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McPhee

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[54] **PORT SYSTEM FOR MEDICAL HUMIDIFIER CONTAINER**

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

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[52] **U.S. Cl.** **261/123,** 128/188, 128/194, 222/400.7, 261/DIG. 65, 285/DIG. 22

[51] **Int. Cl.** **B01f 3/04,** A61m 15/00

[58] **Field of Search** ..... 222/400.7, 153, 3, 5; 128/186–188, 194; 285/DIG. 22; 215/42; 261/123, 78 A, DIG. 65

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[57] **ABSTRACT**

A dual passage adapter for providing an inlet-outlet port system that couples a medical liquid bottle to a medical gas source. The adapter has a snap lock feature which permanently connects it to the medical liquid bottle so the adapter can be used with only one bottle to reduce risk of cross-contamination among patients. Gas and liquid are mixed in the bottle and exit through the adapter as humidified gas which a patient breathes during inhalation therapy.

24 Claims, 5 Drawing Figures

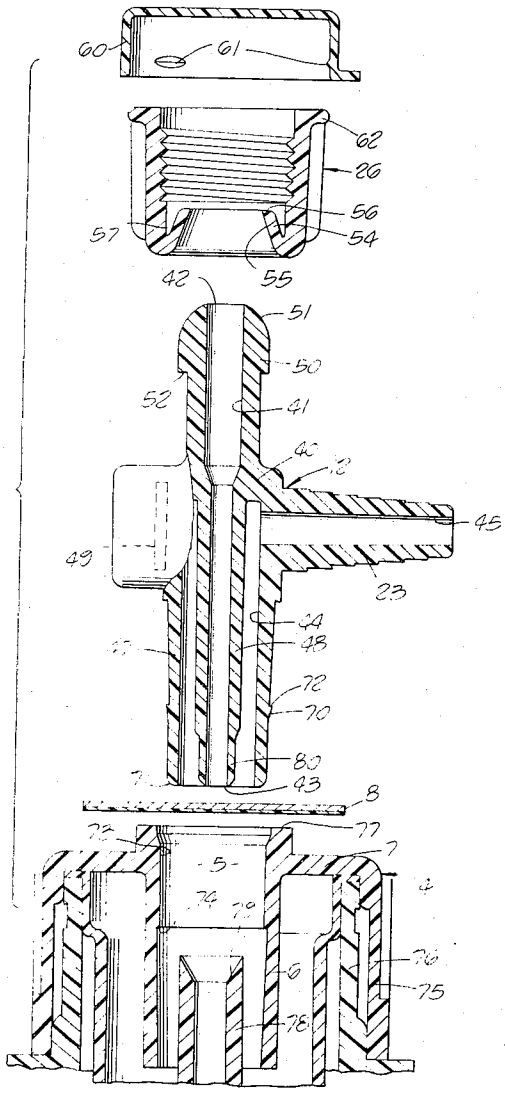
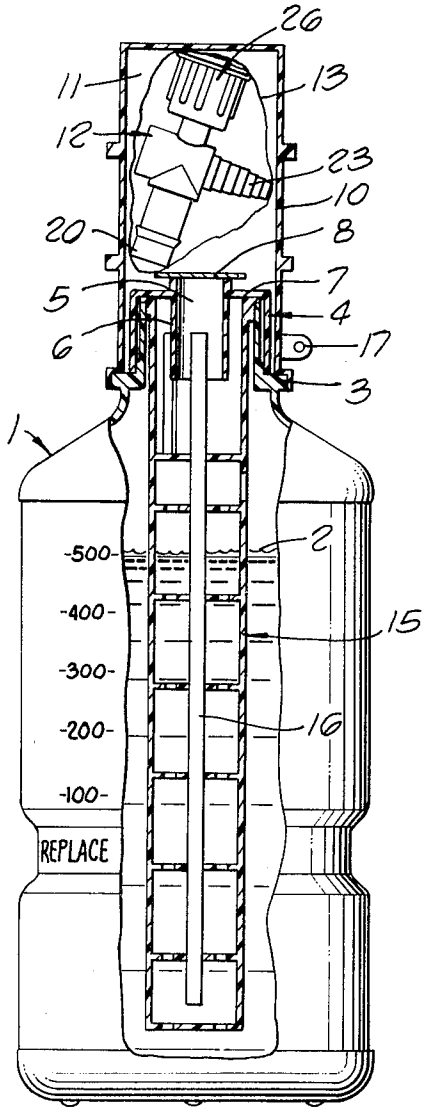


FIG. 1.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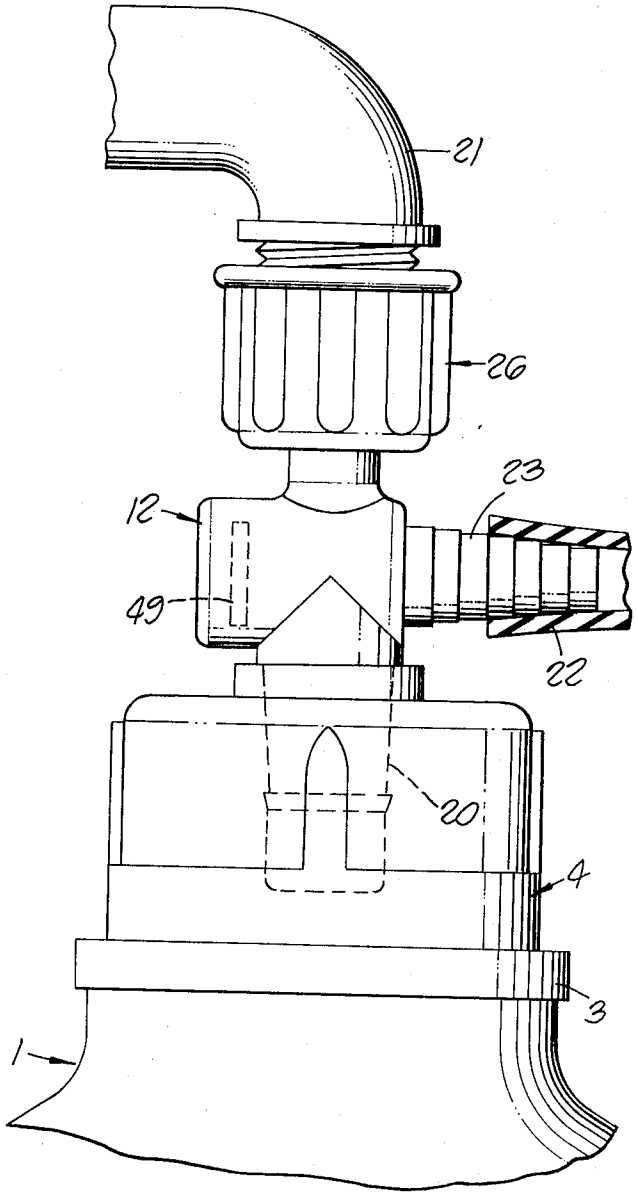
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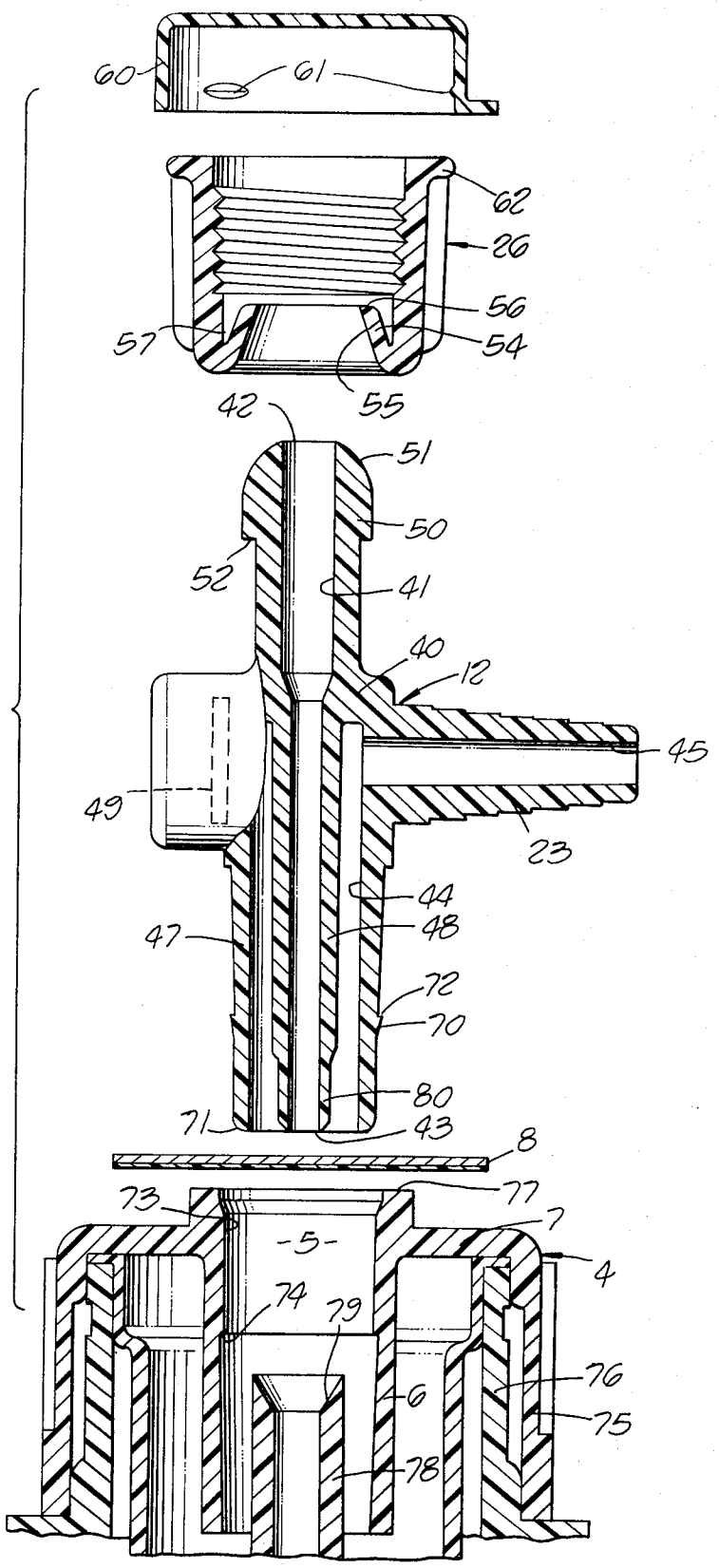
FIG. 2.

FIG. 3.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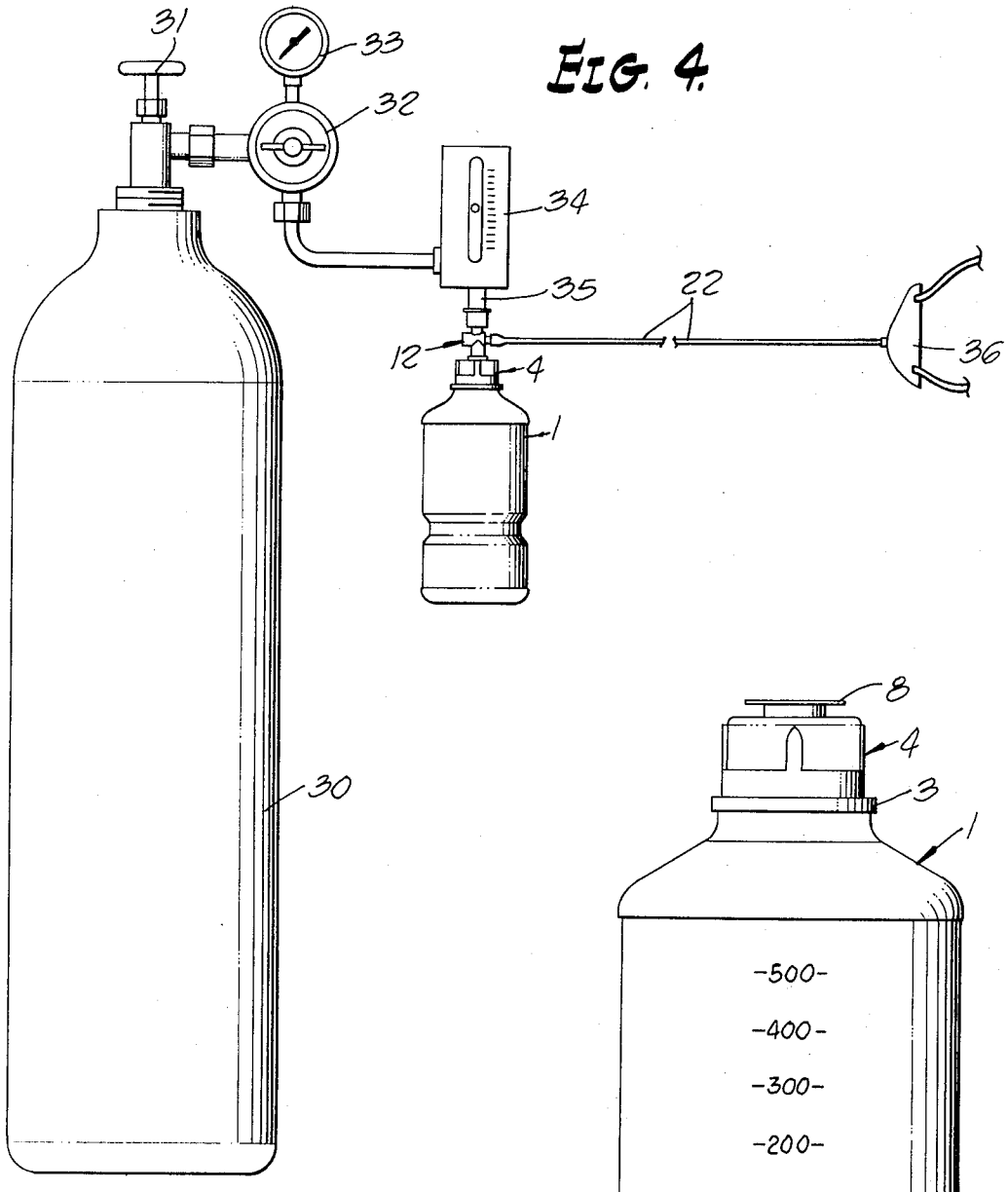

FIG. 4.

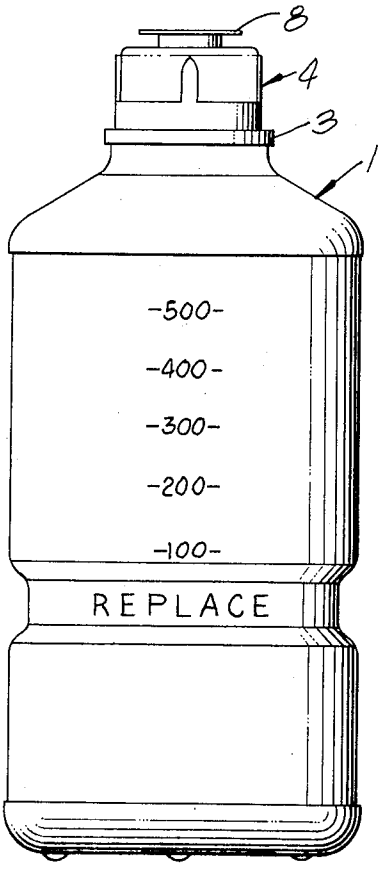

FIG. 5.

PORT SYSTEM FOR MEDICAL HUMIDIFIER CONTAINER

BACKGROUND

Inhalation therapy has been used very extensively in recent years for treatment of emphysema and other lung and respiratory diseases as well as post operative treatment and cardiac patient care. One form of inhalation therapy involves mixing a breathable gas such as air or oxygen with a liquid. This humidified gas is supplied to a mask, nasal cannula, or tent, where it is breathed by the patient and absorbed by his lungs. A conventional medical humidifier system includes a dry gas source such as a portable oxygen tank or central oxygen supply system of a hospital, coupled with a container of the humidifying liquid. Humidification is accomplished by atomizing the liquid into the gas or bubbling the gas through the liquid.

There has been a problem in previous medical humidifier arrangements with the apparatus for connecting and disconnecting the gas and liquid supply sources. It was often a cumbersome procedure to change liquid supply bottles when their liquid contents had been consumed. Elaborate procedures, some with special tools, were proposed to reduce chance of cross-contamination between patients. The coupling structure between the liquid and gas sources carried a higher risk of contamination than other portions of the humidifier because this was the area most handled during connection and disconnection of a liquid supply bottle.

One previous suggestion of coupling the liquid and gas supply sources included a cap at the bottle inlet which cap had an integral thin plastic nipple. This nipple had to be snipped off with a pair of scissors to open the bottle. A separate outlet of the same bottle also had an integral thin plastic nipple that had to be snipped with scissors. The problem with this proposal was that scissors are not always sterile and could pick up considerable contamination when used to cut bandages, etc., in general hospital use. Also there would be a problem with this proposal if a nurse or physician misplaced his scissors because there would be no way of opening the system.

I have overcome the problems of previous connecting arrangements of liquid and gas in medical humidifiers by providing a simple, easy-to-use connection arrangement that requires no tools and reduces the risk of cross-contamination between patients.

SUMMARY OF THE INVENTION

In my invention I have provided a special adapter with a dry gas inlet passage and a humidified gas outlet passage which adapter snap locks into permanent connection with a bottle cap to provide an inlet-outlet port system for the bottle. The special adapter is supplied to the hospital encased in a sterile chamber of an outer cap of the bottle. Immediately before use a nurse tears off the outer cap, removes a barrier closing off the bottle outlet and then pushes the special adapter into the bottle closure where it locks into permanent connection with the bottle. The adapter is then connected to an oxygen or other dry gas source where the adapter suspendingly supports the bottle while its liquid contents are consumed in the humidifying process.

THE DRAWINGS

FIG. **1** is a front elevational view partially in section showing the bottle adapter and outer cap combination as supplied to hospitals ready to use;

FIG. **2** is an enlarged fragmentary front elevational view of the adapter after it has been connected to the bottle and to a gas supply source;

FIG. **3** is an exploded enlarged sectional view showing the various parts of the special adapter;

FIG. **4** is a front elevational view showing the adapter supporting the medical liquid bottle from a flow meter connected to an oxygen tank; and

FIG. **5** is a front elevational view showing the medical liquid bottle after the outer cap has been removed but before the adapter has been inserted into the closure system.

DETAILED DESCRIPTION

With reference to the attached drawings, FIG. **1** shows the liquid supply unit for a medical humidifier as the unit is supplied to hospitals by the manufacturer. The unit includes a bottle **1** containing a liquid **2** to be consumed in the humidifying process. At the top of bottle **1** is a neck portion **3** that defines an outlet of the bottle. Permanently bonded to the neck surrounding the outlet is an inner cap **4.** This inner cap **4** has a central passage **5** defined by a sleeve **6** which is integrally formed with a top wall **7** of the inner cap. A tear off barrier film **8** of thermoplastic and metal foil seals off passage **5** and is bonded to sleeve **6.** The bond between barrier film **8** and sleeve **6** is sufficiently strong to withstand steam or water immersion sterilization at 240° – 260° F. and maintain a bacteria-tight seal. However, after sterilization the film **8** can be peeled off to open passage **5.** Thus the cap **4** and barrier **8** completely close the bottle so that no liquid can escape before, during, and after sterilization until a nurse or physician peels off the barrier film **8.**

Fitting over the inner cap **4** and the neck portion of the bottle is an outer cap **10** with a large interior hollow chamber **11.** This outer cap **10** is permanently bonded to the bottle and has a rip apart tear strap **17** for gaining access to the inner cap. Prior to peeling off tear strip **17** the outer cap forms a protective package for the inner closure **4.** Fitting inside hollow chamber **11** is a special adapter **12** which is encased in a flexible protector bag **13.**

Directly below the outer cap **10** and inner cap **4** is a multistage sieve column **15** submerged in the liquid **2** of bottle **1.** Dry gas, such as oxygen, is supplied through a dry gas supply tube **16** and is humidified in the column. This mixing column is of modular snap together construction and is explained in more detail in my copending patent application entitled "Mixing Column for Medical Humidifier and Method of Humidifying Inhalable Gases," filed June 19, 1972, Ser. No. 264,314.

As shown in FIG. **1,** the unit supplied to the hospital is ready for use. When an inhalation therapy procedure is ready to be performed the nurse or physician removes outer cap **10** by ripping off a peel tab **17.** This leaves the bottle as shown in FIG. **5.** The special adapter **12** is then removed from the outer cap **10** and its protector bag **13** opened to expose only the adapter's lower end **20.** Preferably, a weakened rip open structure is provided on the flexible protector bag **13.**

Next the barrier 8 is peeled off of the inner cap 4 to open up the entrance passage 5 of the inner cap. The adapter's lower end 20 is then forced down into passage 5. The bag may be kept on an upper portion of the special adapter to protect it from contamination by the nurse's hands as it is shoved into the inner cap passage 5.

After the adapter 12 has been snap-locked into the bottle closure as shown in FIG. 2, a screw cap 26 at an upper end of the adapter is then threadingly secured to an oxygen or other dry gas source 21. This dry gas source is shown schematically as a nipple outlet in FIG. 2. The term "dry gas" is used to distinguish the input gas, such as oxygen, from the humidified gas delivered to a patient. A supply tube 22 is then connected to a tubular side arm 23 of the adapter. With this connection as shown in FIG. 2, gas from dry gas source 21 is fed through the adapter 12 and into the bottle 1. Here it is humidified by mixing with the bottle's liquid content and is thereafter fed out through tube 22 to a patient. This tube could lead to nasal cannula, oxygen mask, an oxygen tent, etc. The purpose here is to supply humidified gases directly into the lungs of the patient when it can be absorbed by his body.

The complete inhalation therapy humidified system as connected together is best shown in FIG. 4. Here an oxygen tank 30 has a dispensing valve 31 which is connected to a regulator 32 and a pressure gauge 33. The regulator is in turn connected to a flow meter 34. The bottom of the flow meter 34 has a nipple 35 which corresponds to the schematic gas supply line 21 in FIG. 2. The special adapter 12 is connected to the nipple 35 and supports the bottle 1 therebelow. The supply tube 22 here is shown connected to a breathing mask 36.

This is the inhalation therapy system as it is connected ready for use and the invention of this application has to do with the port system at the top of bottle 1 and the special adapter 12 that connects the bottle to the dry gas supply source. The special adapter that is shown in FIG. 1 encased in the outer cap 10 is illustrated in much more detail in FIG. 3. In FIG. 3, the adapter 12 has a body member 40 with a first passage 41 that extends from an upper end 42 to a lower end 43. This passage carries the dry gas from the dry gas source into the liquid supply bottle. Body member 40 also has a second passage 44 that extends upwardly from a bottom end 43 to a mid-portion of the body and there communicates with a passage 45 of a tubular side arm 23. The second passage 44 is annularly disposed between an outer tubular wall 47 and an inner tubular wall 48 which are concentrically located on a common longitudinal vertical axis as shown in FIG. 3. Thus, the passage structure of the body member 40 includes an inlet passage 41 for dry gas and an outlet passage 44 for humidified gas.

The body member 40 also includes a flexible pressure relief valve system 49 which is described in more detail in my co-pending application entitled "Audible Pressure Relief Valve for Medical Humidifier," filed June 19, 1972, Ser. No. 264,349.

At an upper portion of the adapter 12 is a top connecting structure connecting the adapter and attached bottle to a dry gas supply source. This structure includes an upper portion of body member 40 that has an annular flange 50 with a sloping lead-in surface 51 and a retention shoulder 52. A separate element of the connecting structure of adapter 12 is a threaded nut or screw cap 26 with an internal lock flange 54 adjacent one end. This lock flange is separated from an internal wall surface of the lock nut by a space 57 and has a sloping surface 55 that joins with retention surface 56. To assembly the lock nut to the body member 40 the nut is pushed down upon flange 50. The retention surface 56 abuts and slidingly engages shoulder 52 to permanently lock the nut to the body member 40. The lock nut 26, thus, is free to rotate on body member 40. Fitting over an upper end or mouth of lock nut 26 is a protector cover 60 that includes a series of internal locking ribs 61. These ribs snap over an outer flange 62 surrounding a lip of the locking nut to connect the cover and nut together until removed by a nurse or physician immediately prior to use.

At a lower end of the adapter is a bottom connecting structure of external flange 70 with tapered lead-in surface 71 and an abutting shoulder 72. This bottom connecting structure mates telescopically with the sleeve 6 of inner cap 4 in a snap fit that temporarily expands sleeve 6. The internal mating structure of sleeve 6 of the cap is shown in the lower portion of FIG. 3. Here a wedge surface 73 of the inner cap extends between to a tapered lead-in funnel portion adjacent a lip 77 and a retention shoulder 74. This shoulder 74 is perpendicular to a longitudinal axis of sleeve 6 so the adapter can be rotated in sleeve 6 without unscrewing therefrom. As shown in this drawing the cap 4 has a skirt 75 that is permanently bonded to the bottle neck 76. Thus, the only entrance to the bottle is through passage 5 of sleeve 6.

After the removable barrier film 8 has been peeled off from an adhesive or heat-sealed bond with a lip 77 of the inner cap 4, the adapter body 40 is shoved into passage 5. This does two things. First, it intermeshes and permanently locks the abutting shoulder surfaces 72 and 74 together, while allowing the bottle to be rotated through 360° relative to the adapter to orient the bottle's volume indicator for clear viewing. Since the outer cap 4 is permanently connected to the bottle, the adapter 12 is now permanently locked to the bottle and cannot be used for administering a different bottle of liquid.

The second thing to occur when the adapter is shoved into passage 5 is a guided telescopic fitment between the dry gas tube 48 of the adapter and a dry gas tube 78 within the bottle. Dry gas tube 78 has an upper lead-in surface 79 that engages with a thinned wall portion 80 of the adapter's dry gas tube 48. In this manner the tubes 48 and 78 can be axially aligned, and telescopically joined at their ends to create a hollow supply line through the adapter 40 and into a lower portion of the bottle where humidification of the gas begins.

Once the adapter is snap locked into the bottle and cannot thereafter be removed, the adapter is connected to an oxygen tank or an oxygen wall line for suspending the bottle as shown in FIG. 4. The liquid contents of the bottle are then consumed to a recommended level of the bottle. Then the screw nut or cap 26 is loosened from flow meter 34 and the bottle discarded. If a patient needs therapy from more than one bottle, a replacement bottle of liquid is connected as shown in FIG. 4 in the same manner as described above.

An important feature of this structure of the applicant's invention is that the nurse is required to use a new sterile adapter with each bottle that is opened. This keeps down risk of cross-contamination between

patients, and mixing of different medicaments from bottles that proceed through a common adapter. After a single treatment on a single patient the entire bottle and adapter are discarded.

In the above description I have used a specific example to described the improved port system of a liquid supply bottle for a medical humidifier. It is understood by those skilled in the art that certain modifications can be made to this example without departing from the spirit and scope of the invention.

I claim:

1. In a system for administering a humidified medical gas to a patient during inhalation therapy and substantially deterring cross-contamination between patients comprising, for use in combination with a source of dry medical gas to be administered to a patient after humidification and means for connection to said source of medical gas for dispensing the gas;

a disposable dry medical gas humidifying assembly including means for connection to said means for dispensing the dry medical gas from the source; and means for administering humidified medical gas to a patient, said gas humidifying assembly comprising a disposable container for a medical liquid, said container including connection-and-retention means; and an adapter for connecting the dry medical gas source with the medical liquid container comprising a body member having a dry gas passage extending from an inlet adjacent a top portion of the body member to an outlet adjacent a lower portion of the body member, and a humidified gas passage extending from an inlet adjacent a lower portion of the body member upwardly to an exit portion on the body member; first connecting means on the body member at the dry gas passage inlet for connecting the adapter to the medical gas source; second connecting means at the dry gas passage outlet and humidified gas passage inlet for connecting the adapter with the medical liquid container, said second connecting means of the adapter and the connection-and-retention means of said container having interfitting structure including portions that permit the adapter to be manually connected to the container and integrate it as a permanent non-separable part thereof and deter subsequent manual separation therebetween whereby the adapter and medical container are discarded as a unit after inhalation therapy with the unit is completed and reuse of the humidifier assembly is deterred so that cross-contamination between patients is obviated.

2. The combination as set forth in claim **1** wherein the first connection means of the adapter includes a rotatable screw cap including means adapted for removable securement to a threaded nipple of the medical gas source.

3. The combination as set forth in claim **1** wherein the adapter's first and second connecting means include portions integral with the body member and means to physically suspend the medical liquid container from the medical gas source.

4. The combination as set forth in claim **1** wherein the lower connecting means includes an annular flange about said body member which annular flange has a top retention shoulder surface and a lower wedge surface extending downwardly from said shoulder surface.

5. The combination as set forth in claim **4** wherein the container comprises a portable bottle with a mouth and a cap member sealing off said bottle mouth, which cap member has an entrance passage defined by a deformable inner wall surface, said inner wall surface including a lower inwardly-projecting retention shoulder surface and a wedge surface above said shoulder surface, which wedge surface of the cap member is adapted to telescopically receive said wedge surface of the adapter when the inner wall is deformed upon insertion of the lower portion of the body member into the cap member passage so that the two shoulder surfaces can snap together permanently locking the adapter to the cap member of the medical liquid bottle.

6. The combination as set forth in claim **5** wherein the adapter includes means providing a rotatable coupled engagement with the bottle closure and abutting shoulder surfaces on the adapter and closure engage each other whereby the adapter's exit port can be rotationally oriented relative to said bottle.

7. The combination as set forth in claim **6** wherein the adapter and bottle includes means forming a non-separable 360° rotatable connection without separation from the closure.

8. The combination as set forth in claim **5** the cap member includes means permanently bonding it to the mouth of the medical liquid bottle.

9. The combination as set forth in claim **5** wherein the medical liquid bottle includes a gas tube with an upper end having a passage that aligns with and connects to the inlet passage of the adapter upon coupling of the adapter to the bottle closure.

10. The combination as set forth in claim **9** wherein the gas tube in said container is concentrically disposed inwardly of the wedge surface and shoulder structure of the cap member.

11. The combination as set forth in claim **9** wherein the adapter includes an outer tubular member defining the passage that communicates with the exit port of the adapter, and a concentrically inwardly disposed gas tube that defines the inlet passage through the adapter, said gas tube of the adapter having a lower end with coupling structure to connect with the upper end of a gas tube within the container.

12. The combination as set forth in claim **9** wherein the exit port communicates with the interior of the bottle through a concentric passage surrounding the gas tubes of the adapter and bottle.

13. The combination as set forth in claim **1** wherein the upper end of the body member includes a tapered external flange with a retention shoulder; and a rotatable screw threaded cap fitting over said flange and rotatably slidable against said shoulder.

14. The combination as set forth in claim **13** wherein the rotatable screw cap includes an internal wall surface and an annular skirt section spaced from an internal wall of the cap, said skirt being annularly expandable over said flange for permanently and rotationally connecting of the screw cap to said body member.

15. The combination as set forth in claim **13,** wherein the screw cap has a mouth portion, and the combination includes a removable closure for this mouth for maintaining sterile integrity of the adapter.

16. The combination as set forth in claim **15** wherein the screw cap has a lip surface around this mouth and a removable protector cap fits over said rotatable screw

cap lip surface protecting it until ready for connection to a medical gas supply source.

17. For use in medical inhalation therapy the combination of: a liquid-containing bottle having a mouth; a cap sealed to said mouth, and including an entrance port through the cap; a manually removable sealing member closing off said entrance port; a gas-liquid mixing system communicating with the entrance port and adapted to humidify gas with liquid inside said bottle; an outer sterility cap secured to said bottle and enclosing said manually removable sealing member and at least a portion of said bottle closure, said outer sterility cap defining a hollow cavity therein adjacent the bottle closure; and adapter fitting within said cavity of the outer sterility cap, said adapter including a dry gas passage and a humidified gas passage; a medical gas source connecting means on said adapter for securement of the adapter's dry gas passage to a medical gas supply source; bottle connecting means on said adapter for connecting both dry gas and humidified gas passages with the bottle's interior upon removal of the manually removable sealing member and insertion of said closure's bottle means in coupling relationship with said closure port.

18. The combination as set forth in claim **17** wherein the outer sterility cap is permanently secured to said bottle and closure combination and has a frangible rip-off portion for gaining access to said adapter.

19. The combination as set forth in claim **17** wherein there is a protective sheath enclosing said adapter and both adapter and sheath are confined within the cavity of said outer sterility cap.

20. The combination as set forth in claim **17** wherein the bottle connecting means on the adapter and the closure of the bottle include cooperating structures, whereby the adapter can be manually coupled with the closure but cannot thereafter be uncoupled to prevent use of the adapter with more than one bottle.

21. The combination as set forth in claim **17** wherein the sealing member includes a metal-thermoplastic laminated film sealed to said closure across said entrance port, said foil maintaining sterile integrity of the inner portions of the closure and being manually peelable from said closure after the bottle closure and foil have been sterilized by steam or water immersion at 240° – 260° F.

22. A locking port system for an inhalation therapy liquid supply bottle having a closure cap thereon, comprising the improvement of: an expandable and deformable sleeve connected to said closure cap and defining a coupling passage, the internal surface of said sleeve including a retention shoulder and a sloping wedge surface thereabove; a gas tube member within said bottle having an upper end disposed within said deformable sleeve and spaced inwardly from its wall's inner surface; a removable sterility barrier secured to said closure cap and closing off the passage through said sleeve; said barrier being manually removable for coupling the port structure of the supply bottle with a plural passage adapter that has an external shoulder surface for snap engagement with the shoulder of the closure sleeve so that the adapter and closure cap cannot thereafter be separated, thereby avoiding use of the bottle with more than one adapter in its coupling passage.

23. The combination as set forth in claim **22** wherein the shoulder of the expandable sleeve is in a plane perpendicular to a longitudinal axis of a passage through this sleeve so that a mating shoulder surface of a coupled adapter can rotate 360° through any angle relative to the closure system without becoming disengaged from the sleeve.

24. For use in medical inhalation therapy the combination of: a sterile, disposable bottle containing a sterile medical humidifying liquid and having a mouth thereon; a closure cap fitting across said mouth and permanently and integrally secured to said bottle; a deformable sleeve member connected to said closure and defining an entrance port passage into said bottle; a dry gas tube disposed within said bottle and having an upper end concentrically disposed within said sleeve a spaced distance from its inner wall; an adapter having inner and outer concentrically disposed tubes connected together and telescopically received within said sleeve of the closure cap so that the adapter's inner tube mates with the bottle's dry gas tube and the outer tube of the adapter mates with and connects to the sleeve of the closure cap, said coupled adapter and closure system providing means for suspending the bottle and a dry gas conduit through the inner tube of the adapter and the dry gas tube of the bottle, and an outlet humidified gas passage between the inner and outer tubes.

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