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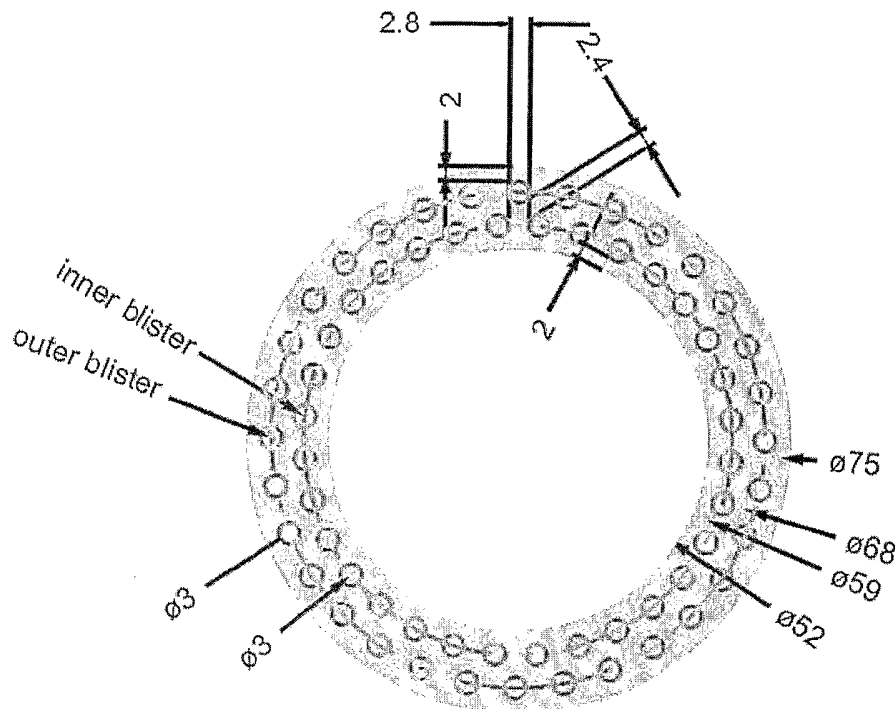
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(54) Title: DRY POWDER INHALER



(57) Abstract: The present invention provides a dry powder inhaler for administering medicaments in solid finely divided form to patients, wherein the dry powder inhaler is in the form of a diskhaler comprising a disk shaped rotatable support and an annular blister pack containing at least 30 blister medicament units.

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DRY POWDER INHALER

FIELD OF INVENTION

The present invention relates to a dry powder inhaler for delivery of medicaments in solid, finely divided form to a patient by oral inhalation. The present invention provides a compact, easy to carry and use, dry powder inhaler with means for dispensing a large number of doses of the medicament.

BACKGROUND OF THE INVENTION

Dry powder inhalers are known in the prior art. Many of the dry powder inhalers are known and marketed. Some of the marketed dry powder inhalers described in prior art include Spinhaler (United States Patent No. 5,239,991), Rotahaler (United States Patent Nos. 4,210,140 and 4,206,758), Turbuhaler (United States Patent Nos. 4,524,769, 4,907,583, 4,668,218) and Diskhaler (United States Patent Nos. 4,811,731, 5,035,237) among the many others. Information about dry powder inhalers and formulations used therein is found in the art, for example textbooks like 'Particulate Interactions in Dry Powder Formulations for Inhalations' by Xian Zeng, Gary Martin and Christopher Marriott.

United States Patent Nos. 4,811,731 (assigned to Glaxo Group Limited) and 5,035,237 relate to a diskhaler kind of a dry powder inhaler for administering medicaments in solid finely divided form to patients wherein the dry powder inhaler comprises a housing, a tray mounted in the housing which is movable between first and second positions relative to the housing, a rotatable support disk provided on the tray and adapted to receive a carrier provided with the medicament container. A plunger is operable to penetrate a container registered therewith to open the container to a pathway leading to an inhalation mouthpiece. This device uses a blister pack with 8 blisters in a single circular row of blisters and thus can accommodate a single medicament pack containing 8 doses only. For dispensing two medicaments it teaches the use of a pair of identical inhalation devices arranged back to back, which may become bulky.

Many of the commercially available dry powder inhalers can either hold only a few medicament units or otherwise are too bulky. The patient is required to carry the bulky unit with him in order to administer the medication when required. In case of diskhaler kind of dry powder inhalers, which are so called because they use a disk shaped blister pack mounted on a disk shaped

rotatable support, we have found that, providing more than 30 number of blister medicament units on the disk shaped blister pack makes the inhaler large and bulky.

OBJECT OF THE INVENTION

- 5 It is the object of the invention to provide a compact, easy to carry and use, dry powder inhaler with means for dispensing a large number of doses of the medicament.

SUMMARY OF THE INVENTION

10 The present invention provides a dry powder inhaler for administering medicaments in solid finely divided form to patients, wherein the dry powder inhaler is in the form of a diskhaler comprising a disk shaped rotatable support and an annular blister pack containing atleast 30 blister medicament units.

15 More specifically, the present invention provides a dry powder inhaler for administering medicaments in solid finely divided form to patients, comprising

- a) a bottom unit,
- b) a rotatable support provided on the bottom unit,
- c) an annular blister pack mounted on the rotatable support wherein the annular blister pack comprises a plurality of blister medicament units arranged in two concentric rings of
20 blister medicament units,
- d) a top cover comprising a movable slider puncture pin assembly, said movable slider puncture pin assembly comprising a puncture pin and means for,
 - (i) positioning the assembly in a first position to register the puncture pin with blister medicament units in first concentric ring for rupturing
25 successively the blister medicament units,
 - (ii) preventing the assembly from moving from the first position until blister medicament units in first concentric ring are exhausted,
 - (iii) thereafter, positioning the assembly in a second position to register the puncture pin with blister medicament units in second concentric ring and
30 rupturing successively the blister medicament units,
- e) air inlet means through which air can enter the dry powder inhaler and air outlet means through which patient can inhale, whereby the medicament from a punctured blister medicament unit will be entrained in the air flow produced by the patient.

Optionally, there is also provided on the dry powder inhaler of the invention, a means for preventing the movable slider puncture pin assembly from moving from the second position until blister medicament units in second concentric ring are exhausted.

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DETAILED DESCRIPTION OF THE PRESENT INVENTION

The dry powder inhaler of the present invention is illustrated by embodiments described here in below.

BRIEF DESCRIPTION OF THE DRAWINGS

10

Many aspects of the invention can be better understood with reference to the following drawings. The components in the drawings are not necessarily to scale, emphasis instead being placed upon clearly illustrating the principles of the present invention. Moreover, in the drawings, like reference numerals designate corresponding parts throughout the several views.

15

Figures 1A, 1B, 1C, 1D, 1E and 1F are the top view, bottom view, section A-A view, top isometric view, bottom isometric view and side view, respectively of the annular ring blister pack holding 30 + 30 medicament doses;

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Figures 2A, 2B show the assembly of the dry powder inhaler;

Figure 3 is the exploded view of the dry powder inhaler;

Figures 4A, 4B, 4C are the cut section views of the dry powder inhaler;

Figures 5A, 5B, 5C, 5D are variations of scored formation of turbulence elements in the passageway connecting the air inlet hole to the air outlet hole in the mouthpiece;

25

Figures 6A, 6B show the puncture pin slider position to puncture blister medicament units 0-30 in the first ring;

Figures 6C, 6D show the puncture pin slider position to puncture blister medicament units 31-60 in the second ring;

Figures 7A, 7B, 7C, 7D, 7E show the puncture pin slider lock positions with respect to the blister pack;

30

Figure 7A shows the blister pack in the position wherein blister medicament unit number 1 is to be punctured;

Figure 7B shows the blister pack indexed to medicament unit number 2;

Figure 7C shows the blister pack when it has reached the 30th blister medicament unit in the first ring;

35

Figure 7D shows the position of the puncture pin slider with respect to the blister pack when the blister medicament unit number 31 is ready to be punctured;

Figure 7E shows the blister pack indexed to medicament unit number 32;

Figures 8A, 8B, 8C are the top isometric, bottom isometric and side views of the puncture pin slider assembly, respectively;

Figures 9A, 9B show the slider positions in the top cover for the 0-30 position and 0-31 position, respectively

Figure 10A shows the exploded view of the rotatable support and the bottom unit

Figures 10B and 10C are the horizontal section view and the vertical section view respectively showing the unidirectional ratchet assembly for the rotatable support with respect to the bottom unit

Figure 11 shows the top views of a preferred embodiment of the inhaler of present invention

Figures 12 and 13 show the internal view of the preferred embodiment of figure 11.

Figure 14 shows the top view of the '16+16 inline' annular blister pack.

Figure 15 shows the top view of the '16+16 staggered' annular blister pack.

Figure 16 shows the top view of the '32+32 inline' annular blister pack.

Figure 17 shows the top view of the '32+32 staggered' annular blister pack.

The figures only represent embodiments of the present invention. The embodiments are meant only for the purpose of illustration of the present invention. Different parts of the dry powder inhaler of these embodiments are labeled in figures 1 to 17 and the labeling is described herein below.

Figure 1

- 1: annular blister pack
- 2: numerical on blister pack
- 3: circular holes in annular blister pack for alignment pin
- 4: rectangular holes in annular blister pack for alignment pin
- 5: notch in blister pack for the slider lock pin
- 6: first ring of plurality of blister medicament units on annular blister pack
- 7: second ring of plurality of blister medicament units on annular blister pack

Figure 2

- 8: mouthpiece cap
- 9: top cover

- 10: bottom unit
- 11: rotatable support for receiving the annular blister pack
- 12: anticlockwise direction of movement of rotatable support
- 13: air inlet hole
- 5 14: cut in top cover for cantilevered movement of the puncture pin
- 15: movable slider puncture pin assembly
- 16: counter window to show number of medicament unit being consumed
- 17: unidirectional movement of slider puncture pin assembly
- 18: position of slider puncture pin assembly to puncture blister medicament units in first ring of
- 10 annular blister pack
- 19: position of slider puncture pin assembly to puncture blister medicament units in second ring of annular blister pack

Figure 3

- 1: annular blister pack
- 15 3: circular holes in annular blister pack for alignment pin
- 4: rectangular holes in annular blister pack for alignment pin
- 8: mouthpiece cap
- 9: top cover
- 10: bottom unit
- 20 11: rotatable support for receiving the annular blister pack
- 13: air inlet hole
- 15: movable slider puncture pin assembly
- 20: slot in top cover for movement of slider puncture pin assembly
- 21: mouthpiece
- 25 22: medicament hole for medicament unit in first ring of annular blister pack
- 23: medicament hole for medicament unit in second ring of annular blister pack
- 24: ratchet on bottom unit for unidirectional rotation of rotatable support
- 25: circular alignment pins on rotatable support for fitting into annular blister pack
- 26: rectangular alignment pins on rotatable support for fitting into annular blister pack

30 **Figure 4**

- 13: air inlet hole
- 15: movable slider puncture pin assembly
- 22: medicament hole for medicament unit in first ring of annular blister pack
- 23: medicament hole for medicament unit in second ring of annular blister pack

27: passageway connecting the air inlet hole to air outlet hole in the mouthpiece

28: air flow to the mouthpiece through the passageway

29: medicament falling into the passageway

30: unidirectional movement of slider puncture pin assembly

5 31: puncture pin

32: slider lock pin

Figure 6

14: cut in top cover for cantilevered movement of the puncture pin

15: movable slider puncture pin assembly

10 31: puncture pin

32: slider lock pin

33: position of slider puncture pin assembly to puncture blister medicament units in first ring of annular blister pack

34: non-return position of slider puncture pin assembly to puncture blister medicament units in

15 second ring of annular blister pack

35: position marking on slider

36: medicament falling into passageway from the first ring of annular blister pack

37: medicament falling into passageway from the second ring of annular blister pack

Figure 7

20 1: annular blister pack

3: circular holes in annular blister pack for alignment pin

4: rectangular holes in annular blister pack for alignment pin

5: notch in blister pack for the slider lock pin

15: movable slider puncture pin assembly

25 16: counter window to show number of medicament unit being consumed

32: slider lock pin

33: position of slider puncture pin assembly to puncture blister medicament units in first ring of annular blister pack

34: non-return position of slider puncture pin assembly to puncture blister medicament units in

30 second ring of annular blister pack

38: direction of indexing of annular blister pack

39: numbered medicament units on the annular blister pack

Figure 8

31: puncture pin

- 32: slider lock pin
- 35: position marking on slider
- 40: ratchet lever in slider puncture pin assembly for non-return movement
- 41: cover for slider puncture pin assembly movement slot in top cover

5 **Figure 9**

- 9: top cover
- 14: cut in top cover for cantilevered movement of the puncture pin
- 33: position of slider puncture pin assembly to puncture blister medicament units in first ring of annular blister pack
- 10 34: non-return position of slider puncture pin assembly to puncture blister medicament units in second ring of annular blister pack
- 42: non-return ratchet lock for slider puncture pin assembly in top cover

Figure 10

- 10: bottom unit
- 15 11: rotatable support for receiving the annular blister pack
- 12: anticlockwise direction of movement of rotatable support
- 13: air inlet hole
- 24: ratchet on bottom unit for unidirectional rotation of rotatable support
- 43: ratchet lever in rotatable support
- 20 44: cavity in the rotatable support for the ratchet lever

Figure 12

- 45: stopper ring in the rotatable support to prevent movement of slider puncture pin assembly from the first ring to second ring of annular blister pack
- 46: removable cover over the passageway connecting the air inlet hole to air outlet hole in the
- 25 mouthpiece
- 47: interlock on the bottom unit to prevent movement of the rotatable support when the blister medicament unit ready for puncturing, has not been punctured

Figure 13

- 48: scored formation of spiral design on the passageway connecting the air inlet hole to air outlet
- 30 hole in the mouthpiece

In an embodiment of the present invention, there is provided a dry powder inhaler, the compact view of which is illustrated in Figures 2A, 2B and 3. The dry powder inhaler for administering medicaments in solid finely divided form to patients comprises principal parts viz., a bottom unit

(10) with a mouthpiece (21), rotatable support (11) for the blister pack, an annular blister pack (01) designed to accommodate a plurality of blister medicament units, top cover (09) comprising a movable slider puncture pin assembly or slider (15) with a puncture pin or plunger (31) to penetrate a blister medicament unit registered therewith, referred to as slider puncture pin assembly or slider herein and illustrated in Figures 4A, 6B, 8 and 9. The slider puncture pin assembly is provided with means comprising a slider lock pin (32), a puncture pin (31) and an optional ratchet lever (40).

The annular blister pack (01) has a plurality of blister medicament units containing the specified amount of a medicament. A plurality of blister medicament units are arranged in two concentric rings around the blister pack. Different numbers of blister medicament units, different configurations of the two rings of the blister pack and different diameter of the blister pack are possible as described herein. The Figures 1A to 1F give an annular blister pack used in a preferred embodiment of the invention, wherein the annular ring blister pack holds 30+30 medicament units in the first and second concentric rings where the medicament units in the first and second ring are in an in-line arrangement as shown in the Figures.

In an embodiment, the first ring (06) and the second ring (07) each contain 30 blister medicament units in-line with each other and the outer diameter of the blister pack is 67.5 mm. Each blister on the blister pack is numbered (02) to indicate the number of the medicament being consumed. The medicament number on the blister pack or a suitable visible element of the blister pack or the rotatable support may be colored red in the region from blister medicament units 50 to 60 in order to give an indication to the patient that only the last ten doses are remaining in the blister pack. There are also provided circular and rectangular holes in the blister pack (03 and 04 respectively) to associate with the alignment pins of the rotatable support in order to give a precise alignment of the blister pack with the rotatable support, preventing any undesirable movement of the blister during dispensing of the medicament and enabling the blister to be punctured in the center giving reproducible dosing. There is provided a notch (05) in the blister pack into which the slider lock pin (32) fits to facilitate the smooth changing over of the puncture pin from the first concentric ring to the second concentric ring of the blister pack when medicament units in the first concentric ring are exhausted, as described herein below.

The movable slider puncture pin assembly is positioned in a first position (see Figures 6A, 6B, 7A and 9A) to register the puncture pin with blister medicament units in first concentric ring for

rupturing successively the medicament units, prevented by the slider lock pin (32) abutting the annular blister pack, from moving from the first position (see Figure 7A) until blister medicament units in first concentric ring are exhausted, thereafter, positioned in a second position when the slider lock pin (32) moves inwards and upwards on an inclined plane on the top cover to be engaged with the notch (05) in the blister pack (see Figures 7C & 7D), to register the puncture pin with blister medicament units in second concentric ring and rupturing successively the medicament units (see Figures 6C, 6D, 7E and 9B). The slider lock pin assembly is prevented from moving from the second position by means of ratchet lever (40) until blister medicament units in second concentric ring are exhausted (see Figures 8A and 9B). It is to be noted that the ratchet lever means is optional and may not be necessary in all designs. In embodiments where the inhaler has a robust design, the ratchet lever is not essential. In such embodiments the slider puncture pin assembly registered with the blister medicament units in the second ring of the annular blister pack cannot be easily moved back to the first ring of the blister pack due to lesser degree of freedom of movement of the slider puncture pin assembly due to such a design of the slider puncture pin assembly as well as due to the operational friction forces.

In a preferred embodiment the first concentric ring is the outer ring and the second concentric ring is the inner ring of the blister pack. The terms outer and inner refer to direction when moving from the boundary to the center, of the blister pack.

Figure 7A illustrates the direction of indexing (38) for blister pack having numbered blister medicament units (39). The bottom unit (10) comprises a mouthpiece (21) and a mouthpiece cap (08). The rotatable support (11) is mounted on the tray of the bottom unit, which comprises an air inlet hole (13) and a ratchet (24) (see Figures 3, 10A and 10C) for the unidirectional rotation of the mounted blister pack support. The bottom unit also contains the medicament hole (22 and 23) through which medicament from the ruptured blister medicament unit in the first ring or second ring in the blister pack empties into the passageway connecting the air inlet hole to the air outlet hole in the mouthpiece. When not in use, the mouthpiece is covered by the mouthpiece cap.

As illustrated in Figures 4A to 4C, the air inlet hole is connected to a passageway (27) and the air flow (28) generated by the inhalation by the patient carries the medicament (29) via the air outlet means in the mouthpiece into the respiratory tract of the patient. In the illustrated embodiment, the angle of the air inlet hole passage may be from 45° to 135°. It is preferred that the angle is greater than 90°. Angle used in the more preferred embodiment is 106.5°. In the above

embodiment of the present invention, the blister medicament units are located between the air inlet hole and the mouthpiece. In alternate embodiments, the air inlet hole(s) are located between the two rings of the blister medicament units or between the blister medicament unit and the mouthpiece opening or outlet. The wall of the passageway leading into the air outlet hole can have various configurations of the scored formations of the turbulence elements. The scored formation acts to add turbulence to the medicament entrained in the air stream. The formation may be in the form of protrusions or projections of various shapes, for example, spiral, single or multiple ribs, linear, helical, circular, cone, wedge, rectangular and the like. The formation can also be in the form of depressions or dimples of various shapes, for example, spiral, linear, helical, circular, cone, wedge, rectangular and the like. Figures 5A to 5D show different configurations of the scored formations of the turbulence elements on the wall of the passageway connecting the air inlet hole to the air outlet hole on the mouthpiece.

The rotatable support (11) comprises a plurality of circular holes or depressions along the circumference of the disk arranged in two concentric rings, corresponding to the blister medicament units of the blister pack in order to receive the blister medicament units of the annular blister pack. The rotatable support may have elevations/projections called as alignment pins, which can fit into the corresponding holes in the blister pack such that the blister pack gets aligned with the rotatable support in precise manner and register the blister precisely with the puncture pin. The alignment pins may be circular (25) or rectangular (26) in shape. The rotatable support is provided with a means for unidirectional movement, which comprises a ratchet lever (43) for associating with the ratchet (24) of the bottom unit as can be seen from Figures 10A to 10C. Cavity (44) in the rotatable support allows ratchet lever (43) to flex outwards to enable unlocking from ratchet (24) upon rotation and then flex back into the next available ratchet (24) for locking into the next position. The proper registering of the ratchet lever of the support with ratchet (24) of the bottom unit allows locking of the rotatable support into its position and the shape of the ratchet and the ratchet lever allows only unidirectional movement of the support in the anti clockwise direction. Hence the direction for movement of the rotatable support is in anti clockwise direction (12), as can be seen from Figures 2A and 10A. When the patient moves the rotatable support in the direction of the indexing, a click sound indicates that the next blister of the blister pack is in proper registration with the puncture pin. Alternatively a spring mechanism can be used for the rotational movement of the rotatable support.

On the top of the blister pack is the top cover (09). As can be seen from Figure 2A and 6A, there is provided a numerical indexing means in the form of a counter window (16) in the top cover to show the numerical on the annular blister pack in order to see the number of the medicament unit being consumed. There is also a cut (14) in the top cover for the cantilevered movement of the
5 puncture pin. The counter window is attached to the slider puncture assembly as shown in Figures 8 and 9. The movement of the counter window along with the slider assembly can be seen in figure 7. In Figure 7A, the counter window shows the number one when the puncture pin assembly is registered with the first blister of the first ring of the blister pack. Figures 7b and 7C show the advancement of the number in the counter window with advancement of the rotatable support. Figure 7D shows the counter window showing the number thirty-one corresponding to
10 the first blister medicament unit of the second ring of the blister pack. The counter window may show only the number of the blister medicament unit which is registered with the slider and puncture pin assembly or it may show the numbers of the blister medicament units in both the first and second ring of the blister pack with which the slider and puncture pin assembly is
15 registered with. The counter window and the numbering means are designed for the easy visibility to the patient of the number of the blister medicament unit on the blister pack being consumed. The further advancement of the counter window number along with the puncture pin assembly can be seen in Figure 7E. There is also provided a slider (15) having a position marker (35) on it, in order to shift the position of the puncture pin from the first ring of the blister pack to
20 the second ring. The slider can be moved in one direction (17) only and can be positioned such that the puncture pin is in a position (18) to puncture the first ring of the blister pack initially and later in a position (19) to puncture the second ring of the blister pack. There is a slot (20) in the top cover for the movement of the slider along with the puncture pin. As can be seen from figure 8A, the slider contains a slider lock pin (32), a ratchet lever (40) for non-return delivery and a
25 puncture pin (31) set at an angle so as to puncture the blister at the center and a cover (41) for the slot. As illustrated in Figure 4A, the slider is moved in unidirectional way (30) after 1 to 30 numbered blister medicament units in the first ring of the blister pack have been consumed to take it into a position to puncture 31 to 60 numbered blister medicament units in the second ring of the blister pack.

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Figures 6A and 6B illustrate the puncture pin slider assembly position (33) ready to puncture 1 to 30 numbered blister medicament units in the first ring of the blister pack, starting with blister medicament unit 1. After puncture of the blister unit, the medicament falls (36) into the passageway from the first ring of the blister pack. Figures 6C and 6D illustrate the puncture pin

slider assembly position (34) ready to puncture 31 to 60 numbered blister medicament units in the second ring of the blister pack, starting with blister medicament unit 31. Once the movable slider pin assembly is moved to the second ring position, it is in a non-return position (34) due to the locking of the ratchet lever (40) provided on the movable slider puncture pin assembly with a
5 ratchet lock (42) provided in the top cover of the dry powder inhaler as can be seen from Figure 9B. After puncture of the blister unit, the medicament falls (37) into the passageway from the second ring of the blister pack.

In operation, the patient loads the blister pack in the dry powder inhaler. The slider pin counter
10 window (16) will show the blister number 1 of the first ring to be in position with the puncture pin as illustrated in Figure 7A. He removes the mouth cap, holds the mouthpiece in his mouth, presses the cut in top cover (14) in order to depress the puncture pin and puncture the blister and inhales. The pressing of the top cover depresses the angled puncture pin in the blister so as to puncture the associated blister in the center of the bottom. This makes available the full dose of
15 the medicament in a reproducible manner in the passageway and passes into the mouthpiece of the dry powder inhaler. When the patient inhales, the air enters through the air inlet hole (13) and passes out through the mouthpiece having entrained medicament therein. In order to shift to the next blister, he moves the rotatable support (11) in an anti clock wise direction till a click sound is heard. This operation is continued till the 30th blister is reached and punctured. In this position the
20 slider lock pin (32) moves inwards and upwards along an inclined plane on the top cover and gets engaged with the notch (5) in the blister pack. In order to go to the second ring of blister medicament units, the patient has to slide the slider in the direction (30) permitted so that the slider lock pin moves inwards and upwards on an inclined plane along the notch. When this is done, the puncture pin is registered with the first medicament blister unit of the second ring of
25 blister medicament units of the annular blister pack and the ratchet lever (40) in the movable slider puncture pin assembly becomes firmly locked against the ratchet lock (42) in the top cover of the inhaler to prevent any further movement. Also the slider is now non retractable due to the locking of the ratchet lever and ratchet lock, so as to prevent any non-return movement of the slider back to the first ring. In alternate embodiments, where there is no ratchet lever, the slider
30 puncture pin assembly does not return to the first ring due to the less freedom of movement of the slider assembly unit as well as due to the frictional forces. The puncture pin can now be moved along the second ring of blister medicament units from the doses 31 to 60.

Figures 11, 12 and 13 illustrate a preferred embodiment of the dry powder inhaler of the present invention. In the inhaler of this embodiment, there is additionally present a stopper ring (45) in the rotatable support. This stopper ring acts as a means to prevent the slider puncture pin assembly from moving from the first ring of blister medicament units to the second ring of the blister medicament units on the blister pack till all the blister medicament units on the first ring of the blister pack are consumed. In addition to the stopper ring (45) present on the rotatable support as shown in figure 12A, there is also provided a projection on the slider puncture pin assembly which projects on to the rotatable support and just touches the stopper ring, when the slider puncture pin assembly is in the first ring of the annular blister pack (not shown). The slider puncture pin assembly can only be moved along the first ring to consume the blister medicament units along the first ring of the blister pack, but cannot be moved to the second ring as the projection provided on the slider puncture pin assembly is obstructed by the stopper ring. The movable slider puncture pin assembly can only be moved from the first ring of the blister medicament units to the second ring of the blister medicament units, when all the blister medicament units in the first ring are consumed, and the projection provided on the slider puncture pin assembly encounters a break provided in the stopper ring which coincides with the notch provided in the blister pack, so as to allow the projection provided on the movable slider pin assembly to move inwards and upwards on an inclined plane on the top cover, beyond the stopper ring while simultaneously the slider lock pin of the slider pin assembly also moves inwards and upwards on the inclined plane on the top cover to engage with the notch, so that the puncture pin is now registered with the first blister medicament unit of the second ring of the annular blister pack. Now, the projection of the slider puncture pin assembly, because of its peculiar seating along the inclined plane of the top cover, no longer obstructs the stopper ring and hence the rotatable support can be freely moved ahead to puncture and consume the blister medicament units along the second ring of the annular blister pack. There is also a removable cover (46) over the passageway connecting the air inlet hole to air outlet hole in the mouthpiece as can be seen in figure 12b. This cover can be removed for cleaning of the passageway and mouthpiece. A means is also provided on the bottom unit to prevent movement of the rotatable support when the blister medicament unit ready for puncturing, has not been punctured. The means provided is an interlock (47) which consists of three pins is provided on the bottom unit as shown in figures 12A and 12B. Two of the pins are seen in figure 12A. One pin (not shown) engages with the holes in the rotatable support from beneath. Another pin is activated by the serrations on the periphery of the rotatable support. The third pin is activated by the top cover

when the puncture pin assembly is pressed to consume a blister unit. When the blister unit is not yet punctured, a pin of the interlock engages with the rotatable support from beneath and prevents it from moving ahead. When the blister medicament unit is punctured, and the puncture pin assembly is pressed along with the top cover, the interlock is activated, by which the lower pin
5 releases itself from the rotatable support and now it can be moved ahead. While the rotatable support is being moved, the serration on the outer periphery of the rotatable support activates the lower pin, on account of which the rotatable support is again locked and is unable to move ahead. The inhaler of this embodiment has the preferred spiral configuration (48) of scored formation of the turbulence elements on the passageway connecting the air inlet hole to air outlet hole in the
10 mouthpiece as seen in figures 13A and 13B. In an alternate embodiment, a spring assembly is used in combination with the stopper ring and the projection provided on the slider puncture pin assembly which projects on to the rotatable support.

In a preferred embodiment, the blister pack has 30 blister medicament units in the first ring and
15 30 blister medicament units in the second ring of the annular blister pack, in line with each other (denoted as 30+30 inline) and the outer diameter of the blister pack is 67.5 mm. Different configurations of the two rings of the blister pack and different number of the blister medicament units on the blister pack are also possible and may be encompassed in the scope of the invention. The thirty blister medicament units in the first ring and thirty blister medicament units in the
20 second ring may be staggered or out of line with each other (denoted as 30+30 staggered). Some other configurations of the blister pack which may be used in the present invention include 16 blister medicament units in each of the first and second concentric rings of the blister pack which are either in line with each other (denoted as 16+16 inline) or which are staggered or not in line with each other (denoted as 16+16 staggered); or 32 blister medicament units in each of the first
25 and second concentric rings of the blister pack which are either in line with each other (denoted as 32+32 inline) or which are staggered or not in line with each other (denoted as 32+32 staggered). Figure 14 illustrates an embodiment of a blister pack having 16 blister medicament units in each of the first and second concentric rings of the blister pack, which are in line with each other. The various specifications of the dimensions are given in the figure. The Ø symbol
30 indicates the diameter in mm while the rest of the numbers are the lengths in mm. Thus the outer diameter of the blister pack is 60 mm and the inner diameter is 27 mm. The diameter of the blisters in the first ring and second ring are 5 mm each. Figure 15 illustrates another embodiment of a blister pack having 16 blister medicament units in each of the first and second concentric rings of the blister pack, which are staggered or out of line with each other. Figure 16 illustrates

another embodiment of a blister pack having 32 blister medicament units in each of the first and second concentric rings of the blister pack, which are in line with each other. Figure 17 illustrates yet another embodiment of a blister pack having 32 blister medicament units in each of the first and second concentric rings of the blister pack, which are staggered or out of line with each other.

5 In all the figures 14 to 17, the $\varnothing$ symbol indicates the diameter in mm while the rest of the numbers are the lengths in mm.

In one embodiment, the dry powder inhaler of the invention is disposable and has to be replaced with a new device when all the blister medicament units of the annular blister pack are exhausted.

10 In another embodiment, the dry powder inhaler of the invention is reusable and the exhausted annular blister pack with the two rings of blister medicament units can be replaced with a fresh annular blister pack with two rings of blister medicament units. In this embodiment, there is no ratchet lever in the slider puncture pin assembly for the non-retractable locking of the slider puncture pin assembly when it enters the second ring of the annular blister pack. When all the
15 blister medicament units in the second ring of the blister pack are consumed, the slider puncture pin assembly is pulled back to the outer first ring position in order to register with the first blister medicament unit of the first ring of the fresh annular blister pack.

In an embodiment of the invention, there is present an additional air inlet hole located on the
20 slider puncture pin assembly, leading into the punctured blister medicament unit. This hole is located around the puncture pin and leads into the punctured blister medicament unit and into the medicament hole. In an alternate embodiment, the main air inlet hole (13) located on the top cover is absent and only the air inlet hole on the slider puncture pin assembly is present. The air inlet hole on the slider puncture pin assembly serves to directly entrain the medicament still
25 remaining in the punctured blister medicament unit and making available more of the medicament to the patient.

In all the above embodiments, any one or all the components of the dry powder inhaler can be made photo luminescent to enable the patient to access the inhaler even in darkness. The various
30 components of the dry powder inhaler can be made transparent or translucent in order to make easy the visualization of the blister medicament units used or unused. Also a "soft feel" material can be incorporated in any of the components of the dry powder inhaler preferably the sides of the device where the patient grips the dry powder inhaler in order to administer a dose. The "soft feel" material used may be a TPE (Thermoplastic elastomer) with a shore hardness of about 30 to

about 50. Also as mentioned before, the medicament dose number on the blister pack of doses 50 to about 60 may be in red color to remind the patient of the near exhaustion of the doses in the blister pack. The annular blister pack used in the dry powder inhaler of the invention can be made of any suitable material known in the art. Typically the forming film of the blister may be made from polyvinyl chloride (PVC), polyvinylidene chloride (PVDC) coated PVC, PVC/chlorotrifluoroethylene (CTFE) films, polypropylene (PP), polystyrene (PS), oriented polyamide (OPA)/aluminum/PVC laminates and the like. Typically the lidding material used in the blister may be aluminum foil or its combination with paper and/or polyester (PET) and the like.

Several modifications of the invention can be envisaged without departing from the nature and the scope of the invention as described in the description herein above. For instance the dry powder inhaler can be made of inert metal or reinforced plastics and synthetic polymeric material. The mouthpiece of the dry powder inhaler may be made of any moldable or formed plastic and may be of a suitable size and shape. The dry powder inhaler may optionally have secondary air inlet holes located on the top or bottom or the sides of the mouthpiece in order to achieve an optimum balance of fine particle fraction of the medicament available to the patient and the resistance of the device, in order to be therapeutically effective as well as convenient for use to the patient.

Although the invention has been described in terms of particular embodiments and applications, one of ordinary skill in the art, in light of this teaching, can generate additional embodiments and modifications without departing from the spirit of or exceeding the scope of the claimed invention. It should be emphasized that the above-described embodiments of the present invention, particularly any "preferred" embodiments, are merely possible examples of the invention of implementations, merely set forth for a clear understanding of the principles of the invention. Accordingly, it is to be understood that the drawings and descriptions herein are proffered by way of example to facilitate comprehension of the invention and should not be construed to limit the scope thereof.

CLAIMS:

1. A dry powder inhaler for administering medicaments in solid finely divided form to patients, wherein the dry powder inhaler is in the form of a diskhaler comprising a disk shaped rotatable support and an annular blister pack containing atleast 30 blister medicament units.
- 5 2. A dry powder inhaler for administering medicaments in solid finely divided form to patients, comprising
 - a) a bottom unit,
 - b) a rotatable support provided on the bottom unit,
 - c) an annular blister pack mounted on the rotatable support wherein the annular blister pack
10 comprises a plurality of blister medicament units arranged in two concentric rings of blister medicament units,
 - d) a top cover comprising a movable slider puncture pin assembly, said movable slider puncture pin assembly comprising a puncture pin and means for,
 - (i) positioning the assembly in a first position to register the puncture pin with
15 blister medicament units in first concentric ring for rupturing successively the blister medicament units,
 - (ii) preventing the assembly from moving from the first position until blister medicament units in first concentric ring are exhausted,
 - (iii) thereafter, positioning the assembly in a second position to register the
20 puncture pin with blister medicament units in second concentric ring and rupturing successively the blister medicament units,
 - e) air inlet means through which air can enter the dry powder inhaler and air outlet means through which patient can inhale, whereby the medicament from a punctured blister medicament unit will be entrained in the air flow produced by the patient.
- 25 3. A dry powder inhaler as in claim 2, wherein there is provided a means for preventing the movable slider puncture pin assembly from moving from the second position until blister medicament units in second concentric ring are exhausted.
4. A dry powder inhaler as in claim 3, wherein the means for preventing the assembly from moving from the second position until blister medicament units in second concentric ring are exhausted is a
30 ratchet lever provided on the slider puncture pin assembly.
5. A dry powder inhaler as in claim 2, wherein there is provided a means for unidirectional movement of the rotatable support comprising a ratchet lever in the rotatable support and ratchet in the bottom unit.
6. A dry powder inhaler as in claim 2, wherein the rotatable support is provided with alignment pins,
35 to facilitate alignment of annular blister pack with the rotatable support.

7. A dry powder inhaler as in claim 6, wherein the annular blister pack is provided with holes to associate with the alignment pins of the rotatable support.
8. A dry powder inhaler as in claim 2, wherein the said means on the movable slider puncture pin assembly are as follows
- 5 (a) for positioning the assembly in a first position to register the puncture pin with blister medicament units in first concentric ring for rupturing successively the medicament units; and preventing the assembly from moving from the first position until blister medicament units in first concentric ring are exhausted, there is provided a slider lock pin abutting the annular blister pack,
- (b) for positioning the assembly in a second position to register the puncture pin with blister
10 medicament units in second concentric ring and rupturing successively the medicament units, there is provided a notch on the annular blister pack and an inclined plane on the top cover, so that the slider lock pin can move inwards and upwards on an inclined plane,
9. A dry powder inhaler as in claim 2, wherein for positioning the movable slider puncture pin assembly in a first position to register the puncture pin with blister medicament units in first
15 concentric ring for rupturing successively the medicament units; preventing the assembly from moving from the first position until blister medicament units in first concentric ring are exhausted, there is provided a projection on the slider puncture pin assembly which moves on an inclined plane along the top cover and a stopper ring on the rotatable support.
10. A dry powder inhaler as in claim 2, wherein the inhaler is provided with a means to prevent
20 movement of the rotatable support when the blister medicament unit ready for puncturing has not been punctured.
11. A dry powder inhaler as in claim 10, wherein the means to prevent movement of the rotatable support when the blister medicament unit ready for puncturing has not been punctured, comprises an interlock provided on the bottom unit of the dry powder inhaler.
- 25 12. A dry powder inhaler as in claim 2, wherein a numerical indexing means is provided by a counter window located on the top cover and numerical on the annular blister pack.
13. A dry powder inhaler as in claim 2, wherein the air inlet means is connected to the air outlet means by means of a passageway.
14. A dry powder inhaler as in claim 13, wherein the passageway has scored formations of turbulence
30 elements on its walls.
15. A dry powder inhaler as in claim 14, wherein the scored formations on the walls of the passageway has a spiral configuration.
16. A dry powder inhaler as in claim 2, wherein there is an air inlet hole located on the slider puncture pin assembly, leading into the punctured blister medicament unit.

35

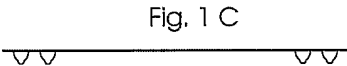
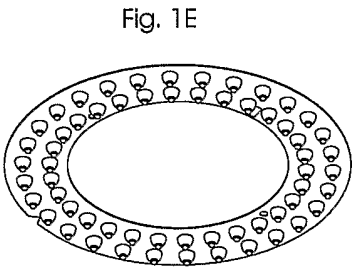
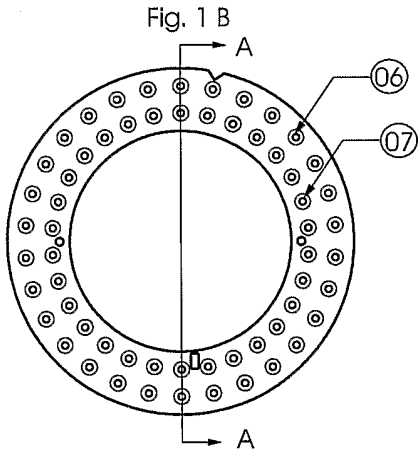
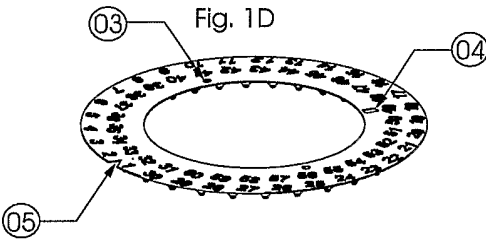
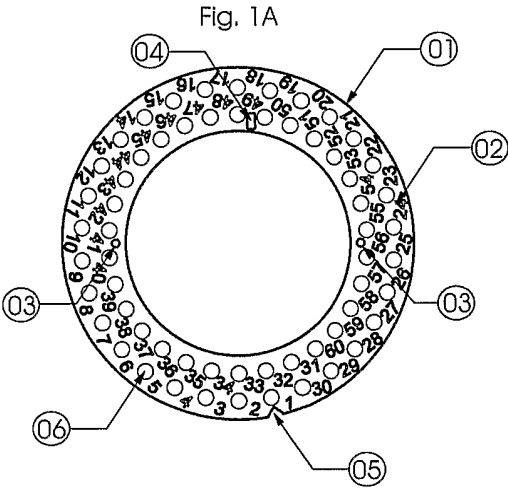


Fig. 2A

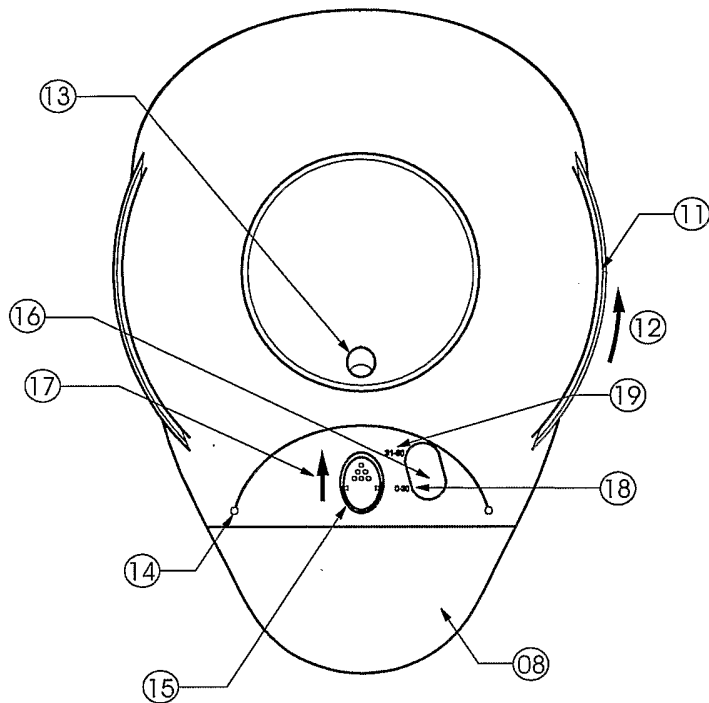


Fig. 2B

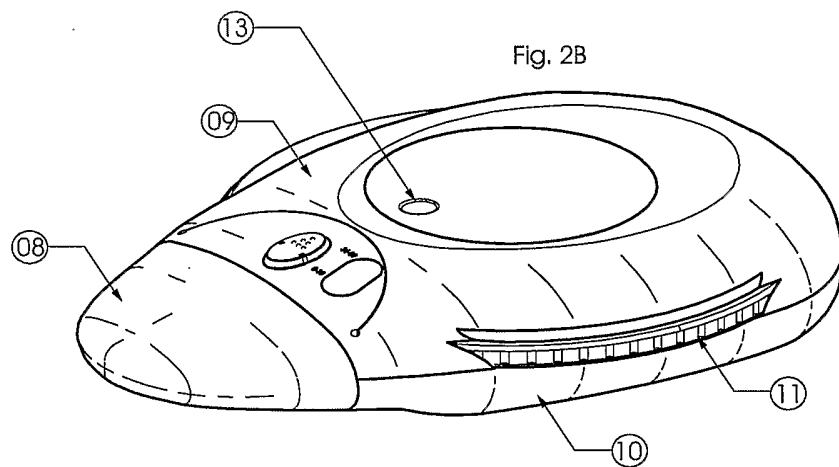
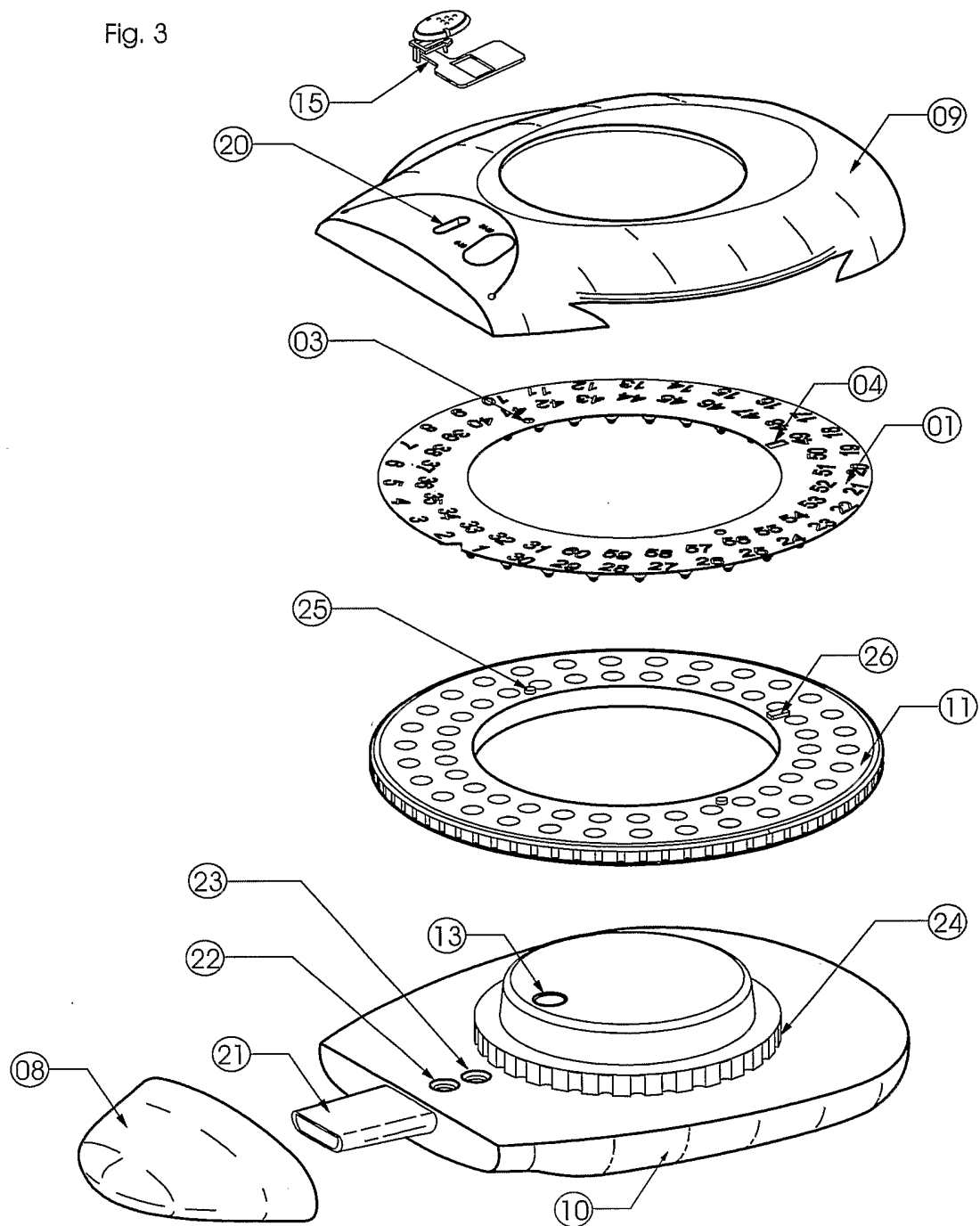


Fig. 3



Slider is moved ahead after 30 medicament units from the outer ring of the blister pack have been punctured in order to puncture units from 31 to 60 in the inner ring.

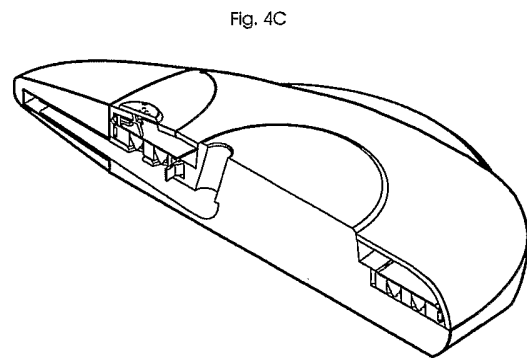
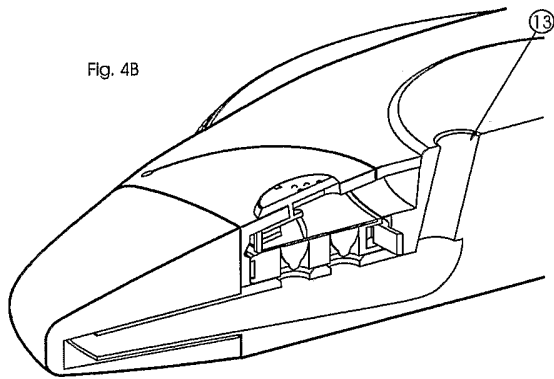
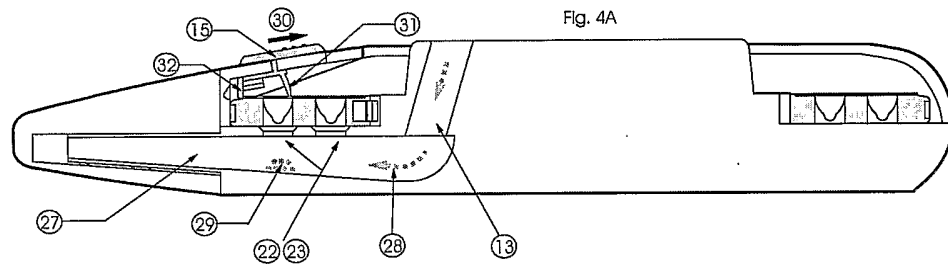


Fig. 5A

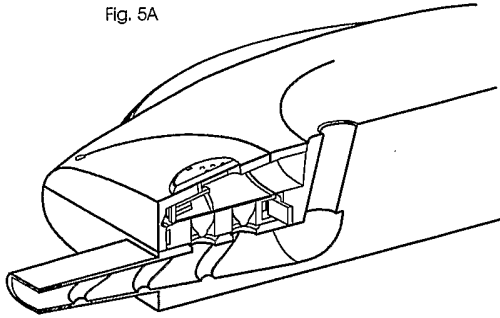


Fig. 5C

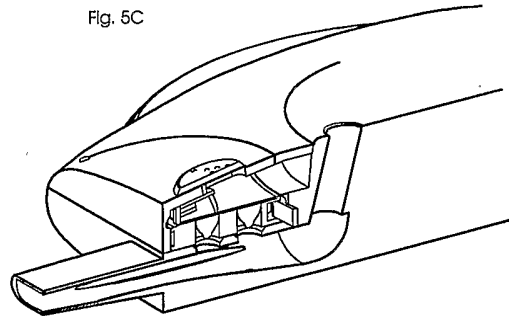


Fig. 5B

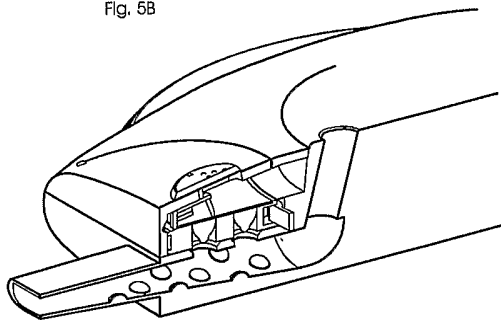


Fig. 5D

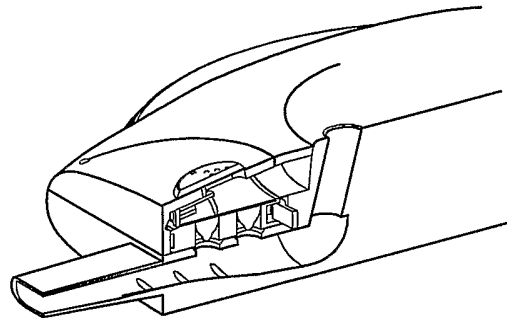


Fig. 6A

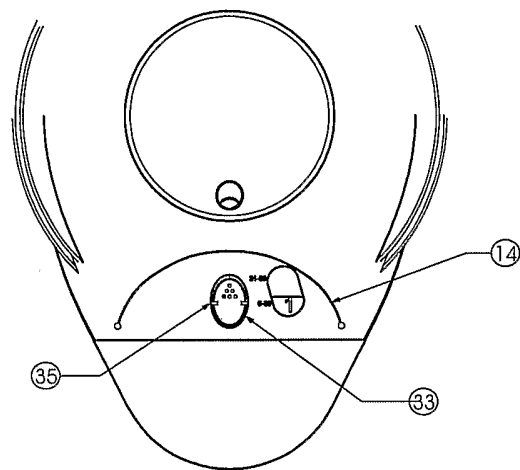


Fig. 6C

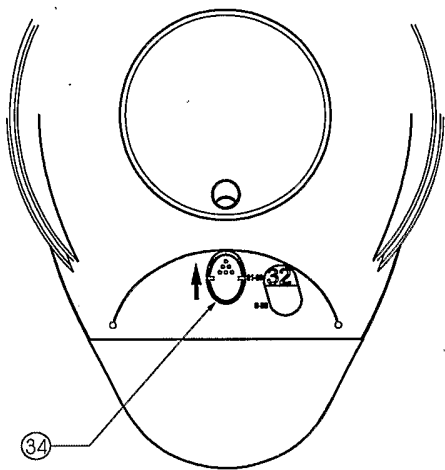


Fig. 6B

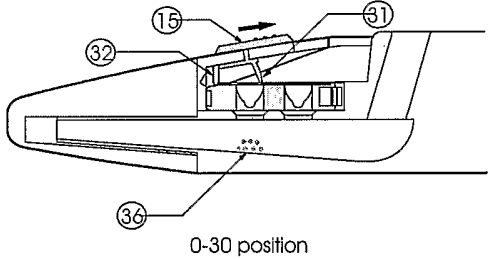
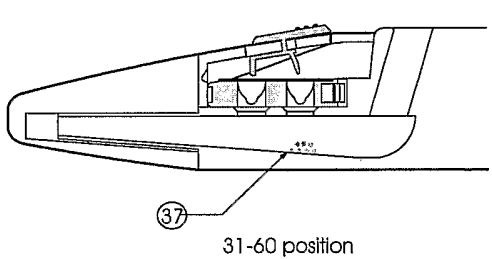
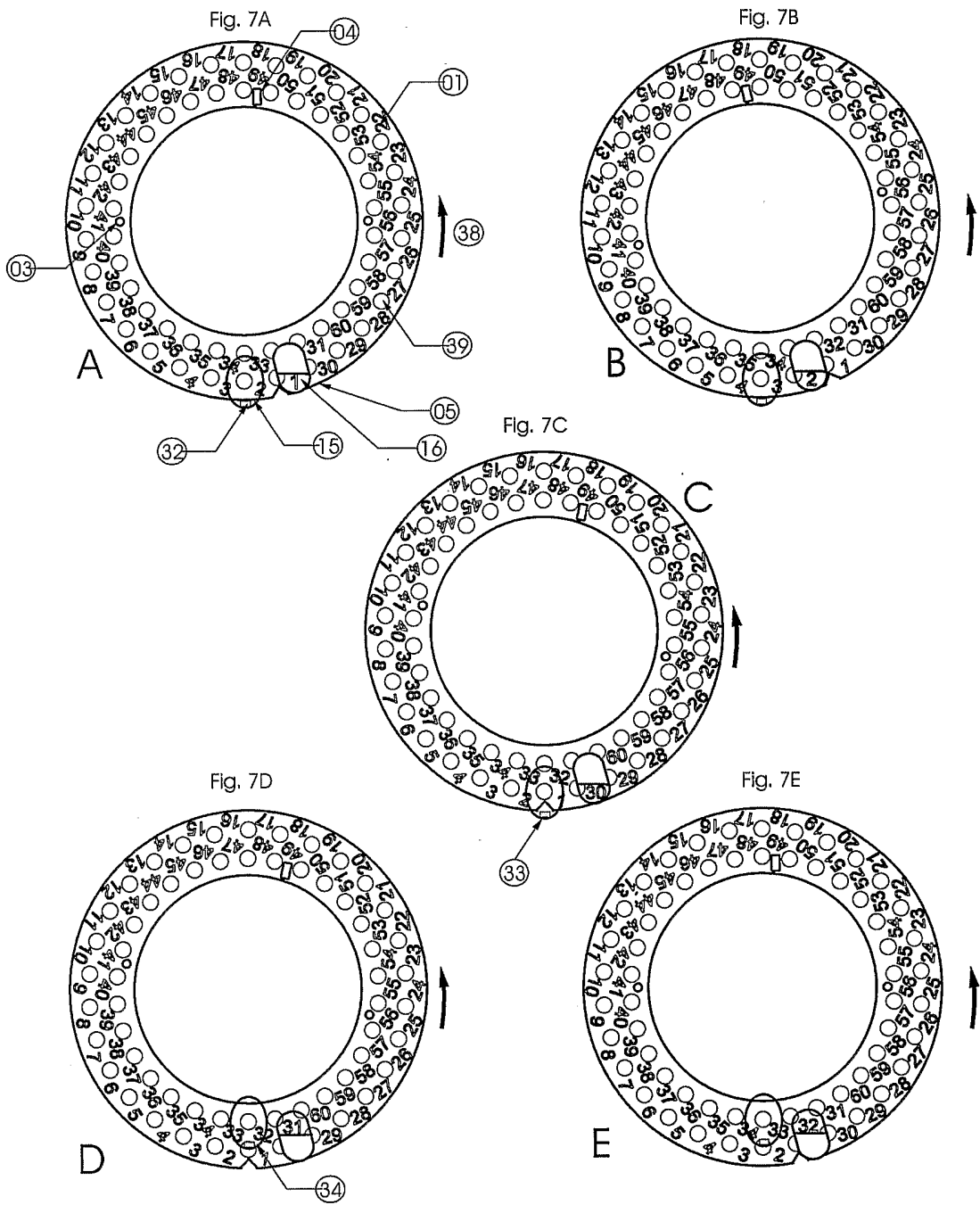
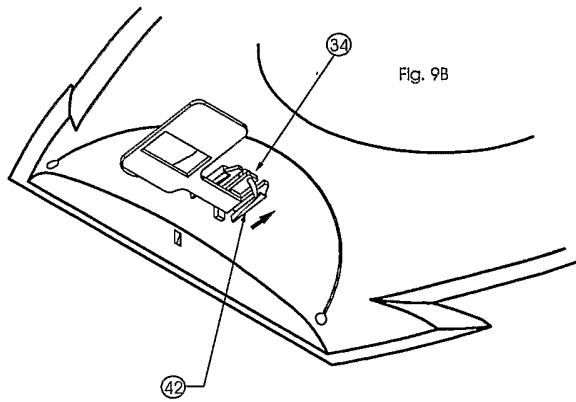
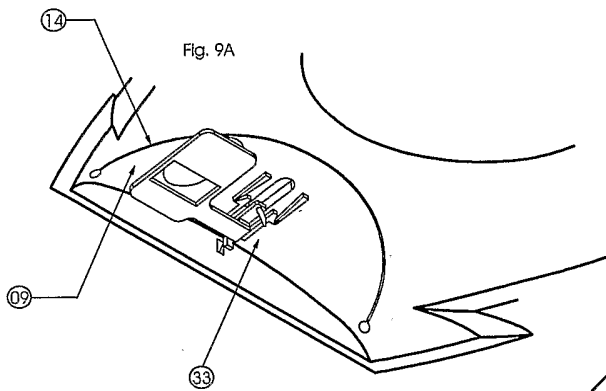
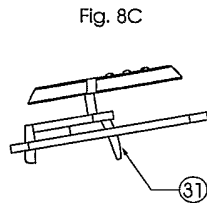
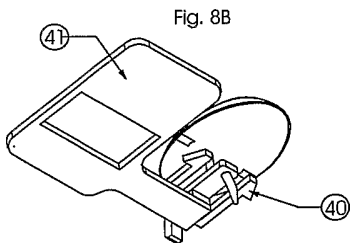
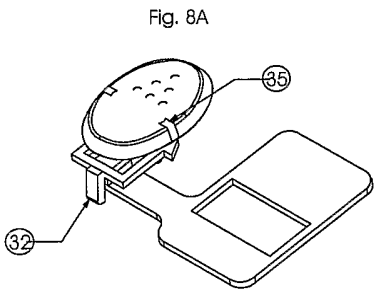
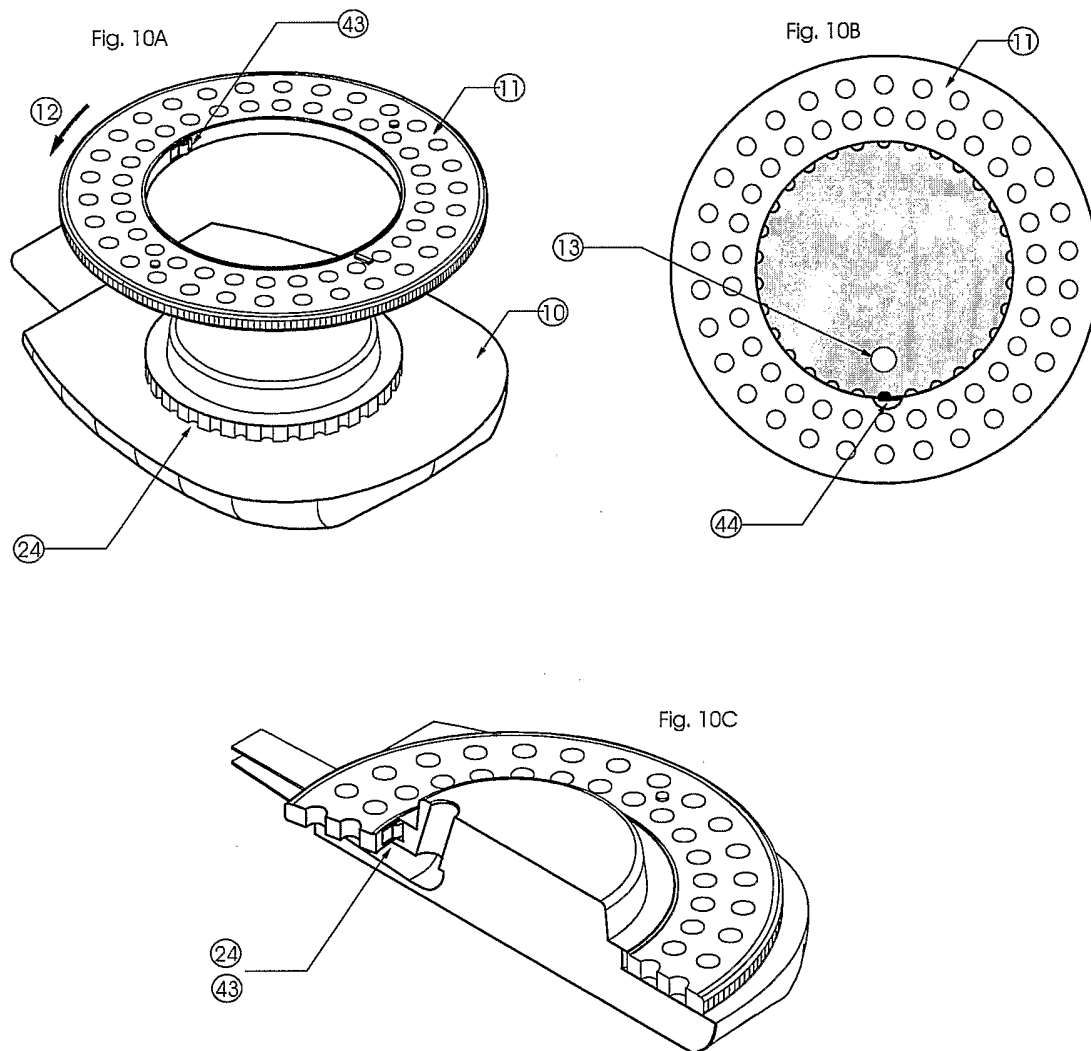


Fig. 6D









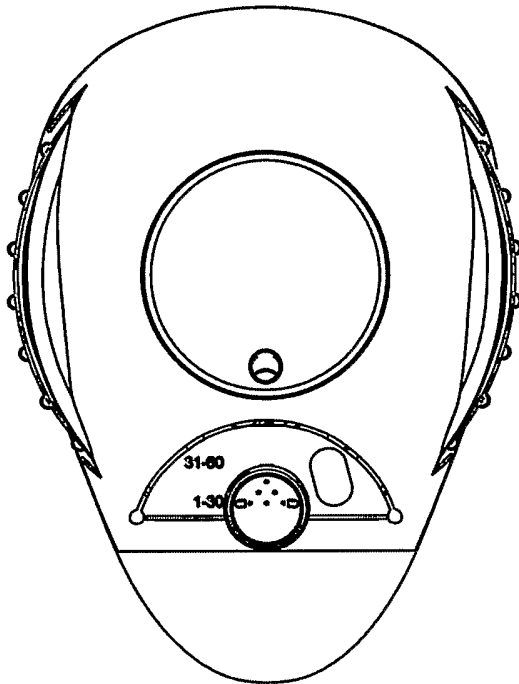


Fig. 11A

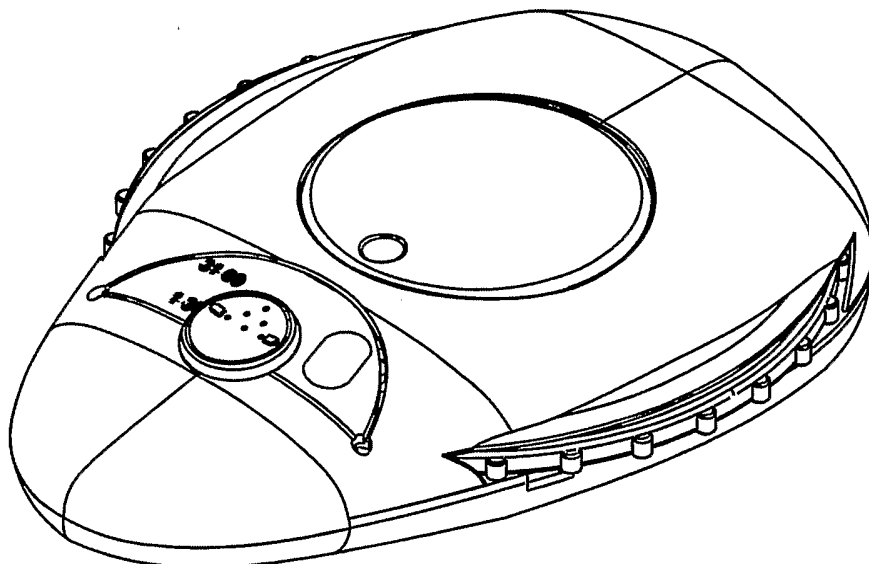


Fig. 11B

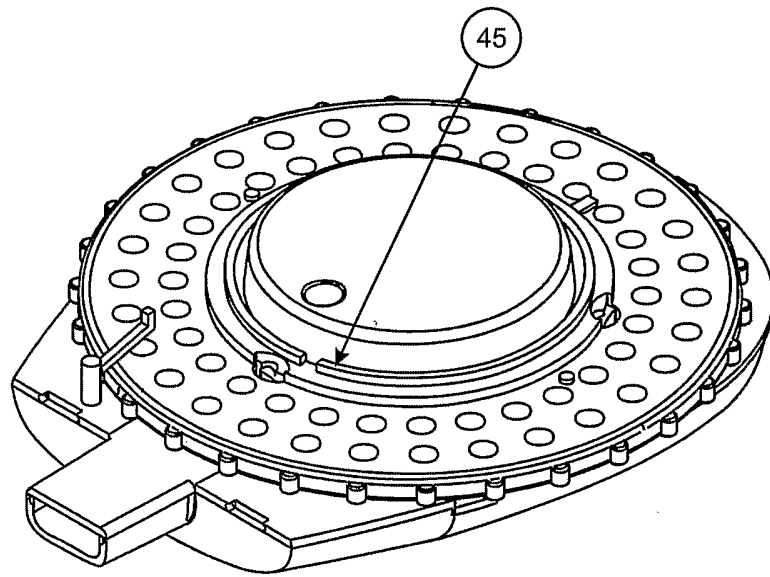


Fig. 12A

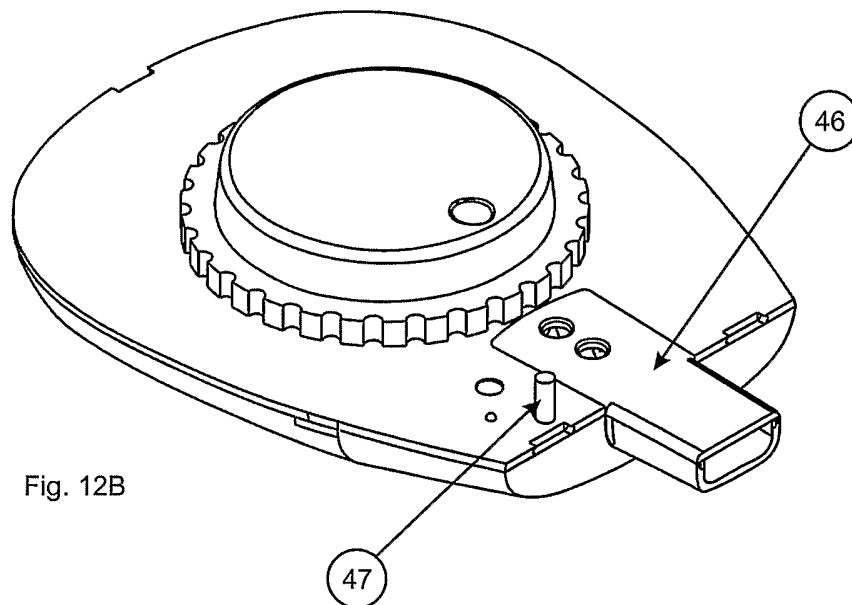
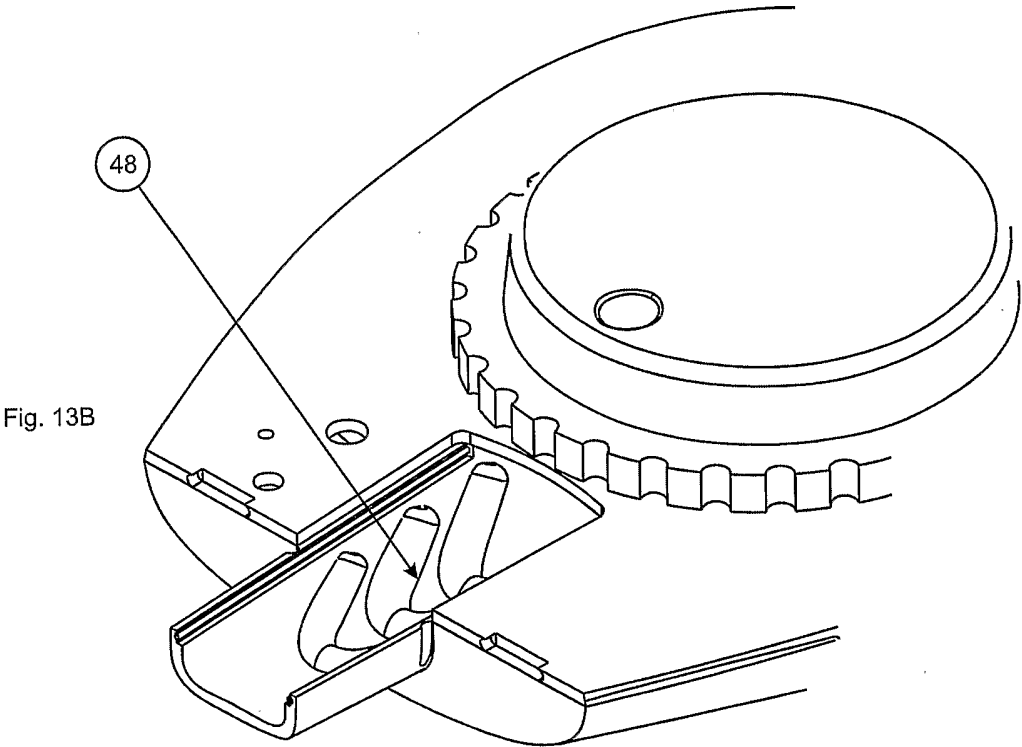
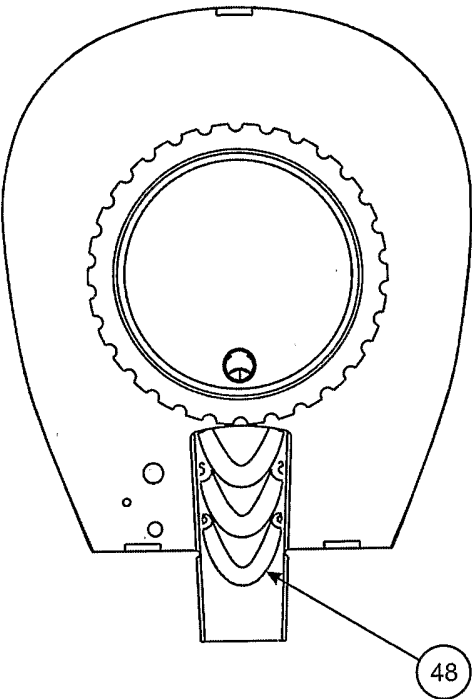


Fig. 12B



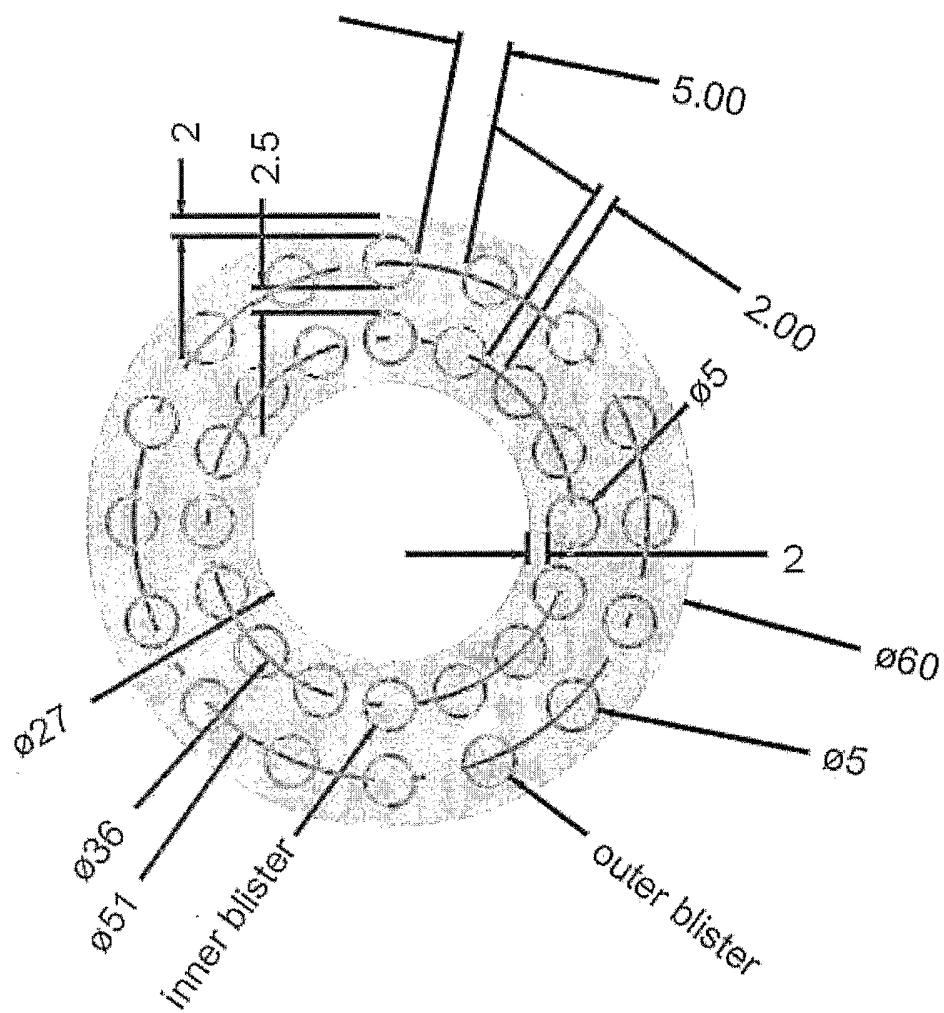


Fig. 14

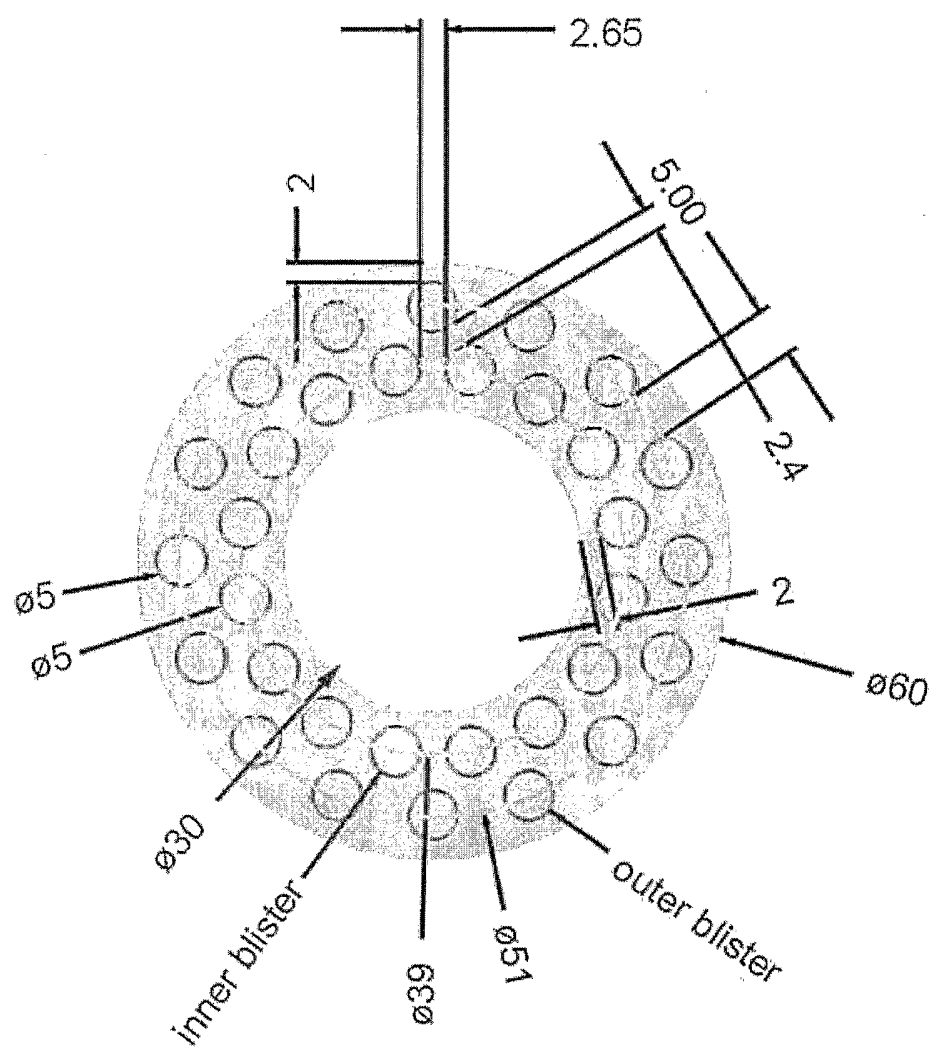


Fig. 15

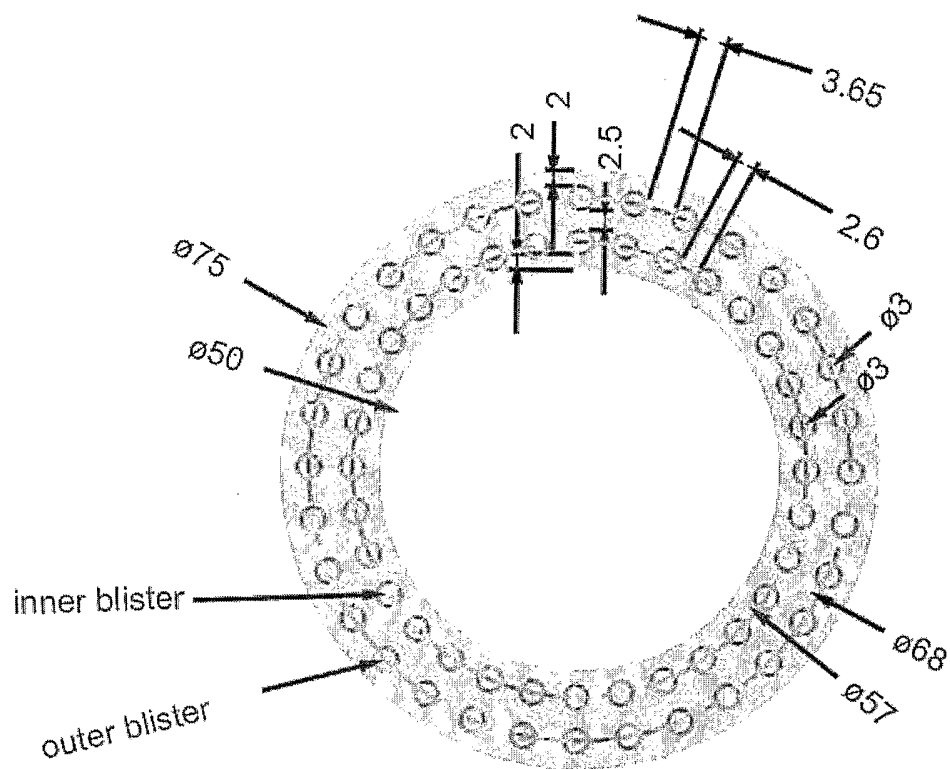


Fig. 16

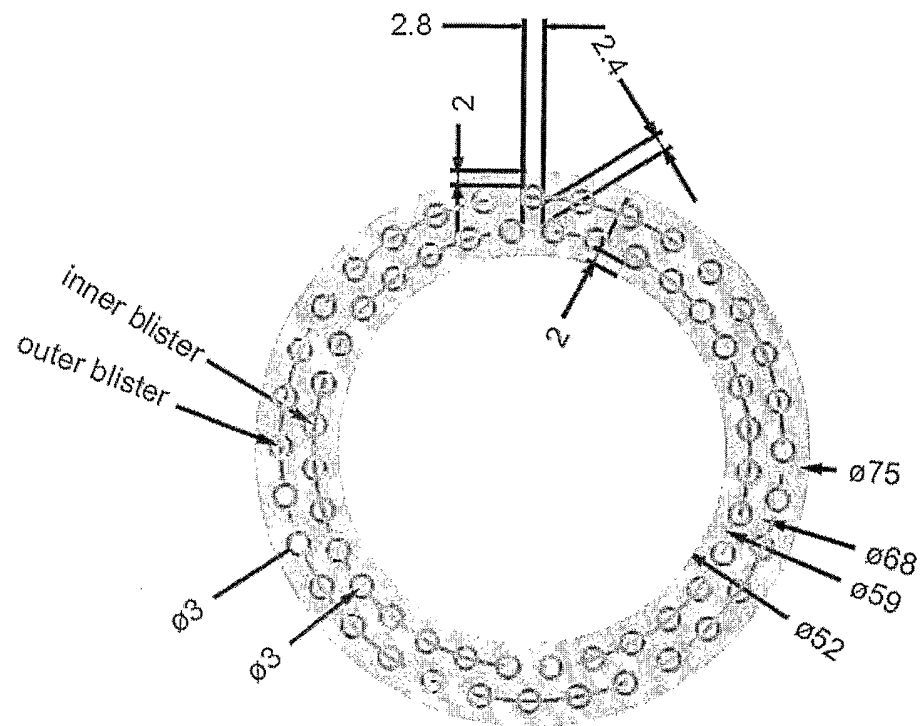


Fig. 17