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 nasal delivery methods for providing for delivery of a substance 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 the subject; a mouthpiece through which the subject in use exhales; and a flexible coupling which couples the mouthpiece to the housing, wherein the flexible coupling provides for asymmetric translation of the mouthpiece relative to the nosepiece, which is constrained so as to maintain a desired relationship between the mouthpiece and the nosepiece, and the asymmetric translation of the mouthpiece relative to the nosepiece provides for greater movement in a direction along the axis of the nosepiece than in a direction laterally to the nosepiece.

In one embodiment the nosepiece includes an outlet from which substance is delivered, and a seat against which the nare of a nostril of the subject is in use seated, in achieving a sealing fit between the nosepiece and the nasal cavity of the subject.

In one embodiment the nosepiece includes a tapered section which in use is located within a nasal cavity of the subject and tapers outwardly from the outlet.

In one embodiment the mouthpiece comprises a tubular section.

In one embodiment the tubular section is formed of a rigid material.

In one embodiment the tubular section is formed of a semi-rigid material.

In one embodiment the flexible coupling is a resilient element.

~~In one embodiment the asymmetric translation of the mouthpiece relative to the nosepiece provides for greater movement in a direction along the axis of the nosepiece than in a direction laterally to the nosepiece.~~

In one embodiment the distal end of the mouthpiece is configured to move a distance at least 1.5 times greater in a direction parallel to the axis of the nosepiece than in a direction orthogonally to the axis of the nosepiece.

In one embodiment the distal end of the mouthpiece is configured to move a distance at least 1.75 times greater in a direction parallel to the axis of the nosepiece than in a direction orthogonally to the axis of the nosepiece.

In one embodiment the distal end of the mouthpiece is configured to move a distance at least 2 times greater in a direction parallel to the axis of the nosepiece than in a direction orthogonally to the axis of the nosepiece.

In one embodiment the flexible coupling comprises an annular coupling member which is attached in one part to the housing and another part to the mouthpiece, such that exhalation through the mouthpiece delivers an air flow into the housing.

In one embodiment the coupling member is configured to allow for the mouthpiece to be moved downwardly through an angle of between about 5 and about 9 degrees relative to the axis of the nosepiece.

In one embodiment the coupling member is configured to allow for the mouthpiece to be moved downwardly through an angle of between about 6 and about 8 degrees relative to the axis of the nosepiece.

In one embodiment the coupling member is configured to allow for the mouthpiece to be moved downwardly through an angle of about 7 degrees relative to the axis of the nosepiece.

In one embodiment the coupling member is formed of a thermoplastic elastomer (TPE).

In one embodiment the TPE has a durometer of between about 40 and about 60.

In one embodiment the TPE has a durometer of between about 45 and about 55.

In one embodiment the TPE has a durometer of about 50.

In one embodiment the delivery device further comprises: a substance supply unit which is manually actuated to deliver substance to the nasal cavity of the subject.

~~In another 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 the subject; a mouthpiece through which the subject in use exhales; and a flexible coupling which couples the mouthpiece to the housing, providing for movement of the mouthpiece relative to the nosepiece.~~

~~In a further 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 in use exhales; and a flexible coupling which couples the mouthpiece to the housing, wherein the flexible coupling provides for asymmetric translation of the mouthpiece relative to the nosepiece; fitting the nosepiece to a nasal cavity of the subject; and locating the mouthpiece in the mouth of the subject by flexing the asymmetric coupling and thereby asymmetrically translating the mouthpiece relative to the nosepiece.~~

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;

Figure 2 illustrates a vertical sectional view of the delivery device of Figure 1, with the mouthpiece in the at rest position;

Figure 3 illustrates a vertical sectional view of the delivery device of Figure 1, with the mouthpiece in a position biased upwardly relative to the nosepiece;

Figure 4 illustrates a vertical sectional view of the delivery device of Figure 1, with the mouthpiece in a position biased downwardly relative to the nosepiece;

Figure 5 illustrates the results of a study to determine adequacy of fit of the delivery device of Figure 1, as compared to three comparator devices;

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 the subject;
a mouthpiece through which the subject in use exhales; and
a flexible coupling which couples the mouthpiece to the housing, wherein the flexible coupling provides for asymmetric translation of the mouthpiece relative to the nosepiece which is constrained so as to maintain a desired relationship between the mouthpiece and the nosepiece, and the asymmetric translation of the mouthpiece relative to the nosepiece provides for greater movement in a direction along the axis of the nosepiece than in a direction laterally to the nosepiece.

2. The delivery device of claim 1, wherein the nosepiece includes an outlet from which substance is delivered, and a seat against which the nare of a nostril of the subject is in use seated, in achieving a sealing fit between the nosepiece and the nasal cavity of the subject.

3. The delivery device of claim 2, wherein the nosepiece includes a tapered section which in use is located within a nasal cavity of the subject and tapers outwardly from the outlet.

4. The delivery device of any of claims 1 to 3, wherein the mouthpiece comprises a tubular section.

5. The delivery device of claim 4, wherein the tubular section is formed of a rigid material.

6. The delivery device of claim 4, wherein the tubular section is formed of a semi-rigid material.

7. The delivery device of any of claims 1 to 6, wherein the flexible coupling is a resilient element.

~~8. The delivery device of any of claims 1 to 7, wherein the asymmetric translation of the mouthpiece relative to the nosepiece provides for greater movement in a direction along the axis of the nosepiece than in a direction laterally to the nosepiece.~~

9.8. The delivery device of any one of claims 1 to ~~7~~8, wherein the distal end of the mouthpiece is configured to move a distance at least 1.5 times greater in a direction parallel to the axis of the nosepiece than in a direction orthogonally to the axis of the nosepiece.

~~10.~~9. The delivery device of claim 8, wherein the distal end of the mouthpiece is configured to move a distance at least 1.75 times greater in a direction parallel to the axis of the nosepiece than in a direction orthogonally to the axis of the nosepiece.

~~11.~~10. The delivery device of claim 8, wherein the distal end of the mouthpiece is configured to move a distance at least 2 times greater in a direction parallel to the axis of the nosepiece than in a direction orthogonally to the axis of the nosepiece.

~~12.~~11. The delivery device of any of claims 1 to 10~~11~~, wherein the flexible coupling comprises an annular coupling member which is attached in one part to the housing and another part to the mouthpiece, such that exhalation through the mouthpiece delivers an air flow into the housing.

~~13.~~12. The delivery device of claim ~~12~~11, wherein the coupling member is configured to provide a hinge section about which the mouthpiece is preferentially hinged when biased upwardly or downwardly by application of a biasing force.

~~14.~~13. The delivery device of claim ~~13~~12, wherein the hinge section is provided to one, upper side thereof, proximate the nosepiece.

~~15.~~14. The delivery device of claim ~~14~~13, wherein the coupling member has a shorter dimension to the one side thereof, thereby ensuring that the mouthpiece is hinged about the one side of the coupling member.

~~16.~~15. The delivery device of claim ~~15~~14, wherein the coupling member has a progressively-increasing dimension to the other, lower side thereof, distal the nosepiece.

~~17.~~16. The delivery device of any of claims ~~12~~–11 to ~~16~~15, wherein the coupling member has an arcuate, bowed profile which becomes larger towards the other side thereof, and provides for stretching when the mouthpiece is biased upwardly and compression when the mouthpiece is biased downwardly.

~~18.~~17. The delivery device of claim ~~17~~16, wherein the bowed profile ~~section~~ is bowed outwardly, whereby the biasing force required to bias the mouthpiece upwardly is less than the biasing force required to bias the mouthpiece downwardly.

~~19.~~18. The delivery device of claim 16 or 17 ~~or 18~~, wherein the bowed profile ~~section~~ of the coupling member is formed of graded material, such that the material of the coupling member is less resilient at the one side thereof than the other side thereof.

~~20.~~19. The delivery device of any of claims ~~12~~–11 to ~~16~~15, wherein the coupling member is formed of graded material, such that the material of the coupling member is less resilient at the one side thereof than the other side thereof.

~~21.~~20. The delivery device of any of claims ~~12~~–11 to ~~20~~19, wherein the coupling member is configured to provide the axis of the mouthpiece at an

angle of between about 45 and about 55 degrees relative to the axis of the nosepiece.

~~22.~~21. The delivery device of claim ~~21~~20, wherein the coupling member is configured to provide the axis of the mouthpiece at an angle of between about 48 and about 52 degrees relative to the axis of the nosepiece.

~~23.~~22. The delivery device of claim ~~21~~20, wherein the coupling member is configured to provide the axis of the mouthpiece at an angle of about 50 degrees relative to the axis of the nosepiece.

~~24.~~23. The delivery device of any of claims ~~21~~ 20 to ~~23~~22, wherein the coupling member is configured to allow for the mouthpiece to be moved upwardly through an angle of between about 7 and about 17 degrees relative to the axis of the nosepiece.

~~25.~~24. The delivery device of claim ~~24~~23, wherein the coupling member is configured to allow for the mouthpiece to be moved upwardly through an angle of between about 9 and about 15 degrees relative to the axis of the nosepiece.

~~26.~~25. The delivery device of claim ~~24~~23, wherein the coupling member is configured to allow for the mouthpiece to be moved upwardly through an angle of between about 10 and about 14 degrees relative to the axis of the nosepiece.

~~27.~~26. The delivery device of claim ~~24~~23, wherein the coupling member is configured to allow for the mouthpiece to be moved upwardly through an angle of about 12 degrees relative to the axis of the nosepiece.

~~28.~~27. The delivery device of any of claims ~~21~~ 20 to ~~27~~26, wherein the coupling member is configured to allow for the mouthpiece to be moved downwardly through an angle of between about 4 and about 10 degrees relative to the axis of the nosepiece.

~~29.~~28. The delivery device of claim ~~28~~27, wherein the coupling member is configured to allow for the mouthpiece to be moved downwardly through an angle of between about 5 and about 9 degrees relative to the axis of the nosepiece.

~~30.~~29. The delivery device of claim ~~28~~27, wherein the coupling member is configured to allow for the mouthpiece to be moved downwardly through an angle of between about 6 and about 8 degrees relative to the axis of the nosepiece.

~~31.~~30. The delivery device of claim ~~28~~27, wherein the coupling member is configured to allow for the mouthpiece to be moved downwardly through an angle of about 7 degrees relative to the axis of the nosepiece.

~~32.~~31. The delivery device of any of claims ~~12~~ 11 to ~~31~~30, wherein the coupling member is formed of a thermoplastic elastomer (TPE).

~~33.~~32. The delivery device of claim ~~32~~31, wherein the TPE has a durometer of between about 40 and about 60.

~~34.~~33. The delivery device of claim ~~33~~32, wherein the TPE has a durometer of between about 45 and about 55.

~~35.~~34. The delivery device of claim ~~33~~32, wherein the TPE has a durometer of about 50.

~~36.~~35. The delivery device of any of claims 1 to ~~35~~34, further comprising:

a substance supply unit which is manually actuated to deliver substance to the nasal cavity of the subject.

~~37. 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 the subject;~~

~~a mouthpiece through which the subject in use exhales; and~~

~~a flexible coupling which couples the mouthpiece to the housing, providing for movement of the mouthpiece relative to the nosepiece.~~

~~38. 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 in use exhales; and a flexible coupling which couples the mouthpiece to the housing, wherein the flexible coupling provides for asymmetric translation of the mouthpiece relative to the nosepiece;~~

~~fitting the nosepiece to a nasal cavity of the subject; and~~

~~locating the mouthpiece in the mouth of the subject by flexing the asymmetric coupling and thereby asymmetrically translating the mouthpiece relative to the nosepiece.~~