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(54) **Levegőáramos adapter légzéssel működtetett szárazpor-inhalátorhoz**

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(54) AIRFLOW ADAPTOR FOR A BREATH-ACTUATED DRY POWDER INHALER

LUFTSTROMADAPTER FÜR ATEMAKTIVIERTEN TROCKENPULVERINHALATOR

ADAPTATEUR D'ÉCOULEMENT D'AIR POUR INHALATEUR DE POUDRE SÈCHE ACTIONNÉ PAR LA RESPIRATION

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Description

Field of the Invention

[0001] The present invention relates to a breath-actuated dry powder inhaler comprising an airflow adaptor. In particular, the present invention relates to a breath-actuated dry powder inhaler comprising an airflow adaptor; and a method for modifying airflow through the outlet port of a deagglomerator of a breath-actuated dry powder inhaler.

Background to the Invention

[0002] Breath-actuated dry powder inhalers are used to deliver medicament to the respiratory tracts of patients. Typically such inhalers comprise a reservoir, or reservoirs, for storing dry powder medicament, means for aerosolising the dry powder medicament for inhalation, and means for delivering the aerosolised medicament to the patient, such as a mouthpiece. Typically, in use, the dry powder medicament is dispensed from a reservoir and then aerosolised as a result of a breath-induced low pressure at the mouthpiece. Once aerosolised, the medicament will generally leave the inhaler through the mouthpiece and be inhaled.

[0003] Known dry powder medicament is composed of very small particles and often provided in a composition including a carrier, such as lactose. Consequently, non-defined agglomerates or aggregates of the dry powder medicament may form at random prior to being delivered to the patient. There has therefore been a need for breath-actuated dry powder inhalers with means for breaking down the agglomerates of medicament, or medicament and carrier, prior to inhalation.

[0004] Deagglomerators for breath-actuated dry powder inhalers are disclosed in WO 01/97889.

[0005] US 5301666 A discloses a powder inhaler having the features of the preamble of claim 1.

[0006] There is, however, a continued need to reduce the flow rate dependence of breath-actuated dry powder inhalers and, in particular, the flow rate dependence of the delivered dose of the medicament they deliver. In particular, there is a need to ensure that different patient groups receive substantially the same delivered dose from the same breath-actuated dry powder inhaler.

[0007] There is also a need for providing breath-actuated dry powder inhalers, and in particular those with deagglomerators, which provide better delivered dose characteristics. Particularly, there is a need for breath-actuated dry powder inhalers which provide improved delivered dose uniformity.

[0008] These and other problems are addressed by a a breath-actuated dry powder inhaler comprising an airflow adaptor; and a method for modifying airflow through the outlet port of a deagglomerator according to the independent claims. Further advantageous embodiments are disclosed in the dependent claims.

Summary of the Invention

[0009] Accordingly, in a first aspect the present invention provides a breath-actuated dry powder inhaler comprising an airflow adaptor. The airflow adaptor comprises a first conduit having a proximal end and a distal end, wherein the proximal end of the first conduit allows fluid communication from a deagglomerator outlet port to the distal end of the first conduit. The airflow adaptor further comprises at least one second conduit for allowing air to flow from a proximal end of the adaptor to a distal end of the adaptor independently of the airflow in the conduit when a breath induced low pressure is applied to the distal end of the airflow adaptor, wherein the ratio of the sum of the cross-sectional areas of the at least one second conduit to the cross-sectional area of the first conduit is such that when a breath induced low pressure is applied to the distal end of the airflow adaptor from about 20% to about 50% of the resulting airflow is through the at least one second conduit.

[0010] It has surprisingly been found that by providing a breath-actuated dry powder inhaler comprising an airflow adaptor with at least one second conduit for allowing air to flow from a proximal end of the adaptor to a distal end of the adaptor independently of the airflow in the conduit when a breath induced low pressure is applied to the distal end of the airflow adaptor, wherein the ratio of the sum of the cross-sectional areas of the at least one second conduit to the cross-sectional area of the first conduit is such that when a breath induced low pressure is applied to the distal end of the airflow adaptor at least 20% of the resulting airflow is through the at least one second conduit, the flow rate dependency of the device is reduced.

[0011] Without being bound by any particular theory, this is believed to be because while the airflow adaptor of the invention causes an increase in the volumetric flow rate, i.e. the volume of air passing through the airflow adaptor per second, for a given breath induced low pressure at the distal end of the airflow adaptor, it actually lowers the linear flow rate through the conduit, i.e. the velocity of air passing through the conduit, for a given breath-induced low pressure. The consequence of this is that a given increase or decrease, i.e. a change, in the breath-induced low pressure at the distal end of the airflow adaptor results in a reduced change in the linear flow rate through the conduit. Thus, the flow rate dependence of the breath-actuated dry powder inhaler is reduced.

[0012] It has further been surprisingly found that by providing the means for allowing air to flow from a proximal end of the adaptor to a distal end of the adaptor independently of the airflow in the conduit when a breath induced low pressure is applied to the distal end of the airflow adaptor, the dose delivery characteristics of a breath-actuated dry powder inhaler, and in particular the breath-actuated dry powder inhaler's delivered dose uniformity, are improved.

[0013] This is particularly surprising because, as explained above, for a given breath induced low pressure, the linear flow rate through the conduit is reduced. This would have been expected to reduce the performance of the breath-actuated dry powder inhaler, rather than improve it, because higher flow rates were thought to typically lead to more deagglomeration and better dose delivery.

[0014] Without being bound by any particular theory, the improvement is believed to be because, in use, the spread of medicament leaving the conduit is limited by the secondary airflow formed by the means for allowing air to flow from a proximal end of the adaptor to a distal end of the adaptor independently of the airflow in the conduit when a breath induced low pressure is applied to the distal end of the airflow adaptor.

[0015] The means for allowing air to flow from a proximal end of the adaptor to a distal end of the adaptor independently of the airflow in the conduit when a breath induced low pressure is applied to the distal end of the airflow adaptor comprises at least one second conduit. Preferably, the at least one second conduit comprises two, three, four or six conduits. Typically, the conduit and at least one second conduit are substantially parallel, preferably parallel.

[0016] Multiple second conduits are preferred because, in use, they provide improved control of the medicament leaving the conduit and therefore better delivered dose characteristics. Without being bound by any particular theory, two second conduits will control medicament spread in one plane, three second conduits will control the medicament spread in two planes, and four second conduits will control medicament spread in two planes better than three second conduits. Further second conduits provide even more control over medicament spread.

[0017] Preferably the distal end of the conduit comprises a first circumferential flange. In an embodiment, the at least one second conduit is in the form of at least one aperture in the first circumferential flange. Preferably, the first circumferential flange comprises two, four or six apertures.

[0018] The conduit and/or at least one second conduit may have any cross-sectional shape. Preferably the cross-sectional shape of the conduit and/or at least one second conduit is circular, triangular or square, most preferably circular. The diameter of the conduit and/or at least one second conduit may vary along the length of the conduit and/or at least one second conduit, for instance the conduit and/or at least one second conduit may be frustroconical, although the diameter of the conduit and/or at least one second conduit may also be constant along their length. In preferred embodiments the conduit and/or at least one second conduit are cylindrical.

[0019] The ratio of the sum of the cross-sectional areas of the at least one second conduit to the cross-sectional area of the conduit is such that when a breath induced low pressure is applied to the distal end of the airflow adaptor from about 20% to about 50%, more preferably from about 20% to about 30% of the resulting airflow is through the at least one second conduit.

[0020] Typically, the sum of the cross-sectional areas of the apertures in the first circumferential flange will be from about 0.75 mm^2 to about 20 mm^2, more preferably from about 5 mm^2 to about 16 mm^2, and even more preferably from about 9 mm^2 to about 11 mm^2. Where the at least second conduit is in a form other than apertures in the first circumferential flange, the sum of cross-sectional areas of the at least one second conduits may also be in the above preferred ranges.

[0021] Typically, the conduit will have a cross-sectional area of from about 25 mm^2 to about 50 mm^2, preferably from about 30 mm^2 to about 45 mm^2, and most preferably from about 35 mm^2 to about 45 mm^2.

[0022] In a further embodiment, the airflow adaptor comprises a second circumferential flange at the proximal end of the airflow adaptor; typically the second circumferential flange comprising at least one aperture, preferably four apertures. Typically the number of apertures in the second circumferential flange will match the number of apertures in the first circumferential flange.

[0023] Preferably, the sum of the cross-sectional areas of the apertures in the second circumferential flange will be from about 0.75 mm^2 to about 20 mm^2, more preferably from about 5 mm^2 to about 16 mm^2, and even more preferably from about 9 mm^2 to about 11 mm^2. Typically the sum of the cross-sectional areas of the apertures in the second circumferential flange will be the same as that of those in the first circumferential flange.

[0024] In a further embodiment, the ratio of the sum of the cross-sectional areas of the apertures in the second circumferential flange to the cross-sectional area of the conduit is such that when a breath induced low pressure is applied to the distal end of the airflow adaptor from about 20% to about 30% of the resulting airflow is through the apertures.

[0025] Typically the airflow adaptor is in the form of a single unitary structure, although in some embodiments it may comprise more than one part. Preferably, the airflow adaptor is in the form of a single, injection moulded unitary structure.

[0026] In a further aspect of the invention the inhaler further comprises a deagglomerator. Typically the deagglomerator comprises an inner wall defining a swirl chamber for deagglomerating the dry powder.

[0027] In an embodiment the deagglomerator comprises an inner wall defining a swirl chamber extending along an axis from a first end to a second end; a dry powder supply port in the first end of the swirl chamber for providing fluid communication between a dry powder delivery passageway of an inhaler and the first end of the swirl chamber; at least one inlet port in the inner wall of the swirl chamber adjacent to the first end of the swirl chamber providing fluid communication between a region exterior to the de-agglomerator and the first end of the swirl chamber; an outlet port providing fluid communication

between the second end of the swirl chamber and the airflow adaptor; whereby a breath induced low pressure at the distal end of the airflow adaptor causes air to flow into the swirl chamber through the dry powder supply port and the inlet port.

[0028] In addition to the benefits described above for the airflow adaptor, it has been further found that by introducing the airflow adaptor in combination with a deagglomerator the performance of the deagglomerator itself can be improved. Without being bound by any particular theory, it is believed that this is because the lower linear flow of air through the conduit as a result of the airflow adaptor has the effect reducing changes in the velocity of the airflowing through the swirl chamber of the deagglomerator as a result of corresponding changes in the breath induced low pressure. During use, this has the effect of reducing the flow rate dependence of the delivered fine particle dose.

[0029] Furthermore, the lower linear flow rate through the conduit may also have the effect of reducing the formation of secondary vortices and stalled airflow within the swirl chamber, and areas of high sheer on the walls of the swirl chamber, both of which may adversely affect the performance of the deagglomerator.

[0030] In an embodiment the deagglomerator further comprises vanes at the first end of the swirl chamber extending at least in part radially outwardly from the axis of the chamber, each of the vanes having an oblique surface facing at least in part in a direction transverse to the axis. In a further embodiment the at least one inlet port comprises two diametrically opposed inlet ports.

[0031] In a further aspect the invention provides a method for modifying airflow through the outlet port of a deagglomerator of a dry powder inhaler. The method comprises the steps of providing an airflow adaptor comprising a first conduit having a proximal end and a distal end, the airflow adaptor further comprising at least one second conduit for allowing air to flow from a proximal end of the adaptor to a distal end of the adaptor independently of airflow in the conduit, wherein the ratio of the sum of the cross-sectional areas of the at least one second conduit to the cross-sectional area of the first conduit is such that when a breath induced low pressure is applied to the distal end of the airflow adaptor from about 20% to about 50% of the resulting airflow is through the at least one second conduit; arranging the conduit such that it provides fluid communication from the outlet port of the deagglomerator to the distal end of the conduit; and applying a breath induced low pressure to the distal end of the airflow adaptor such that air flows through the conduit and the means for allowing air to flow from the proximal end of the adaptor to the distal end of the adaptor independently. Typically, the method for modifying airflow through the outlet port of a deagglomerator will reduce the linear flow rate through the outlet port.

Description of the Figures

[0032]

Figure 1 shows a view of the distal end of an airflow adaptor.

Figure 2 shows a view of the proximal end of an airflow adaptor.

Figure 3 shows an alternative embodiment of the airflow adaptor.

Figure 4 shows a deagglomerator for use with airflow adaptor.

Figure 5 shows a deagglomerator including a swirl chamber bypass port.

Figure 6 shows a breath-actuated dry powder inhaler.

Figure 7 shows a section through a breath-actuated dry powder inhaler.

Detailed Description

[0033] The present invention provides a breath-actuated dry powder inhaler comprising an airflow adaptor, the airflow adaptor comprising an airflow adaptor for a breath-actuated dry powder inhaler, the airflow adaptor comprising: a first conduit having a proximal end and a distal end, wherein the proximal end allows fluid communication from a deagglomerator outlet port to the distal end of the conduit, and wherein the airflow adaptor further comprises at least one second conduit for allowing air to flow from a proximal end of the adaptor to a distal end of the adaptor independently of the airflow in the conduit when a breath induced low pressure is applied to the distal end of the airflow adaptor, wherein the ratio of the sum of the cross-sectional areas of the at least one second conduit to the cross-sectional area of the first conduit is such that when a breath induced low pressure is applied to the distal end of the airflow adaptor from about 20% to about 50% of the resulting airflow is through the at least one second conduit.

[0034] Figure 1 shows an airflow adaptor according to the invention, in particular it shows the distal end of the airflow adaptor (100). The airflow adaptor comprises a conduit (101) with a first circumferential flange (106). The conduit shown has a circular cross-section; however, it may have any cross-sectional shape, for instance circular, square or triangular.

[0035] The airflow adaptor also comprises means for allowing air to flow from a proximal end of the adaptor to a distal end of the adaptor independently of the airflow in the conduit when a breath induced low pressure is applied to the distal end of the airflow adaptor (102, 103,

104, 105). The means for allowing air to flow from a proximal end of the adaptor to a distal end of the adaptor independently of the airflow in the conduit when a breath induced low pressure is applied to the distal end of the airflow adaptor (102, 103, 104, 105) are in the form of four apertures in the first circumferential flange (106). In alternative embodiments there may be other numbers of apertures, for instance one, two, three, five, six, eight or more. The apertures shown have a circular cross-section; however, they may have any cross-sectional shape, for instance circular, square or triangular.

[0036] Figure 2 shows a view of the proximal end (201) of the airflow adaptor (200). The airflow adaptor comprises a conduit (202) with a first circumferential flange (203). The conduit shown has a circular cross-section; however, it may have any cross-sectional shape, for instance circular, square or triangular.

[0037] The airflow adaptor also comprise means for allowing air to flow from a proximal end of the adaptor to a distal end of the adaptor independently of the airflow in the conduit when a breath induced low pressure is applied to the distal end of the airflow adaptor (204, 205, 206, fourth not shown). The means for allowing air to flow from a proximal end of the adaptor to a distal end of the adaptor independently of the airflow in the conduit when a breath induced low pressure is applied to the distal end of the airflow adaptor (204, 205, 206, fourth not shown) are in the form of four apertures in the first circumferential flange (203).

[0038] In alternative embodiments there may be other numbers of apertures, for instance one, two, three, five, six, eight or more. The apertures shown have a circular cross-section; however, they may have any cross-sectional shape, for instance circular, square or triangular.

[0039] The airflow adaptor (200) shown in Figure 2 further comprises a second circumferential flange (208). The second circumferential flange comprises four apertures (210, 211, 212, fourth not shown). The circumferential flange may, however, comprise any number of apertures, for instance one, two, three, four, six or eight apertures. The apertures shown have a circular cross-section; however, they may have any cross-sectional shape, for instance circular, square or triangular.

[0040] The first and second circumferential flanges may be of any shape; however, they are preferably of a shape which enables them mate with the mouthpiece of a dry powder inhaler. Preferably, they mate such that during use air will not flow across the mating surface.

[0041] The proximal end (209) of the conduit (202) allows fluid communication from a deagglomerator outlet port to the distal end of the conduit. In particular, the airflow adaptor (200) shown in Figure 2 has a mating surface (214) for mating with the outlet port of a deagglomerator outlet port. Preferably, they mate such that during use air will not flow across the mating surface. It is understood that in certain embodiments, the outlet port and the airflow adaptor may be a unitary structure.

[0042] Figure 3 shows a view of the proximal end (301) of the airflow adaptor (300). The airflow adaptor comprises a conduit (302) with a first circumferential flange (303). The conduit shown has a circular cross-section; however, it may have any cross-sectional shape, for instance circular, square or triangular.

[0043] The airflow adaptor also comprises means for allowing air to flow from a proximal end of the adaptor to a distal end of the adaptor independently of the airflow in the conduit when a breath induced low pressure is applied to the distal end of the airflow adaptor (304, 305, 306, fourth not shown). The means for allowing air to flow from a proximal end of the adaptor to a distal end of the adaptor independently of the airflow in the conduit when a breath induced low pressure is applied to the distal end of the airflow adaptor are in the form of four second conduits (304, 305, 306, fourth not shown) running from the second circumferential flange (308) to the first circumferential flange (309). The second conduits shown have circular cross-sections (310, 311, 312, fourth not shown); however, they may have any cross-sectional shape, for instance circular, square or triangular.

[0044] The proximal end (309) of the conduit (302) is suitable for making fluid communication with the outlet port of a deagglomerator of a dry powder inhaler. In particular, the airflow adaptor (300) shown in Figure 3 has a mating surface (310) for mating with an outlet port of a deagglomerator of a dry powder inhaler. Preferably, they mate such that during use air will not flow across the mating surface. It is understood that in certain embodiments, the outlet port and the airflow adaptor may be a unitary structure.

[0045] The airflow adaptor of the invention may be moulded from any suitable polymeric material. Suitable polymeric materials include polypropylene and acrylonitrile butadiene styrene (both available from BASF).

[0046] Figure 4 shows a deagglomerator (400) suitable for including the airflow adaptor (not shown). The deagglomerator (400) comprises: an inner wall (412) defining a swirl chamber (414) extending along an axis (A) from a first end (418) to a second end (420); a dry powder supply port (422) in the first end (418) of the swirl chamber (414) for providing fluid communication between a dry powder delivery passageway of an inhaler and the first end (418) of the swirl chamber (414); at least one inlet port (424, 425) in the inner wall (412) of the swirl chamber (414) adjacent to the first end (418) of the swirl chamber (414) providing fluid communication between a region exterior to the de-agglomerator (400) and the first end (418) of the swirl chamber (414); an outlet port (432) providing fluid communication between the second end (420) of the swirl chamber (414) and an airflow adaptor (not shown); whereby a breath induced low pressure at the distal end of the airflow adaptor (not shown) causes air to flow into the swirl chamber (414) through the dry powder supply port (422) and the inlet port (424,425).

[0047] Preferably, the at least one inlet port (424, 425) comprises two diametrically opposed inlet ports (424, 425) that extend in a direction substantially transverse

to the axis A and substantially tangential to the circular cross-section of the swirl chamber (414). As a result, airflows, illustrated by arrows 2 and 3 in Figure 4, entering the swirl chamber (414) through the inlet ports are at least initially directed transverse with respect to the axis A of the swirl chamber and collide with the airflow entering through the supply port (422) to create turbulence. The combined airflows, illustrated by arrow 4 in Figure 4, then collide with the inner wall (412) of the swirl chamber (414), form a vortex, and create additional turbulence as they move towards the second end (420) of the swirl chamber.

[0048] Referring to Figure 4, the de-agglomerator (400) includes vanes (426) at the first end (418) of the swirl chamber (414) extending at least in part radially outwardly from the axis A of the swirl chamber. Each of the vanes (426) has an oblique surface (428) facing at least in part in a direction transverse to the axis A of the swirl chamber. The vanes (426) are sized such that at least a portion of the combined airflows 4 collide with the oblique surfaces (428). Preferably, the vanes comprise four vanes (426), each extending between a hub (430) aligned with the axis A and the wall (412) of the swirl chamber (414).

[0049] As shown in Figure 4, the de-agglomerator (400) further includes an outlet port (432) for providing fluid communication between the second end (420) of the swirl chamber (414) and the airflow adaptor (not shown). A breath induced low pressure at the distal end of the airflow adaptor (not shown) causes the airflow through the supply port (422) and the airflows 2, 3 through the inlet ports and draws the combined airflow 4 through the swirl chamber (414). The combined airflow 4 then exits the swirl chamber (414) through the outlet port (432). Preferably the outlet port (432) extends substantially transverse to the axis A, such that the airflow 4 will collide with an inner wall of the outlet port (432) and create further turbulence.

[0050] During use of the de-agglomerator in combination with a breath-actuated dry powder inhaler including a dry powder delivery passageway and a dry powder reservoir for exposing a predetermined amount of dry powder to the delivery passageway, patient inhalation at the distal end of the airflow adaptor causes airflows 2 and 3 to enter through, respectively, the dry powder supply port (422) and the inlet ports. Although not shown, the airflow through the supply port (422) entrains the dry powder into the swirl chamber (414). The airflow and entrained dry powder are directed by the supply port (422) into the swirl chamber in a longitudinal direction, while the airflows 2 and 3 from the inlet ports are directed in a transverse direction, such that the airflows collide and substantially combine.

[0051] A portion of the combined airflow 4 and the entrained dry powder then collide with the oblique surfaces (428) of the vanes (426) causing particles and any agglomerates of the dry powder to impact against the oblique surfaces and collide with each other. The geometry of the swirl chamber (414) causes the combined airflow 4 and the entrained dry powder to follow a turbulent, spiral path, or vortex, through the swirl chamber. As will be appreciated, the decreasing cross-sections of the swirl chamber (414) continuously changes the direction and increases the velocity of the spiralling combined airflow 4 and entrained dry powder. Thus, particles and any agglomerates of the dry powder constantly impact against the wall (412) of the swirl chamber (414) and collide with each other, resulting in a mutual grinding or shattering action between the particles and agglomerates. In addition, particles and agglomerates deflected off the oblique surfaces (428) of the vanes (426) cause further impacts and collisions. The constant impacts and collisions cause any agglomerates to break into additional particles, and cause the particles to be substantially micronised.

[0052] Upon exiting the swirl chamber (414), the direction of the combined airflow 4 and the entrained dry powder is again changed to a transverse direction with respect to the axis A, through the outlet port (432). The combined airflow 4 and the entrained dry powder retain a swirl component of the flow, such that the airflow 4 and the entrained dry powder spirally swirls through the outlet port (432). Since the micronised powder and any remaining agglomerates maintain the swirl imparted from swirl chamber (414), the swirling flow causes additional impacts in the outlet port (432) so as to result in further breaking up of any remaining agglomerates prior to being inhaled by a patient.

[0053] Figure 5 shows a deagglomerator (500) with the airflow adaptor (501) according to the invention. The deagglomerator (500) comprises: an airflow adaptor (501) providing fluid communication between the outlet port (530) and a region exterior to the deagglomerator; an inner wall (512) defining a swirl chamber (514) extending along an axis (B) from a first end (518) to a second end (520); a dry powder supply port (522) in the first end (518) of the swirl chamber (514) for providing fluid communication between a dry powder delivery passageway of an inhaler and the first end (518) of the swirl chamber (514); at least one inlet port (524, 525) in the inner wall (512) of the swirl chamber (514) adjacent to the first end (518) of the swirl chamber (514) providing fluid communication between a region exterior to the de-agglomerator and the first end (518) of the swirl chamber; an outlet port (530) providing fluid communication between the second end (520) and the airflow adaptor (501); and at least one swirl chamber bypass port (502, 503, 504, 505). The at least one swirl chamber by-pass port (502, 503, 504, 505) allow air to flow (shown by arrows labelled 5) from a proximal end of the airflow adaptor to a distal end of the airflow adaptor (501) independently of the swirl-chamber (514) when a breath-induced low pressure is applied to the distal end of the airflow adaptor. The breath induced low pressure at the distal end of the airflow adaptor (501) also causes air to flow into the swirl chamber (514) through the dry powder supply port (522) and the at least one inlet port (524, 525). The combined airflow (arrow 4) leaves the airflow adaptor (501) through the conduit (507)

(shown by arrow 6).

[0054] The at least one swirl chamber bypass port shown in Figure 5 is in the form of four apertures (502, 503, 504, 505) in a first circumferential flange (506) of a conduit (507) of the airflow adaptor (501). The airflow adaptor (501) shown in Figure 5 further comprises an optional second circumferential flange (508) which also comprises four apertures (509, 510, 511, fourth not shown). When present, in use, the apertures (509, 510, 51 1, fourth not shown) in the second circumferential flange (508) also form part of the swirl chamber bypass port.

[0055] The airflow adaptor shown in Figure 5 is the airflow adaptor shown in Figure 3. The second conduits of Figure 3 perform the function of swirl chamber bypass ports. Indeed any of the airflow adaptors described herein when combined with a deagglomerator as set out in Figure 4 provide a swirl chamber bypass port.

[0056] Preferably, the ratio of the sum of the cross-sectional areas of the at least one swirl chamber bypass ports to the cross-sectional area of outlet port is such that that when a pressure breath induced low pressure is applied to the distal end of the airflow adaptor from about 20% to about 30% of the resulting airflow is directed through the at least one swirl chamber bypass port.

[0057] The percentage of airflow flowing through different parts of the airflow adaptor and deagglomerator may be calculated using methods known in the art. In particular they can be calculated by measuring the volumetric flow through an airflow adaptor according to the invention at a given pressure gradient and comparing it to the volumetric flow through a similar airflow adaptor with the same conduit, but no means for allowing air to flow from a proximal end of the adaptor to a distal end of the adaptor independently of the airflow in the conduit when a breath induced low pressure is applied to the distal end of the airflow adaptor. In this instance, both measurements should be made with the same pressure gradient, preferably 4KPa. The same method can be applied in the case of deagglomerators comprising airflow adaptors comprising swirl chamber by-pass ports. In this instance, however, it is the swirl chamber by-pass ports that are removed.

[0058] Suitable breath-actuated dry powder inhalers for including the deagglomerators and airflow adaptors of the present invention are disclosed in US6748947 and are sold under the trade name SPIROMAX™.

[0059] Figure 6 shows the external appearance of a breath-actuated dry powder inhaler (600) according to the invention. The breath-actuated dry powder inhaler comprises an airflow adaptor (601) having a conduit (602) and four second conduits (603, 604, 605, 606). In this instance, the conduit (602) and the second conduits (603, 604, 605, 606) have circular cross-sections.

[0060] Figure 7 shows a breath-actuated dry powder inhaler (700) comprising a deagglomerator (701) including an airflow adaptor (702) according to the invention.

[0061] The airflow adaptor (702) comprises a conduit (703) with a first circumferential flange (704) comprising four apertures (not shown). The airflow adaptor further comprises a second circumferential flange (705) also comprising four apertures (not shown). The apertures in the first and second circumferential flanges perform the function of swirl chamber bypass ports (by performing the function of the at least one second conduits). Accordingly, in use, a breath-actuated low pressure at the distal end (706) of the airflow adaptor (702) causes air to flow through the apertures (not shown) in the first (704) and second (705) circumferential flanges. The breath-actuated low pressure at the distal end (706) of the airflow adaptor (702) also causes air to entrain medicament and deliver it to the swirl chamber (707) via a supply port.

[0062] In use, a first breath-actuated airflow for entraining a dry powder from an inhaler is directed into a first end of a swirl chamber extending along a longitudinal axis from the first end to a second end. The first airflow is directed in a longitudinal direction. A second breath-actuated airflow is then directed in a substantially transverse direction into the first end of the swirl chamber such that the first and the second breath-actuated airflows collide and substantially combine. A portion of the combined airflows is then directed in a spiral path towards the second end of the swirl chamber, and all the combined airflows and any dry powder entrained therein are delivered through an outlet port in the second end of the swirl chamber to an airflow adaptor. A third breath-actuated airflow is directed to the airflow adaptor having bypassed the swirl chamber. Typically, in use, the third breath-actuated airflow will form before the first breath-actuated airflow is sufficient to entrain medicament.

[0063] Preferably, a portion of the combined first and second airflows is deflected off vanes non-rotationally fixedly attached to the first end of the swirl chamber and extending at least in part radially outwardly from the axis of the swirl chamber. Each of the vanes has an oblique surface facing at least in part in a direction transverse to the axis, such that the portion of the combined airflows is deflected in a substantially longitudinal direction towards the second end of the swirl chamber.

[0064] Typically, the dry powder medicament used in the breath-actuated dry powder inhaler comprises a medicament active selected from the group consisting of anti-inflammatory agents, anti-cholinergic agents, β_2-adrenoreceptor agonists, anti-infective agents, anti-histamines and combinations thereof.

[0065] Suitable anti-inflammatory agents include corticosteroids and NSAIDs. Suitable corticosteroids which may be used include those oral and inhaled corticosteroids and their pro-drugs which have anti-inflammatory activity. Examples include methyl prednisolone, prednisolone, dexamethasone, fluticasone propionate, 6a, 9a-difluoro-17a-[(2-furanylcarbonyl) oxy] - 11 -hydroxy-16a-methyl-3-oxo-androsta-1, 4-diene-17 -carbothioic acid S- fluoromethyl ester, 6a, 9a-difluoro-11-hydroxy-16a-methyl-3-oxo-17a-propionyloxy-androsta-1, 4-diene-17p-carbothioic acid S- (2-oxo-tetrahydro-furan-3S-

yi) ester, beclomethasone esters (e. g. the 17-propionate ester or the 17,21-dipropionate ester), budesonide, flunisolide, mometasone esters (e. g. the furoate ester), triamcinolone acetonide, rofleponide, ciclesonide, butixocort propionate, RPR- 106541, and ST-126. Preferred corticosteroids include fluticasone propionate, 6a, 9c-difluoro-11-hydroxy-16a-methyl-17a-[(4-methyl-1, 3-thiazole-5-carbonyl) oxy] - 3-oxo-androsta-1, 4-diene-17, 8-carbothioic acid S-fluoromethyl ester and 6a, 9a- difluoro-17a-[(2-furanylcarbonyl) oxyl-11-hydroxy-16a-methyl-3-oxo-androsta-1, 4- diene-17p-carbothioic acid S-fluoromethyl ester, more preferably 6a, 9a-difluoro-17a- [(2-furanylcarbonyl) oxy]-11-hydroxy-16a-methyl-3-oxo-androsta-1, 4-diene-17 - carbothioic acid S-fluoromethyl ester.

[0066] Suitable NSAIDs include sodium cromoglycate, nedocromil sodium, phosphodiesterase (PDE) inhibitors (e. g. theophylline, PDE4 inhibitors or mixed PDE3/PDE4 inhibitors), leukotriene antagonists, inhibitors of leukotriene synthesis, iNOS inhibitors, tryptase and elastase inhibitors, beta-2 integrin antagonists and adenosine receptor agonists or antagonists (e. g. adenosine 2a agonists), cytokine antagonists (e. g. chemokine antagonists) or inhibitors of cytokine synthesis.

[0067] Suitable other (32-adrenoreceptor agonists include salmeterol (e. g. as the xinafoate), salbutamol (e. g. as the sulphate or the free base), formoterol (e. g. as the fumarate), fenoterof or terbutaline and salts thereof.

[0068] Suitable anticholinergic agents are those compounds that act as antagonists at the muscarinic receptor, in particular those compounds, which are antagonists of the M 1 and M2 receptors. Compounds include the alkaloid of the belladonna plants as illustrated by the likes of atropine, scopolamine, homatropine, hyoscyamine; these compounds are normally administered as a salt, being tertiary amines.

[0069] Particularly suitable anticholinergics include ipratropium (e : g. as the bromide), sold under the name Atrovent, oxitropium (e. g. as the bromide), glycopyrrolate (e. g. as the bromide), and tiotropium (e. g. as the bromide) (CAS-139404-48-1). Also of interest are: methantheline (CAS-53-46-3), propantheline bromide (CAS-50-34-9), anisotropine methyl bromide or Valpin 50 (CAS-80-50-2), clidinium bromide (Quarzan, CAS-3485-62-9), copyrrolate (Robinul), isopropamide iodide (CAS-71-81-8), mepenzolate bromide (U. S. patent 2,918, 408), tridihexethyl chloride (Pathilone, CAS-4310-35-4), and hexocyclium methylsulfate (Tral, CAS-115-63-9). See also cyclopentolate hydrochloride (CAS-5870-29-1), tropicamide (CAS-1508-75-4), trihexyphenidyl hydrochloride (CAS-144-11-6), pirenzepine (CAS-29868-97-1), telenzepine (CAS-80880-90-9), AF-DX 116, or methoctramine, and the compounds disclosed in WO01/04118.

[0070] Suitable antihistamines (also referred to as H1-receptor antagonists) include any one or more of the numerous antagonists known which inhibit H1-receptors, and are safe for human use. All are reversible, competitive inhibitors of the interaction of histamine with H1-receptors. Examples include ethanolamines, ethylenediamines, and alkylamines. In addition, other first generation antihistamines include those which can be characterized as based on piperizine and phenothiazines. Second generation antagonists, which are non-sedating, have a similar structure-activity relationship in that they retain the core ethylene group (the alkylamines) or mimic the tertiary amine group with piperizine or piperidine. Exemplary antagonists are as follows : Ethanolamines : carbinoxamine maleat, clemastine fumarate, diphenylhydramine hydrochloride, and dimenhydrinate.

[0071] Ethylenediamines : pyrilamine amleate, tripelennamine HCl, and tripelennamine citrate.

[0072] Alkylamines : chlropheniramine and its salts such as the maleate salt, and acrivastine.

[0073] Piperazines: hydroxyzine HCl, hydroxyzine pamoate, cyclizine HCl, cyclizine lactate, meclizine HCl, and cetirizine HCl.

[0074] Piperidines: Astemizole, levocabastine HCl, loratadine or its descarboethoxy analogue, and terfenadine and fexofenadine hydrochloride or another pharmaceutical acceptable salt.

[0075] Azelastine hydrochloride is yet another H1 receptor antagonist which may be used in combination with a PDE4 inhibitor.

[0076] Particularly suitable anti-histamines include methapyrilene and loratadine.

[0077] Generally, powdered medicament particles suitable for delivery to the bronchial or alveolar region of the lung have an aerodynamic diameter of less than 10 micrometers, preferably less than 6 micrometers. Other sized particles may be used if delivery to other portions of the respiratory tract is desired, such as the nasal cavity, mouth or throat. The medicament may be delivered as pure drug, but more appropriately, it is preferred that medicaments are delivered together with excipients (carriers) which are suitable for inhalation. Suitable excipients include organic excipients such as polysaccharides (e.g. starch, cellulose and the like), lactose, glucose, mannitol, amino acids, and maltodextrins, and inorganic excipients such as calcium carbonate or sodium chloride. Lactose is a preferred excipient.

[0078] Particles of powdered medicament and/or excipient may be produced by conventional techniques, for example by micronisation, milling or sieving.

[0079] Additionally, medicament and/or excipient powders may be engineered with particular densities, size ranges, or characteristics. Particles may comprise active agents, surfactants, wall forming materials, or other components considered desirable by those of ordinary skill.

Claims

1. A breath-actuated dry powder inhaler (600; 700) comprising an airflow adaptor (100; 200; 300; 501; 601; 702), the airflow adaptor (100; 200; 300; 501;

601; 702) comprising:

a first conduit (101; 202; 302; 507; 602; 703) having a proximal end and a distal end, wherein the proximal end allows fluid communication from a deagglomerator outlet port (530) to the distal end of the first conduit (101; 202; 302; 507; 602; 703), and at least one second conduit (102-105; 204-206; 304-306; 502-505; 603-606) for allowing air to flow from a proximal end of the adaptor (100; 200; 300; 501; 601; 702) to a distal end of the adaptor (100; 200; 300; 501; 601; 702) independently of the airflow in the first conduit (101; 202; 302; 507; 602; 703) when a breath induced low pressure is applied to the distal end of the airflow adaptor (100; 200; 300; 501; 601; 702),

characterised in that the ratio of the sum of the cross-sectional areas of the at least one second conduit (102-105; 204-206; 304-306; 502-505; 603-606) to the cross-sectional area of the first conduit (101; 202; 302; 507; 602; 703) is such that when a breath induced low pressure is applied to the distal end of the airflow adaptor (100; 200; 300; 501; 601; 702) from 20% to 50% of the resulting airflow is through the at least one second conduit (102-105; 204-206; 304-306; 502-505; 603-606).

2. The inhaler according to claim 1 wherein the distal end of the first conduit (101; 202; 302; 507; 602; 703) comprises a first circumferential flange (106; 203; 303; 506; 704) and the second conduit (102-105; 204-206; 304-306; 502-505; 603-606) is in the form of at least one aperture in the first circumferential flange (106; 203; 303; 506; 704).

3. The inhaler according to claim 2 wherein the first circumferential flange (106; 203; 303; 506; 704) comprises two, preferably four apertures.

4. The inhaler according to any preceding claim wherein the airflow adaptor (100; 200; 300; 501; 601; 702) comprises a second circumferential flange (208; 308; 508; 705) at the proximal end of the airflow adaptor (100; 200; 300; 501; 601; 702), the second circumferential flange (208; 308; 508; 705) comprising at least one aperture, preferably four apertures.

5. The inhaler according to claim 4 wherein the ratio of the sum of the cross-sectional areas of the apertures in the second circumferential flange (208; 308; 508; 705) to the cross-sectional area of the first conduit (101; 202; 302; 507; 602; 703) is such that when a pressure breath induced low pressure is applied to the distal end of the airflow adaptor (101; 202; 302; 507; 602; 703) at least 20%, of the resulting airflow is through the apertures.

6. The inhaler according to any one of claims 1 to 5, further comprising a deagglomerator (400; 500; 701) comprising:

an inner wall (412; 512) defining a swirl chamber (414; 514) extending along an axis (A) from a first end (418; 518) to a second end (420; 520);
a dry powder supply port (422; 522) in the first end (418; 518) of the swirl chamber (414; 514) for providing fluid communication between a dry powder delivery passageway of an inhaler and the first end (418; 518) of the swirl chamber (414; 514);
at least one inlet port (424, 425; 524, 525) in the inner wall (412; 512) of the swirl chamber (414; 514) adjacent to the first end of the swirl chamber (414; 514) providing fluid communication between a region exterior to the deagglomerator (400; 500) and the first end (418; 518) of the swirl chamber (414; 514);
an outlet port (432; 530) providing fluid communication between the second end (420; 520) of the swirl chamber (414; 514) and the airflow adaptor (100; 200; 300; 501; 601; 702);
whereby a breath induced low pressure at the distal end of the airflow adaptor (100; 200; 300; 501; 601; 702) causes air to flow into the swirl chamber (414; 514) through the dry powder supply port (422; 522) and the inlet port (424, 425; 524, 525).

7. A method for modifying airflow through the outlet port of a deagglomerator of a breath-actuated dry powder inhaler comprising the steps of:

a) providing an airflow adaptor (100; 200; 300; 501; 601; 702) comprising a first conduit (101; 202; 302; 507; 602; 703) having a proximal end and a distal end, the airflow adaptor (100; 200; 300; 501; 601; 702) further comprising at least one second conduit (102-105; 204-206; 304-306; 502-505; 603-606) for allowing air to flow from a proximal end of the adaptor (100; 200; 300; 501; 601; 702) to a distal end of the adaptor (100; 200; 300; 501; 601; 702) independently of airflow in the first conduit (101; 202; 302; 507; 602; 703),;
b) arranging the first conduit (101; 202; 302; 507; 602; 703) such that it provides fluid communication from the outlet port of the deagglomerator to the distal end of the first conduit (101; 202; 302; 507; 602; 703); and
c) applying a breath induced low pressure to the distal end of the airflow adaptor (100; 200; 300; 501; 601; 702) such that air flows through the first (101; 202; 302; 507; 602; 703) and second conduits (102-105; 204-206; 304-306; 502-505; 603-606);

characterised in that the ratio of the sum of the cross-sectional areas of the at least one second conduit (102-105; 204-206; 304-306; 502-505; 603-606) to the cross-sectional area of the first conduit (101; 202; 302; 507; 602; 703) is such that when a breath induced low pressure is applied to the distal end of the airflow adaptor (100; 200; 300; 501; 601; 702) from 20% to 50% of the resulting airflow is through the at least one second conduit (102-105; 204-206; 304-306; 502-505; 603-606).

8. A method according to claim 7 wherein the linear flow rate through the outlet port is reduced.

Patentansprüche

1. Atemzuggesteuerter Trockenpulverinhalator (600, 700), bestehend aus einem Luftstromadapter (100, 200, 300, 501, 601, 702), wobei der Luftstromadapter (100, 200, 300, 501, 601, 702) Folgendes umfasst:

   einen ersten Kanal (101, 202, 302, 507, 602, 703) mit einem proximalen Ende und einem distalen Ende, wobei das proximale Ende eine Fluidverbindung zwischen einer Desagglomeratorauslassöffnung (530) und dem distalen Ende des ersten Kanals (101, 202, 302, 507, 602, 703) gewährleistet, und mindestens einen zweiten Kanal (102-105, 204-206, 304-306, 502-505, 603-606) zur Gewährleistung eines Luftflusses zwischen einem proximalen Ende des Adapters (100, 200, 300, 501, 601, 702) und einem distalen Ende des Adapters (100, 200, 300, 501, 601, 702) unabhängig vom Luftfluss im ersten Kanal (101, 202, 302, 507, 602, 703), wenn ein durch Atemzug erzeugter Niedrigdruck auf das distale Ende des Luftstromadapters (100, 200, 300, 501, 601, 702) ausgeübt wird,
   dadurch gekennzeichnet, dass das Verhältnis der Summe der Querschnittsflächen mindestens eines zweiten Kanals (102-105, 204-206, 304-306, 502-505, 603-606) zur Querschnittsfläche des ersten Kanals (101, 202, 302, 507, 602, 703) dergestalt ist, dass bei Ausüben eines durch Atemzug erzeugten Niederdrucks auf das distale Ende des Luftstromadapters (100, 200, 300, 501, 601, 702) 20 % bis 50 % des resultierenden Luftflusses durch mindestens einen zweiten Kanal (102-105, 204-206, 304-306, 502-505, 603-606) gelenkt werden.

2. Inhalator nach Anspruch 1, wobei das distale Ende des ersten Kanals (101, 202, 302, 507, 602, 703) einen ersten umlaufenden Flansch (106, 203, 303, 506, 704) umfasst und der zweite Kanal (102-105, 204-206, 304-306, 502-505, 603-606) in Form von mindestens einer Öffnung im ersten umlaufenden Flansch (106, 203, 303, 506, 704) vorliegt.

3. Inhalator nach Anspruch 2, wobei der erste umlaufende Flansch (106, 203, 303, 506, 704) zwei, vorzugsweise vier Öffnungen umfasst.

4. Inhalator nach einem der vorangehenden Ansprüche, wobei der Luftstromadapter (100, 200, 300, 501, 601, 702) einen zweiten umlaufenden Flansch (208, 308, 508, 705) am proximalen Ende des Luftstromadapters (100, 200, 300, 501, 601, 702) umfasst, wobei der zweite umlaufenden Flansch (208, 308, 508, 705) mindestens eine Öffnung, vorzugsweise vier Öffnungen besitzt.

5. Inhalator nach Anspruch 4, wobei das Verhältnis der Summe der Querschnittsflächen der Öffnungen im zweiten umlaufenden Flansch (208, 308, 508, 705) zur Querschnittsfläche des ersten Kanals (101, 202, 302, 507, 602, 703) dergestalt ist, dass bei Ausüben eines durch Atemzug erzeugten Niedrigdrucks auf das distale Ende des Luftstromadapters (101, 202, 302, 507, 602, 703) mindestens 20 % des resultierenden Luftflusses durch die Öffnungen gelenkt werden.

6. Inhalator nach einem der Ansprüche 1 bis 5, der weiterhin einen Desagglomerator (400, 500, 701) umfasst, der Folgendes umfasst:

   eine Innenwand (412, 512), die eine Wirbelkammer (414, 514) definiert, die sich entlang einer Achse (A) von einem ersten Ende (418, 518) zu einem zweiten Ende (420, 520) erstreckt;
   eine Trockenpulverzufuhröffnung (422, 522) im ersten Ende (418, 518) der Wirbelkammer (414, 514) zur Gewährleistung einer Fluidverbindung zwischen einem Trockenpulverdurchlasskanal eines Inhalators und dem ersten Ende (418, 518) der Wirbelkammer (414, 514);
   mindestens eine Einlassöffnung (424, 425, 524, 525) in der Innenwand (412, 512) der Wirbelkammer (414, 514) angrenzend an das erste Ende der Wirbelkammer (414, 514) zur Gewährleistung einer Fluidverbindung zwischen einer außerhalb des Desagglomerators (400, 500) befindlichen Region und dem ersten Ende (418, 518) der Wirbelkammer (414, 514);
   eine Auslassöffnung (432, 530) zur Gewährleistung einer Fluidverbindung zwischen dem zweiten Ende (420, 520) der Wirbelkammer (414, 514) und dem Luftstromadapter (100, 200, 300, 501, 601, 702); wobei ein durch Atemzug erzeugter niedriger Druck am distalen Ende des Luftstromadapters (100, 200, 300, 501, 601, 702) Luft in die Wirbelkammer lenkt (414, 514) und zwar durch die Trockenpulverzufuhröffnung

(422, 522) und die Einlassöffnung (424, 425, 524, 525) hindurch.

7. Eine Methode zur Modifizierung des Luftflusses durch die Auslassöffnung eines Desagglomerators eines atemzuggesteuerten Trockenpulverinhalators, die folgende Schritte umfasst:

a) Bereitstellen eines Luftstromadapters (100, 200, 300, 501, 601, 702) mit einem ersten Kanal (101, 202, 302, 507, 602, 703) mit einem proximalen Ende und einem distalen Ende, wobei der Luftstromadapter (100, 200, 300, 501, 601, 702) weiterhin mindestens einen zweiten Kanal (102-105, 204-206, 304-306, 502-505, 603-606) zur Gewährleistung eines Luftflusses von einem proximalen Ende des Adapters (100, 200, 300, 501, 601, 702) zu einem distalen Ende des Adapters (100, 200, 300, 501, 601, 702) unabhängig vom Luftfluss im ersten Kanal (101, 202, 302, 507, 602, 703) umfasst;
b) den ersten Kanal (101, 202, 302, 507, 602, 703) dergestalt vorsehen, dass eine Fluidverbindung zwischen der Auslassöffnung des Desagglomerators und dem distalen Ende des ersten Kanals (101, 202, 302, 507, 602, 703) gewährleistet wird; und
c) Ausüben eines durch Atemzug erzeugten Niedrigdrucks auf das distale Ende des Luftstromadapters (100, 200, 300, 501, 601, 702) sodass Luft durch den ersten (101, 202, 302, 507, 602, 703) und den zweiten Kanal (102-105, 204-206, 304-306, 502-505, 603-606) fließt;
dadurch gekennzeichnet, dass das Verhältnis der Summe der Querschnittsflächen von mindestens einen zweiten Kanal (102-105, 204-206, 304-306, 502-505, 603-606) zur Querschnittsfläche des ersten Kanals (101, 202, 302, 507, 602, 703) dergestalt ist, dass bei Ausüben eines durch Atemzug erzeugten Niedrigdrucks auf das distale Ende des Luftstromadapters (100, 200, 300, 501, 601, 702) zwischen 20 % und 50 % des resultierenden Luftflusses durch mindestens einen zweiten Kanal (102-105, 204-206, 304-306, 502-505, 603-606) gelenkt werden.

8. Eine Methode nach Anspruch 7, bei der der lineare Durchfluss durch die Auslassöffnung reduziert wird.

Revendications

1. Un inhalateur de poudre sèche actionné par la respiration (600; 700) comprenant un adaptateur de débit d'air (100; 200; 300; 501; 601; 702), l'adaptateur de débit d'air (100; 200; 300; 501; 601; 702) comprenant: un premier conduit (101; 202; 302; 507; 602; 703) ayant une extrémité proximale et une extrémité distale, dans lequel l'extrémité proximale permet la communication fluide depuis un orifice de sortie de désagglomérateur (530) vers l'extrémité distale du premier conduit (101; 202 ; 302; 507; 602; 703), et au moins un second conduit (102-105; 204-206; 304-306; 502-505; 603-606) pour permettre à l'air de circuler d'une extrémité proximale de l'adaptateur (100; 200; 300; 501; 601; 702) à une extrémité distale de l'adaptateur (100; 200; 300; 501; 601; 702) indépendamment du débit d'air dans le premier conduit (101; 202; 302; 507; 602 ; 703) lorsqu'une faible pression induite par la respiration est appliquée à l'extrémité distale de l'adaptateur de débit d'air (100; 200; 300; 501; 601; 702), **caractérisé en ce que** le rapport de la somme des surfaces transversales d'au moins un second conduit (102-105; 204-206; 304-306; 502-505; 603-606) par rapport à la surface transversale du premier conduit (101; 202; 302; 507; 602; 703) est tel que lorsqu'une faible pression induite par la respiration est appliquée à l'extrémité distale de l'adaptateur de débit d'air (100; 200; 300; 501; 601; 702), 20% à 50% du débit d'air résultant passe au moins à travers un second conduit (102-105; 204-206; 304-306; 502-505; 603-606).

2. L'inhalateur selon la revendication 1, dans lequel l'extrémité distale du premier conduit (101; 202; 302; 507; 602; 703) comprend un premier rebord circonférentiel (106; 203; 303; 506; 704) et le deuxième conduit (102- 105; 204-206; 304-306; 502-505; 603-606) se présente sous la forme d'au moins un orifice dans le premier rebord circonférentiel (106; 203; 303; 506; 704).

3. L'inhalateur selon la revendication 2, dans lequel le premier rebord circonférentiel (106; 203; 303; 506; 704) comprend deux, et de préférence quatre orifices.

4. Un inhalateur selon l'une quelconque des revendications précédentes, dans lequel l'adaptateur de débit d'air (100; 200; 300; 501; 601; 702) comprend un second rebord circonférentiel (208; 308; 508; 705) à l'extrémité proximale de l'adaptateur de débit d'air (100; 200 ; 300; 501; 601; 702), le second rebord circonférentiel (208; 308; 508; 705) comprenant au moins un orifice, et de préférence quatre orifices.

5. Un inhalateur selon la revendication 4, dans lequel le rapport entre la somme des surfaces transversales des orifices du second rebord circonférentiel (208; 308; 508; 705) par rapport à la surface transversale du premier conduit (101; 202; 302; 507; 602; 703) est tel que lorsqu'une faible pression induite par la respiration est appliquée à l'extrémité distale de l'adaptateur de débit d'air (101; 202; 302; 507; 602; 703), au moins 20% du débit d'air résultant pas-

se à travers les orifices.

6. Un inhalateur selon l'une quelconque des revendications 1 à 5, contenant en outre un désagglomérateur (400; 500; 701) comprenant :

une paroi intérieure (412; 512) définissant une chambre de turbulence (414; 514) se prolongeant le long d'un axe (A) depuis une première extrémité (418; 518) jusqu'à une seconde extrémité (420; 520);
un orifice d'alimentation en poudre sèche (422; 522) dans la première extrémité (418; 518) de la chambre de turbulence (414; 514) destiné à fournir une communication fluide entre un passage de dispense de poudre sèche d'un inhalateur et la première extrémité (418; 518) de la chambre de turbulence (414; 514);
au moins un orifice d'entrée (424, 425; 524, 525) dans la paroi intérieure (412; 512) de la chambre de turbulence (414; 514) adjacente à la première extrémité de la chambre de turbulence (414; 514) établissant une communication fluide entre une région extérieure au désagglomérateur (400; 500) et la première extrémité (418; 518) de la chambre de turbulence (414; 514);
un orifice de sortie (432; 530) établissant une communication fluide entre la seconde extrémité (420; 520) de la chambre de turbulence (414; 514) et l'adaptateur de débit d'air (100; 200; 300; 501; 601; 702) ; permettant qu'une faible pression induite par la respiration appliquée à l'extrémité distale de l'adaptateur de débit d'air (100; 200; 300; 501; 601; 702) entraîne la circulation de l'air dans la chambre de turbulence (414; 514) à travers l'orifice d'alimentation en poudre sèche (422; 522) et l'orifice d'entrée (424, 425; 524, 525).

7. Un procédé permettant de modifier le débit d'air à travers l'orifice de sortie d'un désagglomérateur d'un inhalateur de poudre sèche actionné par la respiration, comprenant les étapes suivantes :

a) la fourniture d'un adaptateur de débit d'air (100; 200; 300; 501; 601; 702) comprenant un premier conduit (101; 202; 302; 507; 602; 703) ayant une extrémité proximale et une extrémité distale, l'adaptateur de débit d'air (100 ; 200; 300; 501; 601; 702) comprenant en outre au moins un second conduit (102-105; 204-206; 304-306; 502-505; 603-606) pour permettre à l'air de circuler d'une extrémité proximale de l'adaptateur (100; 200; 300; 501; 601; 702) à une extrémité distale de l'adaptateur (100; 200; 300; 501; 601; 702), indépendamment du débit d'air circulant dans le premier conduit (101; 202; 302; 507; 602; 703) ,;
b) la disposition du premier conduit (101; 202; 302; 507; 602; 703) de telle sorte qu'il fournisse une communication fluide à partir de l'orifice de sortie du désagglomérateur vers l'extrémité distale du premier conduit (101; 202; 302; 507; 602 ; 703); et
c) l'application de la respiration induisant une faible pression à l'extrémité distale de l'adaptateur de débit d'air (100; 200; 300; 501; 601; 702) de telle sorte que l'air circule à travers le premier (101; 202; 302; 507; 602; 703) et le deuxième conduits (102-105; 204-206; 304-306; 502-505; 603-606);

caractérisé en ce que le rapport de la somme des surfaces transversales d'au moins un second conduit (102-105; 204-206; 304-306; 502-505; 603-606) par rapport à la surface transversale du premier conduit (101; 202; 302; 507; 602; 703) est tel que lorsqu'une faible pression induite par la respiration est appliquée à l'extrémité distale de l'adaptateur de débit d'air (100; 200; 300; 501; 601; 702), 20% à 50% du débit d'air résultant passe au moins à travers un second conduit (102-105; 204-206; 304-306; 502-505; 603-606).

8. Un procédé selon la revendication 7, dans lequel la vitesse de débit linéaire à travers l'orifice de sortie est réduite.

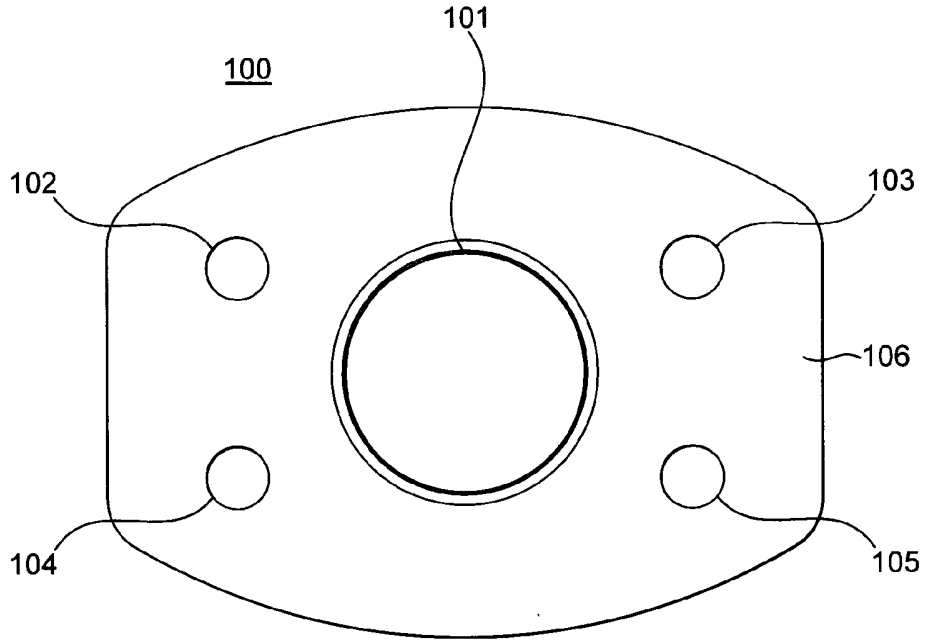

101
100
102
103
106
104
105

FIG. 1

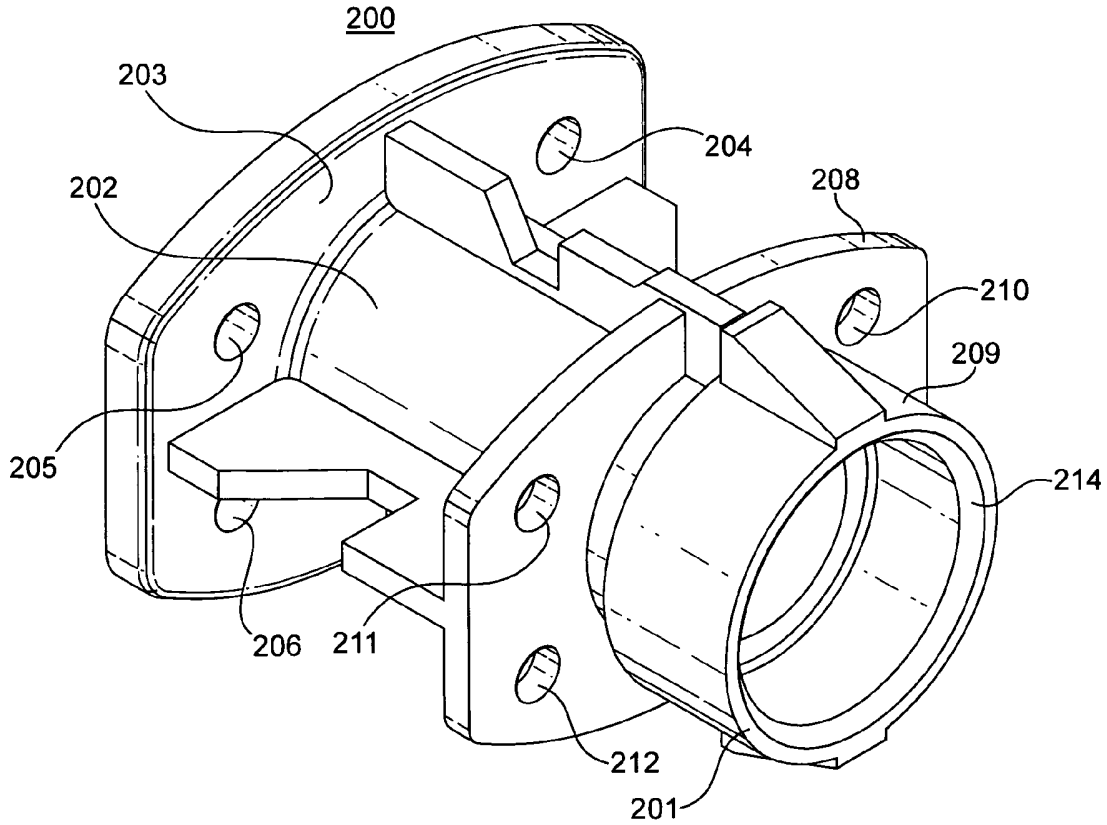

200
203
204
202
208
210
209
205
214
206
211
212
201

FIG. 2

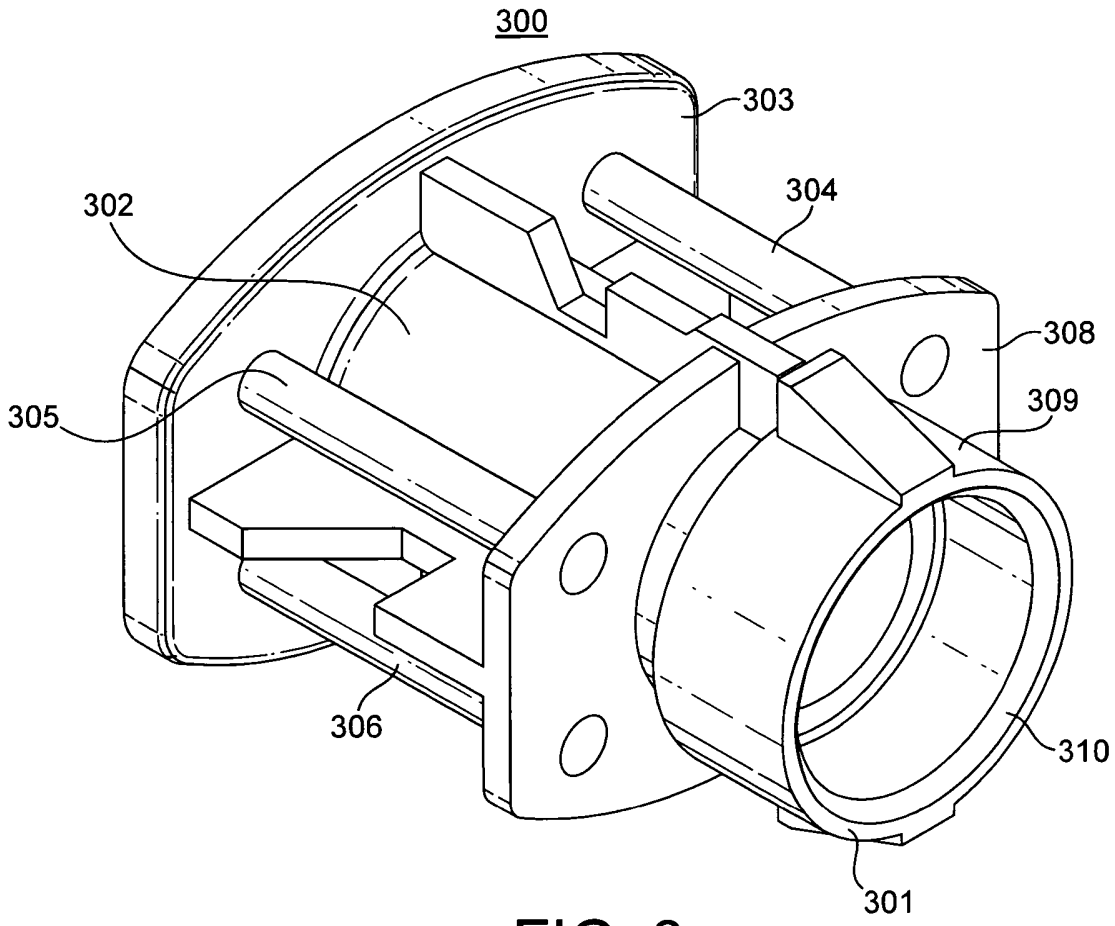


FIG. 3

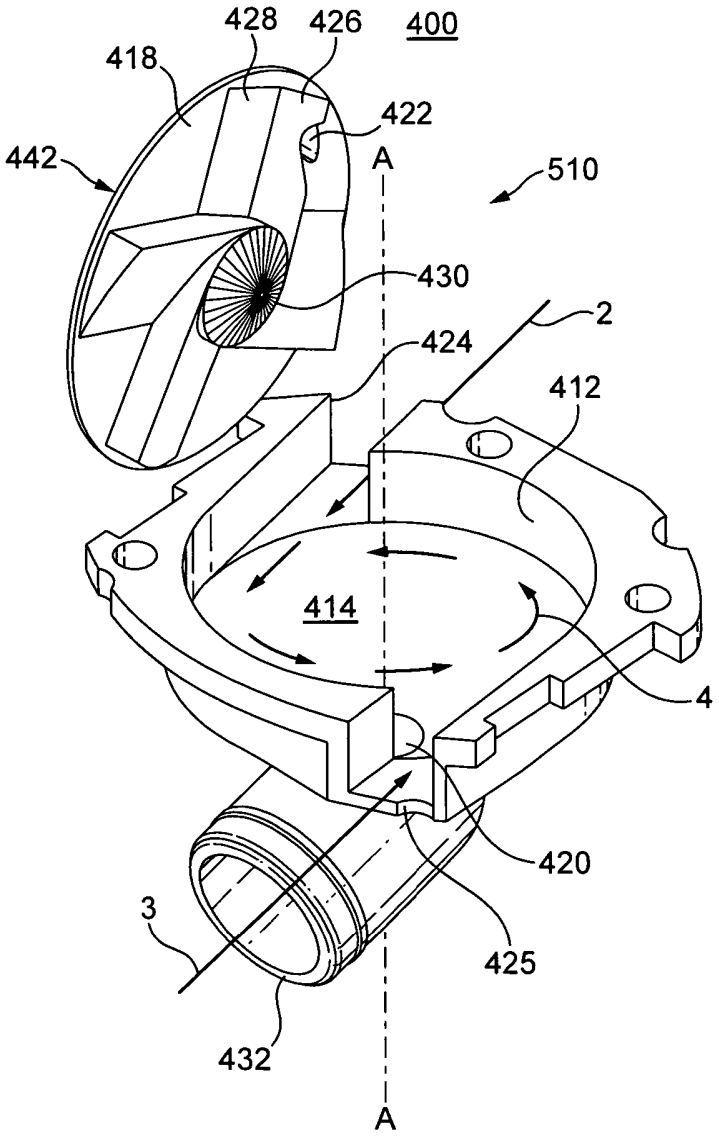
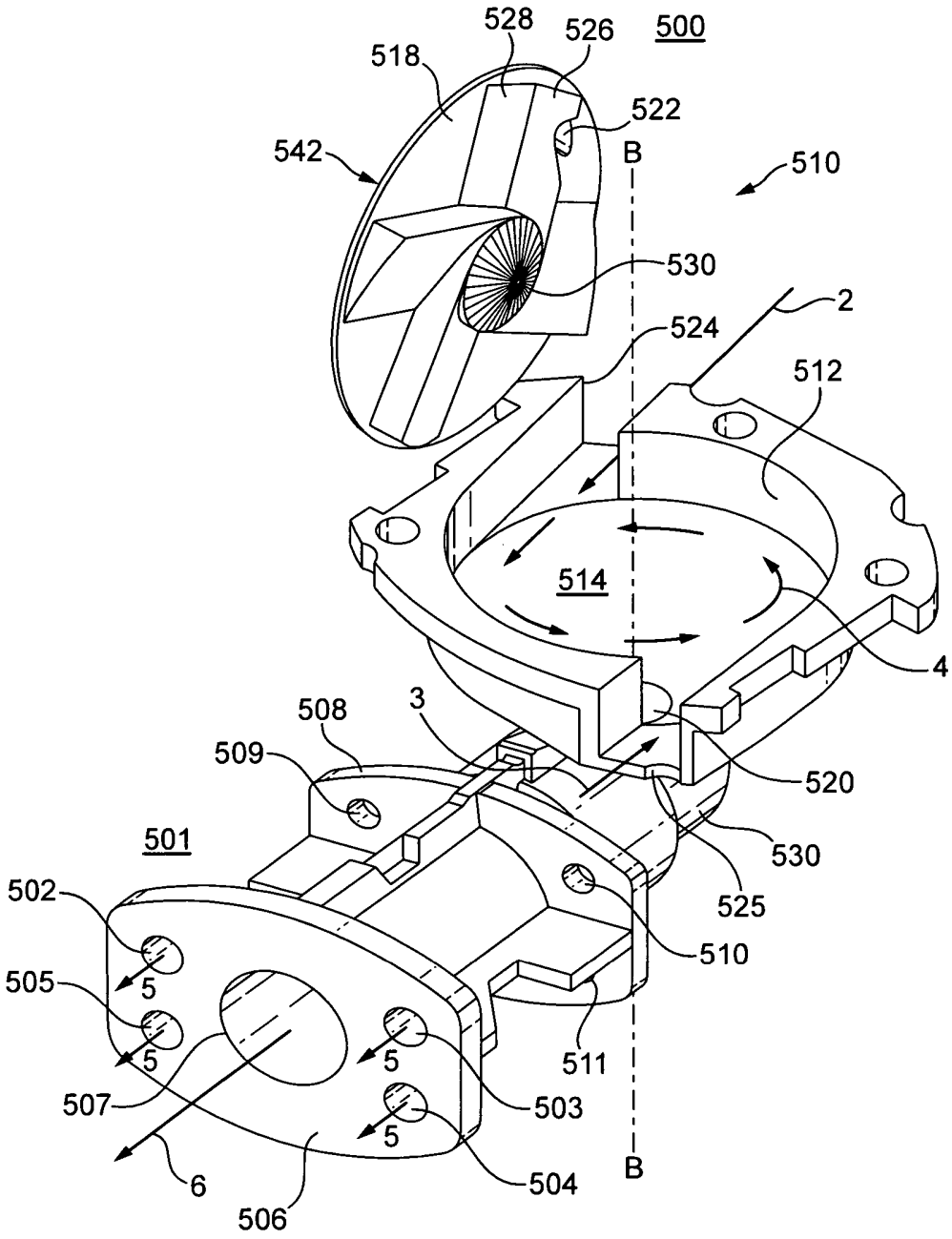


FIG. 4


528
526
500
518
522
542
B
510
530
2
524
512
514
4
508
3
509
520
501
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502
525
510
505
5
5
5
5
511
507
503
6
504
506
B

FIG. 5

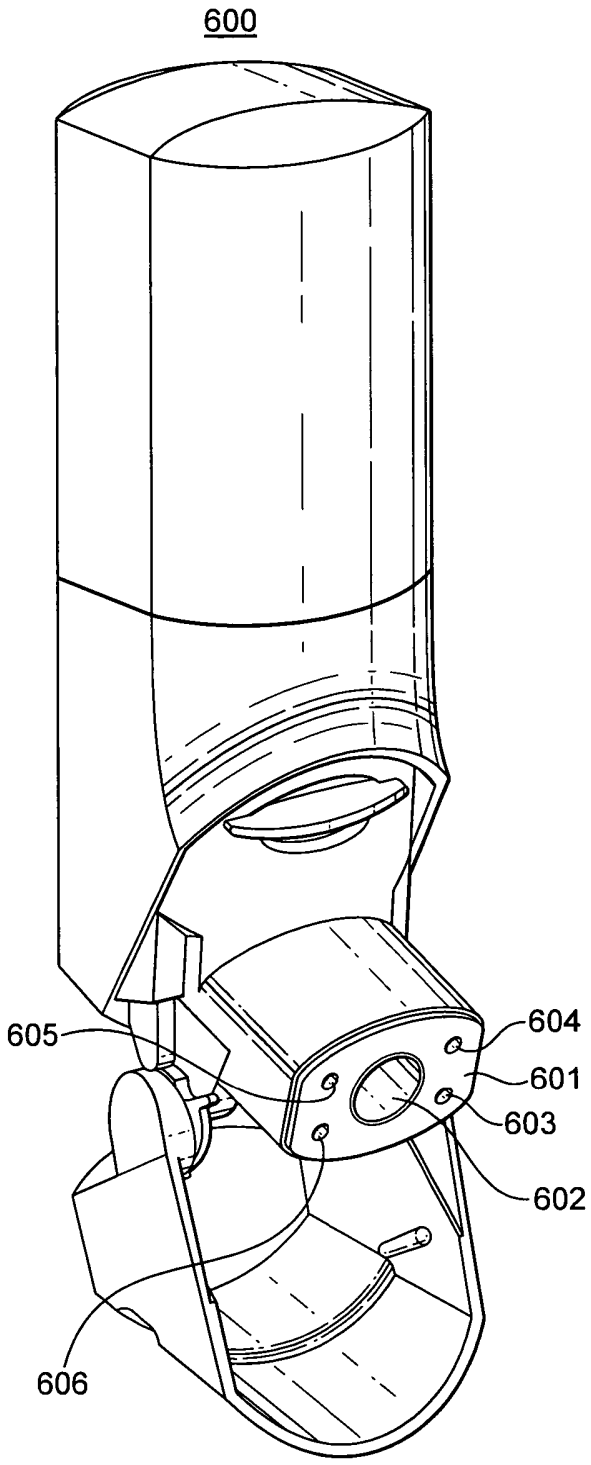

FIG. 6

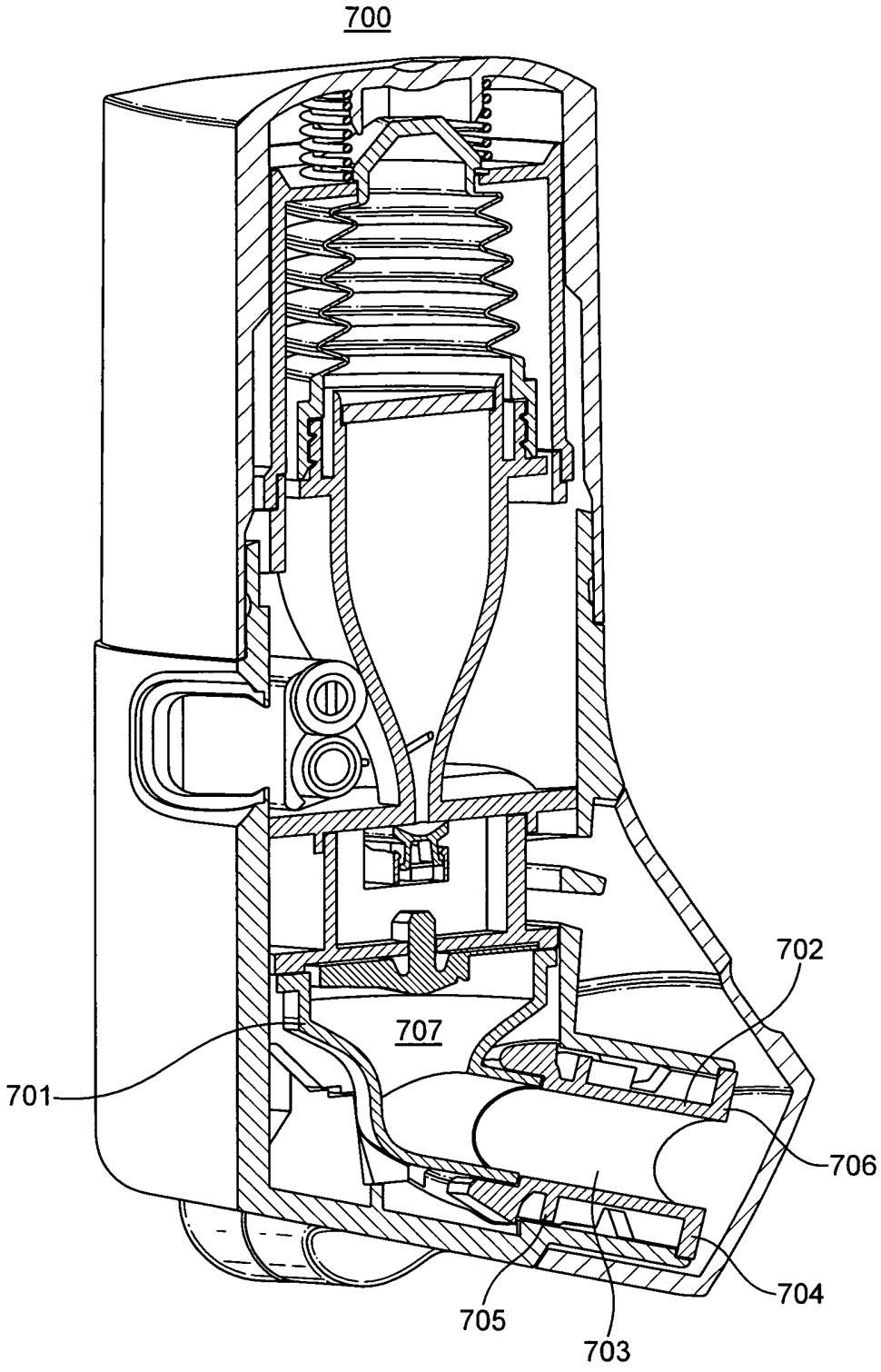

FIG. 7

REFERENCES CITED IN THE DESCRIPTION

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Patent documents cited in the description

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LEVEGŐÁRAMOS ADAPTER LÉGZÉSSEL MŰKÖDTETETT SZÁRAZPOR-INHALÁTORHOZ

SZABADALMI IGÉNYPONTOK

1. Légzéssel működtetett szárazpor-inhalátor (600; 700), amely magában foglal egy levegőáramos adaptert (100; 200; 300; 501; 601; 702), amely levegőáramos adapter (100; 200; 300; 501; 601; 702) magában foglal:

egy első vezetéket (101; 202; 302; 507; 602; 703), amelynek van egy proximális vége és egy disztális vége, amely proximális vég lehetővé teszi a közegvezető kapcsolatot egy deagglomerátor kivezetőnyílásától (530) az első vezeték (101; 202; 302; 507; 602; 703) disztális végéig, és legalább egy második vezetéket (102-105; 204-206; 304-306; 502-505; 603-606), hogy az első vezetékbeli (101; 202; 302; 507; 602; 703) levegőáramtól függetlenül lehetővé váljon a levegő áramlása az adapter (100; 200; 300; 501; 601; 702) proximális végétől az adapter (100; 200; 300; 501; 601; 702) disztális végéig, amikor légzéssel létrehozott kis nyomás adódik a levegőáramos adapter (100; 200; 300; 501; 601; 702) disztális végére,

azzal jellemezve, hogy a legalább egy második vezeték (102-105; 204-206; 304-306; 502-505; 603-606) keresztmetszeti területei összegének az első vezeték (101; 202; 302; 507; 602; 703) keresztmetszeti területéhez viszonyított aránya akkora, hogy amikor légzéssel létrehozott kis nyomás adódik a levegőáramos adapter (100; 200; 300; 501; 601; 702) disztális végére, akkor a keletkező levegőáram 20%-50%-a halad át a legalább egy második vezetéken (102-105; 204-206; 304-306; 502-505; 603-606).

2. Az 1. igénypont szerinti inhalátor, amelyben az első vezeték (101; 202; 302; 507; 602; 703) disztális vége magában foglal egy első kerületi peremet (106; 203; 303; 506; 704), és a második vezeték (102-105; 204-206; 304-306; 502-505; 603-606) legalább egy, az első kerületi peremben (106; 203; 303; 506; 704) lévő nyílás formájában van.

3. A 2. igénypont szerinti inhalátor, amelyben az első kerületi perem (106; 203; 303; 506; 704) két, előnyös módon négy nyílást foglal magában.

4. Az előző igénypontok bármelyike szerinti inhalátor, amelyben a levegőáramos adapter (100; 200; 300; 501; 601; 702) magában foglal egy második kerületi peremet (208; 308; 508; 705) a levegőáramos adapter (100; 200; 300; 501; 601; 702) proximális végén, amely második kerületi perem (208; 308; 508; 705) magában foglal legalább egy nyílást, előnyös módon négy nyílást.

5. A 4. igénypont szerinti inhalátor, amelyben a második kerületi peremben (208; 308; 508; 705) lévő nyílások keresztmetszeti területei összegének az első vezeték (101;

202; 302; 507; 602; 703) keresztmetszeti területéhez viszonyított aránya akkora, hogy amikor légzéssel létrehozott kis nyomás adódik a levegőáramos adapter (101; 202; 302; 507; 602; 703) disztális végére, akkor a keletkező levegőáram legalább 20%-a halad át a nyílásokon.

6. Az 1-5. igénypontok bármelyike szerinti inhalátor, amely magában foglal továbbá egy deagglomerátort (400; 500; 701), amely magában foglal:

egy belső falat (412; 512), amely egy tengely mentén (A) egy első végtől (418; 518) egy második végig (420; 520) kiterjedő örvénykamrát (414; 514) határol;

egy szárazpor-betápláló nyílást (422; 522) az örvénykamra (414; 514) első végében (418; 518) közegvezető kapcsolat biztosítása céljából egy inhalátor szárazpor-szállító járata és az örvénykamra (414; 514) első vége (418; 518) között;

legalább egy bevezetőnyílást (424, 425; 524, 525) az örvénykamra (414; 514) belső falában (412; 512) az örvénykamra (414; 514) első vége mellett, amely közegvezető kapcsolatot biztosít egy, a deagglomerátorhoz (400; 500) képest külső terület és az örvénykamra (414; 514) első vége (418; 518) között;

egy kivezetőnyílást (432; 530), amely közegvezető kapcsolatot biztosít az örvénykamra (414; 514) második vége (420; 520) és a levegőáramos adapter (100; 200; 300; 501; 601; 702) között;

és a légzéssel létrehozott kis nyomás a levegőáramos adapter (100; 200; 300; 501; 601; 702) disztális végén előidézi a levegő beáramlását a szárazpor-betápláló nyíláson (422; 522) és a bevezetőnyíláson (424, 425; 524, 525) át az örvénykamrába (414; 514).

7. Eljárás egy légzéssel működtetett szárazpor-inhalátor deagglomerátorának kivezetőnyílásán áthaladó levegőáram módosítására, amely eljárás az alábbi lépéseket foglalja magában:

a) rendelkezésre bocsátunk egy levegőáramos adaptert (100; 200; 300; 501; 601; 702), amely magában foglal egy proximális véggel és disztális véggel rendelkező első vezetéket (101; 202; 302; 507; 602; 703), a levegőáramos adapter (100; 200; 300; 501; 601; 702) magában foglal továbbá legalább egy második vezetéket (102-105; 204-206; 304-306; 502-505; 603-606), hogy az első vezetékbeli (101; 202; 302; 507; 602; 703) levegőáramtól függetlenül lehetővé váljon a levegő áramlása az adapter (100; 200; 300; 501; 601; 702) proximális végétől az adapter (100; 200; 300; 501; 601; 702) disztális végéig;

b) az első vezetéket (101; 202; 302; 507; 602; 703) úgy helyezzük el, hogy közegvezető kapcsolatot biztosít a deagglomerátor kivezetőnyílásától az első vezeték (101; 202; 302; 507; 602; 703) disztális végéig; és

c) légzéssel létrehozott kis nyomást adunk a levegőáramos adapter (100; 200; 300; 501; 601; 702) disztális végére úgy, hogy levegő áramlik át az első (101; 202;

302; 507; 602; 703) és a második vezetéken (102-105; 204-206; 304-306; 502-505; 603-606);

azzal jellemezve, hogy a legalább egy második vezeték (102-105; 204-206; 304-306; 502-505; 603-606) keresztmetszeti területei összegének az első vezeték (101; 202; 302; 507; 602; 703) keresztmetszeti területéhez viszonyított aránya akkora, hogy amikor légzéssel létrehozott kis nyomást adunk a levegőáramos adapter (100; 200; 300; 501; 601; 702) disztális végére, akkor a keletkező levegőáram 20%-50%-a halad át a legalább egy második vezetéken (102-105; 204-206; 304-306; 502-505; 603-606).

8. A 7. igénypont szerinti eljárás, amelyben a lineáris áramlási sebességet a kivezetőnyíláson keresztül csökkentjük.

(A meghatalmazott)

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