Title: AEROSOL MEDICATION DELIVERY APPARATUS WITH NARROW ORIFICE

Abstract: An aerosol medication delivery apparatus includes a holding chamber (4) having an input end (6) and an output end (14) and defining an interior space (19). The output end comprises an orifice (47) having a cross-sectional area of less than about 60 mm². In one preferred embodiment, the orifice has a circular cross-section. Preferably, the orifice has a diameter of between about 2.0 mm and about 7.50 mm. In one preferred embodiment, an inhalation valve and exhalation valve (110) is located at the output end. A method of using the holding chamber is also provided.
AEROSOL MEDICATION DELIVERY APPARATUS WITH NARROW ORIFICE

CROSS-REFERENCE TO RELATED APPLICATIONS

This application claims the benefit of U.S. Provisional Application No. 60/377,528, filed May 3, 2002, the entirety of which is incorporated herein by reference.

FIELD OF THE INVENTION

The present invention relates to an aerosol delivery apparatus, and in particular, to an aerosol medication delivery apparatus having a narrow orifice.

BACKGROUND

Aerosol medication delivery systems are used, in general, to administer medication in aerosol form to the lungs of a user. For example, some systems use a pressurized metered-dose inhaler (pMDI), which typically includes a container in which the medication particles are stored under pressure, and an actuator used to dispense the medication from the container. In other systems, a holding chamber is connected to one of the container or actuator, as shown for example in U.S. Patent No. 6,293,279, assigned to Trudell Medical International, and which is hereby incorporated herein by reference. The holding chamber reduces the need for the user to coordinate activation of the pMDI canister with inhalation, helps reduce the delivery of nonrespirable medication particles from the canister, and helps reduce the impaction of medication particles in the user's oropharynx and upper airway. In some configurations, shown for example in the U.S. Patent No. 6,293,279 and U.S. Patent No. 5,881,718, the apparatus can be provided with one or both of an inhalation and exhalation valve(s) at an output end of the chamber. The output end is typically configured with a mouthpiece, which is received in the mouth of the user, or with a mask, which is placed over the mouth and nose of the user.
Users of the aforementioned devices often suffer from various bronchial ailments that can reduce lung capacity and output, which problems can be exacerbated with young children, domestic cats and domestic dogs. Many of these devices, however, are not especially suited for users with low tidal volumes, such as neonatal. In particular, such devices typically have an orifice at the output end of the holding chamber that is greater than 78 mm². Such relatively large openings may not produce the sweeping force necessary to draw aerosol out of a chamber with low tidal volumes, especially when the device is configured with inhalation/exhalation valves. As used herein, the word “user” includes humans and animals, including domestic cats and dogs.

**SUMMARY**

By way of introduction, various preferred embodiments of an aerosol medication delivery apparatus include a holding chamber having an input end and an output end and defining an interior space. The length of the holding chamber as measured from the input end to the output end is at least 70 mm and the diameter of the holding chamber is at least 20mm. In one preferred embodiment, the holding chamber has a length of 120 mm and the diameter of the holding chamber is 40 mm. The output end comprises an orifice having a cross-sectional area of less than about 60 mm². In one preferred embodiment, the orifice has a circular cross-section. Preferably, the orifice has a diameter of between about 2.0 mm and about 7.5 mm.

In one aspect, one preferred embodiment of the apparatus includes an inhalation and exhalation valve at the output end. In other aspects, methods of using the holding chamber are provided.

The foregoing paragraphs have been provided by way of general introduction, and are not intended to limit the scope of the following claims. The presently preferred embodiments, together with further advantages, will be best understood by reference to the following detailed description taken in conjunction with the accompanying drawings.
BRIEF DESCRIPTION OF THE DRAWINGS

FIGURE 1 is a perspective view of an aerosol medication delivery system.

FIGURE 2 is an exploded perspective view of the aerosol medication delivery system shown in FIG. 1.

FIGURE 3 is an exploded perspective view of an alternative embodiment of a holding chamber.

FIGURE 4 is a perspective view of one preferred embodiment of an adapter.

FIGURE 5 is a side view of the adapter shown in FIG. 4.

FIGURE 6 is a cross-sectional view of the adapter taken along line 6-6 of FIG. 5.

FIGURE 7 is an end view of the adapter shown in FIG. 4.

FIGURE 8 is a side view of an alternative embodiment of an adapter.

FIGURE 9 is a cross-sectional view of the adapter shown in FIG. 8 during inhalation.

FIGURE 10 is a cross-sectional view of the adapter shown in FIG. 8 during exhalation.

FIGURE 11 is an enlarged, partial cross-sectional view taken along line 11 in FIG. 10.

FIGURE 12 is a partial side view of an alternative embodiment of an aerosol medication delivery system.

FIGURE 13 is a partial cross-sectional view of the aerosol medication delivery system shown in FIG. 12 taken along line 13-13 of FIG. 12.

DETAILED DESCRIPTION OF THE PRESENTLY PREFERRED EMBODIMENTS

Referring to FIGS. 1 and 2, one preferred embodiment of an aerosol medication delivery system includes a pMDI canister holding portion 2, or dispenser, coupled to a chamber housing 4, otherwise referred to as a holding chamber, at an input end 6 thereof. A medication container 8, for example a pMDI canister is disposed in a cavity 12 formed in the dispenser, with a stem of
the canister being inserted into a well 10 formed in the bottom of the dispenser. Preferably, the dispenser 2 is pivotally connected to the chamber housing 4 so that the dispenser 2 can be pivoted and translated for storage inside the chamber housing when the device is not in use. The term “medication” or “medicament” and variations thereof as used herein means any substance used in therapy.

In an alternative embodiment shown in FIG. 3, the apparatus does not include an integrated dispenser secured to the holding portion 20, but rather includes a backpiece 22 at the input end thereof. The backpiece 22 is preferably made of an elastomeric material and includes an opening 24 shaped to receive a mouthpiece portion of a separate pMDI dispenser. Various configurations of chamber housings and dispensers are shown in U.S. Patent Nos. 6,293,279, 5,012,803, and 5,012,804, the entire disclosures of which are hereby incorporated herein by reference. It should be understood that a holding chamber can also be used in conjunction with medication delivery containers other than a pMDI container, including for example and without limitation nasal sprayers and powder inhalers.

As shown in FIGS. 1 – 3, the chamber housing 4, 20 defines an interior space 19 and further includes an output end 14, through which the medication is dispensed to the user. The length of the chamber housing 4, 20 defined between points A to B as shown in FIGS 1 and 3 is preferably between about 70 mm and about 160 mm and most preferably between about 80 mm and about 120 mm. The interior cross sectional area of the chamber housing 4, 20 is preferably between about 700 mm² and about 7500 mm² and most preferably between about 700 mm² and about 2100 mm². In a preferred embodiment, the chamber housing 4, 20 has a length of about 120 mm and an interior cross sectional area of about 2000 mm².

As shown in the embodiment of in FIGS. 1 and 2, the output end 14 includes a downstream portion 23 that is releasably secured to a main housing 21 with one or more fastening elements 25, 27. For example, the fastening elements
can be configured as tabs and recesses in one preferred embodiment, which provides a snap-fit between the main housing 21 and the downstream portion 23.

In one preferred embodiment, shown in FIGS. 4-7, an adapter 30 includes an input end 32 configured as an insert portion that is fitted in an opening 27 formed in the output end 14 of the chamber housing. Conversely, the input end 32 can be fitted over or around an end portion of the chamber housing. The adapter further includes an output end 34 that, in one preferred embodiment, is shaped to be received in the mouth of the user. For example, the output end 34 can have an outer circular cross-section, or it can be elliptical, oval, obround or any other shaped suitable for insertion into the mouth of the user. Alternatively, an additional mouthpieces (not shown) can be fitted in or around the output end. In yet another alternative, a mask (not shown) can be fitted in or around the output end, wherein the mask is shaped to be disposed over the face, preferably including the mouth and nose, of the user. In yet another alternative embodiment, a nasal applicator, provided for example with prongs, can be fitted into or around the output end.

A middle portion 36 joins the input and output end. In one preferred embodiment, the middle portion 36 has an inner, central portion 40 that is tapered and follows the contour of an interior channel formed in the adapter. The shape of the middle portion, and in particular the central portion 40, provides indicia to the user about which end to secure to the holding chamber by indicating the flow direction. Additional indicia, besides the shape, such as arrows and words, can also be provided. Preferably, the middle portion includes a plurality of ribs 38 extending radially from the central portion 40 which join the input and output ends 32, 34.

Referring to FIGS. 6 and 7, the channel 42 has an upstream end 44 and a downstream end 46, which terminates in and defines an orifice 47. In one preferred embodiment, the channel 42 has a length of between about 20 mm and about 50 mm, more preferably a length of between about 25 mm and about 40 mm, and even more preferably a length of about 32 mm.
Preferably, the downstream end 46 has a cross-sectional area that is less than the cross-sectional area of the upstream end 44. Preferably, the channel 42 tapers between the upstream and downstream ends. Preferably the ratio of the cross-sectional area of the channel at the upstream end to the downstream end is between about 1.5:1 and about 6:1, and more preferably at a ratio of about 4:1.

For example, in one preferred embodiment, the upstream end 44 has a cross-sectional area of between about 200 mm² and about 350 mm², and more preferably about 283 mm², although greater and lesser areas may be suitable. In one preferred embodiment, the opening at the upstream end 44 is configured as a circular opening having a diameter between about 18 mm and about 20 mm, and more preferably a diameter of about 19 mm. Of course, other non-circular shapes and/or cross-sectional areas are acceptable.

Also in one exemplary preferred embodiment, the downstream end 46, and the orifice 47 formed at the end thereof, has a cross-sectional area of between about 3 mm² and about 201 mm², more preferably between about 7 mm² and about 78.5 mm², more preferably less than about 60 mm², even more preferably less than about 25 mm², and in one embodiment, preferably about 19.6 mm². In one preferred embodiment, the opening 47 at the downstream end 46 configured is a circular opening having a diameter between about 2 mm and about 16 mm, more preferably between about 3 mm and about 10 mm, more preferably less than about 7 mm, and more preferably about 5 mm. Of course, other non-circular shapes and/or cross-sectional areas are acceptable. Also, it should be understood that the channel may have a uniform cross-sectional area between the upstream and downstream end, preferably in the dimensions and ranges described above with respect to the downstream end.

In one preferred embodiment, an initial length 48 of the channel at the upstream end, for example about 4 mm, has a uniform cross-sectional area. Thereafter, the channel preferably tapers. For example, in one preferred embodiment, the channel includes a transitional region 50 having a concave shape, for example with a radius of about 20 mm, a frusto-conical portion 52, and a lower transitional region 54 having a convex shape, for example with a radius of about
20 mm. A final length 56 of the channel at the downstream end, for example about 2.92 mm, preferably again is configured with a uniform cross-sectional area. Preferably, the angle of the sidewalls of the conical portion is about 22° from the central axis 58, forming an angle A of about 44°. Of course, it should be understood that the curved transitional regions can be eliminated, or provided with different radii of curvature. Likewise, the lengths of the initial and final lengths of the channel can be omitted, and also the linear portion between the curved transition areas, such the entire cross-sectional area is tapered or changes along the length of the channel. Alternatively, the channel may be stepped down from a first cross-sectional area to a lesser second cross-sectional area, without any taper.

Referring to FIG. 6, the downstream end 46 of the channel 42, with its orifice 47, opens into an exhaust chamber 60 formed in the output end 34 of the adapter. Preferably, the exhaust chamber 60 has a length of about 16 mm, and a cross-sectional area of about 177 mm². In one preferred embodiment, the exhaust chamber 60 has a circular cross-section with an inner diameter of about 15 mm. In one preferred embodiment, an endotracheal (ET) tube having an outer diameter of about 15 mm is configured to fit therein.

Referring to another preferred embodiment of the adapter, shown in FIGS. 12 and 13, the middle portion 90 is configured with a radially extending annular rib 62 positioned between the output and input ends. The rib 62 forms a shoulder 64 having a recess or annular channel 66 which receives an end 69 of the housing and limits the distance the adapter is inserted into the end of the chamber housing. A shoulder 68 also defines an outwardly facing annular channel 70 or recess that may receive the flange of a mouthpiece or mask as it is inserted onto or around the output end of the adapter. Referring to FIG. 13, the exhaust chamber 60 extends around the output end of the channel, to direct the aerosol into the center of the ET tube adapter or center of the mask connector.

In yet another preferred embodiment of the adapter, shown in FIGS. 8-11, the output and input ends are made as separate pieces 100, 102 that are secured one to the other in a snap-fit engagement, or by other devices such as a friction fit or locking device. In this embodiment, a valve 110, which serves both as an
inhalation and exhalation valve, has an outer peripheral edge 112 configured with an enlarged portion or bead that is trapped and secured in a cavity 104 formed between the output and input pieces. The valve 110 includes a flexible U-shaped hinge portion 114 extending between the edge and a base portion 116 of the valve. The base portion has a first and second side 118, 120. The first side 120, which is directed toward the output piece, defines a sealing surface that mates with an annular rib portion 122 of the output piece. The rib portion 122 is spaced from an end surface 126 of the input piece to form an exhaust channel 124 therebetween, with the base portion 116 disposed therebetween in the exhaust channel 124. The valve 110 further includes a duckbill portion, having a pair of flat, flexible side walls 128, which extends upwardly from the periphery of a central opening formed in the base portion 116 and defines an apex 130. Preferably a slit is formed at the apex 130. The output piece 102 further includes a plurality of openings 132, or exhaust ports, that communicate with the exhaust chamber 60 of the adapter via the exhaust channel 124. Preferably, the valve 110 is circular, and includes an annular base portion 116, hinge portion 114 and edge portion 112.

It should be understood that the adapter could be molded as a one-piece unit with the valve being in-molded with the adapter, or inserted as a separate component. In addition, it should be understood that the valve can be configured in different shapes and can include a valve that has a central opening with a peripheral portion of the valve being seated on a valve seat, for example a baffle member secured in or adjacent to the channel. In such a configuration, the central portion moves away from the valve seat during inhalation, while an outer peripheral edge of the valve moves away from a valve seat formed on the output piece during exhalation. It should also be understood that the device can be configured with separate inhalation and exhalation valves.

It should be understood that the channel 42, with its downstream and upstream ends 46, 44 can be formed integrally in the output end of the chamber housing, for example by molding, without the need for an adapter. Likewise, the output end of the adapter, defining the mouthpiece, can be formed integrally as part of the chamber housing downstream of the channel. Alternatively, the output
end of the adapter can be formed as a separate piece that is mounted to the chamber housing, having a channel, with a valve disposed therebetween as explained above with respect to FIGS. 8-11. As such, it should be understood that the term "output end" of the holding chamber includes the adapter when it is associated therewith. Likewise, it should be understood that the term "chamber housing" includes and incorporates the adapter when it is mounted thereto.

Preferably, the adapter 30 and the chamber housing 14 are made of a hard plastic, such as polypropylene. The valve member 110 is preferably made of a flexible material, including for example and without limitation a silicone, a thermoplastic elastomer, rubber, Ethylene-Propylene-Diene-Monomer (EPDM) or Berfluodelaastomers (FFKN).

In operation, the user actuates the dispenser 2, or other device, so as to discharge a medication, preferably in aerosol form, through the input end 6 into the interior space of the holding chamber 4, or chamber housing. The user thereafter inhales through the output end of the adapter 34, 102 and holding chamber. As the user inhales, the medicament, which is preferably in aerosol form, is drawn through the channel 42 from the upstream to the downstream ends 44, 46 thereof. The medicament is then expelled into the exhaust chamber 60 and through the user's mouth via an ET tube where it is deposited in their lungs.

In one preferred embodiment, which includes an inhalation and exhalation valve 110, the edges of the flat sidewalls 128 of the duck bill move away from each other at the slit formed at the apex 130 upon inhalation due to a pressure differential applied to the upstream side of the duckbill, so as to allow the medicament to move through the opening formed thereby. At the same time, the pressure is applied to the upstream side 118 of the base portion so as to seal the downstream side 120 against the valve seat formed by the rib portion 122.

Upon exhalation, a pressure is exerted on the downstream side of the sidewalls 128 causing the duck bill to close. The exhalation pressure, however, is also exerted on the downstream side 120 of the base portion 116, causing the base portion 116 to move away from the valve seat 122 as the hinge flexes 114. As the base portion 116 is unseated, the exhaust air from the user escapes through the
channel 124 and openings 132 to the ambient environment. In this way, exhalation by the user does not force air, or any contaminants, back into the holding chamber 4.

The narrow orifice 47 formed in the output end 14, whether integrally or by way of an adapter, is ideally suited for administering medication to users or patients with low tidal volumes in the range of between about 5 ml to about 100 ml, and more preferably between about 5 ml and about 20 ml. The term "tidal volume" as used herein means the average volume inhaled and exhaled during periodic breathing, and generally needed to satisfy metabolic requirements. In particular, the narrow orifice 47, alone and in conjunction with the tapered channel 42, maximizes the emitted dose and respirable fraction of the aerosol. In particular, the velocity of the particles is increased and, is particularly concentrated along the axis or centerline of the channel 42. The increased velocity may increase the number of respirable particles from the population of larger particles, as well as help carry the particles through the system.

The holding chamber with its narrow orifice, whether integrally molded or formed in an adapter portion thereof, is suitable for both spontaneously breathing patients as well as those requiring assisted ventilation.

Although the present invention has been described with reference to preferred embodiments, those skilled in the art will recognize that changes may be made in form and detail without departing from the spirit and scope of the invention. As such, it is intended that the foregoing detailed description be regarded as illustrative rather than limiting and that it is the appended claims, including all equivalents thereof, which are intended to define the scope of the invention.
CLAIMS

1. An aerosol medication delivery apparatus comprising:
a holding chamber having an input end and an output end and
defining an interior space, wherein said output end comprises an orifice having a
cross-sectional area of less than about 60 mm².

2. The invention of claim 1 wherein said cross-sectional area is less
than about 25 mm².

3. The invention of claim 1 wherein said orifice has a circular cross-
section.

4. The invention of claim 3 wherein said orifice has a diameter of
between about 2.0 and about 7.5 mm.

5. The invention of claim 4 wherein said diameter is about 5 mm.

6. The invention of claim 1 wherein said output end comprises a
channel having an upstream end and a downstream end, wherein said channel
defines said orifice at said downstream end.

7. The invention of claim 6 wherein said downstream and upstream
ends have first and second cross-sectional areas respectively, wherein said first
cross-sectional area of said downstream end is less than said second cross-
sectional area of said upstream end.

8. The invention of claim 6 wherein said channel is tapered from said
upstream end to said downstream end.

9. The invention of claim 1 wherein said output end further comprises
an inhalation valve disposed downstream of said orifice.

10. The invention of claim 9 wherein said output end further comprises
an exhalation valve.
11. The invention of claim 1 wherein said output end of said holding chamber comprises an adapter defining said orifice.

12. The invention of claim 11 wherein said adapter comprises a mouthpiece shaped to be inserted into the mouth of a user.

13. The invention of claim 11 wherein said adapter comprises a mask shaped to be placed over the nose and mouth of a user.

14. The invention of claim 1 wherein said holding chamber has a length defined between said input end and output end of between about 80mm and about 120 mm.

15. The invention of claim 13 wherein said holding chamber has an interior cross sectional area of between about 70 mm² and about 2100 mm².

16. A method of administering an aerosol medication to a user comprising:
   depositing a medication into a holding chamber through an input end of said holding chamber; and
   drawing said medication from said holding chamber through an orifice formed in an output end of said holding chamber, wherein said orifice has a cross-sectional area of less than about 60 mm².

17. The invention of claim 16 wherein said cross-sectional area is less than about 25 mm².

18. The invention of claim 16 wherein said orifice has a circular cross-section.

19. The invention of claim 18 wherein said orifice has a diameter of between about 2.0 and about 7.5 mm.

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20. The invention of claim 19 herein said diameter is about 5 mm.

21. The invention of claim 16 wherein output end comprises a channel having an upstream end and a downstream end, wherein said channel defines said orifice at said downstream end and wherein said drawing said medication from said holding chamber through said orifice comprises drawing said medication through said channel from said upstream end to said downstream end.

22. The invention of claim 21 wherein said downstream and upstream ends have first and second cross-sectional areas respectively, wherein said first cross-sectional area of said downstream end is less than said second cross-sectional area of said upstream end.

23. The invention of claim 21 wherein said channel is tapered from said upstream end to said downstream end.

24. The invention of claim 16 wherein said output end further comprises an inhalation valve disposed downstream of said orifice, and further comprising inhaling and thereby drawing said medication through said inhalation valve.

25. The invention of claim 24 wherein said output end further comprises an exhalation valve, and further comprising exhaling at least in part through said exhalation valve.

26. The invention of claim 16 wherein said output end of said holding chamber comprises an adapter defining said orifice.

27. The invention of claim 26 wherein said adapter comprises a mouthpiece, and further comprising inserting said mouthpiece into the mouth of a user and inhaling through said mouthpiece.
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Further documents are listed in the continuation of Box C. See patent family annex.

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