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(54) **MEDICAL NEBULIZATION DEVICE**

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Related U.S. Patent Documents

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(52) **U.S. Cl.** **128/200.21**; 128/200.14; 128/203.12; 128/204.14
(58) **Field of Search** 128/200.14–200.24, 128/203.12, 204.18, 207.14–207.18, 200.11, 204.14, 202.27; 239/338, 352; D24/110–110.6; 261/78.1; D28/91.1

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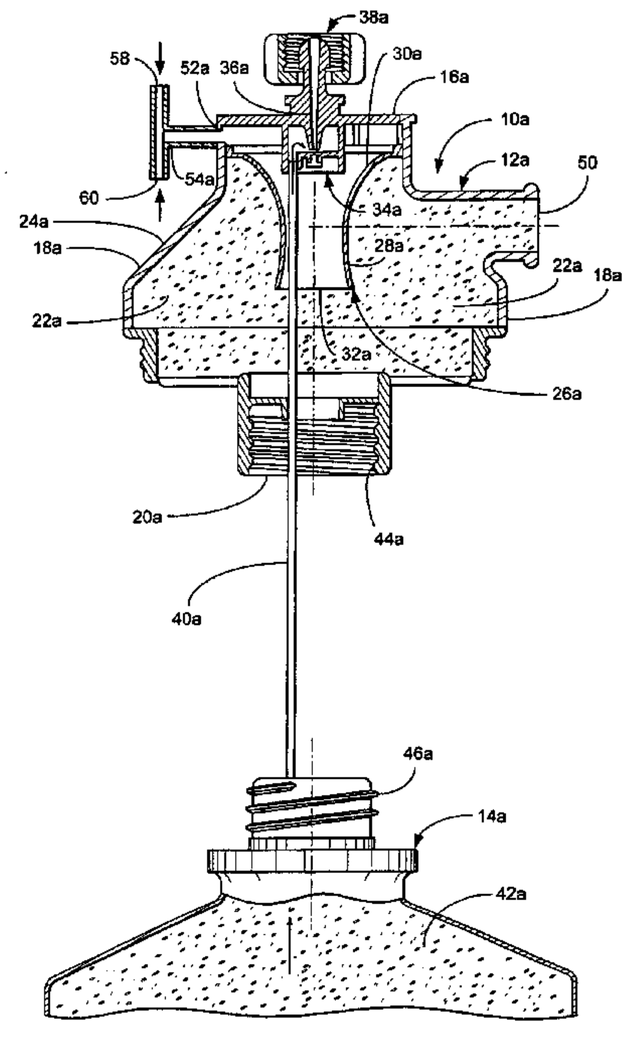
(57) **ABSTRACT**

The improved medical nebulization device includes a head and a removeable depending liquid reservoir. The head has a closed top, closed sides and open bottom defining a central space in which is secured a nebulization chamber having closed sides and an open top and open bottom. A nebulization baffle is connected to the head top and extends into the nebulization chamber. A liquid draw tube is connected to the baffle and depends from the chamber into the reservoir. A nebulized aerosol output port extends between the space outside the chamber and a point peripheral of the head for supplying nebulized aerosol to a patient. An auxiliary multiple gas entrainment inlet port, with removeable cap, extends into the chamber at a point remote from the output port and is adapted to supply auxiliary gases such as a mixture of oxygen and helium. The liquid reservoir in one embodiment includes a graduated liquid measuring scale and is transparent. The baffle in one embodiment is an annular flow aerosol nozzle secured to the underside of the top of the head. The device permits accurate adjustment of the types of nebulized liquid-gas mixture supplied to a patient.

29 Claims, 2 Drawing Sheets



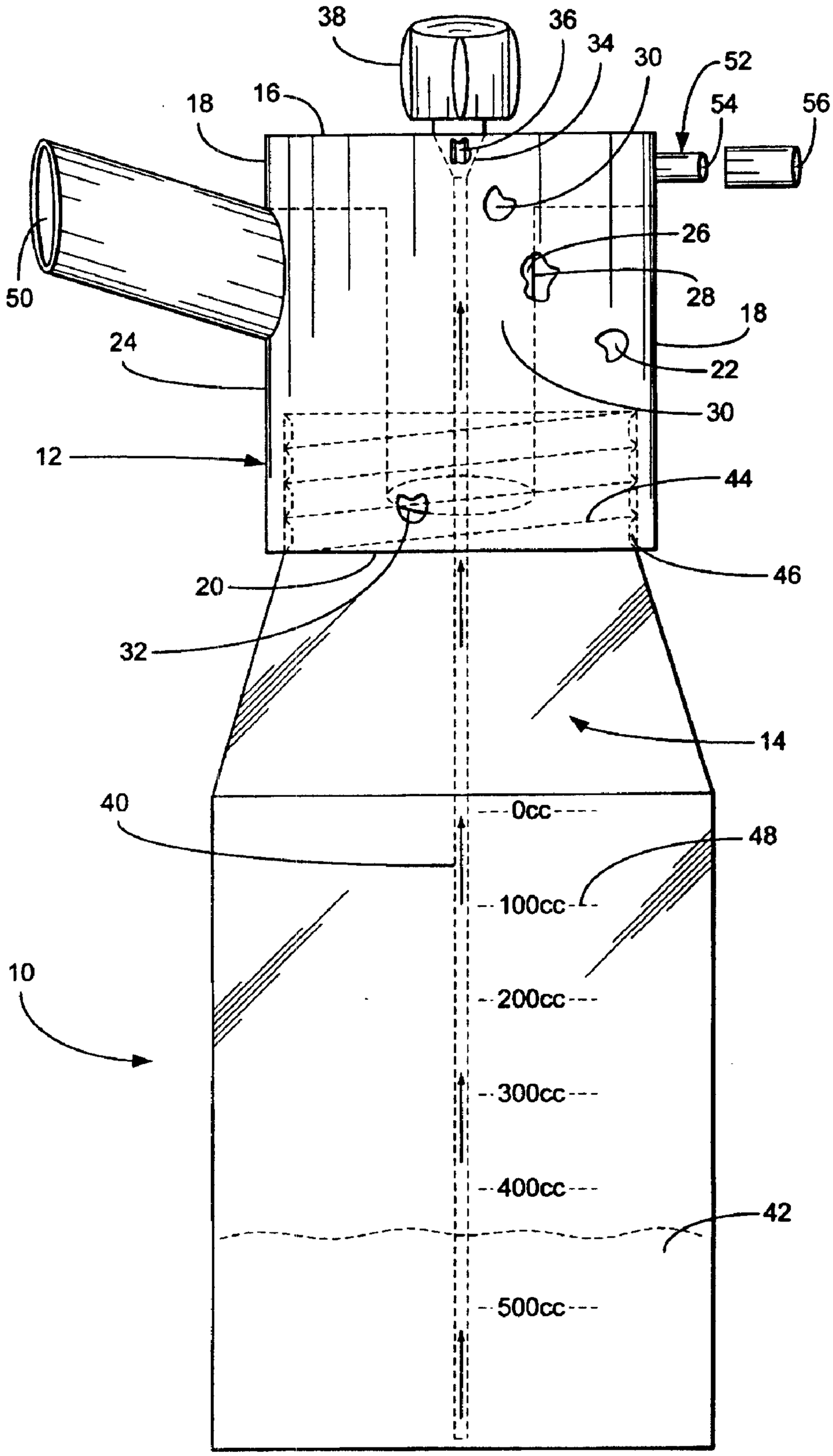

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FIG. 1

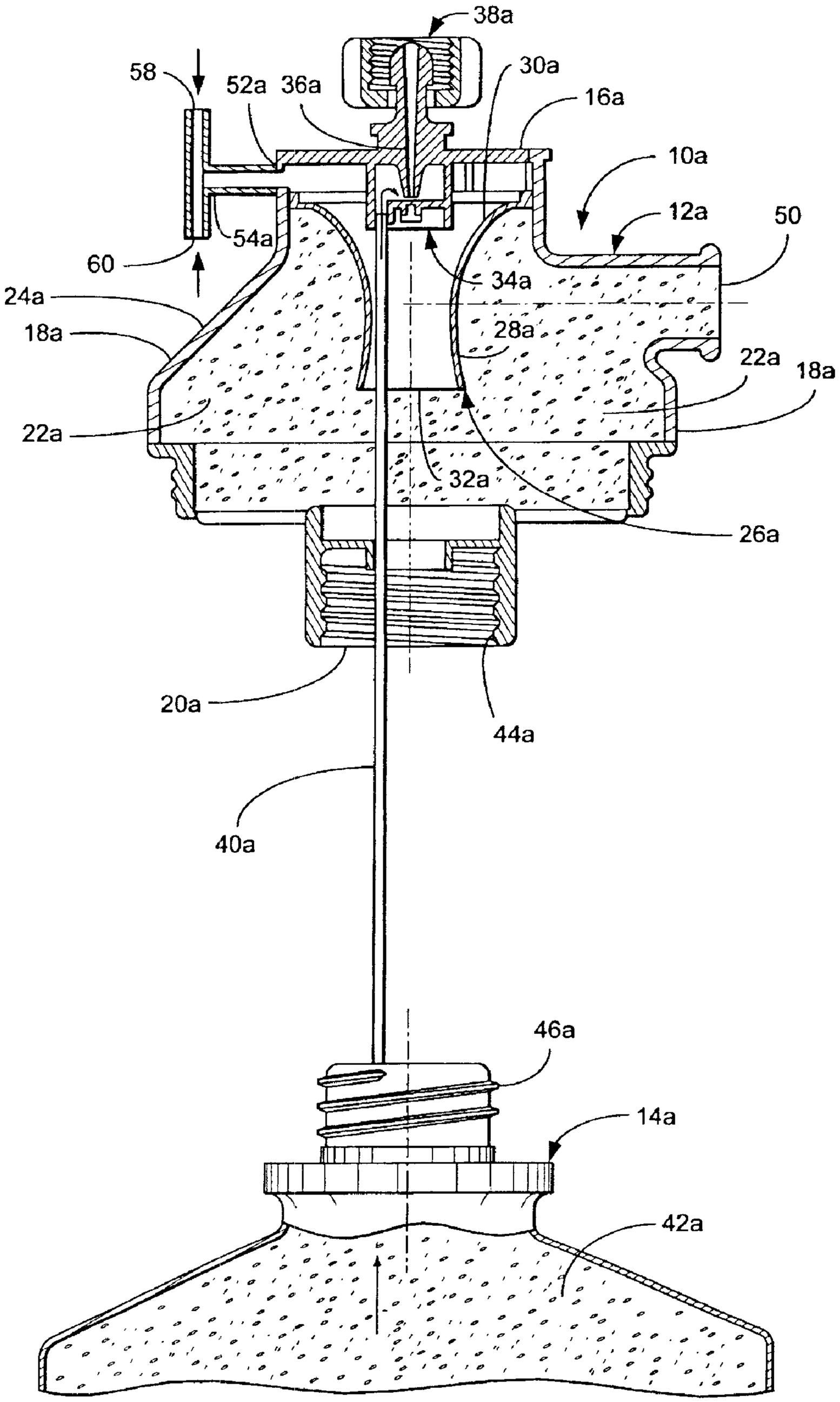
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FIG. 2

MEDICAL NEBULIZATION DEVICE

Matter enclosed in heavy brackets [ ] appears in the original patent but forms no part of this reissue specification; matter printed in italics indicates the additions made by reissue.

BACKGROUND OF THE INVENTION

1. Field of the Invention

The present invention generally relates to a medical device and more particularly to an improved medical nebulization device which provides means for supplying one or more auxiliary gases for nebulization, as well as a main stream of nebulizing gases.

2. Prior Art

Aerosol therapy in the field of respiratory care is indicated for retained secretions, humidification of inspired gas and to directly administer bronchodilator medications to the smooth muscles of a patient's airways. The administration of aerosols improves bronchial hygiene, hydrates retained secretions and, when used with bronchial dilators, relieves shortness of breath in compromised patients, that is, those with asthmatic or chronic obstructive pulmonary conditions (COPD).

Typically, asthmatic and COPD patients are treated with a conventional hand held nebulizing device to deliver aerosolized medications to the sensitized airways. For example, in the conventional emergency treatment of asthma, a hand held small volume nebulizer is utilized with a typical dose of 0.5 cc of Albuterol Sulfate solution, repeated 3–4 times in an E.R. in combination with steroids to help reduce the inflammatory process and shortness of breath in the patient.

Moreover, it has been found that the early administration of large doses (10–15 mg) per hour of medication/saline by means of a nebulizer can have positive dramatic effects on patient outcomes, reducing hospital stay times by as much as 3 days. The nebulizer not only delivers large amounts of medication to the affected areas but deposits them even in the smaller peripheral airways. Large amounts of nebulized saline delivered by the nebulizer assist in breaking down mucus plugs in the patient's airways and cooling and moisturizing those airways.

3. Applicant's Inferences from the Prior Art

For those compromised asthmatic and COPD patients who exhibit swollen and mucus obstructed airways, it may also be beneficial to utilize a secondary and lighter weight inert gas to deliver medications to bypass obstructed airways. Helium, an inert and metabolically stable gas, readily diffuses into swollen airways. A mixture of 80% oxygen and 20% helium would therefore be useful for such purposes.

The ideal nebulizing device for medical use would permit continuous nebulization for extended periods of time, utilizing small particle size aerosol for maximum deposition in the airways, and also have the capability of introducing in a controlled manner through a secondary inlet port lighter gas as needed to facilitate deposition of aerosolized medication into the lung parenchyma. Such device should be driven by a primary gas source or either oxygen or air but permit bleeding in of lighter gas as required for a special application.

Currently, the continuous nebulizing devices available do not meed the requirements set forth above for the ideal device. None of the current devices are capable of entraining a secondary small amount of special inert gas from a supplemental gas source. It would be highly desireable to

provide a medical nebulizing device meeting the criteria for the ideal device.

SUMMARY OF THE PRESENT INVENTION

The improved nebulizing device of the present invention satisfies all the foregoing needs. The device is substantially as set forth in the Abstract of the Disclosure.

Thus, the device comprises a nebulizing head and a removeable liquid medication-holding reservoir attached to the bottom thereof. The head has a closed top, closed sides and open bottom defining a central space in which is secured a nebulization chamber having closed sides and an open top and bottom. The chamber can be funnel or hour glass shaped or the like.

A nebulization baffle or annular flow aerosol nozzle is secured to the underside of the head top and disposed within the chamber. A liquid syphon or draw tube has its upper end connected to the baffle and extends down through the chamber and into the reservoir.

A nebulized aerosol output port extends between the space outside the chamber in the head and a point peripheral of one side of the head and may have an extension which directs the aerosol towards and into the patient.

Of primary importance, an auxiliary multiple gas entrainment inlet port is provided which, at its outer end has a removeable seal cap, and extends from a point peripheral of the head and remote from the outlet port to a point within the chamber. This inlet port permits auxiliary gases such as light weight helium or another gas alone or in admixture with oxygen or air or the like to be bled into the primary gas stream flow path through the nebulizer head and thus to exit with and as part of the output aerosol when and as needed, without interrupting the continuous output flow of aerosol from the device. Such primary flow powers the auxiliary gas through the device.

Preferably, the primary oxygen and/or air flow through the device is driven by pressurized gas from a flowmeter. The gas passing through the device draws liquid such as a mixture of medication and saline solution from the reservoir up the draw tube by a Venturi effect to and through a spraying and baffle system within the device to provide a fine aerosol mist of, for example, 2.5–3.0 um particle size. The device may be driven by a primary gas source of, for example, 50 psi operating at, for example, 13 liters/min. to provide about 25–30 cc/hr of aerosol.

Preferably, the reservoir has a graduated scale on it and a large capacity of, for example, about 200–500cc or more of medication/saline solution so that continuous nebulization can be carried out for up to about 20 hrs or more without recharging the reservoir.

Further features of the improved nebulization device of the present invention are set forth in the following detailed description and accompanying drawings.

DRAWINGS OF THE INVENTION EMBODIMENTS

FIG. **1** is a schematic side elevation, partly in dotted outline and partly broken away, showing a first preferred embodiment of the improved nebulization device of the present invention; and,

FIG. **2** is a schematic side elevation, partly broken away and partly in cross-section, of a second preferred embodiment of the improved nebulization device of the present invention, showing a mixture of medication and saline solution in the reservoir of the device, and with the reservoir separated from the device head.

DETAILED DESCRIPTION OF THE EMBODIMENTS

FIG. **1**

Now referring more particularly to FIG. **1** of the drawings, a first preferred embodiment of the improved nebulizing device of the present invention is schematically depicted therein.

Thus, device **10** is shown which comprises a nebulizing head **12** releasably connected to a liquid-containing reservoir **14**. Head **12** includes a closed top **16**, closed sides **18** and an open bottom **20** collectively defining a generally central space **22**. Head **12** is preferably in the form of a shell **24** of glass, plastic or the like, and is preferably generally cylindrical.

A nebulization chamber **26** is secured at its upper end to the inner surfaces of sides **18** and depends therefrom within the central portion of space **22** below top **16** and above bottom **20** and may be formed as an integral part of shell **24**, if desired.

In FIG. **1**, chamber **26** is shown as having closed sides **28** and open top **30** and open bottom **32**, and is generally funnel shaped.

Head **12** also includes a nebulization baffle **34** conventional design secured to the underside of head top **16** and having a central passageway **36** extending vertically down through top **16**, through which the main stream of nebulizing gas (not shown) can pass into and through baffle **34** after connection of a primary gas line (not shown) to baffle **34** through a nipple nut adapter **38** carried by top **16**. The bottom of baffle **34** is connected to the upper end of a hollow draw tube **40** up through which liquid **42** in reservoir **14** is drawn by suction or Venturi effect into baffle **34** for aerosolizing, that is, nebulizing.

Head **12** is releasably secured to reservoir **14** by mating threads **44** and **46**, respectively, in the inner surface of the bottom portion of head **12** and outer surface of reservoir **14** at the upper end thereof. Preferably, reservoir **14** is transparent and bears a graduated vertical scale **48** for determining the amount of liquid **42** in reservoir **14**. Scale **48** can be molded into or separately applied to reservoir **14**, as desired.

Head **12** also includes a nebulized aerosol output port **50** defined in a side **18** or head **12** and extending into communication with space **22** but external of chamber **26**, as shown in FIG. **1**. Port **50** extends peripheraly of head **12** and preferably is elongated and funnel shaped for delivery of the nebulized aerosol to a patient.

Head **12** further includes a novel auxiliary gas entrainment inlet port **52** defined in a side **18** and extending into space **22**, specifically into the upper portion of chamber **26**. Inlet port **52** is provided with an external tube portion **54** extending peripherally of shell **24**, and a removeable seal cap **56**, in FIG. **1** shown removed from portion **54**. The auxiliary gas can be a light weight gas such as helium or the like, fed alone through inlet port **52** to chamber **26**, or a mixture of such gas with oxygen and/or air or the like.

This auxiliary gas is used intermittently as needed and is powered through device **10** by primary gas such as oxygen and/or air driven under pressure into device **10** from a pressurized gas supply source. Such source is connected to device **10** through nipple **38** and the primary gas passes through passageway **36** in baffle **34** and then into nebulization chamber **26**, causing by venturi effect liquid **42** to be drawn up through tube **40** into baffle **34** for nebulization with such primary gas.

The resulting aerosol exits chamber **26** and out of device **10** through output port **50** to the patient. The auxiliary gas from inlet port **52** meets the nebulized aerosol in chamber **26** and exits therewith through port **50**. In effect, such auxiliary gas is bled into the flowstream in head **12** when and as needed, without interrupting the production of aerosol and its output from device **10**.

Device **10** can therefore be operated to provide an intermittent or continuous output of nebulized aerosol, preferably a continuous stream of the aerosol. Usually, the auxiliary gas or gases are used for periodic bleeding into the main gas flow in device **10** for specialized augmentation of the content of the aerosol output. Device **10** thus provides features which improve the function of a medical nebulizer for improved treatment of a patient, in contrast to conventional medical nebulizers.

FIG. **2**

A second preferred embodiment of the improved medical nebulization device of the present invention is schematically depicted in FIG. **2**. Thus, device **10**a is shown. Components thereof similar to those of device **10** bear the same numerals but are succeeded by the letter "a".

Device **10**a is substantially identical to device **10** except as follows:

a) The detailed configuration of the annular flow aerosol nozzle **34**a comparable to the baffle of FIG. **1** is shown, liquid **42**a being drawn up through tube **40**a into the bottom portion of nozzle **34**a to a point immediately below the lower end of passageway **36**a;

b) Sides **28**a of nebulization chamber **26**a are hour-glass shaped with a wider upper end and flared lower end for improved secondary throat entrainment of aerosol particles, in contrast to the vertical tubular sides **28** of chamber **26**; and

c) Auxiliary gas inlet port **52**a has a tubular portion **54**a which extends peripheral of shell **24**a and is bifurcated into two separate injection lines **58** and **60** for separate introduction of two different gases from separate pressurized sources.

The other features and advantages of device **10**a are similar to those of device **10**. Accordingly, devices **10** and **10**a have substantial advantages over the prior art devices.

Various modifications, changes, alterations and additions can be made in the improved medical nebulization device of the present invention, its components and parameters. All such modifications, changes, alterations and additions as are within the scope of the appended claims form part of the present invention.

What is claimed is:

1. An improved medical nebulization device, said device comprising, in combination:

a) a nebulizer head comprising, in combination:

i) a shell having a closed top and sides and open bottom defining a generally central space;

ii) a nebulization chamber having an open top and bottom and closed sides secured at said nebulization chamber sides to said shell sides within said shell central space, said nebulization chamber sides being curved downwardly and inwardly to form a secondary entrainment throat;

iii) an annular flow aerosol nozzle secured to the underside of said shell top within said nebulization chamber;

iv) an oxygen supply inlet extending through said shell top into said nozzle;

v) a liquid draw tube connected to said nozzle and depending extending downwardly therefrom;

vi) a nebulized aerosol output port defined in one of said shell sides peripheral of said nebulization chamber, and,

vii) an auxiliary multiple gas entrainment inlet port having a removable cap, said auxiliary inlet port being defined in another of said shell sides and extending into the upper portion of said nebulization chamber, the bottom of said head having means for releasably connecting said head to a liquid reservoir; and,

b) a liquid reservoir extending below and releasably connected to said head through said connector means, said liquid draw tube extending into said reservoir, said reservoir including a closed bottom and sides and open top sealed by said connector means to said head.

2. The improved nebulization device of claim **1** wherein said shell top includes adapter means for releasably connecting said head to a source of oxygen.

3. The improved nebulization device of claim **2** wherein said auxiliary multiple gas entrainment inlet port has a plurality of separate spaced injection lines, each one of which lines has a removable cap.

4. The improved nebulization device of claim **3** wherein said nebulized aerosol output port extends peripheral of said shell and forms a funnel for directing said nebulized aerosol to a patient.

5. The improved nebulization device of claim **4** wherein said auxiliary multiple gas entrainment inlet port extends into said shell peripheral of said annular flow aerosol nozzle.

6. The improved nebulization device of claim **5** wherein said liquid draw tube extends into the bottom of said annular flow aerosol nozzle and wherein said nebulization chamber is curved downwardly in an hour-glass shape to form said secondary entrainment throat.

7. The improved nebulization device of claim **6** wherein said device comprises at least one of glass and clear plastic and wherein auxiliary multiple gas entrainment inlet port is adapted to be connected to sources of oxygen and helium.

8. A method of administering a medicinal aerosol to a patient, comprising:

providing a medical nebulization device comprising a reservoir, a nebulizing nozzle spaced from the reservoir and communicating with a primary gas inlet, a draw tube extending from the reservoir and having an opening adjacent the nebulizing nozzle, an outlet, and a secondary gas inlet, the secondary gas inlet being operable between an open and a closed condition;

at least partially filling the reservoir with liquid medicine;

attaching the primary gas inlet to a source of pressurized gas to that pressurized gas flows through the nozzle, thus nebulizing liquid medicine flowing from the reservoir through the draw tube;

directing nebulized medicine through the outlet and into the patient's airway;

opening the secondary gas inlet and attaching a source of a secondary gas comprising helium to the secondary gas inlet so that secondary gas flows into the nebulization device and is mixed with the nebulized medicine within the nebulization device; and

detaching the source of secondary gas from the secondary gas inlet and closing the secondary gas inlet.

9. The method of claim 8, wherein the primary gas comprises oxygen.

10. The method of claim 9, wherein the secondary gas comprises a mixture of helium and oxygen.

11. The method of claim 8, wherein nebulized medicine is directed into the patient's airway both before and after attachment and detachment of the source of secondary gas.

12. The method of claim 11, wherein attaching and detaching the source of secondary gas does not interrupt the flow of nebulized medicine to the patient.

13. The method of claim 11, wherein the source of secondary gas is repeatedly temporarily attached to and detached from the secondary gas inlet.

14. The method of claim 8, wherein the secondary gas inlet has a removable cap, and opening and closing the secondary gas inlet comprises removing and replacing the cap.

15. The method of claim 8, wherein the secondary gas has a lighter weight than the primary gas.

16. The method of claim 8, wherein the secondary gas is selectively introduced into the nebulization device without interrupting the nebulization of medicine by the primary gas and the flow of nebulized medicine through the outlet.

17. The method of claim 8, additionally comprising providing a tertiary gas inlet operable between an open and a closed condition, and selectively attaching a source of tertiary gas to the tertiary gas inlet so that tertiary gas flows into the nebulization device and is mixed with the nebulized medicine.

18. The method of claim 8, wherein the secondary gas inlet comprises a first connector and a second connector configured so that the secondary gas inlet can be attached to more than one gas source.

19. A method of treating a patient, comprising:

providing a container comprising a reservoir, a nebulizing apparatus, a primary gas inlet communicating with the nebulizing apparatus and configured to be attached to a source of pressurized primary gas, a secondary gas inlet, and an outlet;

at least partially filling the reservoir with liquid;

placing the primary gas inlet into communication with the source of pressurized primary gas so that the primary gas and a portion of the liquid flow to the nebulizing apparatus and the primary gas nebulizes the liquid to produce an aerosol in the container, at least a portion of the aerosol exiting the container through the outlet;

selectively placing the secondary gas inlet into communication with a source of secondary gas without interrupting the production of aerosol and the exit of aerosol through the outlet, wherein the secondary gas is lighter than air.

20. The method of claim 19, wherein the primary gas is chosen from the group containing oxygen and air.

21. The method of claim 20, wherein the secondary gas comprises helium.

22. The method of claim 20, wherein the secondary gas comprises a mixture of oxygen and helium.

23. The method of claim 22, wherein the secondary gas comprises a mixture of about 80% oxygen and 20% helium.

24. The method of claim 19, wherein the secondary gas is lighter than the primary gas.

25. The method of claim 19, wherein the liquid comprises a medication, and the medicine is nebulized to produce a medicinal aerosol.

26. The method of claim 25, wherein the medication comprises a bronchodilator medication.

27. The method of claim 25, wherein the medication comprises albuterol.

28. The method of claim 19 additionally comprising removing the secondary gas inlet from communication with the source of secondary gas without interrupting the production of aerosol and the exit of aerosol through the outlet.

29. The method of claim 28 additionally comprising selectively sealing the secondary gas inlet with a sealing member when the secondary gas inlet is not in communication with the source of secondary gas.

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