Nov. 13, 1956 N. M. NESSET ET AL 2,770,234

PARENTERAL ADMINISTRATION OF LIQUIDS

Filed April 5, 1954 2 Sheets-Sheet 1

Fig. 1

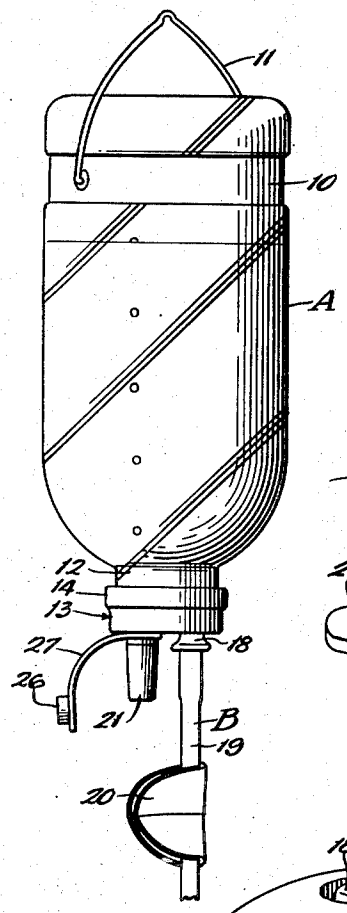


Fig. 2

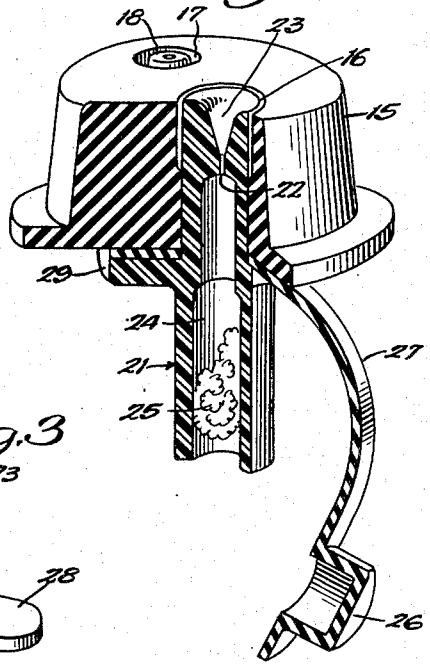


Fig. 3

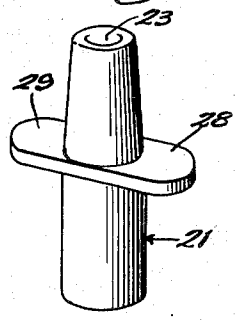
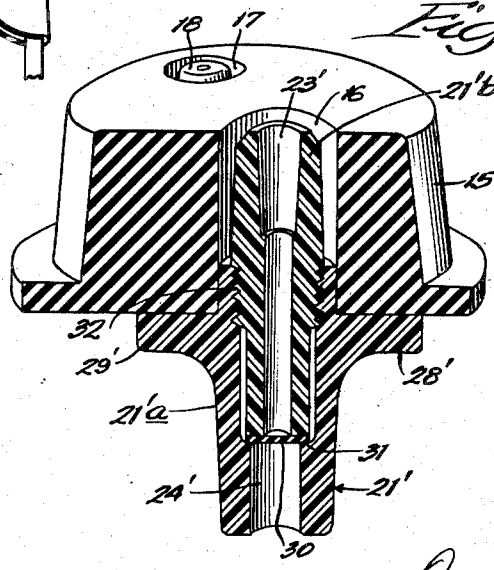


Fig. 4



INVENTORS:
Maurice M. Nesset and
BY Cyrus R. Broman,
Dawson, Tilton & Graham
ATTORNEYS.

Nov. 13, 1956 N. M. NESSET ET AL 2,770,234

PARENTERAL ADMINISTRATION OF LIQUIDS

Filed April 5, 1954 2 Sheets-Sheet 2

Fig. 5

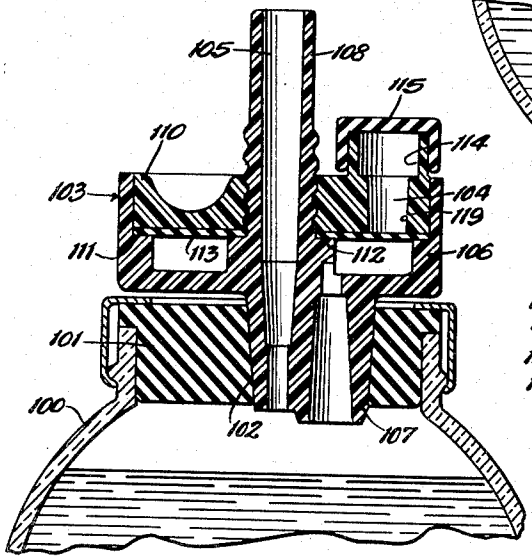


Fig. 6

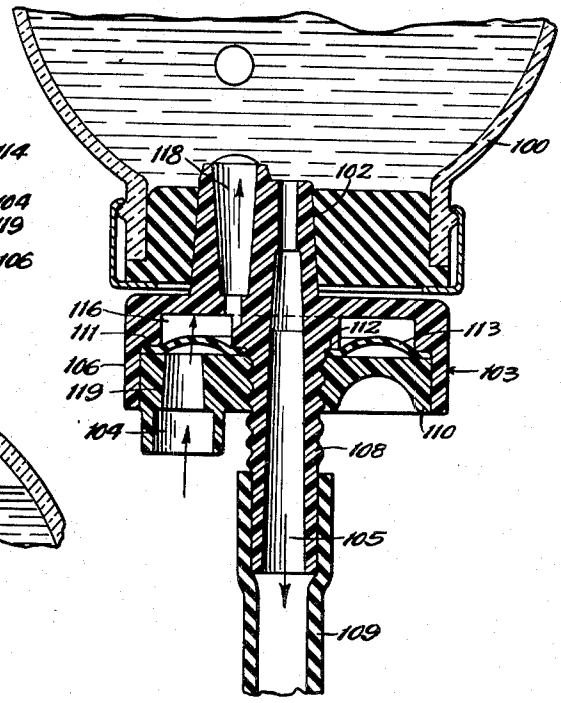


Fig. 7

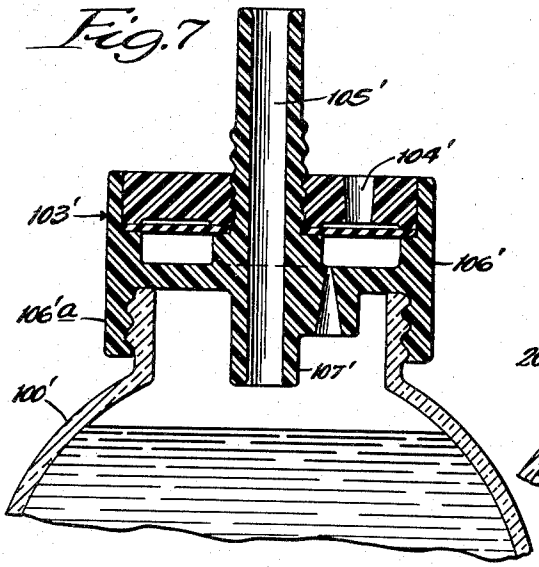


Fig. 8

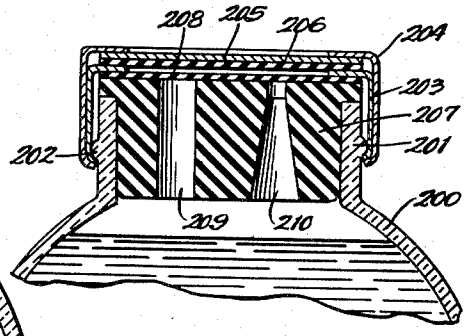
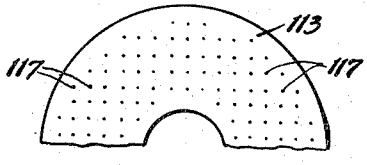


Fig. 9



INVENTORS:
Maurice M. Nesset and
BY Cyrus R. Broman,
Dawson, Tilton & Graham,
ATTORNEYS.

United States Patent Office 2,770,234 Patented Nov. 13, 1956

2,770,234

PARENTERAL ADMINISTRATION OF LIQUIDS

Naurice M. Nesset, Palatine, and Cyrus R. Broman, Evanston, Ill., assignors to Baxter Laboratories, Inc., Morton Grove, Ill., a corporation of Delaware

Application April 5, 1954, Serial No. 421,054

8 Claims. (Cl. 128—214)

This invention relates to the parenteral administration of liquids, and more particularly, to a device for visually determining that the flow of an intravenous liquid is proceeding at a selected rate. The dispensing device or parenteral administration set of this invention has its greatest utility when used to dispense substantially transparent aqueous solutions, such as saline solutions, glucose and invert sugar solutions, and plasma. However, it can also be advantageously used for relatively opaque fluids such as whole blood.

This application is a continuation-in-part of our copending application Serial No. 364,684, filed June 29, 1953.

In the design and operation of parenteral administration sets, it has been found necessary to provide means to admit air to the space above the liquid in the container as the liquid is dispensed for the purpose of equalizing the pressure within and without the container, thereby preventing a negative pressure from building up within the container and stopping the flow of liquid. In some instances, it has been the practice to provide an air tube extending from the air inlet opening in the stopper to a point adjacent the bottom of the container so that when the container is inverted the free end of the tube will project above the surface of the liquid and communicate directly with the air space above the liquid.

It is also desired to provide means which permit the rate of flow to be selectively varied, and which also makes possible a visual determination that the selected rate is being maintained. In other words, one of the desired elements of the administration set is some type of flow indicator. The customary flow indicator takes the form of a "drip chamber" interposed in the conduit from the container to the point of administration. The upper portion of the drip chamber is provided with a nozzle from which the liquid falls a drop at a time into the lower portion of the chamber which is partially filled with the liquid, thus permitting the drops to be counted as a measure of the rate of flow for a given time.

The use of air tubes and drip chambers of the type described has a number of disadvantages both from operational and economic standpoints, but heretofore no satisfactory alternative has been developed.

It is therefore an object of this invention to provide a parenteral administration set which eliminates both the conventonal air tube and drip chamber. More particularly, it is an object of this invention to provide a simplified air inlet structure for a container of an intravenous liquid which performs the functions of both the conventional air inlet tube and drip chamber, that is, which both admits air to the space above the liquid and also provides an accurate indication of the rate at which the liquid is being dispensed. It is a further object of this invention to provide means for admitting air from the exterior of an intravenous solution container to a point beneath the surface of the solution when the container is inverted, while at the same time preventing the liquid from leaking out of the container through the air inlet passage. It is

a still further object of this invention to provide a means for admitting air in the manner described which is characterized by the further fact that the air is admitted in discrete increments, i. e., separate bubbles, which are of sufficiently large size and sufficiently spaced apart to be easily countable, thereby permitting the air bubbles per minute to be counted as a direct measure of the rate of liquid flow. In this connection, it is another object of this invention to provide an air inlet structure which releases bubbles of air beneath the surface of the fluid during the administration without any substantial variation in the mass of air within each bubble during the course of the administration, and which will therefore compensate for the release of an equivalent volume of fluid at a uniform ratio, for example, say one air bubble per .1 cc. of liquid. In this connection, it is a specific object to provide a parenteral administration set capable of admitting the same number of air bubbles per unit of liquid dispensed irrespective of the rate of liquid flow. Another specific object of this invention is to provide a parenteral administration set having an air inlet structure of the type described which also is adapted to permit maintaining the number of air bubbles liberated per minute at a substantially constant rate during the entire administration, and which is unaffected by the decreasing liquid level in the container. Another object is to provide a modified form of our invention that incorporates both the air inlet passage and the liquid outlet passage in a single connection which permits the use of a container equipped with a single-holed stopper. Further objects and advantages will appear as the specification proceeds.

Specific embodiments of this invention are illustrated in the accompanying drawing, in which—

Fig. 1 is a partial elevational view of a parenteral administration set embodying the principles of this invention; Fig. 2, a cut-away perspective view of the container closure and air inlet structure which are largely responsible for the new results achieved; Fig. 3, a perspective view of the air inlet tube of Figs. 1 and 2; Fig. 4, a cut-away view similar to Fig. 2, but showing a modified form of the invention; Fig. 5, a cross-sectional view of an intravenous container equipped with a plug-in fitting illustrating another embodiment of the principles of this invention; Fig. 6, a cross-sectional operational view of the embodiment of Fig. 5; Fig. 7, a cross-sectional view similar to Fig. 5, showing a modified structure; Fig. 8, a cross-sectional view of an intravenous solution package embodying still another form of the present invention; and Fig. 9, a fragmentary plan view of the air-permeable diaphragm incorporated in the structure of Figs. 5 and 6.

The preferred environmental or cooperating structure for the air inlet means of the present invention can be described as a transparent-walled container having an intravenous liquid therein and adapted to be supported for the administration of said liquid by gravity flow, including means providing an outlet passage for the liquid. In combination with this structure, there is provided in accordance with the present invention means for admitting air beneath the surface of the liquid within the container in visually-observable bubbles at a countable rate directly proportional to the liquid outflow rate through the outlet passage. The advantage and new result thus achieved is that the number of bubbles per unit of time is a measure of the rate of liquid flow.

Looking first mainly at Fig. 1, there is shown part of an apparatus for the parenteral administration of an aqueous base liquid including a liquid supply container or bottle A and a conduit means or assembly B, providing a communicating passage extending from container A to the point of administration of the liquid. By way of specific example, container A may have an intravenous saline solution therein which flows downwardly through

conduit assembly B into the vein of the patient through a needle (not shown).

In the specific illustration given, in order to provide for the supporting of container A in an inverted position, as shown, it is provided with a recessed ring **10** having a support bail **11** pivotally connected thereto. Container A is also provided with a neck portion **12** enclosing an open mouth which is covered by a closure or cap assembly **13** having a retaining ring **14** which holds plug or stopper member **15** in place.

Stopper **15** is preferably constructed of a resilient flexible material such as soft rubber and is provided with an air inlet opening **16** and a liquid outlet opening **17**, as shown more clearly in Fig. 2. When openings **16** and **17** are of the type illustrated, it is customary to provide a diaphragm or seal (not shown) on the outside of the stopper **15**, which is removed to prepare the container for the administration. Usually a hollow plug-in connection **18** is inserted in opening **17** with its lower end secured to a flexible hose **19**. It is preferable to provide hose **19** with an adjustable clamp for constricting the hose to regulate the rate of flow, for example, a control clamp **20** of malleable metal can be disposed about a portion of hose **19**.

In the preferred embodiments of this invention as illustrated in the various figures of the drawing, there is provided a valveless, constantly-open air inlet passage having a substantially constant resistance to the inflow of air at a given flow rate and arranged to admit air beneath the upper surface of the intravenous liquid while it is being administered. Further, the air inlet passage has a portion restricting the inflow of air and providing a liquid seal, and another portion inwardly thereof providing an air collection chamber for releasing air bubbles into the solution. Preferably, the air inlet passage terminates in an outlet within or beneath the neck portions of the containers, and is dimensioned and arranged for releasing discrete, visually-observable bubbles, so that the bubbles will rise from the level of the container neck to the upper surface of the intravenous liquid within the container.

In the embodiment of Figs. 1 to 3, an air inlet tube **21** is inserted into passage **16**, as illustrated in Fig. 2. Air inlet tube **21** provides a capillary portion **22** and inwardly therefrom an air collection chamber portion **23**. In the illustration given, the air inlet passage through tube **21** gradually enlarges in cross-sectional area above capillary portion **22** into air collection chamber **23**.

Air inlet tube **21** and stopper **15**, where the stopper provides part or all of the air inlet passage, can be formed of a wide variety of different materials, including plastics, glass, rubber, metals, wood, etc. In other words, the material of construction is not especially critical. However, for simplicity of manufacture it is convenient to mold the air inlet tubes from a suitable plastic. Stopper **15** is preferably made of soft rubber.

Although it is not essential for the operation of the embodiment of Figs. 1 to 3, it is preferred to provide outwardly of capillary passage **22** a filter chamber **24**. Filter chamber **24** receives a wad or ball **25** of air-permeable fibrous material such as loosely intermeshed fibers of cotton. The air entering filter chamber **24** passes through filter plug **25** before entering container A, thereby removing particles of dirt or other solid contaminants in the air which might otherwise enter the solution.

If desired, the outer end of tube **21** can be equipped with a removable closure. In the illustration given, the outer end of tube **21** is provided with an attached cap **26** of flexible resilient material having a hinge portion **27** which permits cap **26** to be seated and unseated without separating it from the tube **21**.

Air inlet tube **21** can be adapted to cooperate with stopper **15** in positioning the tube relative to the stopper. For example, air inlet tube **21** is shown provided with

laterally-extending arms **28** and **29**, which abut the outer end of stopper **15** when the tube **21** is correctly positioned, as shown more clearly in Fig. 2.

Fig. 4 illustrates a modified form of the air inlet tube of Figs. 1 to 3, the corresponding parts being indicated by the same numbers except that the numbers are primed. The principal difference is that instead of capillary portion **22**, there is provided a porous disk or diaphragm **30**, providing minute air passages therethrough. By way of specific example, disk **30** can be formed of ordinary filter paper which has been treated with a water-repellent material like a silicone. In this way disk **30** is made substantially impervious to water while remaining pervious to air, that is, disk **30** is a non-liquid-penetrable, air-permeable membrane.

In the illustration given, air inlet tube **21'** is formed in two parts, **21'***a* and **21'***b*, as shown more clearly in Fig. 4. The outer portion **21'***a* has an enlarged bore above annular shoulder **31** into which the outer reduced end of part **21'***b* is received, the two parts being threadedly connected at **32**. The outer edge portion of disk **30** rests on annular shoulder **31** and is clamped thereto by the outer end of part **21'***b*.

If desired, a cotton plug, such as plug **25**, can be inserted in chamber **24'**, but this is not necessary since disk **30** acts as a filter for the incoming air, and this is one of the advantages of the embodiment of Fig. 4. As in the embodiment of Figs. 1 to 3, the air passing inwardly through the air inlet passage collects in an air collection chamber, designated by the number **23'**. Air inlet tube **21'** is provided with positioning shoulders **28'** and **29'** to limit the insertion of air inlet tube into passage **16**, but it is not necessary that the positioning shoulders be brought into engagement with stopper **15** as long as a liquid-tight seal is obtained between the walls of stopper passage **16** and the walls of the air inlet tube.

A modified form of our invention is shown in Figs. 5 and 6, which is particularly adapted for use with a container **100** equipped with a single-holed stopper **101**. Stopper **101** is provided with a single passage or opening **102**. Passage **102** is provided with a plug-in fitting **103** which provides a passage **104** for admitting air to container **100** beneath the surface of the liquid therein when the container is inverted, and a separate passage **105** for dispensing the liquid from the container.

In the illustration given, fitting **103** includes a cup-shaped body **106** which may be constructed of a molded plastic. Cup-shaped body **106** has a neck-like portion **107** for insertion into passage **102**. Cup-shaped body **106** also has a tubular portion **108** enclosing liquid outlet passage **105** for connection to conduit **109**.

The inner end of tubular portion **108** is provided with threads for threadedly receiving annular plug or disk **110**, which in turn is received on the inside of cup-shaped body **106**. At an intermediate point, the inside surfaces of body **106** are offset at **111** and **112** to provide two annular shoulders. A non-liquid penetrable, air-permeable ring **113** has its outer and inner edges respectively supported on shoulders **111** and **112** and clamped thereto by the pressure of plug **110**. Plug **110** provides passage **104** for the admission of air, and in the illustration given has an outwardly-extending ring **114** aligned therewith for receiving a cap **115**.

As illustrated more clearly in Fig. 6, in operation of the air inlet structure of Figs. 5 and 6, air passes inwardly from passage **104** through membrane **113** into the annular space **116**. The inward pressure differential across membrane **113** will cause it to bulge inwardly as shown slightly exaggerated in Fig. 6. This permits the whole area of the diaphragm to act for the transmission of air into annular space **116**, and this is important for high rates of flow. Further, this permits membrane **113** to be formed in the manner illustrated more clearly in Fig. 9. As illustrated, membrane **113** is formed of a thin plastic film having a plurality of minute slits or punctures **117**

therethrough. Slits **117** are shown as distributed over the whole surface area, and this is preferred. Membrane **113** also acts as a filter.

The innermost portion of the air inlet passage, designated by the number **118**, communicates with annular passage portion **116** and cooperates therewith in providing an air collection chamber similar to air collection chambers **23** and **23'**, as previously described. Passage portion **118** also provides the outlet for the air into the intravenous solution, which outlet is adapted for forming discrete, visually-observable bubbles. It has been found that the size of the bubbles released into the solution can be regulated by proper dimensioning of the outlet opening from the air collection chamber. For example, bubbles containing a volume of approximately 0.1 cc. are formed when the outlet opening has a diameter of 0.2 inch.

It is preferred to mold the parts of fitting **103**, except for membrane **113** and cap **115**, out of plastic such as a phenolic resin, but other materials can be used. It is preferred to adapt fitting **103** for a series hookup. The outer end portion of air passage **104** can be molded with a standard Luer taper, as illustrated in the drawing at **119**. This permits conventional needle shank adaptors to be employed as the means for connecting a tube leading from a second container to a container equipped with the fitting **103**.

A slight modification of fitting **103** is illustrated in Fig. 7, being designated by the number **103'**. In this form, the cup-shaped body **106'** is provided with an inwardly-extending skirt portion **106'a** having internal threads engageable with the threads on the neck of container **100'**, as illustrated in Fig. 7. The corresponding elements of the embodiment of Fig. 7 have been given the same numbers as the embodiment of Figs. 5 and 6, except that the numbers have been primed, and therefore the previous discussion of the corresponding elements of the embodiment of Figs. 5 and 6 will be seen to apply.

Fig. 8 illustrates a still further embodiment of the present invention, as the complete package would appear. The container **200** is provided with a neck portion **201** having a bead **202** on the outside thereof for use in clamping the closure assembly to the container. The closure employed is like the one described in Falk Patent No. 2,108,583, consisting of an inner clamping ring **203** and an outer clamping ring **204** with a metal disk **205** and a flexible rubber disk **206** therebetween. In the structure described in Patent No. 2,108,583, inner clamping ring **203** holds the rubber stopper in place, and it also has this function in the structure of Fig. 8, the rubber stopper being designated by the number **207**. In addition, a non-liquid penetrable, air-permeable diaphragm **208** is clamped beneath inner ring **203** and against plug **207**. Plug **207** is provided with a liquid outlet passage **209** and an air inlet passage **210**.

Operation

The operation of this invention is well illustrated in connection with the embodiment of Figs. 5 and 6. Fig. 6 shows the invention in operation as part of a parenteral administration set, air flowing in through passage **104** and the intravenous liquid being dispensed through passage **105**. It will be understood that before this condition is achieved, certain preliminary steps may be desirable, such as clearing the set of air by passing a portion of the liquid downwardly through conduit **109**. This can usually be, and in the case of the embodiment of Figs. 1 to 3 is, preferably accomplished while the air inlet passage is capped, for example by cap **115**. The liquid will drain out through conduit **109** until sufficient vacuum is developed in the air space above the liquid in container **100** to hold up the column of liquid in conduit **109**. The needle is then inserted in the vein of the patient, and the administration is commenced by removing cap **115** and thereby opening the air inlet passage.

When the air inlet passage is first opened, bubbles will rise rapidly and close together from the air inlet tube until the pressure within the container air space, plus the hydrostatic head of liquid in the container, is sufficient to balance the external atmospheric pressure. Then at this equilibrium condition, for each increment of liquid flowing out through the outer passage there will be a definite mass or volume of air transferred to the air space above the liquid in the form of relatively large bubbles and the bubbles will be spaced apart, thus making them easily countable. The number of air bubbles per minute can be selectively controlled by adjusting the clamp or control means on conduit **109** with which it will be understood that the conduit is provided, as illustrated in Fig. 1 in connection with another embodiment of this invention.

In actual operation, the liquid-impervious character of membrane **113** is largely a safety feature, since normally both annular chamber **116** and bubble-forming chamber **118** will be filled with air. The same is true of capillary portion **22** in the embodiment of Figs. 2 and 3, which provides a liquid seal in the event that liquid descends to the level of capillary portion, although it would not usually do so during normal operation.

It has been found that the rate of liquid administration can be maintained substantially constant during the entire course of administration, and that if the operation of the set is interrupted in any manner, the desired rate will be automatically re-established. If the container is accidentally disturbed by bumping or shaking, the flow will only be temporarily disrupted. The disturbing of the container may cause the liquid to move downwardly within the air collection chamber. However, as soon as the container is stabilized, the air readily displaces the liquid from the collection chamber, thereby reestablishing the desired conditions for equilibrium operations of the set. At any given setting of the control clamp, the rate of liquid dispensed (hence, the rate of bubble admission) is substantially constant throughout the course of the administration. However, the resistance to flow of air offered by the air inlet passage increases as the rate of air flow increases so that approximately the same number of bubbles is admitted per unit of liquid dispensed for rates of liquid flow commonly used in regulated parenteral administration. For example, administration rates of about one liter per hour have been recognized as the maximum achievable while still permitting the administrator to count the liquid drops in a drip chamber. We have been able to visually count and thereby ascertain the constancy of the number of bubbles per unit of liquid dispensed for administration rates up to one liter per hour when using an embodiment of our invention adapted to admit ten bubbles of air per cc. of liquid dispensed.

The operation of the other embodiments illustrated in the drawing is quite similar to that described above in connection with the embodiments of Figs. 5 and 6. With the embodiment of Fig. 8, it will be understood that the outer clamping ring **204** is removed, as are disks **205** and **206**. The fluid outlet plug-in connector can then be inserted through membrane **208** into fluid outlet passage **209**. The thinness of membrane **208** will permit it to be readily ruptured over opening **209** while remaining intact over the air inlet passage **210**. Air will then pass through membrane **208** into passage **210**, collecting therein and forming bubbles at the outlet therefrom in the manner previously described for the other embodiments.

It will be apparent from the described mode of operation of this invention that the container, or at least the walls thereof, should be transparent, and that best results are obtained when the liquid within the container is transparent or at least sufficiently translucent to permit the air bubbles to be viewed as they rise through the solution. However, it is possible to use the invention in dispensing relatively opaque liquids such as whole blood, since the air bubbles can be observed as they break through the upper surface of the liquid. Moreover, with

liquid suspensions such as blood, the air bubbles perform the additional function of continuously agitating the liquid. Parenteral solution containers are usually constructed of glass.

While in the foregoing specification specific embodiments of this invention have been described in considerable detailt for purpose of illustration, it will be apparent to those skilled in the art that many of the details set forth can be varied widely without departing from the spirit of the invention.

We claim:

1. In combination with the closure for an inverted liquid dispensing container, passage-providing means for exhausting liquid therefrom, passage-providing means for admitting air thereto, said air passage means being obstructed by a non-liquid-penetrable, air-permeable membrane, said air passage means including an air collection chamber inward of said membrane, said chamber being provided with a bubble-forming outlet adjacent the liquid in said container.

2. The combination of claim 1 wherein the bubble-forming outlet is dimensioned and arranged to form a series of countable bubbles of substantially identical volume.

3. A closure for a liquid dispensing container comprising a flanged cylindrical body provided with two passages extending lengthwise therethrough and communicating with the atmosphere, one of said passages being obstructed by a non-liquid-penetrable, air-permeable membrane, said obstructed passage being provided with a bubble-forming outlet adjacent the liquid in said container.

4. In combination with a transparent-walled container at least partially filled with an intravenous liquid, said container being supported in a mouth-downward position, a single-holed closure for said mouth, a fitting extending through said closure comprising liquid passage means and air passage means separate from said liquid passage means, said air passage means being obstructed by a non-liquid-penetrable, air-permeable membrane and provided with an outlet adjacent said liquid of a size adapted to form a series of countable bubbles of substantially identical volume.

5. A fitting for a liquid dispensing container equipped with a single-holed closure comprising a flanged tubular body, one end of which is adapted to be received in air-tight engagement into the hole of said closure, the flanged portion of said tubular body being provided with a peripheral skirt extending away from said received end, a removable, non-liquid-penetrable, air-permeable membrane extending between said peripheral skirt and the outer wall of the unreceived end of said tubular body whereby an annular chamber is formed, means for clamping said membrane in liquid-tight engagement with said peripheral skirt and the outer wall of said unreceived end,

said tubular body being provided with a liquid passage extending longitudinally therethrough and with a separate air passage extending through the said received end and communicating with said annular chamber said air passage at said received end terminating in a bubble forming outlet.

6. The fitting of claim 5 wherein the unreceived end is provided with external threads and wherein the means for clamping said membrane is a molded plastic plug threadably received on said unreceived end, said plastic plug having at least one additional opening therethrough whereby the said membrane is exposed to the atmosphere.

7. A fitting for a dispensing container comprising a molded cup-shaped body having a neck portion extending outwardly the base of said body, said body also being provided with a tubular portion extending inwardly the base of said body, whereby an annular trough is formed by the inner wall of said body and the outer wall of said tubular portion, said body being provided with a pair of passages extending longitudinally thereof, one such passage extending through said neck portion and said tubular portion permitting the removal of liquid from said container, and the second such passage extending through the said neck portion separate from the said liquid passage and communicating with said annular trough terminating in a bubble forming outlet adjacent the liquid in said container, said second passage permitting admission of air into said container, a removable non-liquid-penetrable, air-permeable membrane closing said annular trough to form a liquid-tight chamber, and a plug member removably mounted on said tubular portion bearing against said membrane, said plug being provided with at least one additional opening for exposing said membrane to the atmosphere.

8. The fitting of claim 7 wherein the said cup-shaped body is provided with an internally threaded peripheral skirt extending outwardly the base of said body, said skirt adapting said fitting to be threadably received on the externally threaded neck of a dispensing container.

References Cited in the file of this patent

UNITED STATES PATENTS

2,156,313	Schwab	May 2, 1939
2,214,260	Ravenscroft et al.	Sept. 10, 1940
2,222,371	Nesset	Nov. 19, 1940
2,306,222	Patnode	Dec. 22, 1942
2,333,791	Hutchison	Nov. 9, 1943
2,435,033	Campbell	Jan. 27, 1948
2,556,722	Hersberger	June 12, 1951

FOREIGN PATENTS

2,853	Great Britain	Feb. 8, 1899
987,076	France	Apr. 11, 1951