

[54] **DISPOSABLE LIQUID ENTRAINING SYSTEM**

[75] Inventor: **David W. Deaton**, Dallas, Tex.
 [73] Assignee: **Ahldea Corporation**, Dallas, Tex.
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Primary Examiner—Tim R. Miles
Assistant Examiner—Steven H. Markowitz
Attorney—Richards, Harris & Hubbard

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 [51] Int. Cl..... **B01f 3/04**
 [58] Field of Search..... 128/184, 186, 187, 128/188, 194; 261/76, 78 A, 121 R, 122

[57] **ABSTRACT**

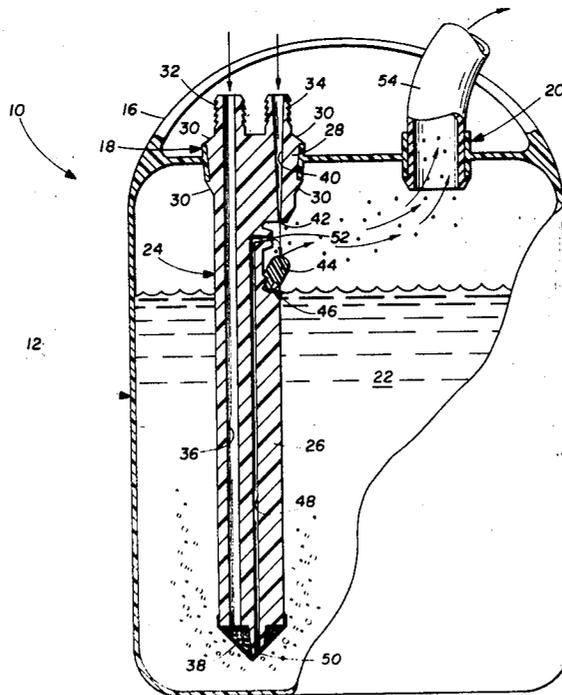
A disposable liquid entraining system includes a liquid container and a vapor generator. Initially, the container is sterilized and is filled with a sterile liquid. Then, the vapor generator is sterilized and is mounted within the container. The vapor generator receives a sterile, pressurized gas, and operates either as a humidifier or as a nebulizer to form a vapor from the liquid in the container. During use, the interior of the container remains sterile, so that any possibility of contamination of the vapor is eliminated. After use, both the liquid container and the vapor generator are discarded.

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6 Claims, 5 Drawing Figures



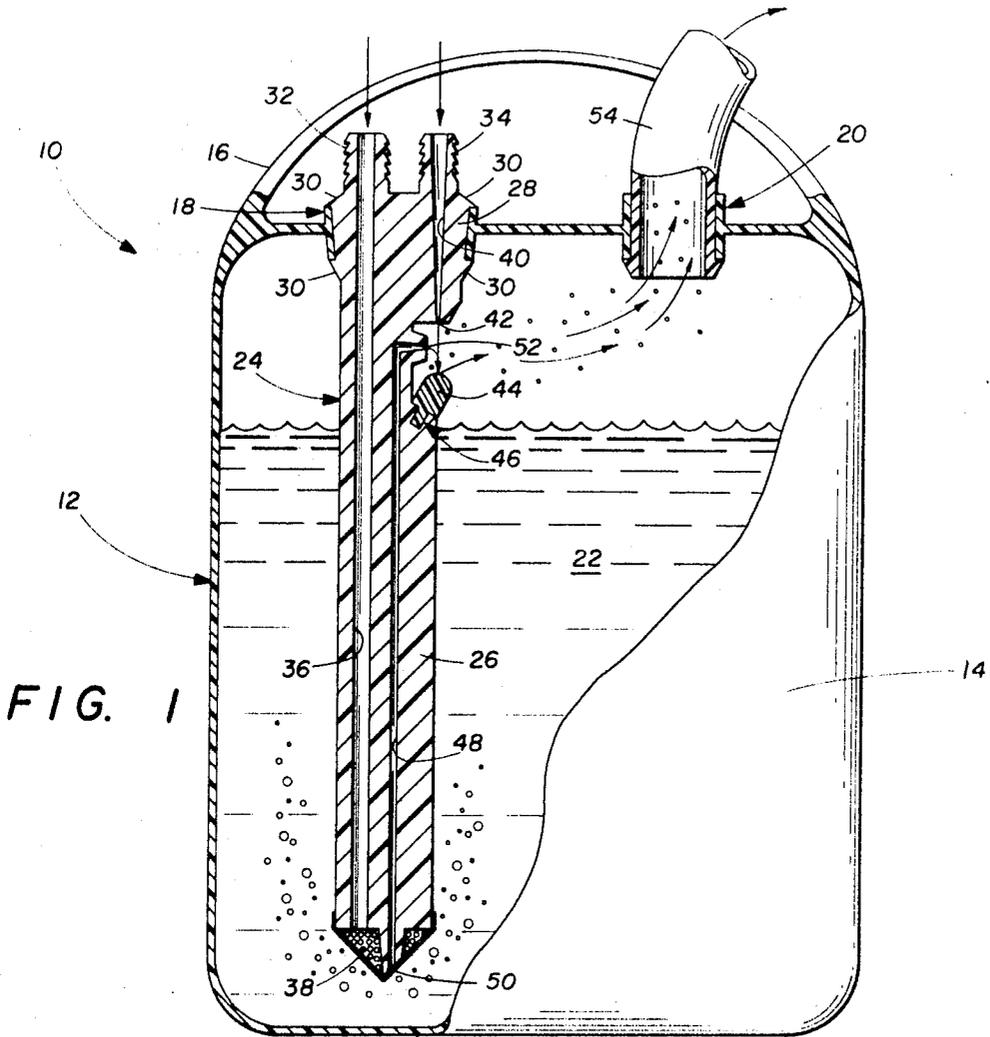


FIG. 1

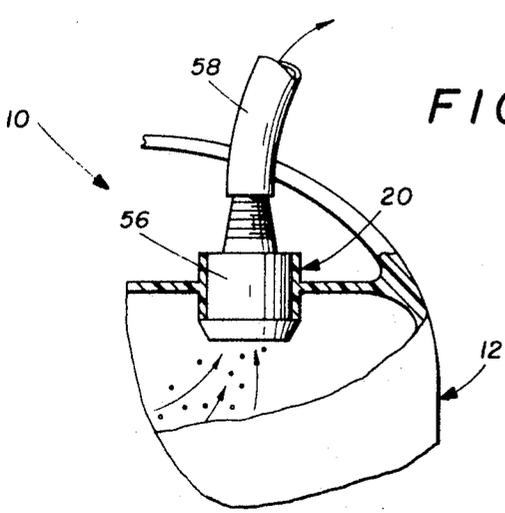
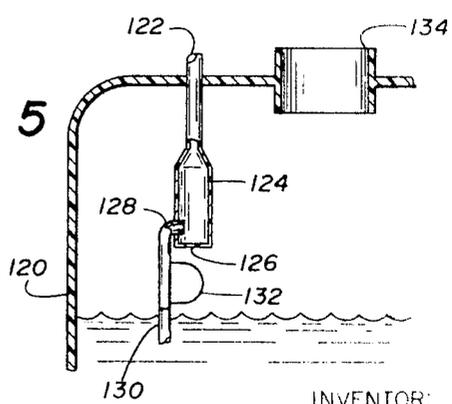


FIG. 2

FIG. 5



INVENTOR:

DAVID W. DEATON

Richards, Harris & Hubbard

ATTORNEYS

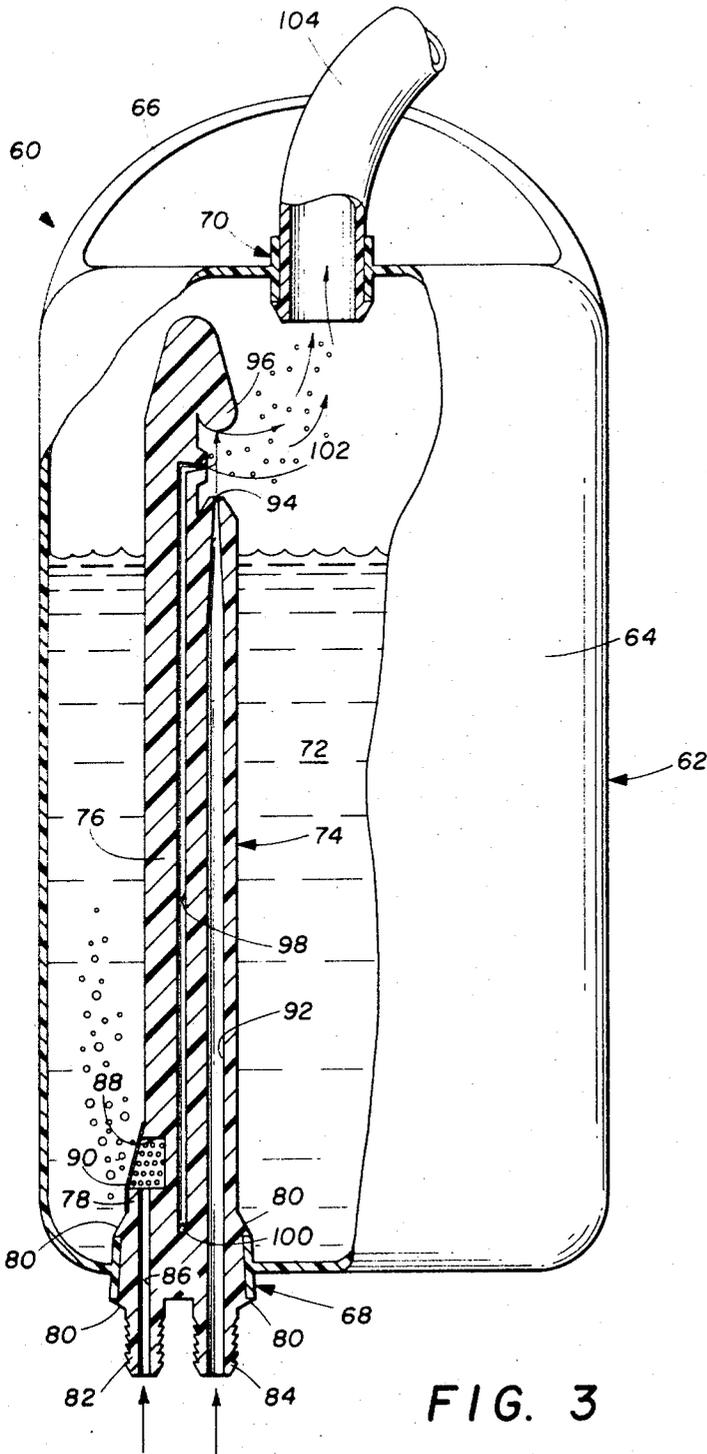


FIG. 3

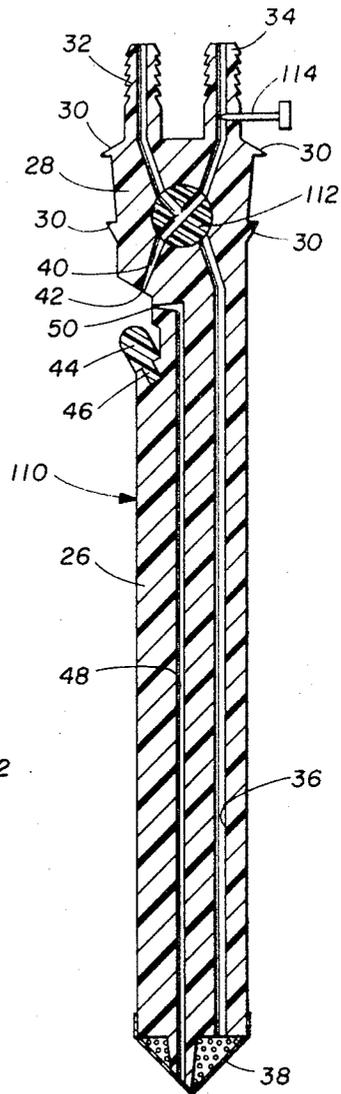


FIG. 4

INVENTOR
DAVID W. DEATON

Richards, Harris & Hubbard
ATTORNEYS

DISPOSABLE LIQUID ENTRAINING SYSTEM**BACKGROUND OF THE INVENTION**

In the practice of the healing arts, a wide variety of ailments are treated by means of inhalation therapy, that is by administering oxygen, oxygen enriched air, and other gases to patients through hoses, tents and the like. Although these gases are usually received in a high pressure, moisture-free state, the inhalation of a completely dry gas is generally considered to be injurious. For this reason, it is now common to employ liquid entraining systems in conjunction with inhalation therapy systems.

At the present time two types of vapor generators are employed in liquid entraining systems. These include humidifiers, which traditionally generate a vapor comprising the gaseous state of a liquid, and nebulizers, which generate a vapor comprising very small liquid droplets. In the operation of both humidifiers and nebulizers, a liquid from a reservoir is transformed into a vapor, and the vapor is entrained in a medicinal gas as the gas is administered.

The reservoirs that are employed in conjunction with presently available liquid entraining systems comprise refillable glass or plastic jars. Liquid entraining system reservoirs of this type are unsatisfactory for a number of reasons. For example, hospital personnel often fail to sterilize the jars between uses. Even if a jar is sterilized, there is no guarantee that the liquid that is used to fill the jars is sterile. And, at the present time, the liquid that is withdrawn from a liquid entraining system reservoir is replaced with unfiltered room air. Microorganisms carried into a reservoir with the air can contaminate the interior of the reservoir, even though the interior was initially sterile.

Regardless of the manner in which microorganisms are introduced into a liquid entraining system reservoir, there is ample time for the microorganisms to multiply within the reservoir. This is because modern liquid entraining systems are capable of operating for as long as eight hours before it is necessary to refill the reservoir. During the latter stages of the operation of such a liquid entraining system, microorganisms that have multiplied within the reservoir are carried out of the reservoir with the liquid, and are entrained in a medicinal gas along with the vapor that is generated from the liquid.

The vapor generators that are utilized in the liquid entraining systems provided heretofore are also capable of contaminating medicinal gases. At the present time, it is believed that contamination of the vapor produced by liquid entraining systems due to microorganisms in vapor generators is less likely than contamination due to microorganisms in liquid reservoirs, because in the operation of most liquid entraining systems, liquid from the reservoir does not remain in the vapor generator for a long period of time. Nevertheless, the presence of microorganisms in the interiors of most of the commercially available vapor generators, and the entrainment of such microorganisms in medicinal gases, is a distinct possibility.

As is fully documented in the paper entitled "Colonization of Infants Exposed to Bacterially Contaminated Mists" written by Hugh L. Moffett and David Allan and published in the American Journal of Diseases of Children, Volume 114, July 1967 pages 21-25, the introduction of microorganisms into medicinal gases is a dangerous practice. Thus, a need exists for a liquid en-

training systems in which any possibility of contamination of the vapor produced by the system is completely eliminated. The present invention fulfills this need, in that it comprises a liquid entraining system in which the vapor generator and the reservoir are sterilized prior to use, in which contamination of the vapor generator and the reservoir is prevented during use, and in which the vapor generator and the reservoir are discarded after use.

SUMMARY OF THE INVENTION

In accordance with the preferred embodiment of the invention a liquid entraining system includes a disposable liquid container, and a disposable vapor generator that operates within the liquid container. The liquid container comprises a flexible bag having a vapor generator receiving port formed in it. The vapor generator is mounted in the vapor generator receiving port, and may function either as a humidifier or as a nebulizer.

More specifically, the vapor generator comprises a member having a humidifier gas passageway extending through it to a point below the surface of liquid in the liquid container. A perforate member mounted over the end of the humidifier gas passageway forms gas flowing through the passageway into bubbles, which flow through to form a vapor. The member also has a nebulizer gas passageway extending through it to a point above the surface of liquid in the liquid container. A liquid delivery passageway extends through the member from an inlet located below the surface of the liquid to an outlet located adjacent the outlet of the nebulizer gas passageway. Gas flowing through the nebulizer gas passageway draws liquid droplets from the liquid delivery passageway. The droplets are then engaged with a target member to form a vapor.

DESCRIPTION OF THE DRAWINGS

A more complete understanding of the invention may be had by referring to the following Detailed Description when taken in conjunction with the drawings, wherein:

FIG. 1 is a front view of a disposable liquid entraining system comprising a first embodiment of the invention in which certain portions have been broken away more clearly to illustrate certain features of the invention;

FIG. 2 is an illustration of an outlet tube adaptor useful in conjunction with disposable liquid entraining systems employing the invention;

FIG. 3 is a front view of a disposable liquid entraining system comprising a second embodiment of the invention in which certain parts have been broken away more clearly to illustrate certain features of the invention;

FIG. 4 is a sectional view of a modified version of a portion of disposable liquid entraining system shown in FIG. 1, and

FIG. 5 is a sectional view of a third embodiment of the invention.

DETAILED DESCRIPTION

Referring now to the drawings, and particularly to FIG. 1 thereof, a disposable liquid entraining system 10 comprising a first embodiment of the invention is shown. The system 10 includes a collapsible liquid container 12 formed from a sterilizable, microorganism impervious substance, for example, a poly-1-olefin such as polyethylene, polypropylene, etc., a polyamide such

as nylon, etc. The container 12 is an integral structure comprising flexible sheets that are joined into a flexible bag by conventional bonding techniques, such as heat sealing.

The collapsible liquid container 12 includes a main portion 14 having a support bail 16 secured to it and having an inlet port 18 and an outlet port 20 mounted in its upper end. The ports 18 and 20 comprise inwardly tapered tubes mounted between the sheets comprising the liquid container 12. In accordance with the preferred embodiment of the invention, the ports 18 and 20 are normally sealed by conventional microorganism impervious seals. For example, conventional penetrable seals, conventional tear open strips, or the like can be used to seal the ports 18 and 20.

In the use of the disposable liquid entraining system 10, the interior of the main portion 14 of the liquid container 12 is initially sterilized. Then, a medically sterile liquid 22 is fed into the main portion 14 of the container 12. The sterile liquid 22 may comprise water or any other liquid, and may include dissolved medicaments, if desired. After a predetermined amount of the liquid 22 has been fed into the container 12, the container is sealed, so that the liquid 22 remains sterile during the transportation and/or storage of the container 12.

The disposable liquid entraining system 10 further includes a vapor generator 24 which is integrally formed from a sterilizable material such as polyethylene, etc. The vapor generator 24 includes a main portion 26 which is cylindrical throughout its length and which extends to a connector portion 28. The connector portion 28 is shaped to mate with the port 18 of the liquid container 12 and includes retaining barbs 30 which cooperate with the port 18. A pair of conventional tube receiving nipples 32 and 34 extend from the outer end of the connector portion 28.

The nipple 32 comprises a humidifier inlet port for the vapor generator 24. A humidifier gas passageway 36 extends through the nipple 32 and through the main portion 26 to the distal end thereof. The end of the vapor generator 24 remote from the connector assembly 28 comprises a conical end cap 38 having a plurality of small diameter holes formed through it. Because of the holes in the end cap 38, gas flowing into the vapor generator 24 through the nipple 32 flows out of the remote end of the vapor generator in the form of small diameter bubbles. In the use of the vapor generator as a humidifier, the bubbles flow through the sterile liquid 22 in the liquid container 12 and absorb liquid therefrom, and then flow out of the container through the outlet port 20.

The nipple 34 comprises a nebulizer inlet port for the vapor generator 24. A nebulizer gas passageway 40 extends through the nipple 34 and through the connector portion 28 to an orifice 42. A target 44 is supported opposite the orifice 42 by a pin and hole connection 46. A liquid delivery passageway 48 extends through the main portion 26 of the vapor generator 24 from a liquid inlet 50 to a liquid delivery orifice 52. The orifice 52 is positioned adjacent a line extending between the orifice 42 and the target 44.

In the use of the vapor generator 24 as a nebulizer, a high velocity jet of oxygen, air, or the like is directed through the passageway 40 and out of the orifice 42. The jet flows across the orifice 52, whereupon liquid is drawn out of the orifice 52, and liquid droplets are en-

trained in the gas jet. When the target 44 is removed from the assembly 24, the jet flowing from the orifice 42 and the liquid droplets entrained therein flow directly out of the liquid container 12 through the outlet port 20.

When the target 44 is positioned as shown in FIG. 1, the liquid droplets entrained in the gas jet are directed into engagement with the target 44. The engagement of the droplets with the target 44 breaks the droplets into very small droplets having diameters ranging up to about 5 microns. The very small droplets are then directed out of the container 12 through the outlet port 20. At the same time, the portion of the liquid comprising the droplets that engage the target 44 flows down the target 44 and recombines with the liquid 22 in the container 12. A more complete description of the operation of nebulizers of the type is shown in FIG. 1, and is contained in U.S. Pat. No. 3,172,406.

In the use of the disposable liquid entraining system 10, the exterior of the vapor generator 24 is initially sterilized. Then, the vapor generator 24 is forced through the seal that normally closes the port 18 and into the interior of the main portion 14 of the collapsible liquid container 12. When the vapor generator 24 is properly positioned in the container 12, the barbs 30 prevent relative movement between the vapor generator and the container, and the port 18 and the connector portion 28 cooperate to form a seal between the vapor generator and the liquid container.

After the vapor generator 24 and the liquid container 12 are interconnected, a source of pressurized gas is connected either to the nipple 32 or to the nipple 34, and the remaining nipple is plugged. At the same time, the outlet port 20 of the container 12 is connected to a patient through a large diameter outlet hose 54. Then, the disposable liquid entraining system 10 is operated either as a humidifier or as a nebulizer and in the latter case either with or without the target 44 in place, to direct a vapor to the patient through the hose 54. The operation of the disposable liquid entraining system 10 is continued until the liquid 22 has been removed from the container 12 whereupon both the container 12 and the vapor generator 24 are discarded.

It will be understood that in certain applications, it is more convenient to employ a small diameter hose as the outlet connection for the disposable liquid entraining system 10. In such a case, an adapter, such as the adapter 56 shown in FIG. 2, is mounted in the outlet port 20 of the container 12, and a small diameter hose 58 is connected to the adapter. It will be further understood that an outlet port suitable for connection to a large diameter hose and/or to a small diameter hose can be formed integrally with the vapor generator 24 if desired. In the latter case, only one part is formed in the liquid container 12.

Preferably the gas entering the vapor generator 24 of the disposable liquid entraining system 10 is either initially sterile or is filtered as it enters the system 10. Due to the collapsible nature of the container 12, there is no need to admit air to the interior of the container during the withdrawal of liquid therefrom. Rather, the container 12 simply collapses as liquid is fed out of the container in the form of vapor flowing through the port 20. Thus, the interior of the liquid container 12 remains sterile throughout the operation of the disposable liquid entraining system 10, and any possibility of contamination of the liquid is completely eliminated.

Referring now to FIG. 3, a disposable liquid entraining system 60 comprising a second embodiment of the invention is shown. The disposable liquid entraining system 60 includes a collapsible liquid container 62 which is similar to the liquid container 12 of the system 10 in that it is integrally formed from sheets of a sterilizable, microorganism impervious material which are joined into a flexible bag. The liquid container 12 includes a main portion 64 having a support bail 66 secured to it and having an inlet port 68 mounted in its lower end and an outlet port 70 mounted in its upper end.

In the use of the collapsible liquid container 62, the interior of the main portion 64 is initially sterilized. Then, a medically sterile liquid 72 is fed into the interior of the main portion 64 of the container 62. The liquid 72 may comprise water or any other liquid and may include dissolved medicaments, if desired. After a predetermined amount of the liquid 72 has been fed into the container 62, the container is sealed, preferably by incorporating conventional sealing techniques that close the ports 68 and 70. This prevents contamination of the liquid 72 during the transportation and/or storage of the collapsible liquid container 62.

The disposable liquid entraining system 60 further includes an integral vapor generator 74. The vapor generator 74 includes a main portion 76 that is cylindrical throughout its length and a connector portion 78. The connector portion 78 is shaped to mate with the inlet port 68 of the liquid container 62 and includes cooperating retaining barbs 80. A pair of conventional hose receiving nipples 82 and 84 extend from the outside end of the connector portion 78.

The nipple 82 comprises a humidifier inlet port for the disposable liquid entraining system 60. A humidifier gas passageway 86 extends through the nipple 82 and through the connector portion 78 to a cavity 88 formed in the main portion 76 of the vapor generator 74. The cavity 88 is covered by a plate 90 having a plurality of small diameter holes formed in it. By means of the holes in the plate 90, gas flowing through the passageway 86, is formed into small diameter bubbles as it flows out of the cavity 88. The bubbles flowing from the cavity 88 pass through the liquid 72 in the container 62 and absorb liquid therefrom, so that a vapor is produced. The vapor flows out of the disposable liquid entraining system 60 through the outlet port 70 of the container 62.

The nipple 84 comprises a nebulizer inlet port for the vapor generator 74. A nebulizer gas passageway 92 extends through the nipple 84 and through the main portion 76 of the assembly 74 to an orifice 94. A target 96 is formed integrally with the assembly 74 and is positioned at a point opposite of the orifice 94. A liquid delivery passageway 98 extends through the main portion 76 of the assembly 74 from an inlet hole 100 to a liquid delivery orifice 102. The orifice 102 is positioned adjacent a line extending between the orifice 94 and the target 96.

In the use of the vapor generator 74 as a nebulizer, a high velocity jet of oxygen, air, or the like is directed out of the orifice 94 toward the target 96. As the jet flows across the orifice 102, liquid is drawn out of the orifice 102, and liquid droplets are entrained in the gas jet. The jet directs the droplets into engagement with the target 96, whereupon the droplets are broken into very small droplets having the diameters ranging up to

about 5 microns. The very small droplets are then directed out of the disposable liquid entraining system 60 through the outlet port 70 of the container 62. At the same time, a portion of the liquid comprising the liquid droplets that engage the target 96 flows down the main portion 76 and is recombined with the liquid 72 in the container 62.

In the use of the disposable liquid entraining system 60, the exterior of the vapor generator 74 is initially sterilized. Then, the vapor generator 74 is forced through the seal that normally closes the port 68 to the position shown in FIG. 3. When the vapor generator 74 is properly positioned, the barbs 80 prevent relative movement between the vapor generator 74 and the container 62, and the connector portion 78 and the port 68 cooperate to form a seal between the vapor generator and the liquid container.

After the vapor generator 74 and the liquid container 12 are interconnected, a source of pressurized gas is connected either to the nipple 82 or to the nipple 84 depending on whether the disposable liquid entraining system 60 is to be employed as a humidifier or as a nebulizer. Then, the remaining nipple is plugged and the outlet port 70 is connected to a patient through a large diameter outlet hose 104. Of course, if a small diameter outlet hose is more convenient, the adapter 54 shown in FIG. 2 can be employed in conjunction with the disposable liquid entraining system 60 shown in FIG. 3. Also, an outlet port suitable for direct connection either to a large diameter outlet hose or to a small diameter outlet hose can be formed integrally with the vapor generator 74, if desired.

Preferably, the gas that is admitted to the disposable liquid entraining system 60 is either initially sterile or is filtered as it enters the system. Due to the collapsible nature of the liquid container 62, there is no need to admit air to the interior of the container as liquid is withdrawn therefrom. Thus, the interior of the liquid container remains sterile throughout the use of the disposable liquid entraining system 60, and any possibility of the contamination of the liquid within the container 62 is completely eliminated. Both the liquid containers 62 and the vapor generator 74 are preferably discarded after use.

Referring now to FIG. 4, there is shown a vapor generator 110 suitable for use in conjunction with a disposable liquid entraining system employing the present invention. The vapor generator 110 is substantially identical to the vapor generator 24 and, accordingly, the reference numerals employed herein to describe the various component parts of the vapor generator 24 have been used in FIG. 4 to designate the same or similar parts. The vapor generator 110 differs from the vapor generator 24 in that it includes a three-way valve 112 mounted in the connector assembly 28 and a needle valve 114 mounted in the nipple 34.

When the vapor generator 110 is employed as a nebulizer, the three way valve 112 is positioned as shown in FIG. 4. Then, a source of sterile pressurized oxygen is connected to the nipple 32 and a source of sterile air is connected to the nipple 34. The valve 112 directs oxygen entering the nipple 32 through the passageway 40 and through the orifice 42, whereupon vapor is entrained in the oxygen. At the same time, the valve 112 mixes air flowing through the nipple 34 with the oxygen. The amount of air that is mixed with the oxygen is controlled by regulating the needle valve 114.

Thus, the use of the vapor generator 110 facilitates both the dilution of oxygen and the entrainment of vapor in oxygen.

When the humidifier/nebulizer assembly 110 is employed as a humidifier, the valve 112 is rotated in a clockwise direction through an arc of 90°. Then, sterile, pressurized oxygen is directed into the assembly 110 through the nipple 32, and sterilized air is directed into the assembly through the nipple 34. The valve 112 directs the oxygen through the passageway 36 and through the end cap 38, whereupon the oxygen is formed into small diameter bubbles. At the same time, the valve 112 mixes air entering the nipple 34 with the oxygen. Again, the amount of air that is mixed with the oxygen is controlled by regulating the needle valve 114. Thus, the vapor generator 110 not only adds vapor to the oxygen passing therethrough, but also adds a predetermined quantity of air to the oxygen.

It will be understood that the component parts of the vapor generator 110 can be modified to suit particular situations. For example, the nipple 32 can be replaced by a Y-shaped nipple that receives both oxygen and air. In such a case, the oxygen and air are mixed before entering the valve 112, and the valve 112 serves only to control the direction of flow of the mixture. Also, the valve 112 can be arranged to direct the oxygen-air mixture into the passageways 36 and 40 simultaneously, if desired. Finally, the needle valve 114 can be replaced by a set of plugs having apertures formed in them that correspond to predetermined oxygen-air ratios.

Referring to FIG. 5, there is shown a third embodiment of the invention. The system shown comprises a collapsible liquid container 120 which is filled with sterile liquid in the manner previously described. An example of a suitable container for use with the system is the sterile, non-pyrogenic 1,000 ml. plastic bag containing sterile water manufactured and sold by Travenol Laboratories Inc. of Morton Grove, Ill. A support bail, not shown, similar to that previously described in FIG. 1 normally supports the bag in an upright position.

A flexible plastic hose 122 is disposed through an inlet port in the top of the container 120 and is attached thereto in a conventional manner, as by heat-sealing techniques which make the hose 122 an integral part of the container 120. Alternatively, hose 122 may be inserted through conventional penetrable seals or the like in the top of container 120. A plastic vapor generating housing 124 is connected to the end of the flexible hose 122 for support within the container 120 above the level of the sterile liquid. Housing 124 comprises a generally cylindrical body having an orifice 126 in the lower portion thereof. A plastic liquid delivery tube 128 opens into the housing 124 and is attached at the lower end thereof to a flexible hose 130. A plastic ball or target member 132 is rigidly attached to the tube 128 and is located adjacent the orifice 126.

An outlet port 134 is also attached to the top of the container 120. The outlet port 134 may be integrally connected to the container 120 and includes structure for normally sealing the outlet port during storage, such as a removable cap or a closed plastic member which may be cut away before use. The outlet port 134 in some instances may be a separate unit which may be inserted into a penetrable seal in the container 120 as shown in FIGS. 1 and 2. A hose is connected to outlet port 134 during operation of the device to deliver vapor to a patient.

In operation of the system shown in FIG. 5, a conventional source of pressurized air is attached through a suitable flowmeter, not shown, to supply a metered amount of gas through the hose 122 and through the orifice 126. Due to the passage of gas across the upper open end of the tube 128, liquid is drawn from the container 120 up the hose 130 and through the member 128. Liquid droplets are then entrained in the flow of gas through housing 124 and are emitted through the orifice 126 for impingement against the target 132. The engagement of the entrained liquid droplets with the target 132 breaks the droplets into very small droplets having diameters ranging up to about 5 microns. Due to the closed nature of container 120, these very small droplets are then forced out of the container 120 through the outlet port 134 to the patient. A portion of the liquid which is not broken up into small droplets flows downwardly from the target 132 for recombination with the remaining liquid in the container 120.

It will be understood that a humidifier unit may also be constructed in a similar manner as the nebulizer shown in FIG. 5, by utilizing flexible hoses for support of the humidifier unit and for supplying water to the humidifier unit from the container. The use of such flexible hose is advantageous in reducing the cost and complexity of manufacture of the device and in providing a system which is extremely compact and may be easily stored.

From the foregoing, it will be understood that the present invention comprises a disposable liquid entraining system including a collapsible liquid container and a vapor generator that operates within the container. Both the liquid container and the vapor generator are sterilized prior to use, the interior of the liquid container is maintained sterile during use, and both the liquid container and the vapor generator are discarded after use. In this way, any possibility of contamination of the vapor produced by the system is completely eliminated.

Although specific embodiments of the invention are illustrated in the drawings and described herein, it will be understood that the invention is not limited to the embodiments disclosed, but is capable of rearrangement, modification and substitution of parts and elements without departing from the spirit of the invention.

What is claimed is:

1. In a disposable liquid entraining system, a liquid container including:
 - a. a collapsible main portion for receiving a medically sterile liquid, and
 - b. a vapor generator receiving port, and a vapor generator including:
 - a. a member having first and second gas passageways extending through it to first and second gas outlets and having a liquid passageway extending through it from a liquid inlet to a liquid outlet positioned adjacent the second gas outlet, and
 - b. means for mounting the member in said vapor generator receiving port with the first gas outlet and the liquid inlet positioned below the surface of the liquid in the liquid container and with the second gas outlet and the liquid outlet positioned above the surface of the liquid.
2. The disposable liquid entraining system according to claim 1 further including means mounted on the

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member for generating bubbles from gas flowing through the first gas passageway.

3. The disposable liquid entraining system according to claim 1 wherein the second gas outlet directs gas flowing through the second gas passageway across the liquid outlet so that liquid droplets are entrained in the gas.

4. The disposable liquid entraining system according to claim 3 further including a target member positioned

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in the path of the liquid droplets.

5. The disposable liquid entraining system according to claim 1 wherein the entire vaporator generator comprises an integral, sterilizable, disposable, structure.

6. The disposable liquid entraining system according to claim 1 and further comprising:

an outlet port in said collapsible main portion for directing gas from said main portion.

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