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Edwards

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[54] **ULTRASONIC NEBULIZER FOR INHALATION THERAPY**

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

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[52] **U.S. Cl.** **128/194,** 128/DIG. 2

[51] **Int. Cl.** **A61m 11/00**

[58] **Field of Search** 128/DIG. 2, 194, 128/193, 192, 186, 185, 172, 173, 173.2; 220/53

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Assistant Examiner—Lee S. Cohen
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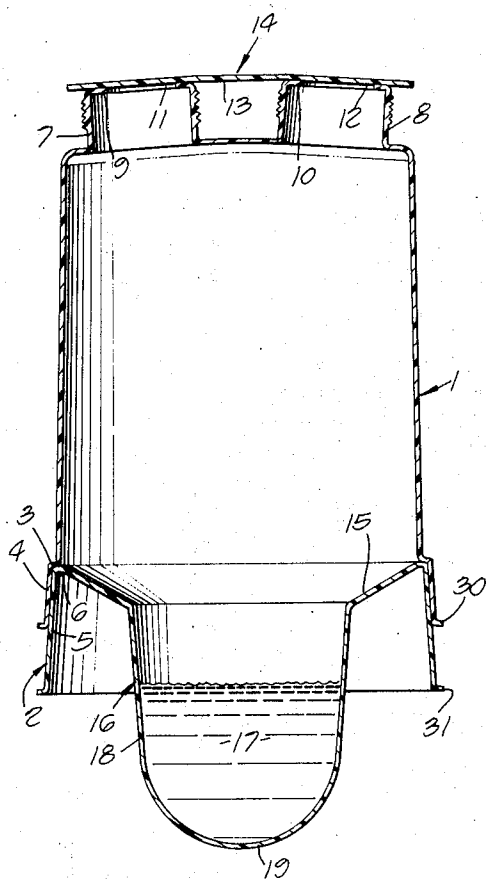
[57] **ABSTRACT**

A disposable "single shot" ultrasonic nebulizer that includes a sealed thermoplastic shell encasing a measured unit dose of nebulizable liquid that occupies less than one half of the shell's volume. The single shot cartridge type nebulizer includes an integral outwardly protruding liquid collecting nebulizer cup that progressively thins to an ultrasonically transparent dome shaped bottom wall. At an opposite end of the shell cartridge are three outwardly protruding measuring cups that provide a frangible inlet-outlet structure and also provide supporting feet for the cartridge when the cartridge is stored, shipped, etc., upside down.

19 Claims, 11 Drawing Figures



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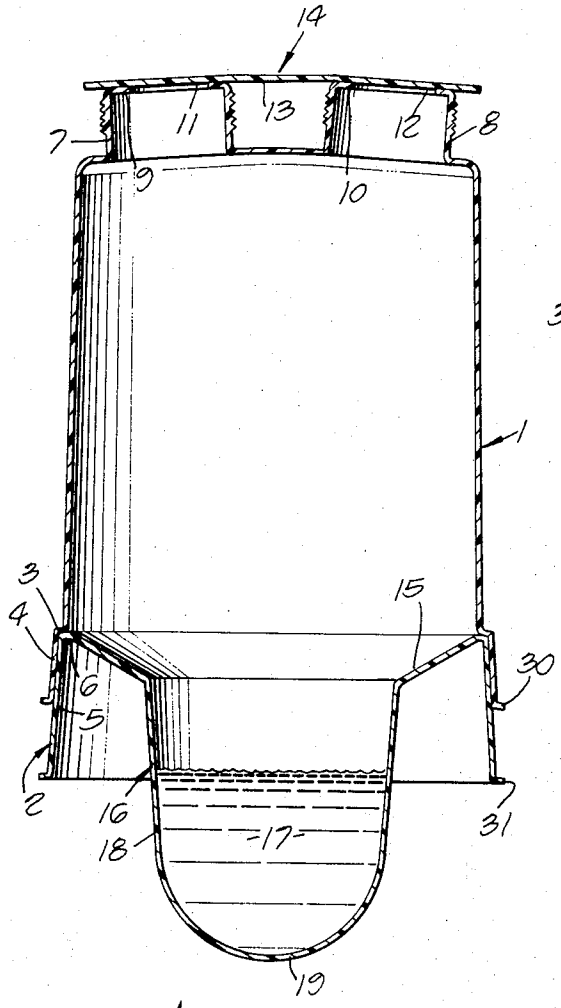


FIG. 1.

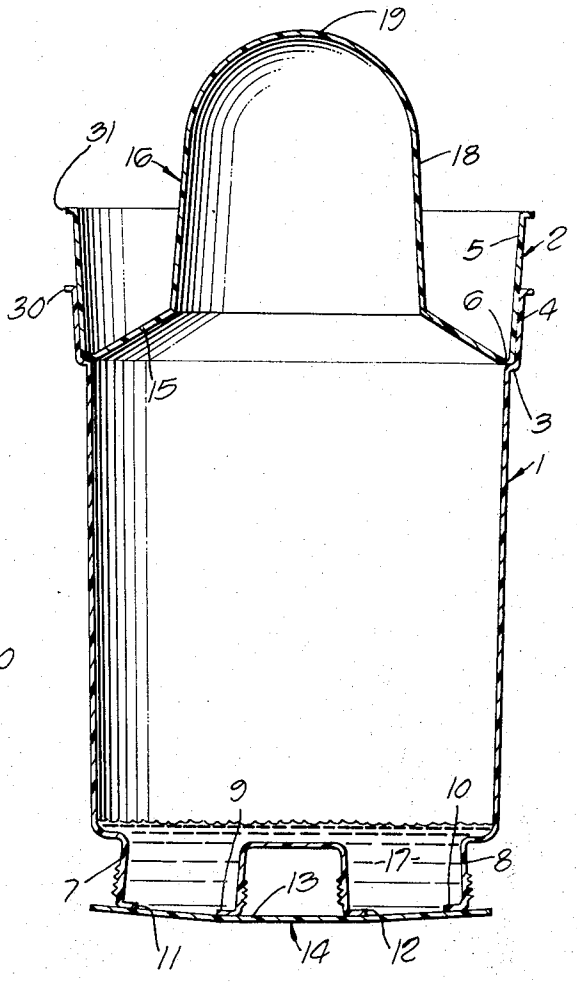
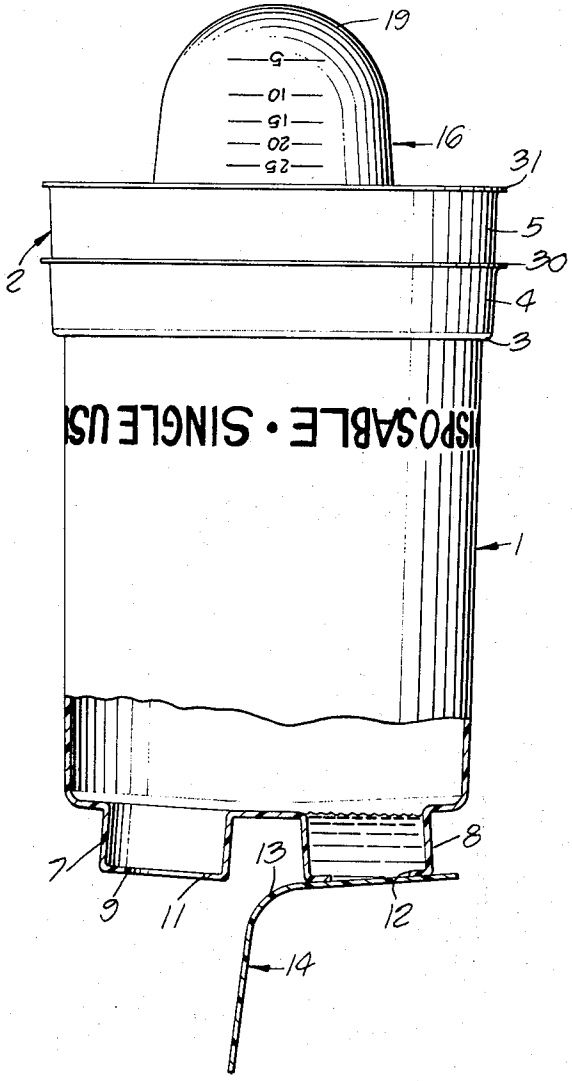


FIG. 2.

FIG. 3.



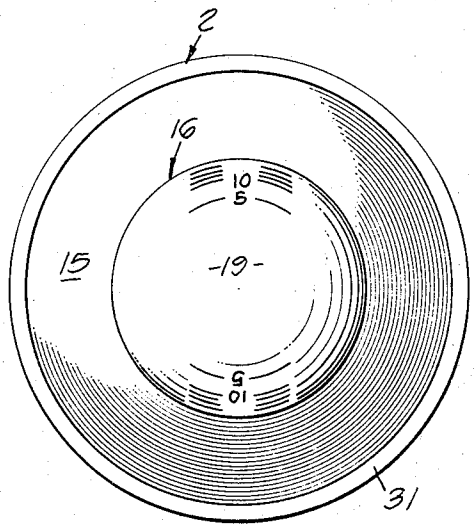


FIG. 4.

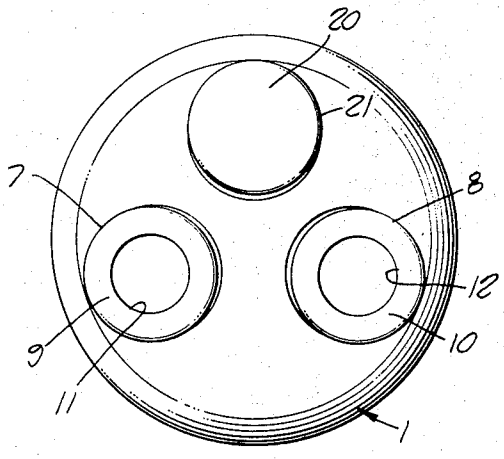


FIG. 5.

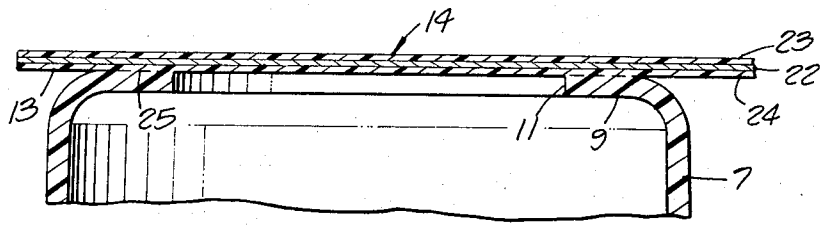


FIG. 6.

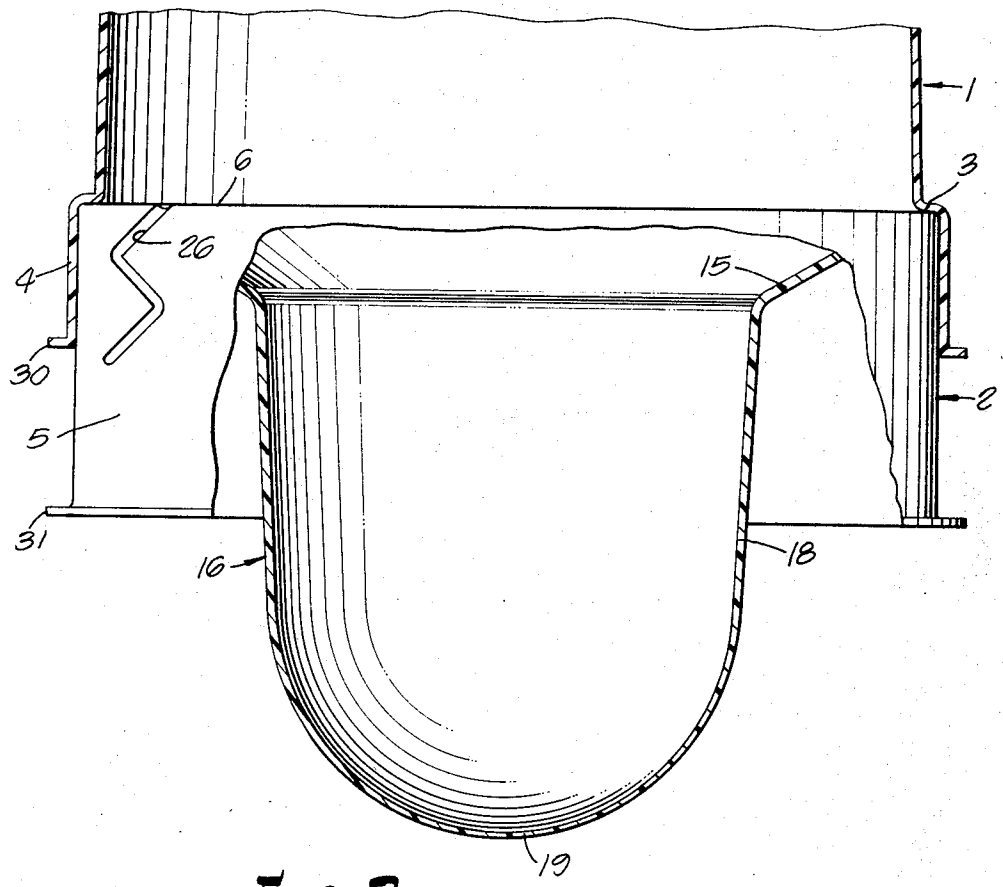


FIG. 7.

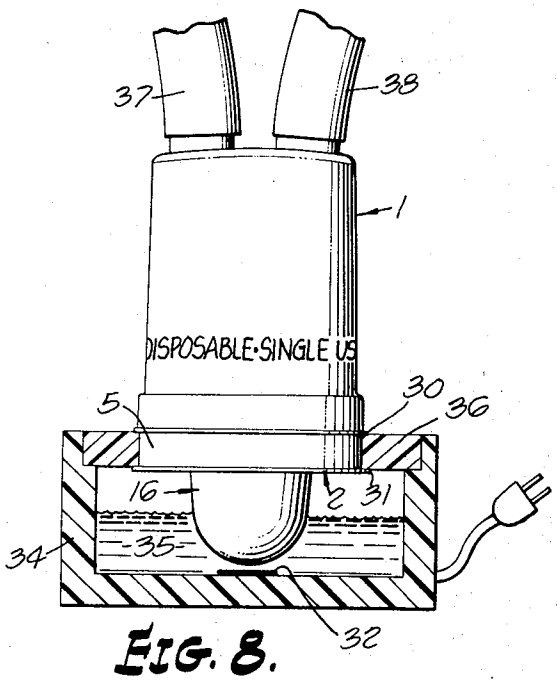


FIG. 8.

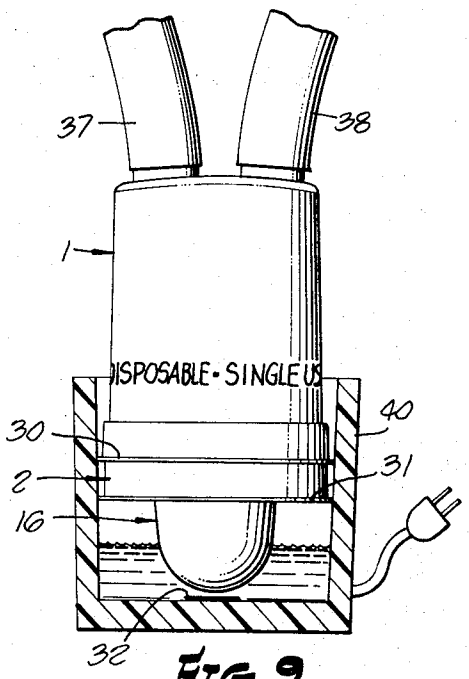


FIG. 9.

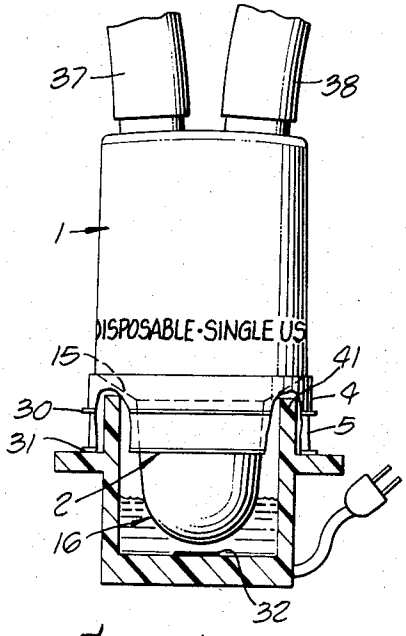


FIG. 10.

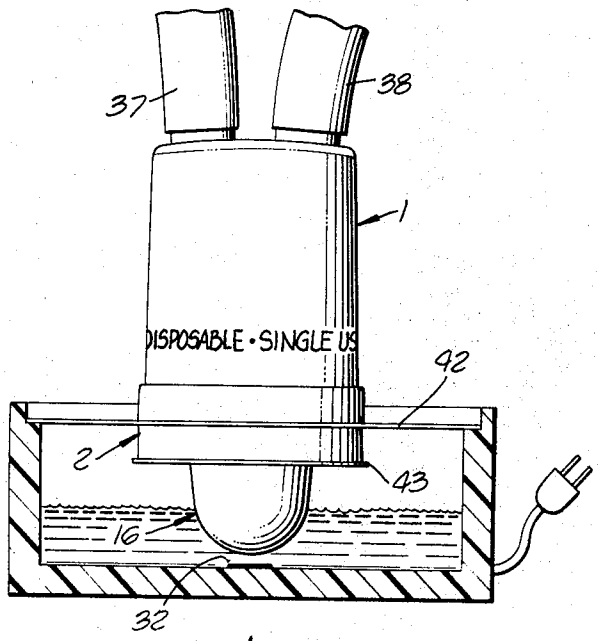


FIG. 11.

ULTRASONIC NEBULIZER FOR INHALATION THERAPY

BACKGROUND

Ultrasonic nebulization has been used increasingly in the treatment of respiratory illnesses in patients. The procedure involves using a machine to apply ultrasonic energy to a liquid surface to break it up into very minute liquid particles which are then inhaled by the patient for treatment of emphysema and other respiratory illnesses. One advantage of ultrasonic nebulization is that the liquid is much easier to absorb by the lungs when the particles are extremely small.

There have been two different types of ultrasonic nebulization used for inhalation therapy. One type is the so-called "continuous" therapy. In such therapy a patient is connected to an ultrasonic nebulizer and maintained thereon for prolonged periods of time, often several hours or days. The nebulizer equipment is continuously fed with replacement liquid as the patient consumes the nebulized liquid.

Another type of ultrasonic nebulization used with increasing frequency in recent years is a "short term" treatment by ultrasonic nebulization for inhalation therapy. The short term treatments are often only a few minutes in duration and the physician intends to give only a small prescribed amount of liquid to the patient. This type of therapy is sometimes called a "single shot" therapy and gives the patient a precise amount of liquid such as 5, 10, 15, 25 or 50 cc. Its relation to continuous ultrasonic nebulization is somewhat similar to the relationship between a quick hypodermic injection into the vein as opposed to a long continuous intravenous feeding.

In the past the set up procedures for both the continuous and "single shot" ultrasonic nebulizations were very lengthy and tedious processes for the nursing personnel. The nurse or physician had to measure out the prescribed dose of nebulizable liquid, pour it into a particular container, and connect up various parts of a nebulizing machine. This procedure inherently was open to human error. For instance, a nurse could improperly measure the liquid, might contaminate it on pouring, etc. This whole process was somewhat similar to the muzzle loading rifles of the past, with the additional problems of maintaining the poured liquid sterile. This sterility is important so as not to throw additional bacterial load on the patient's respiratory system. Patients requiring inhalation therapy are frequently in very weak condition.

SUMMARY OF THE INVENTION

I have overcome the problems with the "single shot" ultrasonic nebulizers of the past. My invention provides a sealed thermoplastic shell with a precise premeasured amount of nebulizable liquid encased by this shell. This shell can be rotated, handled, stored, etc., in any orientation and still maintain the sterile integrity of the inside surface of the shell. The thin thermoplastic shell which contains the sterile nebulizable liquid occupying less than one half of its internal volumne can be thought of as a single shot cartridge similar to modern cartridge type rifle shells. It is quickly inserted into an ultrasonic nebulizer machine, the patient nebulized with a precisely measured volume of liquid, and then the cartridge removed and discarded. This single shot one-time-use cartridge greatly reduces the chance of cross contamination between one patient and another in a hospital.

The structure of the single shot cartridge of a sealed thermoplastic shell includes an integral liquid collecting nebulizer cup with a wall that progressively thins towards integral ultrasonically transparent dome section. This dome protrudes from a bottom end of the thermoplastic shell for coupling with an ultrasonic energy source. At an opposite end of the shell is a frangible inlet-outlet system in the form of three outwardly protruding measuring cups that form a frangible opening system for the cartridge. This frangible seal system maintains the sterile integrity of the cartridge and its nebulizable liquid contents. By breaking this frangible seal to selectively open the measuring cups liquid within the shell can be reduced to a precise smaller dose of liquid.

The single shot nebulizer of this invention also includes a skirt member surrounding the thin walled nebulizer cup of the shell and this skirt has two external parallel flanges. With this configuration of the skirt, the ultrasonic nebulizer fits numerous styles and designs of ultrasonic energy nebulizer sources.

THE DRAWINGS

FIG. 1 is a sectional view of the nebulizer shell showing it with its integral collection cup extending from its bottom as it would be used with a nebulizer machine;

FIG. 2 is the single shot shell cartridge of FIG. 1 showing it inverted as it is shipped, stored and handled;

FIG. 3 is a fragmentary side elevational view showing the measuring pocket of the frangible inlet-outlet system;

FIG. 4 is a top plan view of FIG. 3 showing the nebulizer cup;

FIG. 5 is a bottom plan view of FIG. 3 showing the measuring cups after the frangible seals have been broken;

FIG. 6 is an enlarged fragmentary sectional view showing the frangible inlet-outlet structure of the measuring cups;

FIG. 7 is an enlarged fragmentary sectional view showing the progressively thinning wall of the nebulizer cup and the structure of its integral fused connection to form an integral part of the nebulizer shell;

FIGS. 8 through 11 show the supporting skirt structure with its two parallel flanges and how it supports the single shot nebulizer shell on four different ultrasonic energy machines.

DETAILED DESCRIPTION

Referring to FIGS. 1 and 2, the "single shot" nebulizer of this invention has a semi-rigid thermoplastic shell that is comprised of a generally cylindrical upper body member 1, and a lower body member 2 integrally fused together. The integral connection between upper and lower body member is at an external stepped section of the upper body member that has a ledge 3 and a downwardly extending skirt 4. Telescopically received in this stepped section is an integral skirt member 5 of the lower body portion. A shoulder portion 6 of the lower body member abuttingly engages outward flange 3. The tight telescopic fit between upper and lower body portions is sealed by an integral fusion bond made by ultrasonic welding, spin welding, solvent welding, etc., to create an integral bacteria type fusion between the two portions.

The upper body portion includes two or more integral outwardly protruding measuring cups **7** and **8**, with top surfaces **9** and **10** respectively that define openings **11** and **12** into interiors of the measuring cups. Fitting across surfaces **9** and **10** is a thermoplastic material integrally fusion bonded to these surfaces to create a sealed thermoplastic shell. This thermoplastic surface **13** is a portion of a laminated metal and thermoplastic panel, shown generally as **14**, that forms a manually peelable frangible seal at the surfaces **9** and **10**.

The bottom body portion of the shell includes a tapered drain ring portion **15** that integrally connects between shoulder **6** and a nebulizing cup **16** of the lower body portion. This drain ring **15** funnels liquid **17** as shown in FIG. **1** into nebulizer cup **16**. The configuration of the nebulizer cup **16** performs an important function of this single shot ultrasonic nebulizer. As seen in FIGS. **1** and **2** the collection cup has a tubular side wall **18** that is relatively thick at its upper end where it connects with drain ring portion **15**. This is for firm support of the collection cup **16**. As the tubular wall **18** proceeds downwardly in FIG. **1** it becomes progressively thinner and terminates in very thin bottom dome section **19**. This dome section is between 0.002 and 0.008 inch thick and provides an integral ultrasonically transparent dome section of the nebulizer container.

The "single shot" nebulizer cartridge of FIGS. **1** and **2** provides a bacteria tight sealed barrier shell for the measured unit dose of nebulizable liquid **17**. As shown in both FIGS. **1**, with the dome down, and FIG. **2**, with the dome up, the liquid occupies substantially less than one half of the internal volume of the nebulizer container. The single shot cartridge can be rotated, stored or moved in any orientation and the encased liquid is protected outside from bacterial contamination. The nebulizer container, liquid contents, and inner surface are sterile because they have previously been steam sterilized.

In the past nurses, physicians, laboratory technicians, etc., had to measure and pour a dose of liquid into a nebulizer cup. There was always a chance that either too much or too little liquid would be poured because of human error in measuring. There was also the danger of contaminating both the inner and outer surface of the nebulizer cup if liquid spilled during pouring. In addition, it was time consuming and expensive to manually fill the nebulizer cups. With nebulizer cups that were rewashed, reused on other patients, there was greater chance of cross contamination between patients.

The "single shot" nebulizer of this invention is also capable of delivering a measured amount of liquid that is less than the liquid shown in FIGS. **1** and **2**. This is done by the procedure shown in FIG. **3**. Here the frangible joint at one of the measuring cups **7** has been broken away from panel **14**. This allows measuring cup **7** to drain while the liquid is retained and measured by measuring cup **8**. Upon inverting the FIG. **3** container, the contents of pocket **8** will be dumped back into the collection cup **16**. Although the collection cup is shown as having a very curved generally semispherical bottom wall, other shapes of the collecting cup could be used.

The three measuring cups **7**, **8** and **21** are shown in the bottom plan view of FIG. **5**. It is noted that only measuring pocket **7** and **8** have holes **11** and **12**. Measuring pocket **21** has a solid end wall **20**. All three cup members have annular external ribs for gripping a hose coupling as in FIGS. **8** – **11**. On the measuring pocket for connecting to the incoming air line, the top wall can be punched with a series of small holes with wall portions between the holes deflecting incoming air so it does not materially interfere with the geyser in a center of the nebulizer chamber. This same deflecting or baffling effect can be accomplished by making a C-shaped cut in a top wall of the measuring cup and leaving a small tab that is bent down from the top wall to deflect the incoming air.

FIG. **5** shows these measuring pockets after the frangible thermoplastic bond has been broken between the panel member **14** and the surfaces **9**, **10** and **20** of the measuring cup. The three measuring cups provide a stable three legged stand for the "single shot" nebulizer container which stands on panel member **14** in FIG. **2**. The container is shipped and stored in this position. Panel **14** can also serve as a label with printed identification indicia and instructions.

In FIG. **6** the frangible relationship between the upper ledge surface **9** of measuring cup **7** and panel **14** is shown in more detail. Panel **14** includes a center laminate panel **22** of a metal foil, such as aluminum, sandwiched between an outer thermoplastic material **23** and an inner thermoplastic material **24**. Preferably the inner material is a thermoplastic of a polypropylene or polypropylene derivative. It is important that this thermoplastic material be able to take steam sterilization temperatures at between 240° and 260° F. without breaking loose from the measuring cup **7**. Measuring cup **7** is preferably of a polypropylene or polypropylene derivative thermoplastic material. Its upper ledge surface **9** is integrally fused to the thermoplastic laminate layer **24** at area **25** shown in dotted line in FIG. **6**. If this fused area has been broken it gives a visual indication that the liquid in the shell might have been contaminated. Thus, the shell and its liquid contents should not be used in inhalation therapy. The fused joint **25** formed by either ultrasonic welding or heat welding is so strong the containers are actually shipped, stored and handled with the panel **13** forming the bottom base of the nebulizer container as shown in FIG. **2**. The liquid is constantly against panel **14** but does not leak through integral fusion joint **25**. When ready for connecting to an ultrasonic energy source an overhanging tab on the panel **14** is firmly pulled to fracture the frangible fused thermoplastic joint between the panel **14** and measuring cup **7**. If the top wall of the nebulizer container supporting the measuring cups tends to flex beyond the desired limit, a more upwardly crowned configuration of this top wall can be used.

This sterile integrity of the liquid contents which occupies substantially less than one half of the volume of the nebulizing container is very critical. As mentioned above, the "single shot" container is steam sterilized. Because of the high percentage of air within the container steam sterilization is carried out in a particular way and with the structure of the nebulizer container. As shown in FIG. **7** the bottom portion of the shell includes a vent channel **26** preferably in a tortuous or zigzag shape to resist bacterial growth along itspath. The vent passage **26** is integrally formed in skirt **5** of the lower portion of the thermoplastic shell and also extends across shoulder **6**. Skirt **4** shown in section fits over and protects the vent passage **26**.

The nebulizer unit with sterile liquid contents is constructed as follows. The thermoplastic shell is oriented

as shown in FIG. 2 and then the portion 1 of the shell is filled with a precise amount of liquid. Portion 2 of the shell is then assembled as shown leaving tiny vent 26 open to the atmosphere and as shown in FIG. 7. Thus, when the assembled thermoplastic shell unit is in the position shown in FIG. 2 it is steam sterilized. Pressure differentials between the interior and exterior of the thermoplastic shell are balanced through vent passage 26. This prevents the container which is filled mostly with air from collapsing or exploding during steam sterilization to break the thermoplastic shell. After steam sterilization the portion 2 of the shell at flange 3 is integrally and permanently fused to portion 1 of the shell at shoulder 6. Alternatively the telescoped sections of skirts 4 and 5 could be fused together rather than the shoulders. Either way of sealing causes the vent passage 26 to fuse shut. Thus the liquid charge in the thermoplastic shell is rendered sterile and there is no longer a vent for possible entrance of bacteria. The thermoplastic shell which encases the liquid can be rotated, oriented and handled in any position without endangering the sterile interior of the shell or the liquid therein.

This unit as shown oriented in FIG. 2 is supplied to the hospital ready for a "single shot" administration to a patient. A single shot nebulizer container is adapted to fit to many different types of ultrasonic energy sources. A very important feature of the chamber includes the downwardly extending skirt sections 4 and 5, which have outwardly extending parallel peripheral flanges 30 and 31. The skirts with these flanges are spaced outwardly from the nebulizer collection cup 16 to create an annular recess between the cup and skirts. If desired, the skirts can be spaced closer together than shown to fit the particular structure of ultrasonic energy source machines. In FIG. 8 the nebulizer container is connected to an ultrasonic energy source shown schematically with an ultrasonically vibrating crystal 32 that is in a housing 34. A liquid coupling bath 35 connects the collecting cup's thin ultrasonically transparent dome section with the ultrasonic energy source crystal 32. The dome is supported above the crystal a prescribed distance by a supporting ring 36 that fits between flanges 30 and 31. In FIG. 8 the frangible panel 14 has been broken away and hoses 37 and 38 have been connected to circulate air through the nebulizing chamber, which air picks up the ultrasonically nebulized mist within the chamber.

In FIG. 9 the outwardly extending parallel flanges 30 and 31 wedgingly engage the side wall 40 of a different type ultrasonic energy source.

FIG. 10 illustrates still another structure of ultrasonic energy source machine which is coupled to the nebulizer chamber. This machine has a ring section 41 that extends into the annular space between collection cup 16 and skirts 4 and 5.

In FIG. 11 another ultrasonic energy source is coupled to the "single shot" nebulizing chamber. Here the upper flange 42 of the nebulizer shell has been extended a considerable distance beyond a lower flange 43. With this machine the flange 42 provides the support for the chamber.

In all of these units shown in FIGS. 8 through 11 the nebulizing cartridge is connected to the machine, used once and then discarded. I have found the entire thermoplastic shell cartridge can be formed of a polypropylene. The thin wall upper portion 1 of the chamber is preferably vacuum-formed and then integrally fused to the frangible panel 14. The bottom portion 2 is also preferably thermoformed of polypropylene material to provide the ultrasonically transparent dome of the collecting cup. It is noted that the collecting cup 16, its side wall 18, shoulder 6, skirt 2 and flange 5 are all formed of a single sheet of thermoplastic material. Thus there is no seam required betweem the ultrasonic dome portion 19 and side wall portion 18 of the collecting cup. With the combination of the configuration of the collecting cup with a dome radius less than 2 inches, the polypropylene material and the progressively thinning structure of the collecting cup wall I have unexpectedly discovered that the collection cup can be nebulized until dry of liquid and the ultrasonic energy source does not burn a hole in the cup. Previous nebulizers have been plagued and burned pinholes in their reusable ultrasonically transparent windows when they become dry. A burnt pinhole can cause the nebulizer chamber to become contaminated with the coupling liquid such as shown at 35 in FIG. 8.

In the above description I have used specific examples to describe my "single shot" ultrasonic nebulizeer for inhalation therapy. 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 disposable, measured-dosage, hermetically closed, ultrasonic nebulizer cartridge unit for use in medical therapy comprising in combination:

a single semi-rigid, self-supporting thermoplastic shell;

a measured unit dose of a nebulizable liquid in said shell occupying substantially less than one-half the shell internal volume;

said shell including an upper body member including inlet-outlet structure for connection with means for communicating the nebulized dose to a patient;

means hermetically sealing said inlet-outlet structure and maintaining the interior of said shell in a medical-sterile condition;

said upper body member having a wall connected to an outer margin of an inwardly directed, downwardly converging drain wall forming a drain ring of a substantial area terminating in a substantially reduced area inner margin of the drain wall,

said shell including a liquid collection cup having a mouth connected to the inner margin of said drain wall and a side wall depending therefrom and terminating in a bottom wall for concentrating the entire volume of the nebulizable liquid thereat, the cross section of said collection cup being substantially reduced as compared with said upper body member for concentrating the liquid dose immediately over an ultrasonic energy source; and universal support means on said shell adjacent the lower margin of said upper body member for adapting the cartridge to a plurality of differently constructed ultrasonic energy source apparatuses.

2. The combination as claimed in claim 1 in which said means hermetically sealing sid inlet-outlet structure comprises manually removable frangible seal means capable of withstanding sterilization temperatures of from 240° to 260°F and forming visual indication means whereby fracture of the hermatic seal indi-

cates contamination of the medical dose liquid and aprizes a user that the cartridge should not be administered to a patient.

3. The combination as claimed in claim **2** in which said inlet-outlet structure comprises tubular sleeve elements terminating in peripheral flanges to which said frangible seal means is secured, said seal means including a projecting tab portion projecting beyond the peripheral flange to faciliate manual rupture and removal of the seal means.

4. The structure as claimed in claim **2** in which said bottom wall is convex and comprises the thinnest portion of said collection cup.

5. The combination as claimed in claim **1** in which said collection cup comprises a progressively thinned side wall terminating in a transverse bottom wall ranging from 0.002 to 0.008 inches thick to form an ultrasonically responsive window.

6. The combination as set forth in claim **1** wherein the collecting cup converges toward a bottom outwardly facing convex dome area, and said cup progressively thins from its mouth to a center portion of said convex dome section.

7. The combination as set forth in claim **6** wherein the central dome area is between 0.002 and 0.008 inch thick.

8. The combination as set forth in claim **1,** wherein the shell has a plurality of measuring cup members, at least one of which is openable for draining liquid from the shell to leave a measured amount of liquid within said shell.

9. The combination as set forth in claim **1** wherein said shell includes at least three outwardly protruding measuring cup members having generally co-planar outer surfaces for combining to provide a tripod support for the thermoplastic shell.

10. The combination as set forth in claim **9,** wherein the collecting cup and measuring cup members are on opposite ends of the thermoplastic shell, whereby liquid measured by said measuring cup member will dump into said collecting cup with orientation of the thermoplastic shell to place the collecting cup lowermost.

11. The combination as set forth in claim **1** wherein the thermoplastic shell includes an upper body portion and a lower portion including the collection cup which are integrally fused together.

12. The combination as set forth in claim **11** wherein the lower portion and upper portion telescopically fit together adjacent said fusion bond.

13. The combination as set forth in claim **1** wherein the outer margin of the drain ring fits in a recess of the upper body member and is fused there to said upper body member.

14. The combination as set forth in claim **1** wherein the thermoplastic shell is generally cylindrical and substantially larger in diameter than the collection cup's side wall.

15. The combination as set forth in claim **14** wherein the thermoplastic shell includes a skirt member which encircles said collecting cup at a space distance outwardly therefrom, said collecting cup having a dome area protruding below said skirt member.

16. The combination as set forth in claim **1** wherein the thermoplastic shell universal support means includes a pair of parallel exterior circumferential flanges for supporting the shell on an ultrasonic energy source.

17. The combination as set forth in claim **1** wherein the universal support means includes at least one external annular flange integral with said upper body member adjacent said drain wall.

18. The combination as claimed in claim **1** wherein the universal support means includes an outer annular support surface adjacent the outer margin of the drain wall, said outer annular support surface being spaced outwardly from the drain wall's inner margin so that the cartridge can be supported by structure surrounding an opening that is approximately the size of the outer margin of the collection cup, and can also be supported by structure surrounding an opening approximately the size of the inner margin of the drain wall.

19. The combination as set forth in claim **1** in which said thermoplastic shell has sealable vent means, said vent means being fused shut after sterilization of the shell and the liquid contents being maintained in a medically sterile condition by subjecting the cartridge to temperatures of 240° to 250°F.

* * * * *