

(12) STANDARD PATENT
(19) AUSTRALIAN PATENT OFFICE

(11) Application No. **AU 2016246359 B2**

(54) Title
A nasal medication delivery device

(51) International Patent Classification(s)
A61M 11/00 (2006.01) **A61M 15/00** (2006.01)

(21) Application No: **2016246359** (22) Date of Filing: **2016.01.08**

(87) WIPO No: **WO16/163895**

(30) Priority Data

(31) Number	(32) Date	(33) Country
706864	2015.04.09	NZ

(43) Publication Date: **2016.10.13**

(44) Accepted Journal Date: **2019.10.03**

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(56) Related Art
US 2011/0120456 A1
US 2006/0243274 A1
US 2009/0200397 A1



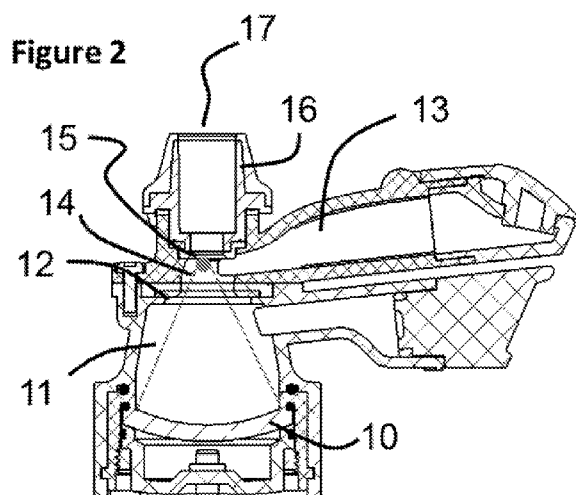
- (51) **International Patent Classification:**
A61M 11/00 (2006.01) *A61M 15/00* (2006.01)
- (21) **International Application Number:**
PCT/NZ2016/050002
- (22) **International Filing Date:**
8 January 2016 (08.01.2016)
- (25) **Filing Language:** English
- (26) **Publication Language:** English
- (30) **Priority Data:**
706864 9 April 2015 (09.04.2015) NZ
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- (81) **Designated States** (*unless otherwise indicated, for every kind of national protection available*): AE, AG, AL, AM, AO, AT, AU, AZ, BA, BB, BG, BH, BN, BR, BW, BY, BZ, CA, CH, CL, CN, CO, CR, CU, CZ, DE, DK, DM, DO, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN, HR, HU, ID, IL, IN, IR, IS, JP, KE, KG, KN, KP, KR, KZ, LA, LC, LK, LR, LS, LU, LY, MA, MD, ME, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM, PA, PE, PG, PH, PL, PT, QA, RO, RS, RU, RW, SA, SC, SD, SE, SG, SK, SL, SM, ST, SV, SY, TH, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, ZA, ZM, ZW.
- (84) **Designated States** (*unless otherwise indicated, for every kind of regional protection available*): ARIPO (BW, GH, GM, KE, LR, LS, MW, MZ, NA, RW, SD, SL, ST, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, RU, TJ, TM), European (AL, AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HR, HU, IE, IS, IT, LT, LU, LV, MC, MK, MT, NL, NO, PL, PT, RO, RS, SE, SI, SK, SM, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, KM, ML, MR, NE, SN, TD, TG).

Published:

— with international search report (Art. 21(3))

(54) **Title:** A NASAL MEDICATION DELIVERY DEVICE



(57) **Abstract:** The invention relates to a delivery device for nasal medication. It addresses need for delivering medication to the nose of a patient. In a preferred embodiment the device has: • A transducer 10 adapted to create an ultrasonic focal zone; • a feeder chamber 13 holding medication; • an energising chamber 14 smaller than the feeder chamber; • a mesh 15; and • an exit 17. The device is formed so that when it is activated the feeder chamber 13 continuously fills the energising chamber 14 with medication (until the feeder chamber has insufficient medication left to achieve this) so that there is a substantially constant supply of medication within the focal zone able to be energised and forced from the energising chamber so as to contact the mesh, become an aerosol, and leave the device by way of the exit.

TITLE

A nasal medication delivery device.

FIELD OF INVENTION

- 5 This invention relates to a device for delivering medication to the nasal cavity of a human patient.

BACKGROUND

- Devices which deliver medication to the nasal cavities are known. In some cases they
10 create an aerosol from liquid medication using compressed gas or piezoelectric energy. They are often referred to as "nebulisers" and they typically have a chamber in which the medication is energised. The medicament is then caused to contact a mesh, or to move through a jet nozzle, to enter the nasal cavities as an aerosol. The mesh may be vibrated directly via a piezo-oscillating element, or indirectly as a result of acoustic energy. The
15 acoustic energy may also be used to drive the medication to the mesh.

- Some nebulisers have a drawback in that their delivery mechanism requires an undesirably large minimum volume of medication before they can do their work. When the medication falls to below that volume a relatively large residual amount is wasted. It is
20 an object of a preferred embodiment of the present invention to go at least some way towards alleviating this problem. However this and any other objects of the preferred embodiment should not be taken as a limitation on the scope of the invention or claims. The object of the invention in its broadest form is simply to provide a useful choice.

25 **SUMMARY OF THE INVENTION**

According to one aspect of the invention there is provided a delivery device for nasal medication, having:

- an ultrasonic energy generator adapted to create a tapered ultrasonic focal zone of concentrated ultrasonic energy;
- 30 • ultrasonic energy transmission medium;
- a feeder chamber holding medication;
- an energising chamber smaller than the feeder chamber, remote from the generator, and arranged to hold medication at the focal zone;
- a mesh; and
- 35 • a nasal prong;

the device formed so that when it is activated:

- ultrasonic energy travels through the transmission medium towards the mesh; and

- the feeder chamber continuously fills the energising chamber with medication (until the feeder chamber has insufficient medication left to achieve this) so that there is a substantially constant supply of medication within the focal zone able to be energised and forced from the energising chamber so as to contact the mesh, become an aerosol, and leave the device by way of the prong.

Optionally the device has a mouthpiece adapted for a human user to blow into and sensing means which, in response to such blowing, causes the medication to be energised and the aerosol to form.

10

Optionally the energising chamber has a volume of 0.1 cm^3 to 0.8 cm^3 , and preferably a volume of 0.2 cm^3 to 0.4 cm^3 .

Optionally the ultrasonic generator comprises a concave transducer adapted to focus ultrasonic energy on the focal zone when activated, such that the medication in the energising chamber becomes acoustically energised and moves towards the mesh.

15

Optionally the device is formed such that it causes the mesh to vibrate as the medication contacts it so as to assist in creating the aerosol.

20

Optionally the device has an exit which is part of the prong.

Optionally the mesh is integral with the prong.

Optionally the mesh is immediately adjacent to the exit so as to prevent or minimise condensation of the aerosol inside the device.

25

Optionally the activation chamber, the generator and exit are at an angle of about 40° to about 80° , and preferably about 50° to about 70° , with respect to the mouthpiece.

30

Optionally the medication is a pharmaceutical or saline solution prior to being energised.

Optionally the feeder chamber has a funnel or flume formed to naturally encourage the medication into the energising chamber.

35

Optionally the energising chamber has a tapered floor to urge medication to gather at the focal zone.

Optionally the energising chamber has a well to urge medication to gather at the focal zone.

5 Optionally the energising chamber is symmetrical.

Optionally the energising chamber is asymmetrical.

10 Optionally the feeder chamber plus the energising chamber collectively have sufficient medication for:

- only 5 or fewer patient doses;
- only 4 or fewer patient doses;
- only 3 or fewer patient doses;
- only 2 or fewer patient doses; or
- 15 • only 1 patient dose;

(a dose in this context is the amount of medication per administration event, as opposed to, for example, the number of acoustic pulses needed to dispense that amount)(the energising chamber may, in some embodiments, be initially empty).

20 According to a further aspect of the invention there is provided a delivery device for nasal medication, having:

- a mouth piece;
- sensing means;
- an ultrasonic energy generator in the form of a concave transducer adapted
- 25 to focus ultrasonic energy on a focal zone;
- a feeder chamber holding medication;
- an energising chamber smaller than the feeder chamber;
- a mesh; and
- a nasal prong;

30 the device formed so that when it is activated the feeder chamber continuously fills the energising chamber with medication (until the feeder chamber has insufficient medication left to achieve this) so that there is a substantially constant supply of medication within the focal zone able to be energised and forced from the energising chamber so as to contact the mesh, become an aerosol, and leave the device by way

35 of the nasal prong;

the sensing means arranged to detect when a user blows into the mouth and to then cause the medication to be energised while the mesh oscillates to produce a pumping action to assist in creating the aerosol;

the feeder chamber having a funnel or flume formed to encourage the medication
5 into the energising chamber; and

the energising chamber having a tapered floor and/or well arranged to urge the medication into the focal zone.

DESCRIPTION OF THE DRAWINGS

10 Some preferred embodiments of the invention will now be described by way of example and with reference to the accompanying drawings, of which:

Figure 1 is an exploded isometric view of a nasal medication delivery device;

Figure 2 is a side cross-sectional view of the supply unit;

Figure 3 is a side view of the exterior of the supply unit;

15 **Figure 4** is an expanded side cross-sectional view showing detail of the supply unit;

Figure 5 is an isometric view of the supply unit;

Figure 6 is an opposite isometric view of the supply unit;

20 **Figure 7** is schematic part cross-sectional view, and exterior view, of the device illustrating angled placement of various parts;

Figure 8 is a side cross-sectional view showing detail of the medicine supply unit of an alternative embodiment of the invention showing a tapered medicine energising chamber; and

25 **Figure 9** is a side cross-sectional view of the medicine supply unit of an alternative embodiment of the invention showing an energising chamber which incorporates a well.

DETAILED DESCRIPTION

Referring to figure 1, the delivery device is used for the administration of therapeutic agents to the nasal cavity of a human patient. It has a main body 1, a breath receptor
30 2, and a medicine supply unit 3.

The Main Body

The main body 1 has an LCD screen 4 to display messages to the user, for example the name of the medicine to be delivered, the time at which the next dose is due to be taken, etc. The main body 1 also has a battery, a USB port 5 for charging the battery
5 or for receiving input generally, an on/off power switch 6, an RFID reader 7 and a breath sensor. All of the electronics for the delivery device are part of the main body 1.

The RFID reader 7 is able to read electronically stored prescription details kept on a tag on the medicine packaging. Those details are used to automatically set the device
10 to deliver the prescribed amount of medicine.

The Breath Receptor

The breath receptor 2 is detachable from the main body 1 with a click-fit arrangement, and has a detachable replaceable mouthpiece 8. The mouthpiece 8 can be gripped
15 between the lips of the user and blown into. As the breath moves through the receptor 2 it is acoustically detected by the sensor in the main body 1, and, as a consequence, the device is triggered to deliver medicine to the user. The breath then passes out the back 9 of the device, having served its purpose. The device only releases medicine while the user is blowing/exhaling. This is because the act of exhaling causes the
20 user's pharynx to close, so that medicine is only delivered to the nose, and not the throat or lungs.

The Medicine Supply Unit

Referring to Figures 2 to 6, the medicine supply unit 3 has a concave piezo-ceramic
25 ultrasonic transducer 10, ultrasonic energy transmission fluid 11 (optionally water), an ultrasonic transparent membrane 12 (which may be formed from a material such as polyetheretherketone (PEEK)), a medicine (liquid) feeder chamber 13, a liquid energising chamber 14, a mesh 15 and a nasal prong 16. The energising chamber 14 may or may not be asymmetrical or angled. The nasal prong 16 and a sub-assembly of
30 the mesh engage the rest of the supply unit 3 by way of a twist lock mechanism to enable it to be easily cleaned or replaced.

With particular reference to Figure 4, the transducer 10 is concave and emits ultrasonic energy that travels through the transmission fluid 11, through the membrane 12 and
35 into a charge of medicine 18a in the energising chamber 14. The charge 18a becomes acoustically energized within an acoustic focal zone 19 created by the transducer,

which produces an acoustic radiation pressure on the inner face of the mesh 15. As a result the mesh 15 oscillates and produces a micro-pumping action of the medicine as it moves through the pores of the mesh 15. Such contact with the mesh 15 causes the medicine to become an aerosol 20, ie at the outer face of the mesh 15. The aerosol 20
5 then passes out of the nasal prong 16 via the exit 17. If the prong is held in the user's nose the aerosol enters his or her nasal cavity to give therapeutic relief.

With further reference to Figure 4, the concave nature of the transducer 10 concentrates ultrasonic energy at the focal zone 19 within the energising chamber 14
10 so that the charge of medicine 18a becomes acoustically activated. The dotted lines in Figure 4 illustrate an ultrasonic energy pathway resulting from the concavity of the transducer 10. The area referred to as the focal zone 19 is a small region of concentrated ultrasonic energy. As indicated, the focal zone preferably incorporates the focal point 19a, the position of which is dependent on the curvature of the
15 transducer. In some embodiments of the invention the focal zone may be equivalent to the focal point.

In the preferred embodiment the energising chamber 14 is approximately 0.2 cm³ to 0.4 cm³ in size. The small size of the energising chamber 14 with respect to the liquid
20 storage chamber 13 means that the size of the focal zone 19 is minimised. This helps to minimise or substantially limit the amount of residual medicine (wastage) in the energising chamber 14 when the feeder chamber is exhausted.

The liquid medicine 18a in the energising chamber 14 is replenished with a new charge
25 of medicine 18b under normal gravity from the feeder chamber 13. This ensures that there is always a charge of medicine 18a ready to be acoustically energized, that is until the medicine in the liquid storage chamber is emptied. When there is insufficient volume of medicine in the energising chamber 14 there will not be enough acoustic radiation pressure to effectively oscillate the mesh 15.

30

Referring to Figure 2, the mesh 15 is located within and is integral with the nasal prong 16, and the exit is an opening 17 at the end of the prong. The pore size of the mesh 15 determines, in part, the size of the aerosol droplets.

35 Referring to Figure 1, the medicine supply unit 3 can be readily detached from the main body 1 for cleaning, disinfection or replacement altogether. It connects to the body 1 via a cavity in the breath receptor 2. With particular reference to Figure 7, the

medicine supply unit is angled slightly upwards to help the medicine flow more easily into the energising chamber 14 and to prevent bubbles forming in either the energising chamber or the transmission media 11. The angle also assists one to better align the path of aerosol leaving the mesh with targeted areas within the nasal cavity.

5

Other Features

In some embodiments of the invention the device will only run if the user has purchased sufficient electronic 'credits', which are communicated to the device wirelessly or by hardwire.

10

Referring to Figures 8 and 9, in some embodiments the energising chamber 13 has a tapered floor or a well provided by the membrane 12, designed to urge medicine 18a to gather centrally in the focal zone so as to prevent or reduce undelivered residues.

15 While some preferred forms of the invention have been described by way of example, it should be appreciated that modifications and improvements can occur without departing from the scope of the following claims.

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25

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CLAIMS

1. A delivery device for nasal medication, the device comprising having:
 - an ultrasonic energy generator that creates a tapered ultrasonic focal zone of concentrated ultrasonic energy;
 - an ultrasonic energy transmission medium;
 - a feeder chamber holding medication;
 - an energising chamber smaller than the feeder chamber, remote from the ultrasonic energy generator, and holding medication at the tapered ultrasonic focal zone;
 - a mesh; and
 - a nasal prong;wherein when the device is activated:
 - ultrasonic energy travels through the ultrasonic energy transmission medium towards the mesh; and
 - the feeder chamber continuously fills the energising chamber with the medication, until the feeder chamber has insufficient medication left to achieve this, so that there is a substantially constant supply of the medication within the tapered ultrasonic focal zone that is energised and forced from the energising chamber so as to contact the mesh to become an aerosol, and leave the device by way of the nasal prong.
2. The device according to claim 1, further comprising:
 - a mouthpiece for a human user to blow into; and
 - a breath sensor for detecting the user blowing into the mouthpiece and in response thereto causing the medication to be energised and the aerosol to form.
3. A device according to claim 1 or 2, wherein the energising chamber has a volume of 0.1 cm³ to 0.8 cm³.
4. A device according to claim 1 or 2, wherein the energising chamber has a volume of 0.2 cm³ to 0.4 cm³.
5. The device according to any one of the preceding claims, wherein the ultrasonic energy generator comprises a concave transducer adapted that focuses the ultrasonic energy on the tapered ultrasonic focal zone such that the medication in the energising chamber becomes acoustically energised and moves towards the

mesh.

6. The device according to any one of the preceding claims, wherein the mesh vibrates as the medication contacts the mesh to assist in creating the aerosol.
7. The device according to any one of the preceding claims, further comprising an exit which is part of the nasal prong.
8. The device according to claim 7, wherein the mesh is integral with the nasal prong.
9. The device according to claim 7 or 8, wherein the mesh is immediately adjacent to the exit and has effect of minimising condensation of the aerosol inside the device.
10. The device according to claim 7, 8 or 9, wherein the energising chamber, the ultrasonic energy generator and the exit are at an angle of about 40° to about 80° with respect to the mouthpiece.
11. The device according to claim 7, 8, 9 or 10, wherein the energising chamber, the ultrasonic energy generator and the exit are at an angle of about 50° to about 70° with respect to the mouthpiece.
12. The device according to any one of the preceding claims, wherein the medication is a pharmaceutical or saline solution.
13. The device according to any one of the preceding claims, wherein the feeder chamber has a funnel or flume that naturally encourages the medication into the energising chamber.
14. The device according to any one of the preceding claims, wherein the energizing chamber has a tapered floor that urges the medication to gather at the tapered ultrasonic focal zone.
15. The device according to any one of the preceding claims, wherein the energising chamber has a well that urges the medication to gather at the tapered ultrasonic focal zone.

16. The device according to any one of the preceding claims, wherein the feeder chamber plus the energising chamber collectively have sufficient medication for one of:

- only 5 or fewer patient doses;
- only 4 or fewer patient doses;
- only 3 or fewer patient doses;
- only 2 or fewer patient doses; and
- only 1 patient dose.

17. A delivery device for nasal medication, the device comprising:

- a mouth piece;
- a breath sensor;
- an ultrasonic energy generator in the form of a concave transducer that focuses ultrasonic energy on a focal zone;
- a feeder chamber holding medication;
- an energising chamber smaller than the feeder chamber;
- a mesh; and
- a nasal prong;

wherein when the device is activated:

the feeder chamber continuously fills the energising chamber with the medication, until the feeder chamber has insufficient medication left to achieve this, so that there is a substantially constant supply of the medication within the focal zone able to be energised and forced from the energizing chamber so as to contact the mesh to become an aerosol, and leave the device by way of the nasal prong;

the breath sensor detects a user blowing into the mouth piece and in response thereto causes the medication to be energised while the mesh oscillates to produce a pumping action to assist in creating the aerosol;

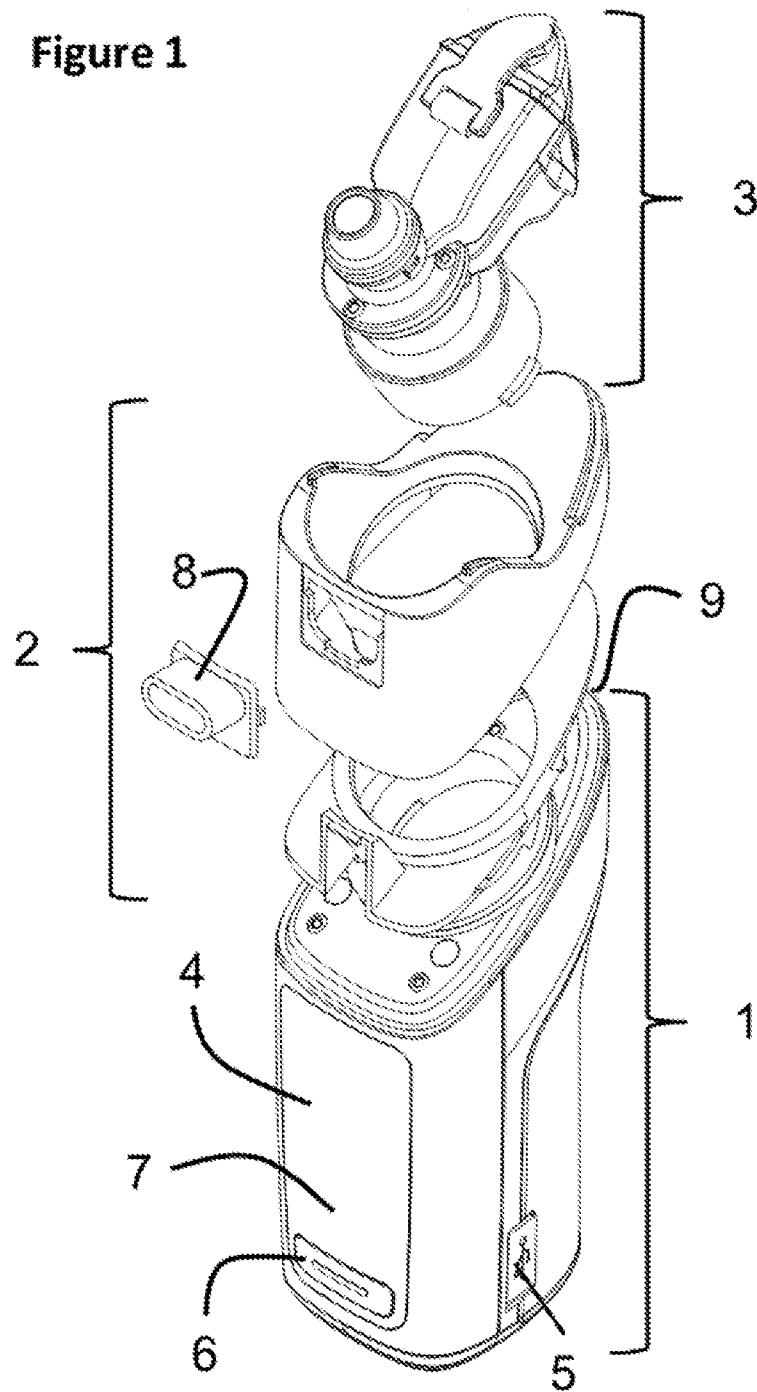
the feeder chamber having a funnel or flume that encourages the medication into the energising chamber; and

the energising chamber having a tapered floor and/or well that urges the medication into the focal zone.

18. The device according to claim 1, wherein the medication in the energising chamber is acoustically energised within the tapered ultrasonic focal zone such that an acoustic radiation pressure is produced on an inner face of the mesh, resulting in oscillation of the mesh to produce a micro-pumping action with respect to the medication.

19. The device according to claim 1, wherein the feeder chamber is at one side of the device only, detachably cantilevers outwardly, and is tilted upwardly from, a location between the nasal prong and the ultrasonic energy generator.
20. The device according to claim 1, wherein:
- the tapered ultrasonic focal zone extends from a floor of the energising chamber to a roof of the energising chamber;
 - the ultrasonic energy generator is concave and acoustically energises a charge of the medication within the ultrasonic focal zone to produce an acoustic radiation pressure on an inner face of the mesh so that the mesh oscillates to cause a micro-pumping action of the medication as it moves through the mesh; and
 - the feeder chamber is at one side of the device only, detachably cantilevers outwardly from a location between the nasal prong and the ultrasonic energy generator.
21. A delivery device for nasal medication, the device comprising:
- an ultrasonic energy generator that creates a tapered ultrasonic focal zone of concentrated ultrasonic energy;
 - an ultrasonic energy transmission medium;
 - an energising chamber holding medication at the tapered ultrasonic focal zone, wherein the energising chamber is remote from the ultrasonic energy generator;
 - a feeder chamber larger than the energising chamber and capable of holding more of the medication, wherein the feeder chamber continuously fills the energising chamber with medication so that there is a substantially constant supply of the medication within the tapered ultrasonic focal zone;
 - a mesh; and
 - a nasal prong;
- wherein the feeder chamber detachably cantilevers outwardly from one side of the device at a location between the nasal prong and the ultrasonic energy generator; and wherein when the device is activated:
- ultrasonic energy travels through the ultrasonic energy transmission medium towards the tapered ultrasonic focal zone; and
 - the medicine within the tapered ultrasonic focal zone is energized and forced from the energising chamber so as to contact the mesh, become an aerosol, and leave the device by way of the nasal prong.

Figure 1



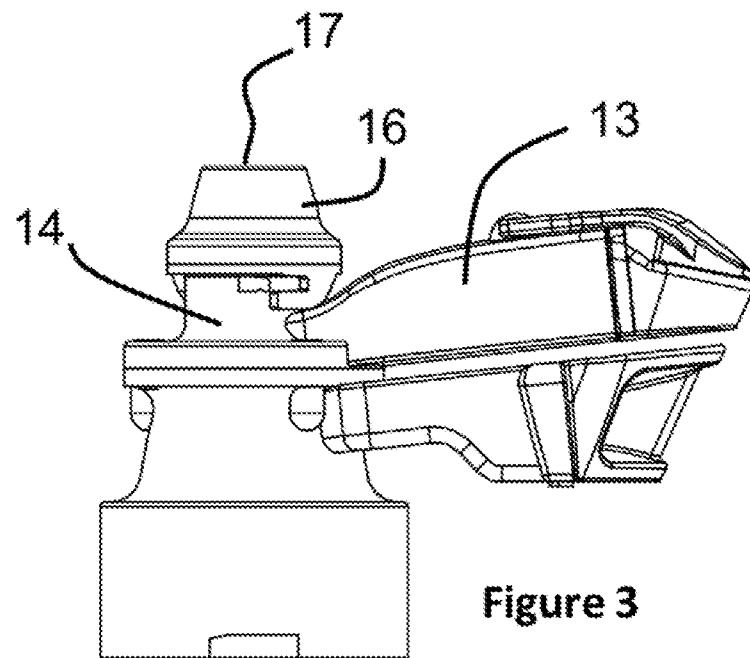
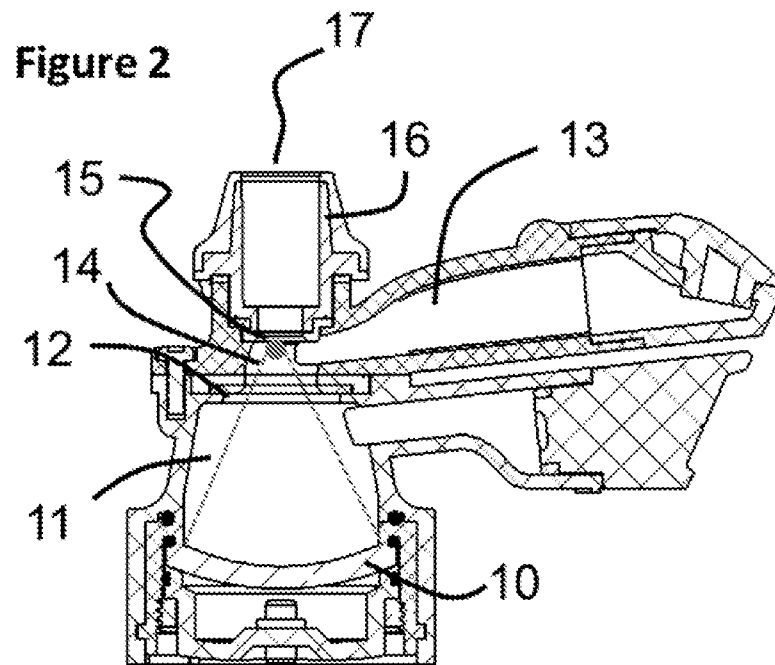


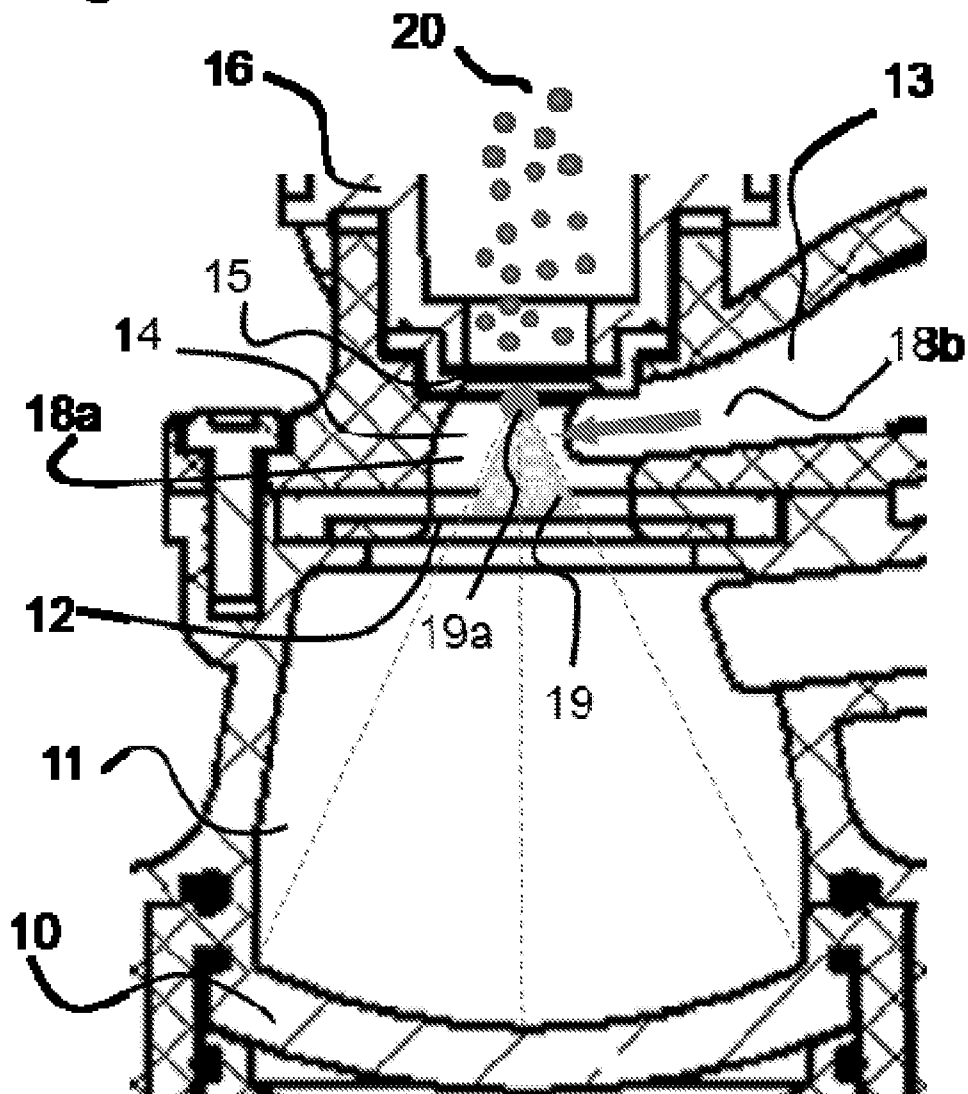
Figure 4

Figure 5

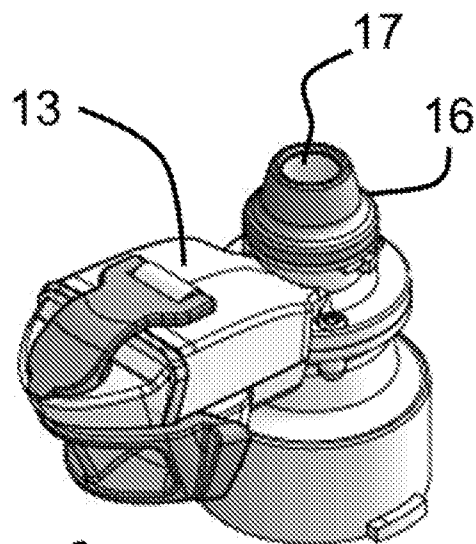
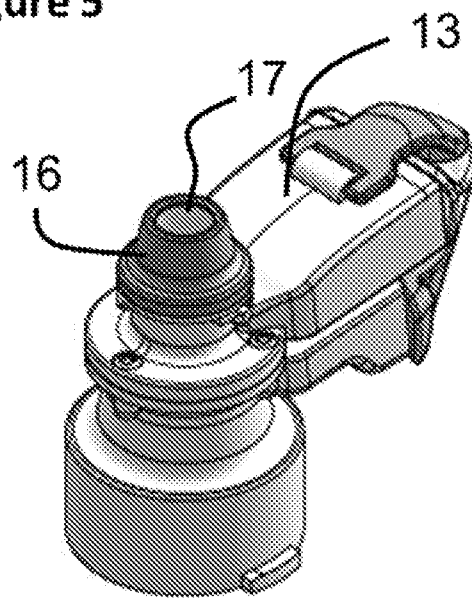


Figure 6

Figure 7

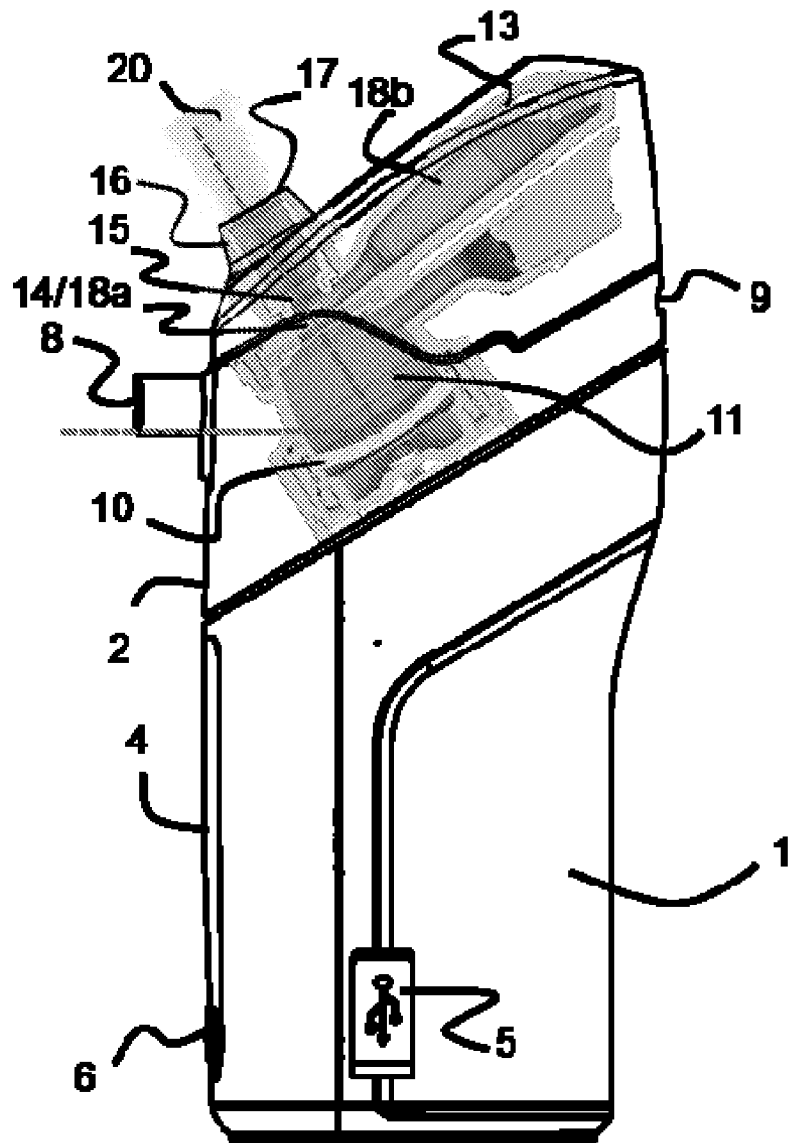


Figure 8

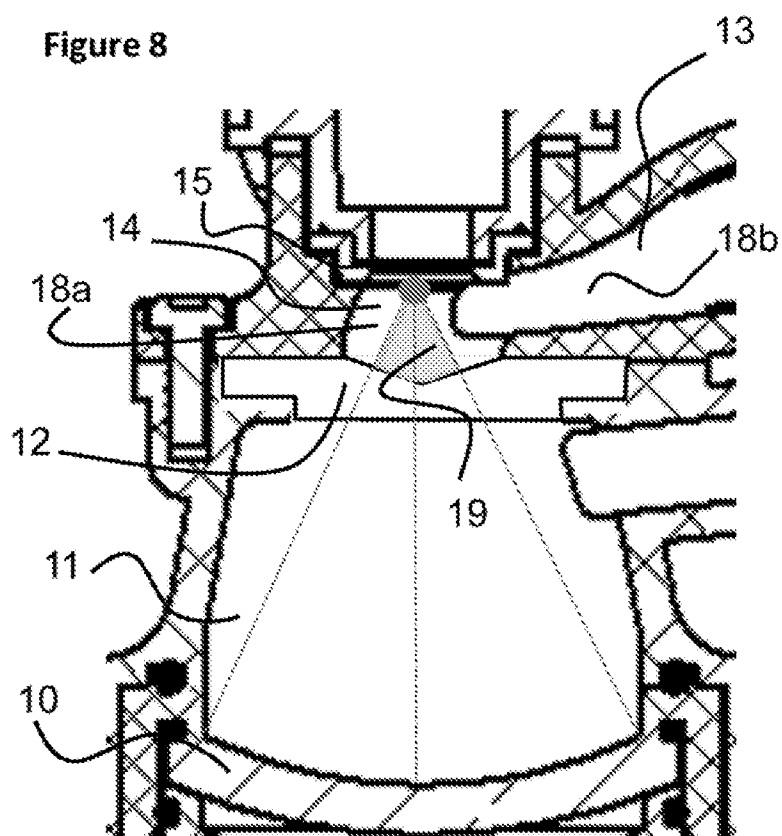


Figure 9

