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(71)	Applicant(s) Angela Eckardt; Ofer Frydling; Raul Goldemann	
(72)	Inventor(s) Raul Goldemann	
(74)	Agent/Attorney WRAY and ASSOCIATES,Level 4 The Quadrant,1 William Street,PERTH WA 6000	
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(54) Title: BREATHING-CONTROLLED INHALATION DEVICE FOR DRY POWDER AND METHOD FOR THE EVEN DIS-TRIBUTION OF SAID DRY POWDER IN THE AIR

(54) Bezeichnung: ATEMZUGSKONTROLLIERTES INHALATIONSGERÄT FÜR TROCKENPULVER UND VERFAHREN ZUM GLEICHMÄSSIGEN VERTEILEN DES TROCKENPULVERS IN LUFT



ing-controlled inhalation device for dry powder and is characterized by a simple design, small size and low production costs. The inventive device has a double dose protector and ensures complete and even distribution of the dry powder during the inhalation procedure. Also disclosed is a method is disclosed which enables a complete and even respirable distribution of the dry powder to be inhaled in the air. The reservoir is coupled to a dosing conveyor dips into submerged in the transfer area in such a way that a predetermined amount of dry powder can be positioned directly at the beginning of the air guiding unit and flowing air guided by the air guiding unit takes on a three dimensional zigzag-like shape. Air drawn in during inhalation is channeled in such a way that acceleration and subsequent decceleration of the air stream occurs alternately and turbulence of the direction of flow is induced.

(57) Abstract: The invention relates to a breath-

(57) Zusammenfassung: Der Erfindung, die atemzugskontrolliertes Inhalationsgerät ein für Trockenpulver betrifft, liegt die Aufgabe zugrunde, ein solches Gerät zu schaffen, das sich durch einen einfachen Aufbau, eine geringe Baugrösse und geringe Herstellungskosten

auszeichnet, mit einem Doppeldosierschutz ausgestattet ist und eine vollständige und gleichmässige Verteilung des Trockenpulvers während des Inhalationsvorganges gewährleistet. Weiterhin soll ein Verfahren geschaffen werden, welches eine vollständige und gleichmässige lungengängige Verteilung des zu inhalierenden Trockenpulvers in der Atemluft ermöglicht. Diese Aufgabenstellung wird erfindungsgemäss dadurch gelöst, dass die Vorratskammer

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Breathing-Controlled Inhalation Device for Dry Powder and Method for the Even Distribution of the Dry Powder in the Air

- The invention relates to a breathing-controlled inhalation 5 device for dry powder, particularly dry powder which has been mixed with medicines, and consists of a casing with a mouthpiece, reservoir for the dry powder located in the casing, as well as an air guiding unit between a transfer area for the dry powder and the 10 mouthpiece, whereby the reservoir is connected to a dosing conveyor which dips in the transfer area in such a way that a predetermined amount of dry powder can be positioned directly at the beginning of the air guiding unit and the attached air guiding unit has an air-flow channel which is provided alternately with narrowings and subsequent enlargements. Furthermore, the invention relates to
- 15 subsequent enlargements. Furthermore, the invention relates to a method for the even distribution of the dry powder with a breathingcontrolled inhalation device.
- For a long time, one of the primary methods for the treatment of respiratory diseases has been the introduction of suitable agents into the respiratory tract. In this regard, the devices used for this - often also as mechanisms to stimulate transport - have gained an evergrowing significance because of the increase in the number of respiratory diseases in the last number of years. In particular, breathing-controlled devices, which represent a mild alternative to propellant-controlled devices, are being increasingly used, since they do not have the unpleasant effect of a stimulating colds.

30 A device of this type is known from DE 40 04 904 Al, in which the agent is kept ready on the periphery of a dosing drum and is regulated radially. The inside of the dosing drum contains a control unit for the active output of the divided inhalation amount from open dosing recesses with a radially outwards direction. Moreover, the bottom of the equally-angled distributed arranged dosing recesses forming slides are centrally camcontrolled. Since this control mechanism is additionally activated by a control key which lies practically along the whole length of the device, the expenditure in this regard is considerable. Moreover, the dosed medicines can be added by means of a forced emptying of the dosing recess.



which remains for the reservoir represents only a fraction of the pocketformat device.

The DE 198 25 434 Al describes an inhalation device in which the dosing device is made taut before the intake of the medicine and is held in this 5 condition on a stopper which can be moved during inhalation. The dosing device is released and accelerated during inhalation, so that the accelerated movement is abruptly interrupted in that the stopper on the dosing device strikes the casing or the bottom of the casing. This sudden interruption of the rotation of the dosing device results in the powdery 10 medicine being released from the dosing cavity at greater speed and being widely distributed in the air channel. This design is also relatively complicated and, in addition, demonstrates the lack of inclusion of floworientated air guidance. The air channel has a straight design and does not permit any circulation or turbulence of the agents to be inhaled.

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Finally, the DE 43 40 768 Al describes a device for the inhalation of powdery agents, which is provided with a special turbulence chamber in spiral form. Incidentally, the complicated construction design is also in this case disadvantageous. Furthermore, the turbulence chamber does facilitate a certain evenness in the distribution of the powder. Nevertheless, the spiral turning of the turbulence chamber leads increasingly to friction and resistance points which prevent complete passage of the particles.

Furthermore, the US-A-5, 699, 789, an inhaler for dry powder, in which a dosing conveyor is provided, shows that the reservoir container which projects into the air-flow channel takes a predetermined amount of dry powder and is positioned inside the air guiding unit. The air which passes through the air-flow channel has to move around both the reservoir container and a nose located near the inlet opening. In this way, a certain turbulence of the air is achieved, though it cannot be ensured that all the conducted dry powder is conveyed through the inlet opening in a homogenously distributed manner.

In the EP-A-938907 an inhalation device for dry powder is described in which inwardly projecting plates are provided alternately in the air-flow channel in order to achieve a turbulence of the air. Because of the high volume of clearance areas in this device it cannot be ensured that the total amount of dosed powder is conveyed outwards during inhalation.

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A similar inhalation device is shown in the WO-A-993305. Powder residue can also remain in the device in this case, which adulterates the dosage.

- 5 The preceding discussion of the background to the invention is intended only to facilitate an understanding of the present invention. It should be appreciated that the discussion is not an acknowledgement or admission that any of the material referred to was part of the common general knowledge in Australia as at the priority date of the application.
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The breathing-controlled inhalation device, as a result of a simple design with few single components, can be cost-effectively manufactured. Moreover, the breathing-controlled inhalation device has a small size, is provided with a double dose protector, and can be used to attain a complete and even distribution of the dry powder during the inhalation

- 15 complete and even distribution of the dry powder during the inhalation procedure. Furthermore, the aforementioned method enables a complete and even respirable distribution in the breath of the dry powder to be inhaled.
- 20 Accordingly, the invention resides in a breathing-controlled inhalation device for dry powder, particularly of dry powder mixed with medicines, comprising a casing with a mouthpiece, a reservoir for the dry powder located in the casing, as well as an air guiding unit between a transfer area for the dry powder and the mouthpiece, whereby the reservoir is connected to a dosing conveyor which dips in the transfer area in such a 25 way that a predetermined amount of dry powder can be positioned directly at the beginning of the air guiding unit and that the attached air guiding unit has a air-flow channel which is provided alternately with narrowings and subsequent enlargements, characterized in that air quiding unit 30 consists of an essentially cylindrical central component, which is provided alternately with semi-spherical indentations which reach from opposite walls of the central component into the air-flow channel, in that the air-flow channel has a rising inhalation area in the application area of the inhalation device, and finally in that the dosing conveyor can be positioned directly downwards in front of the inhalation area. 35

Accordingly, the invention also resides in method for the even distribution of the dry powder in the air with a breathing-controlled inhalation device for dry powder, in which the air drawn in as a result of

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inhalation is conducted through an air guiding unit in such a way that an alternate acceleration and subsequent deceleration of the air-flow takes place in the case of simultaneous turbulence and change in the direction of the flow, whereby a predetermined amount of dry powder is additionally sent to the air-flow at the beginning of the air guiding unit wherein the acceleration of the air-flow is undertaken by means of cross section narrowings in the air guiding unit in the form of semi-spherical indentations, which project alternately into the airflow channel in the air guiding unit from opposite walls of the central component.

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Advantageously, the air guiding unit consists of an essentially cylindrical central component which is provided alternately with semispherical indentations which reach from opposite walls of the central component into the air-flow channel, and in that the air-flow channel has a rising inhalation area in the application area of the inhalation device, and finally in that the dosing conveyor can be positioned directly downwards in front of the inhalation area. An air guiding unit designed in this manner permits a very effective and complete distribution of the dry powder during the inhalation procedure, since the air which has been drawn in circulates and the rising particles can be mixed with each other in an optimal way.

By means of this special arrangement of the inhalation area the dry powder can, when required, get directly into the air-flow channel and can from there be directly drawn in. In this way, the risk of the intrusion of moisture or of an unintentional proportional loss of portioning during inhalation is reduced.

In a further favourable design of the invention the casing is provided with an air inlet which is positioned downwards opposite the inhalation area. The opening of the device in the form of the air inlet permits an increased intake of the particles, independent of the remaining air.

Moreover, a further design is so constructed that the reservoir opposite the inhalation area is blocked in that the dosing conveyor is designed as a flat slide which has a laterally positioned dosing bore hole for the intake of the dry powder, whereby the dosing drill hole is located in the closed condition of the reservoir in this and in dosing position directly in front of the inhalation area of the air guiding unit and that the slide essentially keeps the reservoir permanently locked. In this way a double dose protector can be ensured, since only the amount of dry powder located in the dosing drill hole is available for each inhalation procedure. the inhalation procedure be broken off Should or interrupted then the remainder of the dry powder located in the dosing drill hole is conveyed back into the reservoir or is removed from the inhalation area and is thereby not any more available for a further inhalation procedure.

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A favourable design here ensures that the slide is held in a spring-loaded start position in which the reservoir is locked and that the slide is moveable against a spring resistance in the dosing position. A spring-controlled movement mechanism quarantees that accidental escape, unintended intrusion of moisture or an unintentional actuation of the device are practically excluded. Moreover, an important advantage of this design is that, because of the simplicity of the functional construction, besides the necessary readjusting spring, only one moving part (dosing conveyor) is required, which further guarantees the constant availability for use of the device and minimizes the risk of any possible errors.

The air guiding unit can have a single-part or multi-part design, whereby glass or plastic as cost-effective materials have proved themselves to be particularly suitable. Other suitable materials, such as metals, may also of course be used for the manufacture of the air guiding unit.

Advantageously, the acceleration of the air-flow is effected by means of cross section narrowings in the air guiding unit in the form of semi-spherical indentations which project alternately into the air-flow channel in the air guiding unit from opposite walls of the central component. The air circulation and flow guiding provided in this special method make effective turbulence of the individual dry powder particles possible. The

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movements of the air spread the particles evenly and guarantee optimum distribution at the moment of inhalation.

By means of the concentration of the flow of particles with 5 kinetic energy their movement and distribution capacity is increased and a possible loss of energy caused by gravity is compensated, which makes for an overall improvement of the turbulence effect.

10 The invention is to be explained in greater detail in the following on the basis of a sample design.

In this context are shown:

- 15 Fig. 1a a front view of an inhalation device in nonoperational mode with open mouthpiece conforming to the invention;
 - Fig. 1b a sectional view along the line A-A according to fig. 1a;
- 20 Fig. 1c a sectional view along the line B-B according to fig. 2b;
 - Fig. 1d a perspective representation of the inhalation device according to fig. 1a 1c conforming to the invention;
- 25 Fig. 2a a front view of an inhalation device in nonoperational mode with closed mouthpiece conforming to the invention;
 - Fig. 2b a sectional view along the line A-A according to fig. 2a;
- 30 Fig. 2c a sectional view along the line B-B according to fig. 2b;
 - Fig. 2d a perspective representation of the inhalation device according to fig. 2a - 2c conforming to the invention;
- 35 Fig. 3a a front view of an inhalation device in inhalation operative mode with open mouthpiece conforming to

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the invention;

- Fig. 3b a sectional view along the line A-A according to fig. 3a;
- Fig. 3c a sectional view along the line B-B according to fig. 3b;
- Fig. 3d a perspective representation of the inhalation device according to fig. 3a 3c conforming to the invention;
- Fig. 4a a front view of an inhalation device in inhalation operative mode with closed mouthpiece conforming to the invention;
 - Fig. 4b a sectional view along the line A-A according to fig. 4a;
- Fig. 4c a sectional view along the line B-B according to 15 fig. 4b;
 - Fig. 4d a perspective representation of the inhalation device according to fig. 4a 4c conforming to the invention;
- Fig. 5 an explosion drawing of the individual components of the breathing-controlled inhalation device conforming to the invention.

As shown in fig. 2a-d and 3a-d, the reservoir 4 is essentially kept locked on a permanent basis both in non-operational and operational mode by means of a dosing conveyor 7 (shown separately in fig. 5) designed as a slide 13 (also shown separately in Fig. 5). With regard to the dry powder located in the reservoir an intrusion of external moisture or impurities can thereby be almost ruled out.

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The dosing conveyor 7 has a laterally positioned dosing bore hole 14 (displayed in fig. 1b) for the intake of the dry powder. Before the beginning of the inhalation procedure the dosing drill hole 14 is located in the reservoir 4. A cap 16 (shown separately in fig. 5) provides hygienic protection for the mouthpiece 3. After the cap 16 has been removed (fig. 1a

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and b) the inhalation device 1 is held perpendicularly to the mouthpiece 3 upwards and away from the mouth. After the user has first of all breathed deeply out, avoiding contact with the mouthpiece - i.e. without blowing into the mouthpiece 3 - he then covers the mouthpiece 3 with the lips. To start the inhalation procedure and to transfer the dosing conveyor 7 into the dosing position the former is pressed down against a force which is generated by a spring 15 shown separately in fig. 5 (fig. 3b and 3d, as well as fig. 4b and 4d).

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The dosing drill hole 14 is now located directly in front of the inhalation area 11 of the air guiding unit 5 (fig. 4b and 3b). Since reservoir 4 is connected to the dosing conveyor 7 in such a way that the former dips into the transfer area 6 and the predetermined amount of dry powder can be positioned directly at the beginning of the air guiding unit 5, it is ensured that no unintended loss of portioning before or during inhalation occurs.

The user now breathes in as deeply as possible through the mouth. By means of an air inlet 12 located in casing 2, which - as shown in fig. 3b - is positioned downwards opposite the inhalation area 11, air is drawn in and an air-flow is created inside the inhalation device 1. This carries the particles of the dry powder via the dosing drill hole 14 through the transfer and inhalation area 6, 11 and finally through the air guiding unit 5 until an escape of the particles through the mouthpiece 3 directly into the user's respiratory tract takes place.

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Should the inhalation procedure be broken off or interrupted then the remainder of the dry powder located in the dosing drill hole 14 is conveyed back into the reservoir 4, in that the spring transfers the dosing conveyor into the start position, or is removed from the inhalation area and is thereby not any more available for a further inhalation procedure. In

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this way, the danger of a double dosage is avoided.

The air drawn in as a result of inhalation is conducted through an air guiding unit - shown separately in fig. 5 - in such a way that an alternate acceleration and subsequent deceleration of the air-flow takes place in the case of simultaneous turbulence and change in the direction of the flow.

- This is made possible in that the air guiding unit 5 consists of an essentially cylindrical central component 9 which is provided alternately with semi-spherical indentations 10 which reach from opposite walls of the central component 9 into the air-flow channel 8.
- 15 The air guiding unit 5 can have a single-part or multi-part design, whereby glass or plastic as cost-effective materials have proved themselves to be particularly suitable. Other suitable materials, such as metals, may also of course be used for the manufacture of the air guiding unit.

The acceleration of the air-flow is thereby effected by means of cross section narrowings in the air guiding unit 5, which are alternately located on opposite sides in the air guiding unit 5. The air guiding unit 5, designed in this manner, permits a very effective and complete distribution of the dry powder during the inhalation procedure, since the air which has been drawn in circulates and the rising particles can be mixed with each other in an optimal way.

By means of the concentration of the flow of particles with kinetic energy their movement and distribution capacity is increased and a possible loss of energy caused by gravity is compensated, which makes for an overall improvement of the turbulence effect.

Throughout the specification, unless the context requires otherwise, the word "comprise" or variations such as "comprises" or "comprising", will be understood to imply the inclusion of a stated integer or group of integers but not the exclusion of any other integer or group of integers.

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Breathing-Controlled Inhalation Device for Dry Powder and Method for the Even Distribution of the Dry Powder in the Air

Reference List of Drawings

- 10 1 Inhalation device
 - 2 Casing

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- 3 Mouthpiece
- 4 Reservoir
- 5 Air guiding unit
- 15 6 Transfer area
 - 7 Dosing conveyor
 - 8 Air-flow channel
 - 9 Central component
 - 10 Indentation
- 20 11 Inhalation area
 - 12 Air inlet (not shown)
 - 13 Slide
 - 14 Dosing drill hole
 - 15 Spring
- 25 16 Cap

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The claims defining the invention are as follows:

1. breathing-controlled inhalation device for dry Α powder. particularly of dry powder mixed with medicines, comprising a casing with a mouthpiece, a reservoir for the dry powder located in the casing, as well as an air guiding unit between a transfer area for the dry 5 powder and the mouthpiece, whereby the reservoir is connected to a dosing conveyor which dips in the transfer area in such a way that a predetermined amount of dry powder can be positioned directly at the beginning of the air guiding unit and that the attached air guiding unit has a air-flow channel which is provided alternately with narrowings 10 and subsequent enlargements, characterized in that air guiding unit consists of an essentially cylindrical central component, which is provided alternately with semi-spherical indentations which reach from opposite walls of the central component into the air-flow channel, in that the air-flow channel has a rising inhalation area in the application 15 area of the inhalation device, and finally in that the dosing conveyor can be positioned directly downwards in front of the inhalation area.

2. A breathing-controlled inhalation device according to the claim 1, wherein the casing is provided with an air inlet which is positioned downwards opposite the inhalation area.

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3. A breathing-controlled inhalation device according to claims 1 or 2, wherein the reservoir is locked opposite the inhalation area, in that the dosing conveyor is designed as a flat slide, which has a laterally positioned dosing bore hole for the intake of the dry powder, whereby the dosing drill hole is located in the closed condition of the reservoir in this and in dosing position directly in front of the inhalation area of the air guiding unit and that the slide essentially keeps the reservoir permanently locked.

4. A breathing-controlled inhalation device according to claim 3,

wherein the slide is held in a spring-loaded start position, in which the reservoir is locked and that the slide is moveable against a spring resistance in the dosing position.

5. A breathing-controlled inhalation device according to one of the
5 claims 1 to 4, wherein the air guiding unit has a single-part or multipart design.

6. A breathing-controlled inhalation device according to one of the claims 1 to 5, wherein the air guiding unit is manufactured from glass, plastic or another suitable material.

7. A method for the even distribution of the dry powder in the air with 10 a breathing-controlled inhalation device for dry powder, in which the air drawn in as a result of inhalation is conducted through an air guiding unit in such a way that an alternate acceleration and subsequent deceleration of the air-flow takes place in the case of simultaneous turbulence and change in the direction of the flow, whereby a 15 predetermined amount of dry powder is additionally sent to the air-flow at the beginning of the air guiding unit wherein the acceleration of the air-flow is undertaken by means of cross section narrowings in the air guiding unit in the form of semi-spherical indentations, which project alternately into the airflow channel in the air guiding unit from opposite 20 walls of the central component.

8. A breathing-controlled inhalation device for dry powder medication comprising:

a casing having a mouthpiece;

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a reservoir for dry powder medication within said casing;

an air flow channel in said casing having an outlet coupled to said mouthpiece, an inlet and a transfer area,

said channel comprising a generally cylindrical component having semispherical, indentations formed alternately on opposite walls thereof and extending into said cylindrical component, said channel having a flow area which rises in the region immediately following said transfer area when said device is in the application position; and a dosing conveyor for delivering a predetermined amount of dry powder medication from said reservoir to said transfer<u>area</u> of said air flow channel.

- 9. The inhalation device as claimed at claim 8, wherein said reservoir has an outlet positioned above the inlet of said air flow channel and said dosing conveyor comprises a vertically movable slide member having a hole therein sized to receive a predetermined amount of dry powder medication, said slide member being sliceable between a first position at which said hole is opposite the outlet of said reservoir to receive said predetermined amount of dry powder medication and a second position at which said hole is opposite the inlet of said air flow channel to permit said predetermined amount of dry powder medication to be drawn into said air flow channel.
- 15 10. The inhalation device as claimed at claim 8 or claim 9, further comprising a spring normally urging said slide member to said first position, said slide member being manually movable against the spring resistance to said second position.

11. The inhalation device as claimed at any one of claims 8 to 10 further comprising an air inlet in said casing opposite the inlet to said air flow channel.

12. The inhalation device as claimed at any one of claims 8 to 11 wherein said slide member locks said reservoir against release of dry powder medication when in said second position and limits release of dry powder medication to the volume of said hole when in said first position.

13. The inhalation device as claimed at any one of claims 8 to 12 wherein said indentations are integrally formed in the walls of said generally cylindrical component.

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14. A breathing-controlled inhalation device substantially as herein described.

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15. A breathing-controlled inhalation device substantially as herein described with reference to the accompanying drawings.

5 16. A method of even distribution of dry powders in the air with a breathing-controlled inhalation device for dry powder, said method substantially as herein described.

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Fig. 3

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Fig. 5