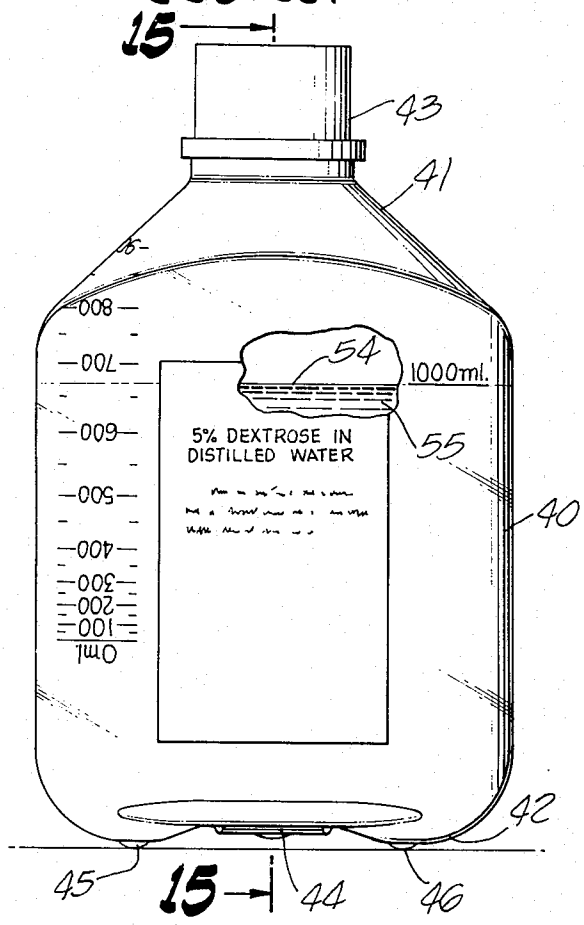


FIG. 12.

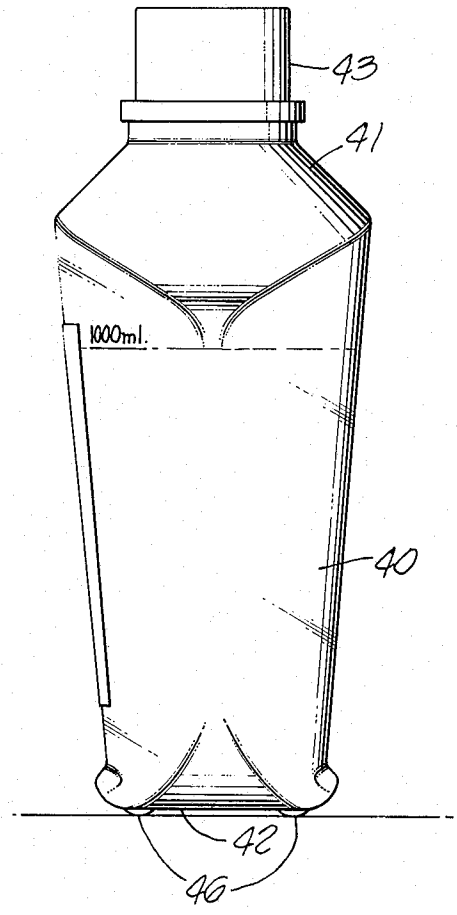


FIG. 13.

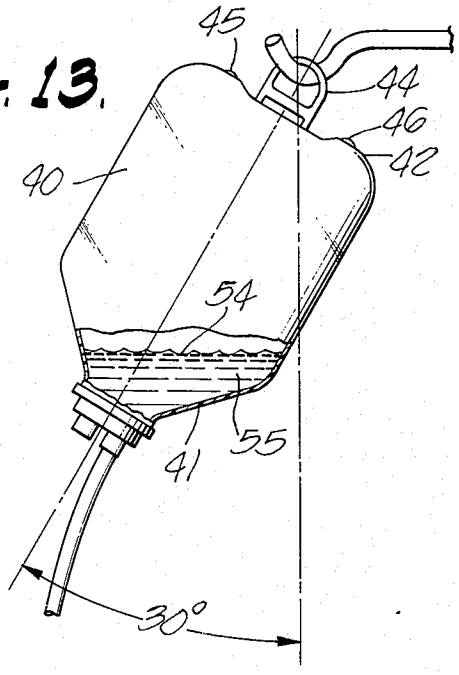
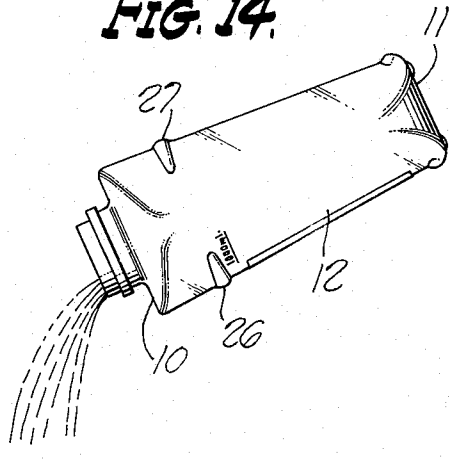


FIG. 14.



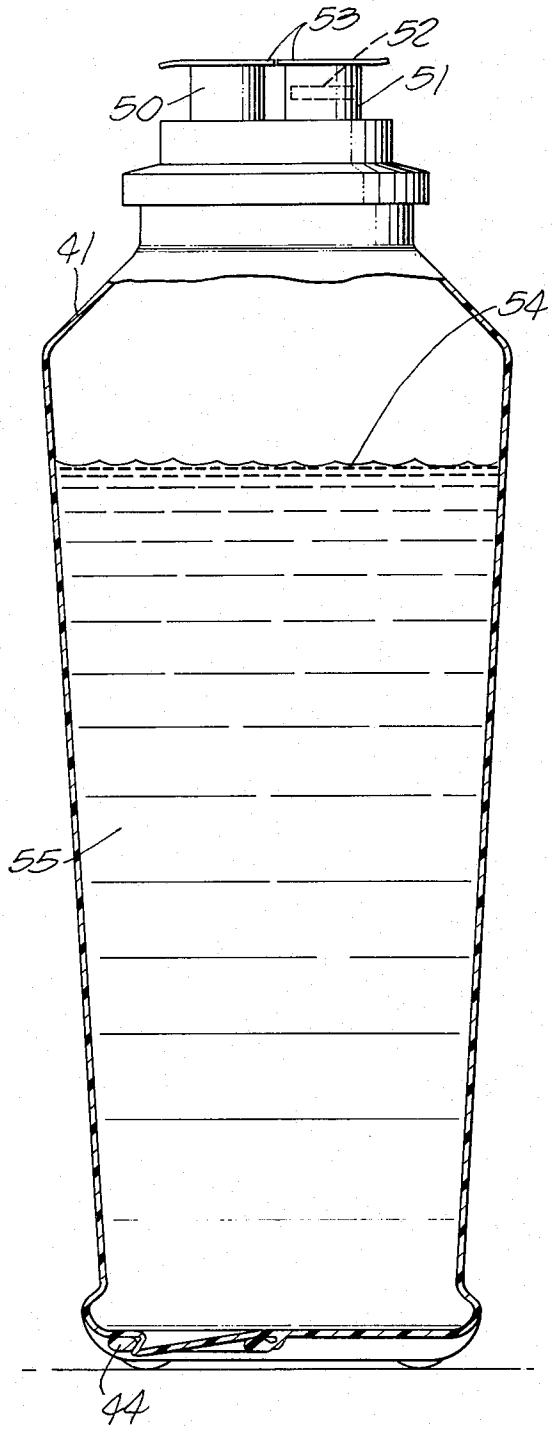


FIG. 15.

FIG. 16.

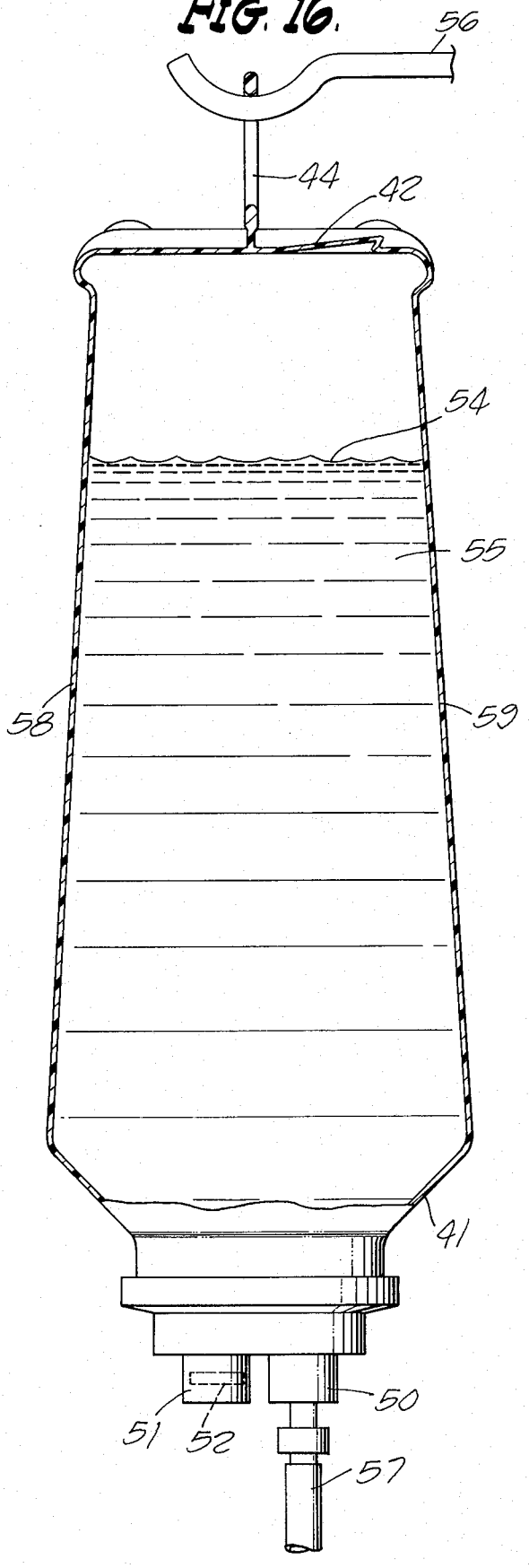


FIG. 17.

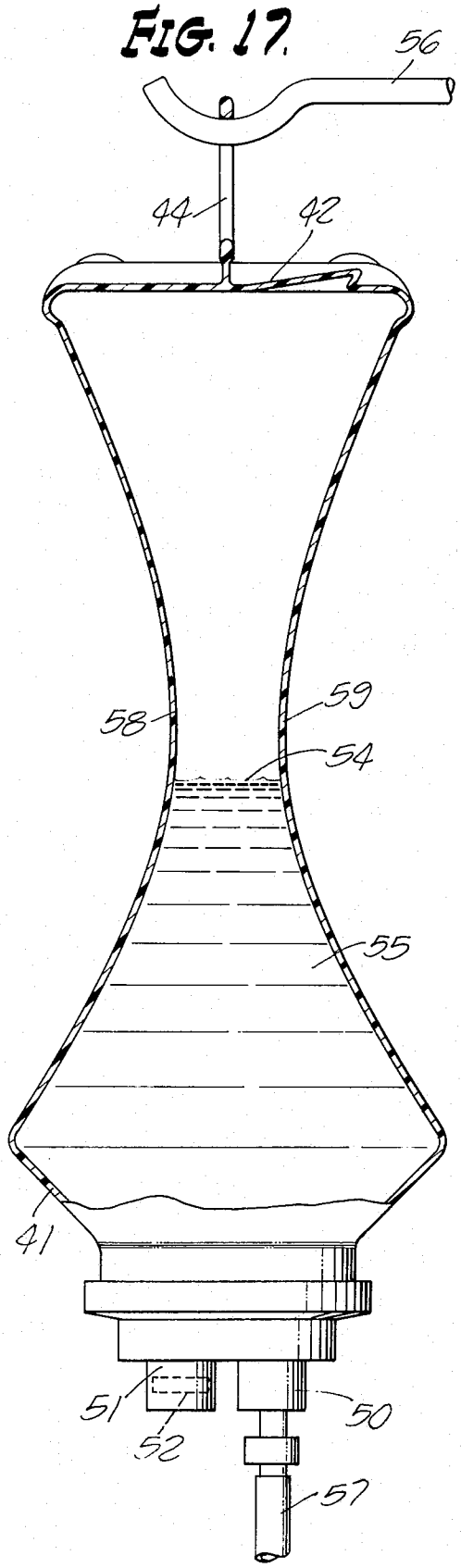

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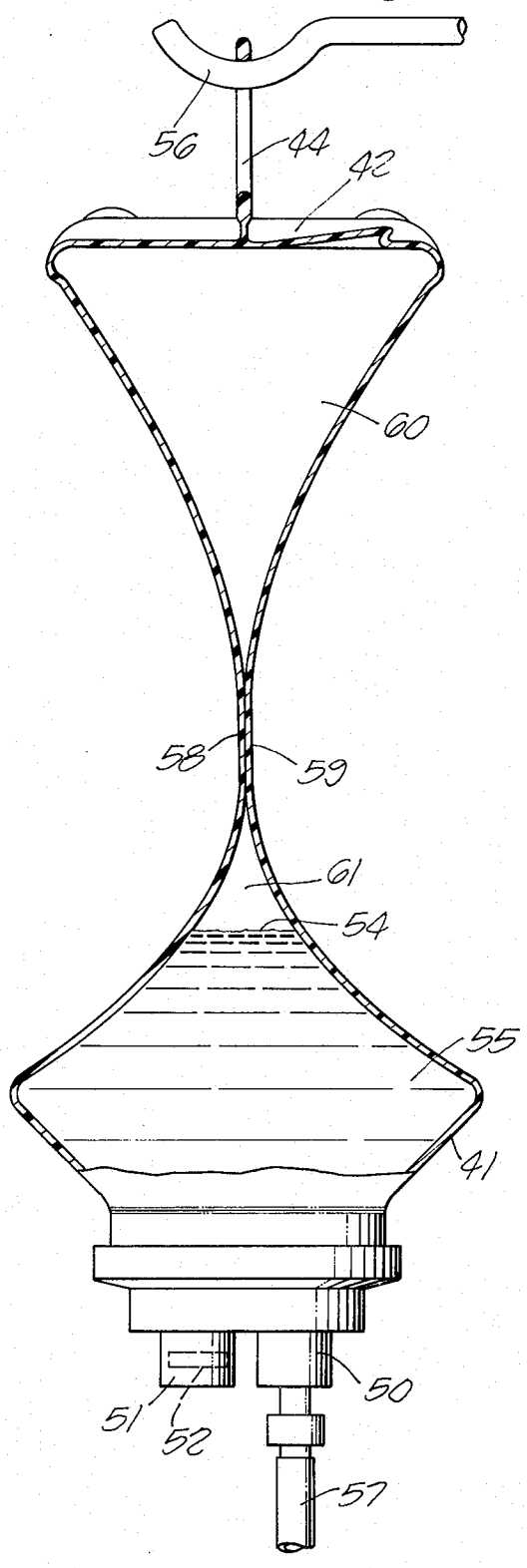
FIG. 18.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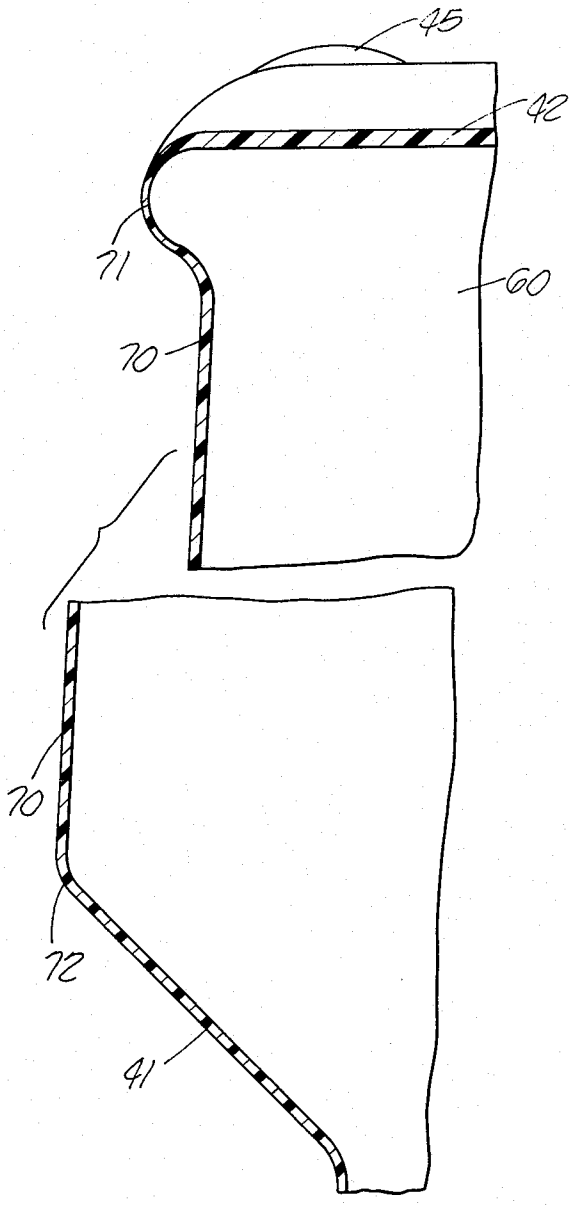


FIG. 19.

FIG. 20.

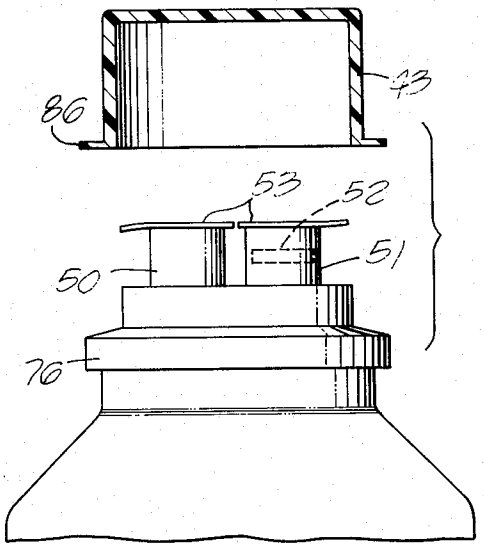
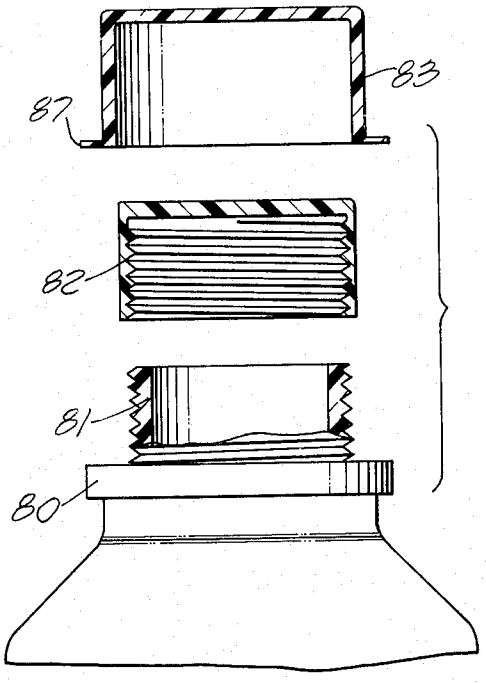


FIG. 21.



THERMOPLASTIC BOTTLE WITH CONTROLLED LATERAL COLLAPSE AND METHOD OF DISPENSING LIQUID THEREFROM

BACKGROUND

Sterile medical liquid, such as a parenteral solution or blood, is commonly infused into a patient's vein from a container hanging above the patient. The sterile liquid flows by gravity through a tubular administration set connected at one end to the container and at an opposite end to a venous needle in the patient.

Sterile parenteral solutions, such as 5% dextrose, normal saline, etc. are frequently supplied to the hospitals in sealed, sterilized containers. These containers are basically of two types — rigid glass bottles, or flexible bags. Such containers come in various sizes such as ¼, ½, 1 and 2 liters, with the 1 liter size being the most commonly used for intravenous therapy. Both types of containers have disadvantages because of their particular structure.

A volumetrically calibrated glass bottle gives an accurate volumeric reading of ±30 ml. of the actual volume of liquid in a 1 liter bottle because a rigid glass bottle retains its shape and maintains an upper surface of the liquid that can be easily read against the calibrations. However, before liquid can drain from a rigid glass bottle there must be an air-inletting system into the bottle so air can replace the dispensed liquid. Typical air inletting systems include an air tube extending into the bottle or a filtered air vent that bubbles air into the bottle through its liquid contents. Because of the air inletting requirements these systems are called "open" systems.

A flexible bag does not require an air-inletting system because its walls can collapse as liquid is dispensed. Such a system is called a "closed" system. A "closed" system is much preferred over an "open" system because there is no requirement for air tubes, filters, etc.

Despite its advantage as a "closed" system the flexible bag has other serious disadvantages. First the flexible bag is limp making it difficult to handle. Also the bag will not effectively support itself upright on its own base. Another disadvantage with a flexible bag is its inaccurate volume measurements. A flexible bag has an uncontrolled collapse and when volumetrically calibrated can give a volumetric reading that it is in error as much as ±200 ml. from the actual volume of liquid in a 1 liter flexible bag. A factor contributing to these inaccurate volumetric readings are the variable teardrop shapes the bags form as they collapse. When the flexible bags are all printed with the same calibrations but collapse differently, this causes great errors in volumetric readings from the calibrations.

To summarize, the rigid glass bottle has the disadvantage of requiring an open-air inletting system to replace a dispensed liquid. The flexible bag has disadvantages of being limp and difficult to handle, and also has an uncontrolled collapse which makes for inaccurate volumetric readings of the dispensed liquid.

SUMMARY OF THE INVENTION

In the present invention an improved thermoplastic bottle has been provided that overcomes the above disadvantages of both the rigid glass bottle and the flexible bag. The thermoplastic bottle of this invention has a structure that (1) supports the bottle upright on its rigid base, (2) causes a "controlled lateral collapse" of the bottle when dispensing to give volumetric accuracy equivalent to that of a rigid glass bottle, and (3) dispenses its entire liquid contents through a "closed" system, while a gas within the bottle is redistributed throughout the bottle to occupy pockets that form at upper and lower ends of the bottle.

The applicant's bottle is of a thermoplastic material and an oval base at one end, an oval shoulder with a dispensing outlet at an opposite end, and a thin flexible oval side wall extending between the base and shoulder. This thin flexible oval side wall extending between the base and shoulder has a major axis and a minor axis. The base and shoulder are substantially more rigid than the flexible side wall and the bottle can be suspended from its rigid base without collapse of this base. Inside the bottle is a sterile liquid occupying 50 to 95% of the bottle's volume with a sterile air space above the liquid. When the thermoplastic bottle is hung from its rigid base with its outlet downward as in intravenous administration, liquid draining by gravity causes the thin flexible oval side wall to deflect inwardly along its minor axis. The rigid oval shoulder and base prevent opposed portions of the side wall from contacting each other at the liquid's upper surface. This maintains the liquid's upper surface in a level condition and readily visible for accurately reading against the volumetric calibrations through its entire descent as the bottle empties. As the bottle partially collapses to dispense its entire liquid contents, the sterile air occupies pockets tht form at the base and shoulder portions of the bottle.

THE DRAWINGS

FIG. **1A** is a side elevational view of the flexible bag of the prior art shown in its storing position;

FIGS. **1B, 1C,** and **1D** are side elevational views of the prior art flexible bag showing it suspended for dispensing;

FIG. **2A** is a side elevational view of a prior art rigid glass bottle showing it in storing position;

FIGS. **2B, 2C,** and **2D** are side elevational views of the rigid glass bottle of the prior art showing it suspended for dispensing;

FIG. **3A** is a side elevational view of the applicant's thermoplastic bottle in storing position:

FIG. **3B** is a side elevational view of applicant's bottle suspended for dispensing;

FIG. **3C** is applicant's bottle with approximately one-half of its contents dispensed;

FIG. **3D** is a side elevational view of applicant's bottle with approximately three-fourths of its contents dispensed;

FIG. **3E** is a side elevational view of applicant's bottle connected with an administration set forming a "closed system";

FIG. **4** is a front elevational view of a first embodiment of applicant's bottle as it is supplied to the hospital;

FIG. **5** is a side elevational view of the bottle of FIG. **4**;

FIG. **6** is a sectional view taken along line **6—6** of FIG. **4**;

FIG. **7** is a sectional view taken along line **7—7** of FIG. **4**;

FIG. **8** is a sectional view taken along line **8—8** of FIG. **4**;

FIG. **9** is a top plan view of the bottle of FIG. **4**;

FIG. **10** is a bottom plan view of the bottle of FIG. **4**;

FIG. **11** is a front elevational view of a second embodiment of applicant's bottle which has a more sloping shoulder configuration than the first embodiment;

FIG. **12** is a side elevational view of the bottle of FIG. **11**;

FIG. **13** is a front elevational view of the bottle of FIG. **11** suspended for dispensing and showing the sloping shoulder feature;

FIG. **14** is a side elevational view of the bottle of FIG. **4** showing a pouring container outlet opening;

FIG. **15** is an enlarged sectional view of the bottle of FIG. **12** with an outlet system for connecting to a parenteral liquid administration set;

FIG. **16** is an enlarged sectional side elevational view of the bottle of FIG. **15** showing it suspended from its rigid base and connected to a parenteral liquid administration set;

FIG. **17** is an enlarged sectional view of the FIG. **16** bottle showing it with approximately one-half of its contents dispensed;

FIG. **18** is an enlarged sectional view of FIG. **16** bottle showing it with approximately three-fourths of its contents dispensed;

FIG. **19** is an enlarged fragmentary view of the upper and lower lefthand corners of the bottle shown in FIG. **16**;

FIG. **20** is an enlarged exploded view of a closure system designed for connection with a parenteral liquid administration set; and

FIG. **21** is an enlarged exploded view of a closure system for dispensing liquid from the applicant's thermoplastic bottle by pouring.

DETAILED DESCRIPTION

With reference to these drawings, FIGS. **1A** through **1D** represent the prior art of flexible thermoplastic bags used for dispensing either intravenous solutions or blood. As shown in FIG. **1A,** the flexible bag **1** has a dispensing spout **2** at one end and a base **3** at an opposite end. One of the main disadvantages of the flexible bag is that it has no definite shape. The bag is limp and difficult to handle and will not support itself upright on its own base.

The flexible bag shown in dispensing position in FIGS. **1B** through **1D** have been used primarily for dispensing blood. With blood, the bag is normally filled with one pint (approximately one-half liter) and the entire contents of the blood bag dispensed at one time to a patient. The accuracy of the blood bag's liquid contents is usually controlled by weighing the blood bag when collecting blood from a donor. Thus, blood bags do not need to be accurately calibrated.

With intravenous solutions, such as 5% dextrose, normal saline, etc., the physician often desires to administer less than the full contents of the container or to know how much has been administered. For instance, from a 1 liter bottle a physician might want to administer 350 ml. This is why volumetric accuracy is extremely important in intravenous solution therapy.

FIG. **2A** shows the second type of prior art medical liquid container which is a rigid glass bottle. Here, rigid glass bottle **4** has a dispensing closure system **5** at one end and a supporting base **6** at an opposite end. Unlike the flexible bag of FIG. **1A,** the rigid glass bottle supports itself upright on its base and retains its shape. In FIG. **2B** the rigid glass bottle is hung from a bail **7,** for dispensing liquid to a patient through a tube **8.**

In FIG. **2C,** the liquid from bottle **4** is approximately one-third administered. In FIG. **2D** the liquid is nearly two-thirds administered.

During administration of liquid from the right glass bottle **4** an air-inletting system **9** replenishes the volume of liquid dispensed with air. In FIG. **2C** this is illustrated by bubbles entering the interior of the bottle and floating upwardly. In an air-inletting system as in FIGS. **2B** through **2D,** extensive and often expensive air inletting systems are required. It is much preferred to have a "closed" collapsible system that does not require any air inletting system.

In the past it has been believed that an air-inletting rigid bottle was required to provide volumetric accuracy of ±30 ml. in a 1 liter bottle. A 1 liter flexible bag might be as inaccurate as ±200 ml. or require tedious impractical techniques to improve the accuracy.

The shortcoming of the prior art containers are, the limp handling characteristics and volumetric inaccuracy of the flexible bag and the air-inletting requirement of a rigid bottle. These problems are overcome with applicant's "controlled collapse" bottle. Applicant's thermoplastic bottle shown in FIG. **3A** is a blow-molded thermoplastic bottle with a rigid shoulder **10** at one end and a rigid base **11** at an opposite end. The rigid shoulder has a dispensing outlet therethrough. Integrally connected to this rigid shoulder and base, and extending therebetween is a thin, flexible, generally oval side wall **12.** In FIG. **3A** the bottle maintains its shape and supports itself upright on rigid base **11.** It will support itself as shown in FIG. **3A** whether the bottle contains liquid or is empty.

When applicant's bottle is supplied to a hospital it contains more than 50% liquid, and the bottle's oval wall is sufficiently transparent for observation of an upper surface of liquid within the bottle. Preferably the container has between 50 and 95% of its total internal capacity filled with liquid, and a constant mass of sterile air occupies the remaining volume. This air phase is large enough to provide a liquid upper surface **14** for volumetric readings when dispensing begins. As liquid is dispensed from this "collapsible" bottle it flows through an administration set **15.** Protrusion **16** shown in FIG. **3B** is not an air-inletting system as in FIG. **2C** above. Instead, protrusion **16** has a passage sealed by a puncturable, resealable resilient rubber pad through which additive medication can be injected with a hypodermic syringe into the "closed" system for administering to the patient. As soon as the hypodermic syringe or other additive device is withdrawn the rubber pad reseals so that no atmospheric air can enter the bottle.

As liquid is dispensed form the bottle, opposed portions **17** and **18** of the oval wall deflect inwardly. These portions **17** and **18** always remain spaced apart until the upper surface **14** of the liquid has descended below these portions. When wall portions **17** and **18** do contact, as in FIG. **3D,** the liquid level **14** is below such portions and still maintains a level surface for accurate volumetric measurement against volumetric calibrations of the bottle. After wall portions **17** and **18** do contact the remaining portions of oval wall **12** continue to deflect inwardly until essentially all of the liquid is dispensed by gravity from the bottle. As shown in FIG. **3E,** the bottle is connected to an an administration set for dispensing through a "closed system" from the bottle through the set and to the patient. In FIG. **3E** an administration set includes a flexible tube which has a tubular rigid spike at an upper end and a rigid adapter

with a venous needle at a lower end of the tube. The administration set also includes an enlarged drip chamber and a roller clamp. When connected as shown in FIG. **3E**, the upper surface of the liquid in the bottle is 7 to 72 inches (17.8 to 193 cm) above the lower end of the administration set to establish a liquid head.

A very important feature of applicant's "controlled collapse" bottle is the extreme accuracy that was unexpectedly found which can be maintained from one bottle to the next in the manufacture of these bottles. It has been found that the volumetric accuracy in a 1 liter bottle with "controlled collapse" gives a repeatable reading of ±30 ml. from one bottle to the next. This is equivalent to the repeatable volumetric accuracy of ±30 ml. in rigid glass bottles. The reason glass bottles have this variance in volume accuracy is because of the thickness of the glass bottle wall which is approximately 0.125 inch (3.3 mm) thick. A 10% increase or decrease in the wall thickness changes the internal diameter 0.025 inch (0.67 mm) and it is the internal dimensions that control the bottle's volumetric accuracy. During manufacture the glass bottle is internally expanded by pressure against a mold contacting its outer surface. There is no mold forming its inner surface and hence the variance. Also, internal glass bumps or thickened portions that sometimes are found in a glass bottle affect its volumetric accuracy.

The applicant's bottle is an extremely thin walled thermoplastic bottle with an oval wall with a thickness of from 0.010 to 0.035 inch (0.25 to 0.94 mm). A 10% variance in applicant's wall thickness has a much lesser effect on its internal volume than the glass bottle above. Numerous bottles have been tested and show very reliable repeatability in the volumetric accuracy. This accuracy in applicant's bottle has been within ±30 ml. for a series of 1 liter bottles. In some cases it has been even more accurate and in the range of ±20 ml. readings for a series of 1 liter bottles.

FIG. **4** shows a front elevational view of a first embodiment of the applicant's bottle which has a generally oval side wall **12** integrally connected to a rigid shoulder **10** and a rigid base **11.** At an upper end of the bottle is a neck flange **20** to which is secured a removable cap **21.** Cap **21** can be either a vented cap as described in my co-pending application entitled "Three Barrier Closure System for Medical Liquid Container" Ser. No. 445,834, filed Feb. 26, 1974, or a non-vented cap as described in a co-pending application entitled, "Frangible Closure System for Medical Liquid Container and Method of Making Same" Ser. No. 338,685, filed Mar. 7, 1973, invented by Pradip Choksi. At a lower end of the bottle is a series of supporting feet represented by numerals **22** and **23.** Also within a recess **24** of the base is a hinged hanger **25** integrally formed with the bottle. At an upper portion of the bottle is an external rib **26** on one side of the bottle and an external rib **27** on an opposite side. These ribs help strengthen the rigidity of the bottle is this area and also provide finger grips to keep the bottle from slipping out of the hand of the nurse or physician.

Volumetric calibrations **30***a* and **30***b* are shown in FIGS. **4** and **5** along the wall section of the oval bottle. Calibration **30***a* is a "fill mark" for measurement when filling the bottle in its upright position. If desired, calibration **30***a* could be replaced with a full scale calibration along the bottle so the amount of liquid in the less-than-full bottle can be determined with the bottle upright. Calibrations **30***b* are for measurement when the bottle is inverted and liquid is dispensed. It is these calibrations **30***b* that are critical for the accurate volume measurement during dispensing. Located between calibrations **30***a* and **30***b* is a flexible label **28** with the bottle's contents and directions for use.

FIGS. **6, 7** and **8** are cross-sectional views taken through the bottle's oval wall along lines **6—6, 7—7,** and **8—8** of FIG. **4.** The oval wall has marginal zones at the left and right sides of FIG. **4** that merge at relatively sharp transverse cross-sectional curvatures predisposing the body for folding along said zones as the bottle collapses. As shown, the bottle has a major axis **31** that is approximately twice the length of minor axis **32.** A cross-section of the bottle is these figures shows the bottle of FIGS. **4** and **5** to have generally parallel sides at ends of the major axis **31** but a generally decreasing length of minor axis **32** from a top portion of the oval side wall to a bottom portion. Thus, in FIG. **4** the bottle appears to have parallel sides and in FIG. **5** the sides converge inwardly from top to bottom causing the bottle to have a more flattened oval configuration adjacent its bottom end. Also adjacent the bottom end of the bottle are opposed thin flex ribs **33** and **34** that extend across ends of the minor axis along only a portion of the bottle's periphery. Adjacent ends of the flex ribs **33** and **34** and extending above the flex ribs are columar support sections of the oval wall that are generally parallel to the bottle's longitudinal axis and prevent the longitudinal collapse of the bottle at the flex ribs when the bottle is sitting upright as in FIG. **4.** The flex ribs do not extend across these columnar support sections.

In FIG. **9** there is a top plan view of FIG. **4** showing the cap **21** and flange **20.** From this view of the rigid shoulder **10** is shown to be generally oval in shape.

FIG. **10** is a bottom plan view of the bottle of FIG. **4** which illustrates the hinged hanger **25** integrally formed with the bottle and being held within recess **24** that extends along the bottle's minor axis. Four feet are shown here, but a different number could be used if desired. Representative feet are indicated at **22** and **23.**

FIGS. **11** and **12** show respectively a front elevational view and a side elevational view of a second embodiment of the bottle. Here the bottle has a generally oval side wall **40** which is connected to a rigid shoulder **41** and a rigid base **42.** As in the first embodiment there is a cap **43,** a hinged hanger **44,** and supporting feet represented by **45** and **46.** The main difference between the first and second embodiments of the bottle is in the shoulder structure. In the first embodiment shoulder **10** is substantially crowned along the major axis to slope relative to the longitudinal axis as shoulder **10** extends outwardly from the bottle. The shoulder **10** in the first embodiment is not substantially crowned along the minor axis but is generally perpendicular to the bottle's longitudinal axis. See FIGS. **4** and **5.** In the second embodiment the bottle shoulder **41** slopes away from the neck at a steep slope of approximately 45° from the longitudinal axis at both its major and minor axis to give a generally conical shoulder as shown in FIGS. **11** and **12.** The purpose for this sloping neck is shown in FIG. **13.** When the bottle of the second embodiment is canted as much as 30° from the vertical it will still dispense its entire liquid content. No liquid is retained in an outer portion of the shoulder. Also, the bottle of the second embodiment has a slightly more converging taper along its minor axis as shown in FIG. **12.** However, the bottle of the second embodiment functions in a "controlled collapse" in the same manner as in the

first embodiment. FIG. **13** illustrates the bottle of the second embodiment used for dispensing intervenous solution in a "closed system".

FIG. **14** shows how the bottle designed for a "closed system" has a structure of its shoulder, base and oval wall that can be used as a pouring container with a different outlet. Despite its collapsibility the bottle has very fine handling characteristics. When the bottle is used as a pouring container a threaded screw cap can be provided beneath cap **21.** Both caps would be removed for pouring. While either the first or second embodiment bottle could be modified at its outlet structure for use as a pouring container, only the first embodiment bottle is illustrated in FIG. **14.**

Substantially enlarged sectional views of the bottle of the second embodiment used for administering parenteral liquids in a "closed system" are shown in FIGS. **15, 16, 17** and **18.** In FIG. **15** the outer cap **21** has been removed to expose two tubular ports **50** and **51.** Port **50** is adapted to receive and form a liquid tight joint with a spike of parenteral solution administration set. Port **51** has a punctural resealable rubber diaphragm **52** through which additive medication can be injected. Sealing off both of these ports is a peelable, metal-thermoplastic laminate foil that protect their sterility. This foil designated as **53** is peeled off immediately before use. In the drawings foil **53** is shown with a cut between the two tubular ports **50** and **51.** This structure is preferred because each portion of the foil can be easily peeled from its perpendicular tubular port without damaging the foil seal with the other tubular port. At the bottom end of the container of FIGS. **15** the hinged hanger **44** is shown tucked into a recess.

When the container of FIG. **15** is supplied to the hospital it has an upper liquid surface of **54** of liquid **55.** It is important that there is a gas, such as air within the bottle to establish the liquid measuring level. This gas could also be an inert gas or mixtures of inert gases. Preferably, the air occupies between 5 and 50% of the container capacity. Exceptionally fine results have been obtained in volumetric accuracy with air occupying approximately 30% of the container's volume when dispensing begins. This air space can be partially filled with additive liquid medication injected into tubular port **51** immediately before dispensing, however, there must be a volume of gas, such as air in the container when dispensing begins. This air will be redistributed within the container so that the readings on calibrations shown most clearly in FIGS. **4** and **11** are accurate. Since air is neither added nor removed from the container after dispensing begins, there is a constant mass of air in the container during dispensing and collapse of the bottle of this invention.

In FIG. **15** the outer closure **43** has been removed and foil **53** is ready to be peeled back from tubular outlet **50** for connecting to an administration set. Such administration set, shown as **57,** has been connected in FIG. **16** and the bottle inverted and hung from its hanger **44** on support **56.** At this point the volumetric reading will indicate that the 1 liter bottle has 1,000 ml. (±30 ml.).

As liquid is dispensed the liquid surface **54** will descend and opposed portions **58** and **59** of the oval side wall that lie along the minor axis will deflect inwardly. See FIG. **17.** This occurs as the liquid is dispensed through a closed system. However, as the side wall portions deflect inwardly the generally oval rigid base **42** and generally oval rigid shoulder **41** retain a spaced relationship between wall portions **58** and **59** until the liquid level **54** has descended below a contact area of these wall portions. This is so that a level, readable liquid surface **54** is maintained throughout the entire descent path of the liquid. If the walls had uncontrolled collapse it would be possible to have them pinch together below the liquid surface **54** causing serious volumetric reading errors.

As the liquid is draining from the bottle, the liquid head causes a slight vacuum to form in the bottle, and this slight vacuum is 0.2 to 2.0 psi (0.014 to 14 Kg/cm^2) below the atmospheric pressure outside the bottle, and this causes the side wall to deflect inwardly. This slight vacuum causes the gas in the bottle to expand slightly (about 2½%). However, this is not significant because the bottle can be calibrated to take into account this slight increase in gas volume within the bottle. Temperatures normally does not affect the volume of the gas because the temperature inside and outside the bottle are normally the same when dispensing, ie. room temperature at 65° to 80° F (18.3° to 26.7° C). Prior to dispensing the bottle has an uncollapsed internal volume; and as liquid dispenses, the bottle assumes a partially collapsed internal volume. This partially collapsed volume is from 10 to 80% of the bottle's uncollapsed volume.

The side wall portions **58** and **59** have come in contact with each other in FIG. **18.** However, the liquid level **54** is below this contact area and a pocket formed at the bottle shoulder is large enough to hold the bottle's remaining liquid contents. Although wall sections **58** and **59** have contacted each other they are not totally sealed off. Thus, air pockets **60** and **61** are in communication with each other and can balance the air mass in the container. As the liquid **55** continues to drain from the bottle shown in FIG. **18** the walls will collapse against each other and the contact area will longitudinally expand closer to the rigid base **42** and closer to the rigid shoulder **41.** When the liquid **55** is completely dispensed the bottle will have a very flat configuration except for rigid base **42** and rigid shoulder **41.** Applicant's thermoplastic bottle requires no vacuum for completely emptying. The sequence of draining as shown through FIGS. **16, 17** and **18** occurs with a conventional gravity dispensing administration set. The slight vacuum within the bottle created by gravity dispensing is opposed by a flexure resistance of the tubular side wall. When the wall will collapse no further, this flexure resistance is in equilibrium with the slight vacuum within the bottle. The volume of gas in the bottle at this slight vacuum is equal to or exceeds the combined volumes of the two pockets so that liquid can completely empty from the bottle.

Once the bottle has emptied, the administration set can be disconnected, which provides an opening into the bottle. When the administration set is disconnected, the side walls will remain partially collapsed, and will not return to their uncollapsed shape. This gives the bottle a shape that is easy to handle, and occupies less space than the original uncollapsed bottle when disposing of the bottle.

Another important feature of the invention is that the gas in the bottle at the vacuum created during gravity dispensing of the liquid through a "closed system" of the bottle and administration set has a volume less than the combined internal volume of the closed system. Thus, the gas volume tends to hold some liquid in the administration set as a safeguard against administering

air into a patient. This air volume will even hold liquid in the set after a venous needle has been removed from such patient, and there is no longer a venous back pressure into the set.

FIG. **19** shows a greatly enlarged sectional fragmentary view of the junctures of the flexible oval sidewall with rigid base **42** and with the rigid shoulder **41.** These fragmentary sections are taken from the upper left-hand area and the lower left-hand area of FIG. **16.** The flexible oval side wall indicated as **70** is integrally connected to rigid base **42** through a thin flex rib **71.** This flex rib **71** appears on the external surface of the bottle as a laterally extending bulged rib adjacent the indented recess for hanger **44.** This thinned rib section **71** protrudes outwardly from collapsible wall **70** and it is thinner than wall **70.** The purpose of flex rib **71,** and the like rib on an opposite side of the bottle, is to aid in flexing wall **70** relative to rigid base **42.** This helps to cause additional flex adjacent to base **42** to diminish the capacity of air pocket **60** as the liquid drains. The flex ribs in a 1 liter bottle can be from 0.008 to 0.015 inch (0.21 to 0.40 mm) thick. The oval wall can be from 0.010 to 0.035 inch (0.35 inch (0.25 to 0.94 mm) thick. Although there is an overlap of thickness ranges the flex rib will be always have a thinner portion than remaining portions of the oval wall of a particular bottle. For instance, an oval wall of 0.012 inch (0.32 mm) might have a flex rib of 0.009 inch (0.23 mm) thick. In addition to its thinner wall section, the arcuate cross sectional shape of the flex rib also aids in its increased flexibility.

At a lower section of FIG. **19** the rigid shoulder **41** is joined to flexible wall **70** at a juncture **72.** There is no thin flex rib at **72** as there is at **71.** This is so the wider portion of the bottle adjacent to dispensing outlet will remain open for receiving a substantial quantity of liquid and lower level **54** below the contact area of wall portion **58** and **59** (FIG. **18**). The bottle has a structure which encourages the bottle to collapse adjacent rigid base **42** and permits the air in the bottle to be redistributed in the bottle for lowering the upper surface of the liquid below a contact point of the walls as liquid is dispensed. Despite this "controlled lateral collapse" during a gravity liquid drain this laterally flexible bottle structure shown in FIG. **19** is sufficiently rigid to support the bottle upright on a flat surface.

Two dispensing outlets for the bottle are shown in FIGS. **20** and **21.** In FIG. **20** the dispensing outlet includes tubular ports **50** and **51.** Tubular port **51** is closed off by a puncturable resealable rubber pad **52.** A peelable foil **53** is sealed across the outer end of both of these tubular sections, and the foil **53** is preferably severed between tubular ports **50** and **51** for convenient independent removal from each tubular section. Fitting over the tubular ports **51** and **52** is a removable closure **43.** This closure can have a frangible portion **86** that is sealed to flange **76** of the bottle. The outlet structure beneath outer cap **42** of FIG. **20** is specifically for administering parenteral solutions through a "closed" system that includes an administration set.

The same bottle of this invention has sufficient rigidity for use as a "pouring container". When used as a pouring container an alternate outlet system is provided on the bottle. Here the bottle (FIG. **21**) includes a flange **80** surrounded by a threading dispensing outlet **81.** Fitting over this outlet is a threaded inner cap **82.** There is also an outer cap **83** with a frangible portion **87** sealed to flange **80** of the bottle. With this optional closure system the container of applicant's invention could be used for a pouring container as shown in FIG. **14.** By providing a bottle with a common body structure that is usable both for an intravenous solution bottle and also for a pouring bottle (depending on the particular outlet structure used) manufacturing costs are greatly reduced in producing these two types of bottles.

The bottle of this invention can be made of a propylene-ethylene copolymer thermoplastic material. The bottle is blowmolded as a homogenous unit that includes the rigid base, rigid shoulder and collapsible oval sidewall. Preferably the rigid shoulder is between 0.040 and 0.060 inch (1.0 to 1.5 mm) thick and the rigid base is between 0.060 and 0.090 inch (1.5 to 2.3 mm) thick. The flexible side wall is from 0.010 to 0.35 inch (0.25 to 0.94 mm) thick. When such bottle is filled with liquid and air and sealed it can then be steam sterilized at 240° to 260° F (116° to 127° C).

In the foregoing specification, specific embodiments have been used to illustrate the invention. However, it is understood by those skilled in the art that certain modifications can be made to these embodiments without departing from the spirit and scope of the invention.

I claim:

1. A "closed" system for administering medical liquid comprising the combination of a substantially transparent thermoplastic bottle with "controlled lateral collapse" for accurately measuring the volume of liquid dispensed without inletting air into the bottle, which bottle includes a rigid oval base adapted to support the bottle in a longitudinally upright position on a flat surface during storage; a rigid oval shoulder with a non-air-inletting dispensing outlet therethrough at an opposite end of the bottle; a laterally flexible generally oval side wall integrally connected to the base and shoulder and having a cross-section with a transverse major axis and transverse minor axis, said transverse major axis remaining generally constant in length at various locations along the bottle's length, and said transverse minor axis becoming progressively shorter as the minor axis proceeds from the oval shoulder to the oval base along the bottle's length; volumetric calibrations on the side wall; a sterile medical liquid initially filling the bottle between 50 and 95% of its internal capacity, and sterile air occupying the remaining portion of the internal capacity of the bottle immediately prior to dispensing from the bottle to provide a level upper surface of the liquid for measuring against the calibration; said bottle having opposed portions of the side wall that progressively deflect inwardly along its minor axis toward each other as liquid is drained by gravity from the outlet, which side wall portions are maintained at spaced relationships until the liquid's upper surface has descended below said side wall portions for accurate measurement of the liquid's upper surface against the calibrations; said rigid oval base having a centrally located recess therein; a hinged thermoplastic hanger integrally formed with the bottle and foldably retained within this recess during storage; a series of protruding feet on the rigid oval base for supporting the bottle on a flat surface during storage; said thermoplastic bottle having a medication additive port closed off by a puncturable resealable rubber diaphragm; a tubular adapter connected to the bottle and surrounding the dispensing outlet; a puncturable diaphragm closing off the tubular adapter; a tubular spike of an administration set wedgingly secured in the tubular adapter; a flexible conduit

connected to the spike at one end and extending to a lower dispensing end of the conduit; and an enlarged drip chamber connected in series with the administration set.

2. A method of administering to a patient medical liquid that has a visible upper surface and occupies between 50 and 95% of the internal capacity of a volumetrically calibrated substantially transparent thermoplastic bottle, the remaining volume of said bottle above said surface being occupied by sterile gas, said bottle having a rigid oval base, a rigid oval shoulder defining an outlet, and a flexible oval side wall connected between the base and shoulder, which side wall has a major axis and a minor axis, said method including the steps of

supporting the bottle in an outlet downward position; collapsing the oval side wall inwardly along the minor axis as liquid is gravity drained without inletting air into the bottle; contacting opposed portions of the oval side wall at ends of its minor axis above the visible upper surface of the liquid in the bottle when the bottle is hung in its outlet downward position; and progressively flattening the bottle by increasing the longitudinal length of contact between the opposed sections of the side wall above the descending upper surface of the liquid in the bottle until the volume of the partially collapsed bottle is equal to or less than the original space above said liquid prior to said collapsing step whereby substantially all the liquid can be dispensed without inletting air into the bottle, and with an accurate volumetric reading of the liquid's visible upper surface from the bottle's calibrations.

3. The method of claim **2,** where the method also includes connecting the dispensing outlet to a tubular administration set to form a closed system of the bottle and administration set.

4. The method of claim **3,** wherein the thermoplastic bottle is of 1 liter size and calibrated between 0 and 1000 ml. and the collapse is carried out to provide a volumetric accuracy in a closed system of ±30 ml.

5. the method as set forth in claim **2,** wherein the bottle's side walls are sufficiently deformed by the inward flexure so that after dispensing its liquid contents and air is allowed to enter the bottle, the bottle does not return to its original shape, and thereby occupies less space than originally for convenient disposal.

6. A liquid administration bottle having a substantially rigid base at one end thereof and a substantially rigid shoulder with a dispensing outlet at the other end thereof, wherein the improvement comprises

said dispensing outlet including tubular port means defining an inner surface sealingly engagable with the outer surface of a hollow spike of a medical administration set for forming an airtight seal therewith and for placing said bottle and set in flow communication; a removable bacteria-tight sealing member secured to said tubular port means; said bottle having a tubular wall extending longitudinally between said base and shoulder, which wall has longitudinally columnar rigidity for supporting the bottle upright on its base and has limited lateral flexibility permitting partial, but not total, collapse of the bottle when the same is inverted and gravity drained to a reduced volume capacity; said bottle containing a measured amount of liquid, which liquid has an upper surface, and an amount of sterile gas above said liquid, which has has a volume at dispensing pressures and temperatures that is equal to or greater than said reduced volume capacity of said bottle, whereby, substantially all of the liquid may be drained from the inverted bottle under the influence of gravity without inletting any additional gas into the bottle.

7. The bottle of claim **6** wherein said liquid is a sterile parenteral solution occupying 50 to 95% of the bottle's uncollapsed volume; said gas above said liquid being sterile air.

8. The bottle of claim **6** wherein said tubular wall of said bottle has portions that contact each other only above the upper surface of said liquid and substantially below said rigid base of the bottle when said bottle is inverted and gravity drained.

9. The bottle of claim **6** in which said tubular wall is substantially transparent and has volumetric calibrations.

10. The bottle of claim **9** wherein said tubular wall is calibrated from 0 to 1,000 ml; said rigid base and shoulder coacting with said flexible tubular wall to control the collapse of said bottle from its uncollapsed condition to said partially collapsed condition to provide a calibration accuracy within ±30 ml over the 0 to 1,000 ml range.

11. The bottle of claim **6** wherein said tubular wall has a thickness between 0.010 and 0.035 inches (0.25 and 0.94 mm) and has an oval cross-sectional shape with a major transverse axis substantially greater than the minor transverse axis thereof.

12. The bottle of claim **11** in which said tubular wall has generally parallel longitudinally-extending portions at the ends of said major transverse axis.

13. The bottle of claim **11** wherein said tubular wall has longitudinally-extending portions at the ends of its minor transverse axis that converge in a direction from said shoulder towards said base.

14. The bottle of claim **6** wherein said shoulder has a thickness between 0.040 and 0.060 inches (1.0 and 1.5 mm), has an oval shape, and has portions that slope towards the bottle's base.

15. The bottle of claim **6** wherein said base has a thickness between 0.060 and 0.090 inches (1.5 and 2.3 mm) and has an oval shape.

16. The bottle of claim **6** wherein said bottle has a pair of flex ribs, each with a thickness between 0.008 and 0.015 inches (0.21 and 0.40 mm), near said base.

17. The bottle of claim **6** wherein said bottle has a pair of gripping flanges near said shoulder.

18. The bottle of claim **6** wherein said bottle is steam sterilizable at 240° to 260°F (116° to 127°C) and is of a propylene-ethylene copolymer.

19. A closed system for administering liquid which includes a bottle having a substantially rigid base and a substantially rigid shoulder with a dispensing outlet, wherein the improvement comprises

said bottle having a tubular wall extending longitudinally between said base and said shoulder; said wall having longitudinal columnar rigidity for supporting the bottle upright on its base and having limited lateral flexibility permitting partial, but not total, collapse of the bottle to a reduced volume capacity; said bottle containing a measured amount of liquid having an upper surface intermediate the base and shoulder and also containing above said surface an amount of sterile gas having a volume at dispensing pressures and temperatures that is equal to or greater than said reduced volume capacity of

said bottle, whereby, substantially all of said liquid can drain by gravity from said bottle when the same is inverted without inletting any additional gas into said bottle; and a tubular administration set connected to said outlet, with said combined bottle and administration set forming the closed system.

20. The system of claim **19** wherein the administration set has a lower dispensing end that is 7 to 72 inches (17.9 to 183 cm) below said upper surface of said liquid in said bottle during gravity dispensing of said liquid.

21. A closed system for administering liquid which includes a bottle having a substantially rigid base and a substantially rigid shoulder with a dispensing outlet, wherein the improvement comprises

said bottle having a tubular wall extending longitudinally between said base and said shoulder; said wall having longitudinal columnar rigidity for supporting the bottle upright on its base and having limited lateral flexibility permitting partial, but not total, collapse of the bottle to a reduced volume capacity; said bottle containing a measured amount of liquid having an upper surface intermediate the base and shoulder and also containing above said surface an amount of sterile gas having a volume at dispensing pressures and temperatures that is equal to or greater than said reduced volume capacity of said bottle, whereby, substantially all of said liquid can drain by gravity from said bottle when the same is inverted without inletting any additional gas into said bottle; and a tubular administration set connected to said outlet, with said combined bottle and administration set forming the closed system; said gas having a volume at dispensing pressures and temperatures less than the total of the volume of said administration set plus said reduced volume capacity of said bottle, whereby, said administration set is prevented from being completely drained of liquid by gravity during an administration procedure.

22. The system of claim **21** wherein said limited lateral flexibility of said tubular wall and said rigidity of said base and shoulder, by permitting only partial collapse of said bottle, produce in combination with said liquid a slight negative pressure within said bottle within the range of 0.2 to 2.0 psi (0.014 to 0.14 kg/cm^2) below atmospheric pressure as said bottle is gravity drained.

23. A liquid administration bottle having a substantially rigid base and a substantially rigid shoulder with a dispensing outlet, wherein the improvement comprises

a generally transparent volumetrically calibrated oval tubular wall with a major transverse axis and a minor transverse axis; said oval wall extending longitudinally between said base and shoulder and having longitudinal columnar rigidity for supporting the bottle upright on its base; said wall also having limited lateral flexibility along its minor axis permitting partial, but not total, collapse of the bottle to a reduced volume capacity, with opposed portions of the tubular wall contacting each other; said bottle containing a measured amount of liquid occupying 50 to 95% of the bottle's uncollapsed volume; said liquid having an upper surface and a sterile gas occupying the remaining volume of the bottle above said surface; said gas having a volume at dispensing pressures and temperatures that is equal to or greater than said reduced volume capacity of said bottle; said rigidity and oval configurations of said base, shoulder, and tubular wall, combined with the proportions of liquid and gas in said bottle, controlling the collapse of the bottle when the same is inverted and gravity drained so that said opposed portions of said tubular wall contact each other only above the upper surface of said liquid; whereby, said bottle may be gravity drained of substantially all of the liquid therein without inletting any additional gas into said bottle.

24. A medical liquid administration bottle having a substantially rigid base at one end thereof and a substantially rigid shoulder with a dispensing outlet at the other end thereof, wherein the improvement comprises

said dispensing outlet including tubular port means defining an inner surface sealingly engagable with the outer surface of a hollow spike of a medical administration set for forming an air-tight seal therewith and for placing said bottle and set in flow communication; a substantially transparent body extending longitudinally between said base and shoulder; said outlet in said shoulder being capable of dispensing liquid from said bottle under the influence of gravity, without the concurrent entry of air, when the bottle is supported and drained in inverted position; said bottle being filled completely with a sterile gas and an infusable sterile liquid, which liquid has an upper surface visible through said transparent body; said body having opposite wall portions is filled and capable of flexing inwardly to engage each other at a point of initial contact intermediate said base and shoulder as said bottle is inverted and drained; the volume of gas in said bottle exceeding the volume of the space in said bottle between said base and said point of initial contact when said opposite wall portions have flexed into engagement; and a graduated scale extending longitudinally along said body; whereby, the upper surface of the liquid as it is drained from said bottle is disposed below the point of initial contact between said opposite wall portions and may be read directly from the scale through the substantially transparent body of the bottle; said body having limited longitudinal columnar rigidity permitting partial, but not total, collapse of said bottle to a state of reduced volume capacity; said gas within the uncollapsed bottle having a volume equal to or greater than said reduced volume capacity, whereby, substantially all of the bottle's liquid contents can be drained by gravity without inletting any additional gas into said bottle.

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