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(54) Title: NASAL DELIVERY DEVICES

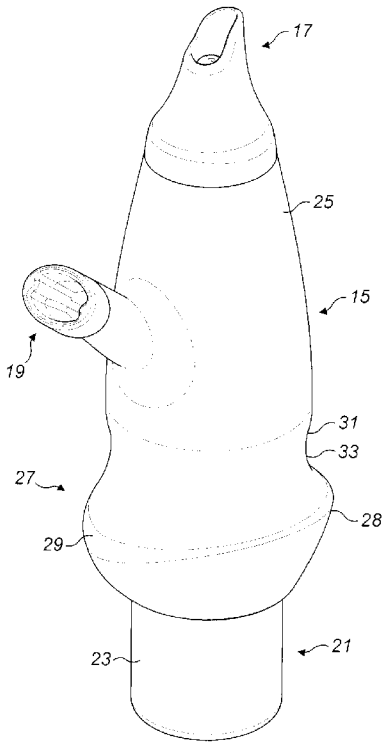

FIG. 1

(57) Abstract: A nasal delivery device comprising: a housing (15); a nosepiece (17) for fitting to a nasal cavity of a subject; a mouthpiece (19) through which the subject in use exhales; and a substance supply unit (21) including an actuation member (23) which extends from one end of the housing and is manually actuated to deliver substance to the nasal cavity of the subject; wherein the housing includes a grip section (27) which is disposed at the one end of the housing from which the actuation member extends, said grip section comprising a first, distal part (28) including at least one projecting grip element (29) by which the subject grips the housing in actuating the actuation member, and a second, proximal part (31) providing a recess (33) in which fingers of the subject are located, said recess promoting proper orientation of the delivery device in a hand of the subject.

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GM, KE, LR, LS, MW, MZ, NA, RW, SD, SL, 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, ML, MR, NE, SN, TD, TG).

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NASAL DELIVERY DEVICES

The present invention relates to a nasal delivery device for and a method of delivering substances, in particular one of a liquid, as a suspension or solution, or a powder, containing a medicament, especially systemic or topical pharmaceuticals, or a vaccine, to the nasal airway of a subject.

Referring to Figure 5, the nasal airway 1 comprises the two nasal cavities separated by the nasal septum, which airway 1 includes numerous ostia, such as the paranasal sinus ostia 3 and the tubal ostia 5, and olfactory cells, and is lined by the nasal mucosa. The nasal airway 1 can communicate with the nasopharynx 7, the oral cavity 9 and the lower airway 11, with the nasal airway 1 being in selective communication with the anterior region of the nasopharynx 7 and the oral cavity 9 by opening and closing of the oropharyngeal velum 13. The velum 13, which is often referred to as the soft palate, is illustrated in solid line in the closed position, as achieved by providing a certain positive pressure in the oral cavity 9, such as achieved on exhalation through the oral cavity 9, and in dashed line in the open position.

There are many nasal conditions which require treatment. One such condition is nasal inflammation, specifically rhinitis, which can be allergic or non-allergic and is often associated with infection and prevents normal nasal function. By way of example, allergic and non-allergic inflammation of the nasal airway can typically effect between 10 and 20 % of the population, with nasal congestion of the erectile tissues of the nasal concha, lacrimation, secretion of watery mucus, sneezing and itching being the most common symptoms. As will be understood, nasal congestion impedes nasal breathing and promotes oral breathing, leading to snoring and sleep disturbance. Other nasal conditions include nasal polyps which arise from the paranasal sinuses, hypertrophic adenoids, secretory otitis media, sinus disease and reduced olfaction.

In the treatment of certain nasal conditions, the topical administration of medicaments is preferable, particularly where the nasal mucosa is the prime pathological pathway, such as in treating or relieving nasal congestion. Medicaments that are commonly topically delivered include decongestants, anti-histamines, cromoglycates, steroids and antibiotics. At present, among the known anti-inflammatory pharmaceuticals, topical steroids have been shown to have an effect on nasal congestion. Topical decongestants have also been suggested for use in relieving nasal congestion. The treatment of hypertrophic adenoids and chronic secretory otitis media using topical decongestants, steroids and anti-microbial agents, although somewhat controversial, has also been proposed. Further, the topical administration of pharmaceuticals has been used to treat or at least relieve symptoms of inflammation in the anterior region of the nasopharynx, the paranasal sinuses and the auditory tubes.

Medicaments can also be systemically delivered through the nasal pathway, the nasal pathway offering a good administration route for the systemic delivery of pharmaceuticals, such as hormones, for example, oxytocin and calcitonin, and analgetics, such as anti-migraine compositions, as the high blood flow and large surface area of the nasal mucosa advantageously provides for rapid systemic uptake.

Nasal delivery is also expected to be advantageous for the administration of medicaments requiring a rapid onset of action, for example, analgetics, anti-emetics, insulin, anti-epileptics, sedatives and hypnotica, and also other pharmaceuticals, for example, cardio-vascular drugs. It is envisaged that nasal administration will provide for a fast onset of action, at a rate similar to that of injection and at a rate much faster than that of oral administration. Indeed, for the treatment of many acute conditions, nasal administration is advantageous over oral administration, since gastric stasis can further slow the onset of action following oral administration.

It is also expected that nasal delivery could provide an effective delivery route for the administration of proteins and peptides as produced by modern biotechnological techniques. For such substances, the metabolism in the intestines and the first-pass-effect in the liver represent significant obstacles for reliable and cost-efficient delivery.

Furthermore, it is expected that nasal delivery using the nasal delivery technique of the present invention will prove effective in the treatment of many common neurological diseases, such as Alzheimer's, Parkinson's, psychiatric diseases and intracerebral infections, where not possible using existing techniques. The nasal delivery technique of the present invention allows for delivery to the olfactory region, which region is located in the superior region of the nasal cavities and represents the only region where it is possible to circumvent the blood-to-brain barrier (BBB) and enable communication with the cerebrospinal fluid (CSF) and the brain.

Also, it is expected that the nasal delivery technique of the present invention will allow for the effective delivery of vaccines.

Aside from the delivery of medicaments, the irrigation of the nasal mucosa with liquids, in particular saline solutions, is commonly practised to remove particles and secretions, as well as to improve the mucociliary activity of the nasal mucosa. These solutions can be used in combination with active pharmaceuticals.

For any kind of drug delivery, accurate and reliable dosing is essential, but it is of particular importance in relation to the administration of potent drugs which have a narrow therapeutic window, drugs with potentially serious adverse effects and drugs for the treatment of serious and life-threatening conditions. For some conditions, it is essential to individualize the dosage to the particular situation, for example, in the case of diabetes mellitus. For diabetes, and, indeed, for many other conditions, the dosage of the pharmaceutical is preferably based on actual real-time measurements.

Currently, blood samples are most frequently used, but the analysis of molecules in the exhalation breath of subjects has been proposed as an alternative to blood analysis for several conditions. Breath analysis is currently used for the diagnosis of conditions such as helicobacter pylori infections which cause gastric ulcers.

WO-A-2000/051672 discloses a delivery device for delivering a substance, in particular a medicament, in a bi-directional flow through the nasal cavities, that is, an air flow which passes into one nostril, around the posterior margin of the nasal septum and in the opposite direction out of the other nostril. This bi-directional air flow advantageously acts to stimulate the sensory nerves in the nasal mucosa, thereby conditioning the subject for the delivery and providing a more comfortable delivery situation.

It is an aim of the present invention to provide nasal delivery devices and methods for delivering substances to a nasal cavity of subject, and in particular relatively-simple mechanically-actuatable delivery devices.

In one aspect the present invention provides a nasal delivery device for delivering substance to a nasal cavity of a subject, the delivery device comprising: a housing; a nosepiece for fitting to a nasal cavity of a subject; a mouthpiece through which the subject in use exhales; and a substance supply unit, which includes an actuation member which extends from one end of the housing and is manually actuated to deliver substance to the nasal cavity of the subject; wherein the housing includes a main body section, from one, base end of which extends the actuation member of the substance supply unit, and a grip section, which is disposed at the one end of the main body section, the grip section comprising a first, distal part which includes at least one projecting grip element by which the subject grips the housing in actuating the actuation member of the substance supply unit, and a second, proximal part which provides a recess in which fingers of the subject are located, whereby the recess promotes proper orientation of the delivery device in a hand of the subject.

In one embodiment the main body section comprises an elongate section.

In one embodiment the at least one projecting grip element is a circumferential lip which extends around or substantially around the periphery of the housing.

In another embodiment the distal part of the grip section comprises first and second projecting grip elements, which project to opposite sides of the housing, with no intermediate elements.

In one embodiment the first and second projecting grip elements are aligned on an axis common with that of the mouthpiece.

In another aspect the present invention provides a method of delivering substance to a nasal cavity of a subject, the method comprising the steps of: providing a nasal delivery device, comprising: a housing; a nosepiece for fitting to a nasal cavity of the subject; a mouthpiece through which the subject exhales; and a substance supply unit, which includes an actuation member which extends from one end of the housing and is manually actuated to deliver substance to the nasal cavity of the subject; wherein the housing includes a main body section, from one, base end of which extends the actuation member of the substance supply unit, and a grip section, which is disposed at the one end of the main body section, the grip section comprising a first, distal part which includes at least one projecting grip element by which the subject grips the housing in actuating the actuation member of the substance supply unit, and a second, proximal part which provides a recess in which fingers of the subject are located; fitting the nosepiece to the nasal cavity of the subject; locating the mouthpiece in the mouth of the subject; and gripping the housing such that fingers of the subject are located in the recess to opposite sides of the housing and adjacent the at least one projecting grip part, thereby promoting proper

orientation of the delivery device in a hand of the subject to effect operation of the delivery device.

In one embodiment the main body section comprises an elongate section.

In one embodiment the at least one projecting grip element is a circumferential lip which extends around or substantially around the periphery of the housing.

In another embodiment the distal part of the grip section comprises first and second projecting grip elements, which project to opposite sides of the housing, with no intermediate elements.

In one embodiment the first and second projecting grip elements are aligned on an axis common with that of the mouthpiece.

Preferred embodiments of the present invention will now be described hereinbelow by way of example only with reference to the accompanying drawings, in which:

Figure 1 illustrates a perspective view of a nasal delivery device in accordance with a first embodiment of the present invention;

Figures 2(a) and (b) illustrate orthogonal side views of the delivery device of Figure 1;

Figure 3 illustrates a perspective view of a nasal delivery device in accordance with a second embodiment of the present invention;

Figures 4(a) and (b) illustrate orthogonal side views of the delivery device of Figure 3; and

Figure 5 schematically illustrates the anatomy of the upper respiratory tract of a human subject.

Figures 1 and 2 illustrate a nasal delivery device in accordance with a first embodiment of the present invention.

The delivery device comprises a housing 15, a nosepiece 17 for fitting in a nasal cavity of a subject, a mouthpiece 19 through which the subject in use exhales, and a substance supply unit 21, which includes an actuation member 23 which extends from one end of the housing 15 and is manually actuated to deliver substance to the nasal cavity of the subject.

The housing 15 includes a main body section 25, in this embodiment an elongate section, from one, base end of which extends the actuation member 23 of the substance supply unit 21.

The housing 15 further includes a grip section 27, which is disposed at the one end of the main body section 25.

The grip section 27 comprises a first, distal part 28 which includes at least one projecting grip element 29 by which a user grips the housing 15, typically between fingers, in actuating the actuation member 23 of the substance supply unit 21, and a second, proximal part 31 which provides a recess or waist 33 in which the fingers of the user are located.

In this embodiment the projecting grip element 29 is a circumferential flange or lip which extends around or substantially around the periphery of the housing 15.

The present inventors have recognized that the provision of the recess or waist 33 adjacent the flange or lip element 29 promotes proper orientation of the delivery device in the hand of the user, insofar as a user is required

to orient the delivery device in a particular manner in the nasal cavity, in order to achieve optimal performance from the delivery device.

Figures 3 and 4 illustrate a nasal delivery device in accordance with a second embodiment of the present invention.

The delivery device of this embodiment is very similar to the above-described first embodiment, and thus, in order to avoid unnecessary duplication of description, only the differences will be described in detail.

In this embodiment the distal part 28 of the grip section 27 comprises first and second projecting grip elements 29a, 29b, which project to opposite sides of the housing 15, with no intermediate elements. In this embodiment the first and second projecting grip elements 29a, 29b are aligned on an axis common with that of the mouthpiece 19.

The present inventors have recognized that this configuration promotes a proper rotational orientation of the delivery device when gripped in the hand of a user, insofar as a user is required to orient the delivery device in a particular manner in the nasal cavity, in order to achieve optimal performance from the delivery device.

Finally, it will be understood that the present invention has been described in its preferred embodiments and can be modified in many different ways without departing from the scope of the invention as defined by the appended claims.

CLAIMS

1. A nasal delivery device for delivering substance to a nasal cavity of a subject, the delivery device comprising:
a housing;
a nosepiece for fitting to a nasal cavity of a subject;
a mouthpiece through which the subject in use exhales; and
a substance supply unit, which includes an actuation member which extends from one end of the housing and is manually actuated to deliver substance to the nasal cavity of the subject;
wherein the housing includes a main body section, from one, base end of which extends the actuation member of the substance supply unit, and a grip section, which is disposed at the one end of the main body section, the grip section comprising a first, distal part which includes at least one projecting grip element by which the subject grips the housing in actuating the actuation member of the substance supply unit, and a second, proximal part which provides a recess in which fingers of the subject are located, whereby the recess promotes proper orientation of the delivery device in a hand of the subject.

2. The delivery device of claim 1, wherein the main body section comprises an elongate section.

3. The delivery device of claim 1 or 2, wherein the at least one projecting grip element is a circumferential lip which extends around or substantially around the periphery of the housing.

4. The delivery device of claim 1 or 2, wherein the distal part of the grip section comprises first and second projecting grip elements, which project to opposite sides of the housing, with no intermediate elements.

5. The delivery device of claim 4, wherein the first and second projecting grip elements are aligned on an axis common with that of the mouthpiece.

6. A method of delivering substance to a nasal cavity of a subject, the method comprising the steps of:
providing a nasal delivery device, comprising: a housing; a nosepiece for fitting to a nasal cavity of the subject; a mouthpiece through which the subject exhales; and a substance supply unit, which includes an actuation member which extends from one end of the housing and is manually actuated to deliver substance to the nasal cavity of the subject; wherein the housing includes a main body section, from one, base end of which extends the actuation member of the substance supply unit, and a grip section, which is disposed at the one end of the main body section, the grip section comprising a first, distal part which includes at least one projecting grip element by which the subject grips the housing in actuating the actuation member of the substance supply unit, and a second, proximal part which provides a recess in which fingers of the subject are located;
fitting the nosepiece to the nasal cavity of the subject;
locating the mouthpiece in the mouth of the subject; and
gripping the housing such that fingers of the subject are located in the recess to opposite sides of the housing and adjacent the at least one projecting grip part, thereby promoting proper orientation of the delivery device in a hand of the subject to effect operation of the delivery device.

7. The method of claim 6, wherein the main body section comprises an elongate section.

8. The method of claim 6 or 7, wherein the at least one projecting grip element is a circumferential lip which extends around or substantially around the periphery of the housing.

9. The method of claim 6 or 7, wherein the distal part of the grip section comprises first and second projecting grip elements, which project to opposite sides of the housing, with no intermediate elements.

10. The delivery device of claim 9, wherein the first and second projecting grip elements are aligned on an axis common with that of the mouthpiece.

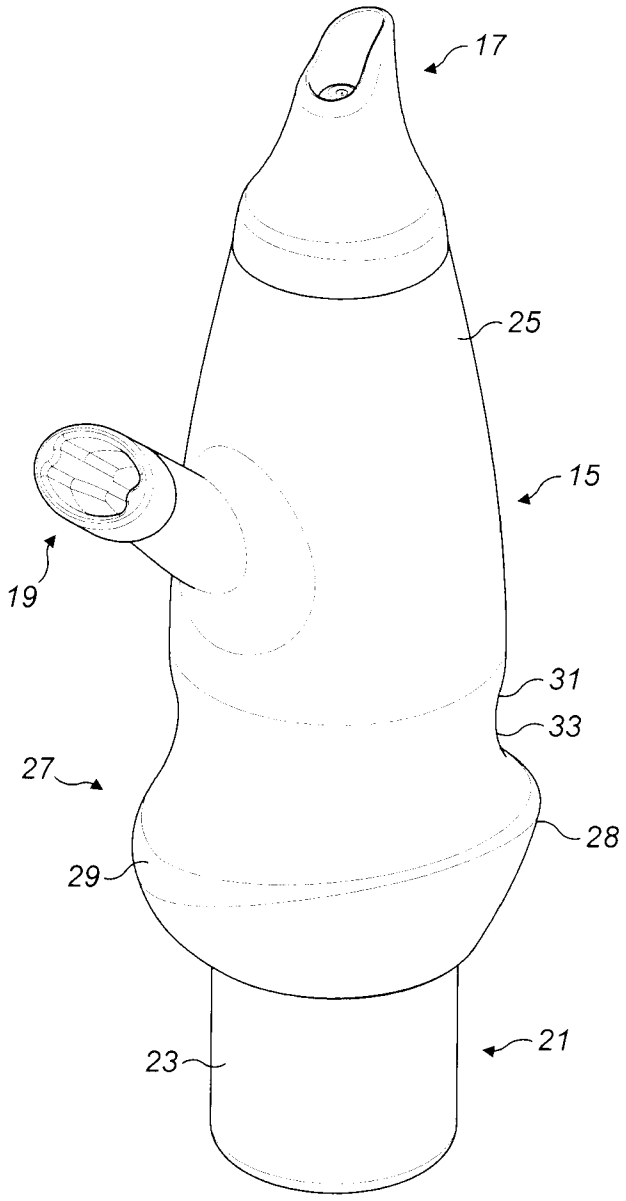

FIG. 1

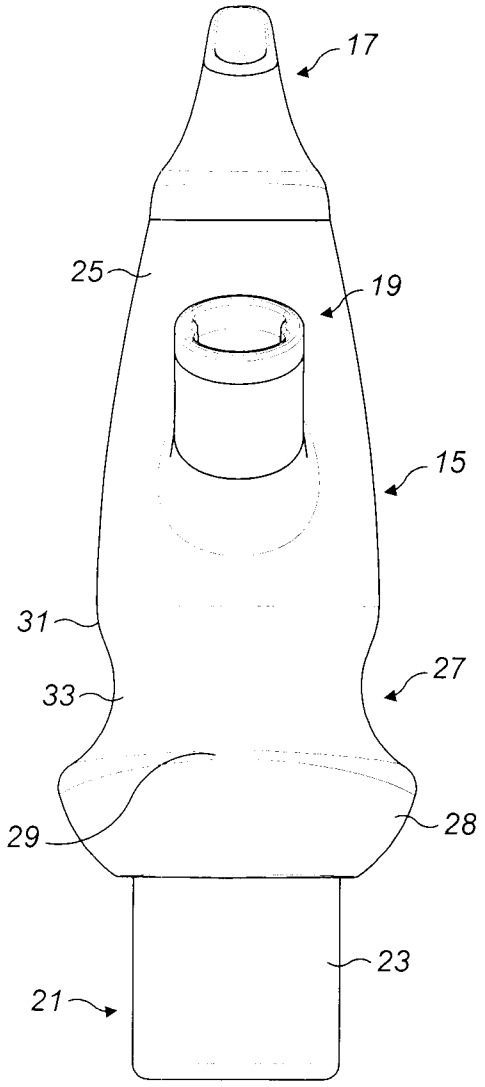

FIG. 2(a)

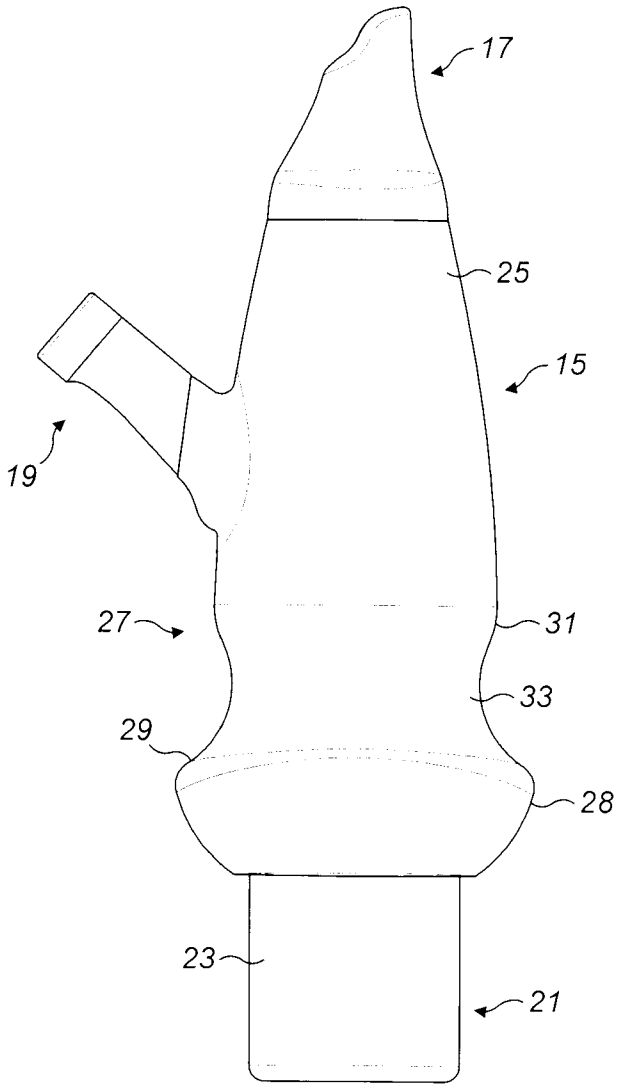

FIG. 2(b)

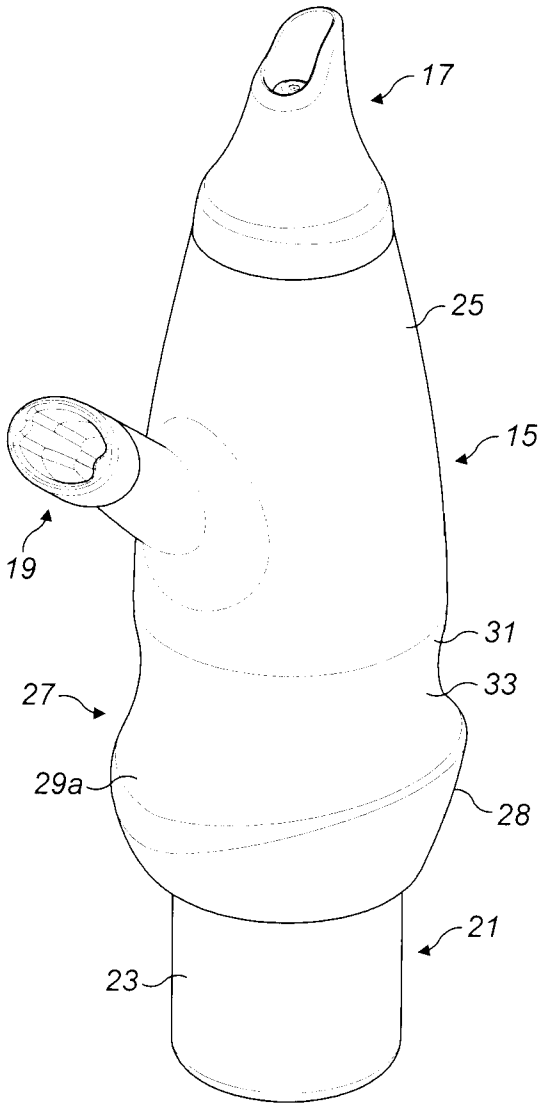

FIG. 3

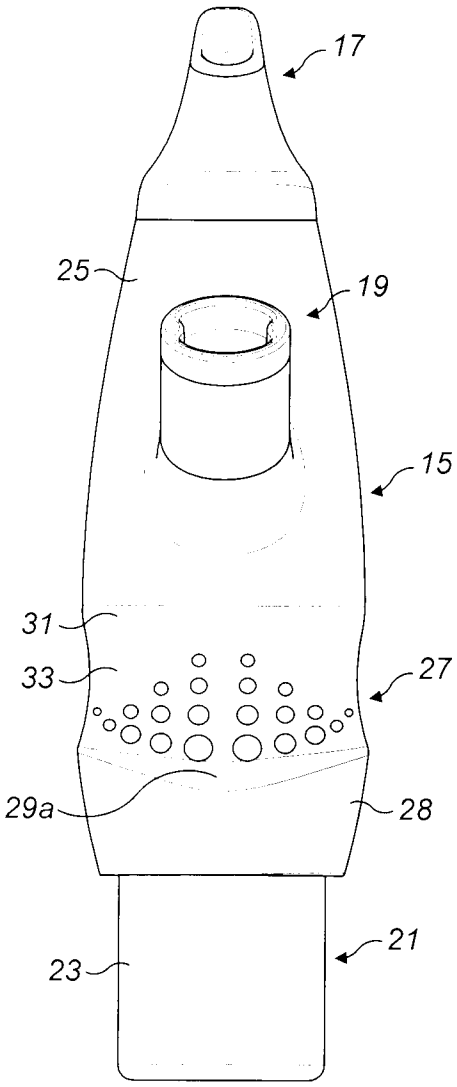

FIG. 4(a)

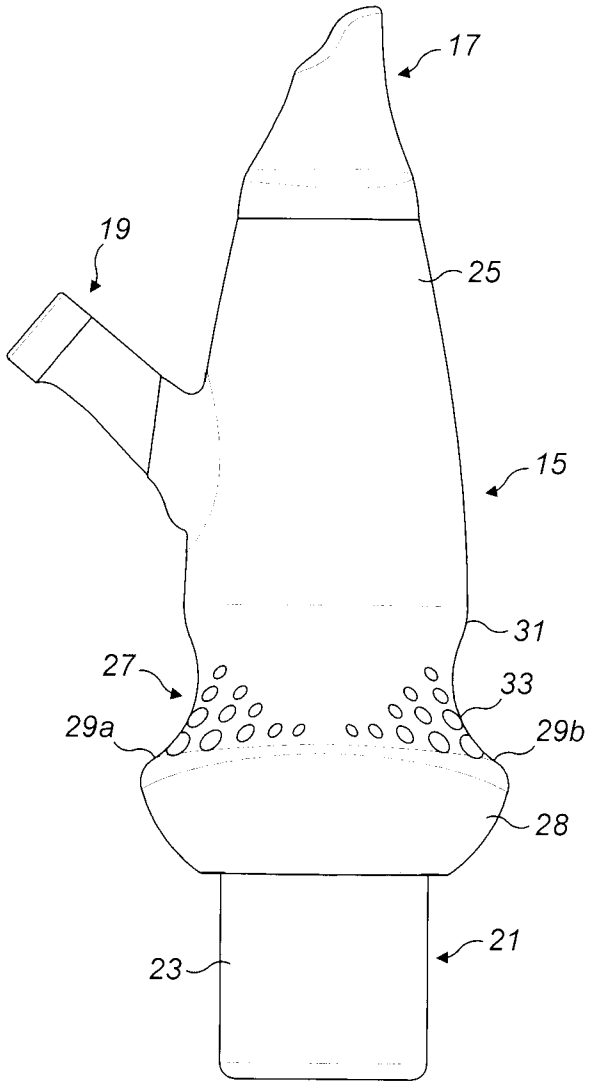

FIG. 4(b)

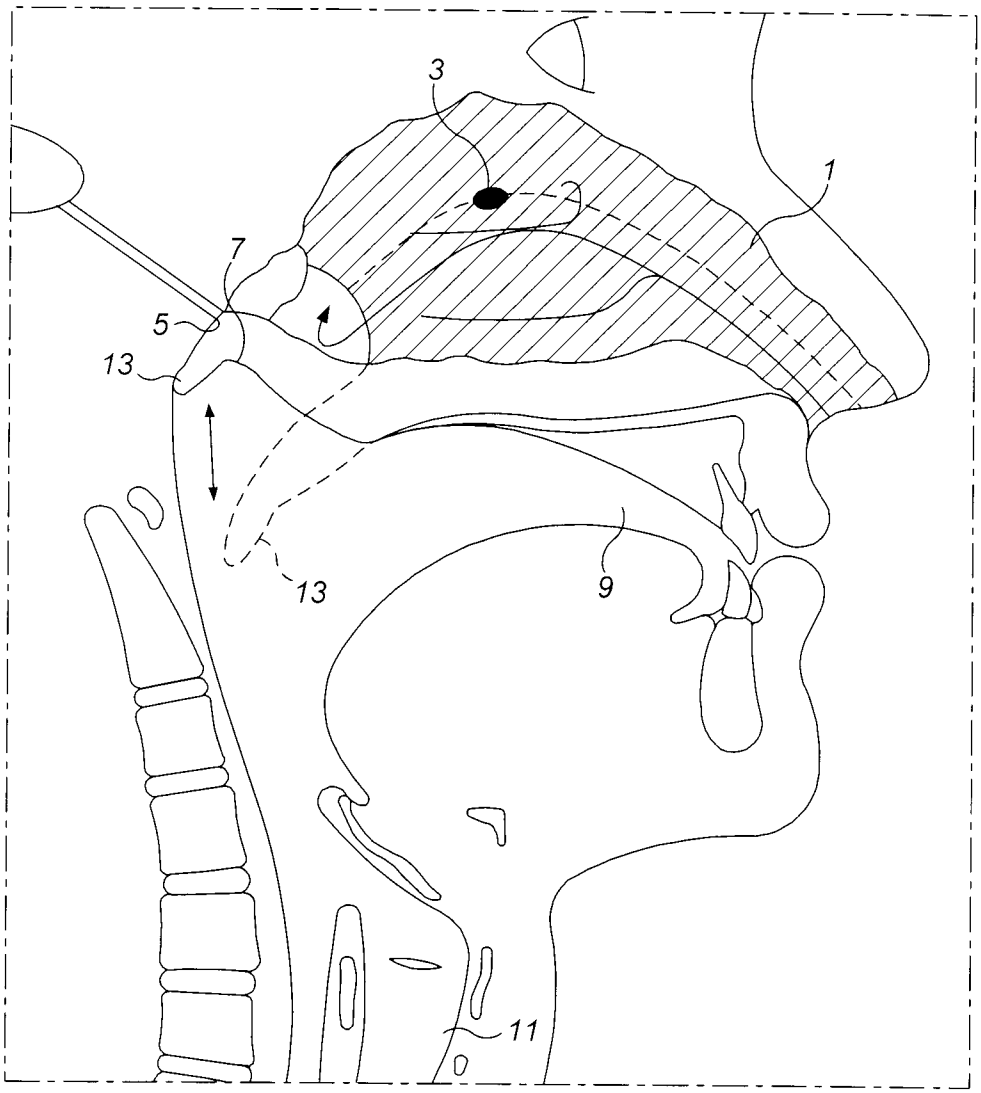

FIG. 5

INTERNATIONAL SEARCH REPORT

International application No
PCT/EP2013/053748

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61M15/08
ADD.

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
A61M

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
EPO-Internal, WPI Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 2009/044172 A1 (OPTINOSE AS [NO]; DJUPESLAND PER GISLE [NO]; SHELDRAKE COLIN DAVID [GB) 9 April 2009 (2009-04-09) the whole document	1-5
A	WO 01/78818 A2 (TRUDELL MEDICAL INT [CA]) 25 October 2001 (2001-10-25) page 14, lines 9-14 figures	1-5
A	WO 2011/153406 A2 (GOVERNMENT OF THE US SECRETARY OF HEALTH AND HUMAN SERVICES CT S FOR D) 8 December 2011 (2011-12-08) pages 24-25, paragraph 110 figures	1-5

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[X] Further documents are listed in the continuation of Box C.

[X] See patent family annex.

* Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier application or patent but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
31 May 2013	07/06/2013

Name and mailing address of the ISA/	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Fax: (+31-70) 340-3016	Azaïzia, Mourad

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Form PCT/ISA/210 (second sheet) (April 2005)

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	WO 2008/122018 A1 (ABBOTT LAB [US]; WILLIAMS III ROBERT C [US]; DEATON DANIEL M [US]; GEN) 9 October 2008 (2008-10-09) page 6, lines 14-16 figures	1-5
A	WO 2008/067254 A2 (ABBOTT LAB [US]; GENOVA PERRY A [US]; WILLIAMS III ROBERT C [US]; DEAT) 5 June 2008 (2008-06-05) page 5, lines 27-30 figures	1-5
A	WO 00/51672 A1 (DJUPESLAND PER GISLE [NO]) 8 September 2000 (2000-09-08) cited in the application the whole document	1-5
A	WO 03/020350 A1 (OPTINOSE AS [NO]; DJUPESLAND PER GISLE [NO]) 13 March 2003 (2003-03-13) the whole document	1-5

2

INTERNATIONAL SEARCH REPORT

International application No.
PCT/EP2013/053748

Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. [X] Claims Nos.: 6-10
because they relate to subject matter not required to be searched by this Authority, namely:

Rule 39.1(iv) PCT - Method for treatment of the human or animal body by therapy

2. [ ] Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

3. [ ] Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. [ ] As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.

2. [ ] As all searchable claims could be searched without effort justifying an additional fees, this Authority did not invite payment of additional fees.

3. [ ] As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:

4. [ ] No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

[ ] The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.

[ ] The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.

[ ] No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
PCT/EP2013/053748

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