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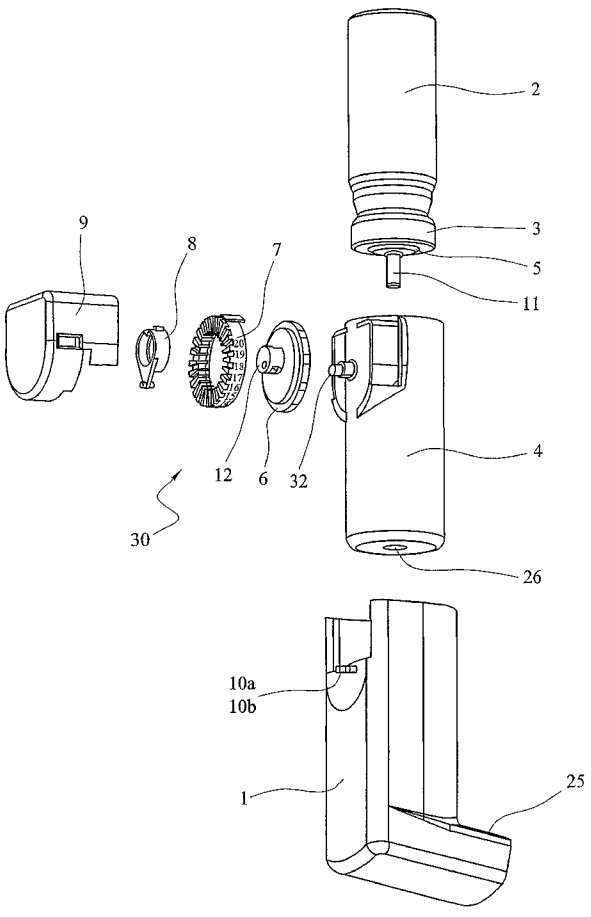

(57) Abstract: A dose counter (30) for a medicament delivery device comprises a rotatable indicator dial (7), and an index mechanism for incrementally rotating the indicator dial (7) when the medicament is dispensed. The index mechanism comprises an index element (8, 13) that selectively engages the indicator dial (7) to incrementally rotate the indicator dial (7), and further comprises a locking element (19, 14) that is moveable from a first position in which it locks rotation of the indicator dial (7) to a second unlocked position in which it allows rotation of the indicator dial (7) when the index element (8) engages the indicator dial (7). The dose counter (30) is preferably of an odometer type and comprises a further indicator dial (6) that rotate the other indicator dial (7) once a predetermined number of doses have been dispensed. In other aspects, the dose counter (30) includes a blanking element (23) to blank the indicator dial (6, 7) and/or a viewing window (24) when all of the doses have been dispensed. Yet another aspects relates to the use of a modified escapement mechanism (17, 10a, 10b) to convert the linear actuation of the device in rotary motion fo the dose counter dial (6).

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DOSE COUNTER WITH AN ODOMETER TYPE DISPLAY

This invention relates to counting the number of doses delivered or remaining in a medicament dispensing device, and in particular in a dry powder or "pressurised metered dose" inhaler devices. More specifically it relates to a dose counter for such a medicament dispensing device which incorporates, in particular, an odometer type display to indicate the doses used and/or remaining.

Inhaler devices are traditionally used to treat pulmonary diseases and have recently been used to deliver other drugs such as insulin. Users of inhaler devices which do not include a means to count and indicate the number of doses used or remaining find it hard to know when their medication may run out, and hence when to replace the inhaler or drug canister.

The FDA (Food and Drug Administration) in the USA issued guidelines ("Integration of Dose-Counting Mechanisms into MDI Drug Products" March 2003) which say that new applications should include a dose counter.

A number of devices with dose counters are therefore appearing on the market. Many of these dose counters however comprise complex mechanisms requiring high accuracy in manufacture and assembly. Indeed it has in fact proven difficult to convert the intermittent motion in the inhaler device which delivers the drug into a suitable motion to drive and increment a counter and dose display.

In addition, and in relation to an odometer type displays which may be preferred to provide a clearer numeric indication of the number of doses, it has also proven

difficult to provide a simple means to accurately and robustly index the odometer dials.

It is also not generally desirable to use electronic counters or displays in such devices, and a simple mechanical arrangement is therefore preferred.

Such a mechanical arrangement, and indeed the dose counter must also not unduly interfere with the operation of the inhaler or other medicament dispensing device. In a number of existing dose counter mechanisms further operation of the inhaler once the specified number of doses have been dispensed is indeed prevented. The inhaler may however still have some remaining medicament, which could be still be used in particular in a emergency, although of course these doses may not be counted.

An example of a prior dose counter arrangement is described in WO 2006/004497. The described dose counter arrangement of WO 2006/004497 includes a pointer gauge type display which rotates to indicate the number of dose remaining or used. This document does not however describe how the pointer is incrementally moved.

EP1237603 and EP 1119383 describe further dose counter arrangements with pointer or indicator dials. These arrangements include rachet mechanisms to increment the pointer or indicator dials. These ratchet mechanisms are however relatively complex, and difficult to assemble, and can generally be improved. Such pointer or indicator dial arrangements may also be unsuitable, and in some cases do not clearly and unambiguously indicate the specific number of doses dispensed or remaining.

WO 01/31578 describes a slightly different dose counter which uses multiple concentrically arranged numbered display dials which are used together to indicate the number of doses used or remaining, with one dial indicating the 'units' and the other indicator the 'tens' such that in combination the number of doses is displayed. The display wheels are incremented by a ratchet drive. Such a display provided by this counter is referred to as an odometer type display since it is similar to a vehicle odometer display. This arrangement is however not without its shortcomings and can be improved. In particular it relies on resilient flexible ratchet which may break, fail to flex and/or otherwise adversely affect operation as well as being difficult to reliably manufacture.

It is therefore desirable to provide an improved dose counter which addresses the above described problems and/or which more generally offers improvements or an alternative to existing arrangements.

In particular an object of this invention is to provide a simple and robust mechanical means to accurately count the doses used and provide indication of doses used or remaining to the user.

More specifically, and in the case of a odometer type display it is an object of an aspect of the invention to provide a robust index and lock mechanism to increment the successive display dials.

Another desirable object of an aspect of the invention is to provide a simple and robust means to convert the reciprocal motion of the actuation of an inhaler into suitable incremental rotary motion of a dose counter

mechanism.

Yet another desirable object of an aspect of the invention is to provide a dose counter arrangement that allows continued operation, if required, while also indicating that a prescribed number of doses have been dispensed.

According to the present invention there is therefore provided a dose counter, and a medicament delivery device including a dose counter, as described in the accompanying claims.

In particular in an embodiment of one aspect of the invention there is provided a dose counter for a medicament delivery device comprising a rotatable indicator dial, and an index mechanism for incrementally rotating the indicator dial when, in use, the medicament is dispensed. The index mechanism comprises an index element that selectively engages the indicator dial to incrementally rotate the indicator dial. The index mechanism also further comprises a locking element that is moveable from a first position in which it locks rotation of the indicator dial to a second unlocked position in which it allows rotation of the indicator dial when the index element engages the indicator dial.

Such an arrangement provides for robust and accurate rotation of the indicator dial to indicate the number of doses whilst prevent accidental rotation and so reducing erroneous indications.

The locking element preferably comprises a locking pin that is selectively engaged within a locking groove. The locking groove preferably comprises a substantially radially

extending groove in the indicator dial, and the locking pin is rotationally fixed and selectively radially moveable relative to the indicator dial.

A plurality of drive elements may be located around the indicator dial and the index mechanism may comprises an indexer mounted on a eccentric to, in use rotate eccentrically relative to the indicator dial, with the indexer having a drive element which is arranged to selectively engage the drive elements of the indicator dial when the indexer eccentrically rotates to an engagement position to incrementally rotate the indicator dial. The locking element may then be located on the indexer and selectively engage the indicator dial to prevent rotation as the indexer is eccentrically rotated, and selectively disengage the indicator dial when the indexer eccentrically rotates to the engagement position to allow the indicator dial to incrementally rotate the indicator dial.

The indexer may further comprise a second locking element that engages a body portion of the dose counter to constrain rotational movement of the indexer and indicator dial.

The indicator dial is preferably annular and the drive elements are defined in a inner annular periphery of the indicator dial. The indexer and eccentric are then mounted within the annular indicator dial such that the indexer eccentrically rotates within the indicator dial to selectively engage the drive elements.

Preferably the indicator dial comprises a second indicator dial, and the dose counter further comprises a first indicator dial rotatably mounted coaxially with the second

indicator dial and which incrementally rotates when, in use, the medicament is dispensed, and which drives the index mechanism to incrementally rotate the second indicator dial when, in use, a predetermined number of doses of the medicament have been dispensed. This may be achieved by mounting the eccentric on the first indicator dial to eccentrically rotate the indexer.

First and second drive lugs may be provided with the first indicator dial then having a corresponding plurality of spaced drive elements around the first indicator dial. The first indicator dial and drive lugs are then mounted such that an actuator, in use, when the medicament is dispensed, reciprocally translates the first indicator dial relative to the drive lugs causing the first drive lug to selectively engage one of the drive elements and rotate the indicator dial when the first indicator dial is translated in a first direction, and then causes the second drive lug to selectively engage a drive element, which may be one of the other drive elements, and rotate the indicator dial in the same direction when the indicator dial is translated in a second return direction to thereby incrementally rotate the first indicator dial when, in use, the medicament is dispensed.

Preferably the dose counter further comprises a viewing window to view the indicator dial, and a blanking element that is adapted to cover at least a portion of the indicator dial or window when the indicator dial, in use, is rotated to a zero position.

In particular in an embodiment of another aspect of the invention there is provided a dose counter for a medicament delivery device comprising a rotatable indicator dial which

incrementally rotates when, in use, the medicament is dispensed, to indicate a number of doses, and viewing window to view the indicator dial. The device further comprises a blanking element that is adapted to cover at least a portion of the indicator dial or window when the indicator dial, in use, is rotated to a zero position.

Such an arrangement more clearly indicates that the device is empty and avoids the risk of the display through continued rotation restarting and displaying an erroneous number of doses.

The blanking element is preferably mounted so as to remain in a fixed position when the indicator dial, in use, is rotated to the zero position.

The indicator dial may comprise a second indicator dial, and the dose counter further comprises a first indicator dial rotatably mounted coaxially with the second indicator dial and which incrementally rotates when, in use, the medicament is dispensed, to incrementally rotate the second indicator dial when, in use, a predetermined number of doses of the medicament have been dispended. The blanking element is then preferably mounted on the second indicator dial and extends over the first indicator dial to cover the first indicator dial and window when the indicator dials, in use, are rotated to the zero position.

The second indicator dial preferably does not rotate once the indicator dials, in use, have been rotated to a zero position. In addition the first indicator dial preferably continues to rotate once the second indicator dial, in use, has been rotated to the zero position.

The dose counter may further comprise an index mechanism driven by the first indicator dial and which incrementally rotates the second indicator dial. In particular there are preferably a plurality of drive elements located around the second indicator dial and the index mechanism comprises an indexer mounted on a eccentric to, in use rotate eccentrically relative to the first indicator dial. The indexer has a drive element which is arranged to selectively engage the drive elements of the second indicator dial when the indexer eccentrically rotates to an engagement position to incrementally rotate the indicator dial.

Furthermore, preferably at least one of the drive elements on the second indicator dial to rotate the second indicator dial is missing such that the second indicator dial does not rotate when the indexer is eccentrically rotated to the position of the at least one missing drive element.

In particular, in an embodiment of yet another aspect of the invention there is provided a dose counter for a medicament delivery device comprising a dose counter for a medicament delivery device comprising a rotatable indicator dial having a plurality of spaced drive elements around the indicator dial, and first and second drive lugs. The indicator dial and drive lugs are mounted such that an actuator, in use, when the medicament is dispensed, reciprocally translates the indicator dial relative to the drive lugs causing the first drive lug to selectively engage one of the drive elements and rotate the indicator dial when the indicator dial is translated in a first direction, and then causing the second drive lug to selectively engage one of the other drive elements and rotate the indicator dial in the same direction when the

indicator dial is translated in a second return direction to thereby incrementally rotate the indicator dial when, in use, the medicament is dispensed.

This provides a simple yet robust mechanism to translate the linear actuation motion of the medicament device into rotational motion of the dose counter.

Preferably the drive lugs at least partially tangentially selectively engage the drive elements to rotate the indicator dial. The drive lugs are preferably translated generally radially with respect to the indicator dial and drive elements.

The drive elements may have a first drive surface to selectively engage the first drive lug and rotate the indicator dial, and a second drive surface to selectively engage the second drive lug and rotate the indicator dial. Preferably the first and second drive lugs have respective drive surfaces which, in use, abut against the corresponding first and second drive surface of the drive elements. At least one of the first and second drive surface of drive lugs or drive elements is at an angle to a radius of the indicator dial.

At least one of the first and second drive lugs may also have a limit surface that selectively engages a corresponding limit surface on one of the drive elements to limit rotation of indicator dial when the indicator dial is being rotated by the other drive lug.

In one embodiment the dose counter comprises a mechanism that incorporates a reversed (modified Sully) escapement mechanism to convert the axial motion of the inhaler

canister to rotary motion of the units dial and then an indexing and lock mechanism to provide motion to the "tens" dial to move it on every tenth actuation. This indexing mechanism is driven by an eccentric attached or integral to the units dial.

Alternatively the reversed escapement mechanism could be replaced in the invention by a ratchet and pawl or other means of converting from axial to radial movement.

Accordingly, embodiments of aspects of this invention provides a means to convert the intermittent motion in an inhaler device which delivers the drug into an intermittent rotary motion of dials which gives a numeric indication of the doses remaining or used.

The present invention will now be described by way of example only with reference to the following figures in which:

Figure 1 shows an exploded view of the inhaler with the dose counter according to an embodiment of the invention;

Figure 2 is a more detailed exploded view of the dose counter mechanism and cover shown in Figure 1;

Figure 3 is a more detailed exploded alternate view of the dose counter mechanism and cover shown in Figure 2 from the other side;

Figure 4 is a schematic end cross sectional view, and Figure 5 is a schematic perspective

view, both showing just the units dial tens dial and indexer of the dose counter of Figure 1, in the position which indicates, in the example shown of a counter which counts from '200' down to zero, '191' doses remaining;

Figures 6 and 7 are similar views to Figures 4 and 5, but show the counter mechanism incremented to the position which indicates '190' doses remaining;

Figures 8 and 9 are similar views to Figures 4 and 5, but show the counter mechanism part way through an actuation, and in a position between indicating '190' and '189' doses remaining;

Figures 10 and 11 are similar views to Figures 4 and 5, but show the counter mechanism in the position which indicates '189' doses remaining;

Figures 12 and 13 are similar views to Figures 4 and 5, but show the counter mechanism in the position which indicates '188' doses remaining; and

Figures 14 and 15 are detailed schematic illustrations showing the engagement of the units dial drive pins with the drive lugs as the canister is depressed and the units wheel is rotated.

Referring to Figure 1, a pressurised metered dose inhaler includes a drug canister 2 located in the body 1. The inhaler is actuated by depression of the canister 2 with

respect to the body 1. When actuated and depressed a metered quantity of the drug is expelled as an aerosol through the a valve assembly 3 of the canister and a mouth piece 15 of the body 1. As such the inhaler is generally conventional.

The pressurised metered dose inhaler also includes a dose counter assembly 30 which is also actuated with each depression of the canister 2, and delivery of a dose, to provide an indication of the number of doses dispensed or remaining. The dose counter assembly 30 is mounted on a canister housing 4. The canister housing 4 is slidingly fitted into the body 1 of the inhaler. The canister housing 4 accepts the canister 2 and is devised such that a valve lower face 5 of the canister 2, which is generally the most accurate reference point on the outside of the valve 3, is firmly located against a surface of the housing. An end of a valve stem 11 of the canister 2 projects through a hole 26 in the bottom of the canister housing 4 and abuts against a portion of the body 1. The canister 2, and cannister housing 4, are depressed by a user, and moved relative to and into the body 1, thereby pressing an end of the valve stem 11 against the body 1, and actuating the valve assembly 3 to expel a metered quantity of the drug as an aerosol through the valve assembly 3 and into the mouth piece 15 of the body 1. The canister housing 4 complete with the canister 2 and dose counter assembly 30 can be removed and replaced at will, and specifically for cleaning the body and nozzle and for replacement of the canister 2.

The dose counter assembly 30 consists of a units dial 6, a tens dial 7, an indexer 8 and a cover 9. The units dial 6 is rotatably mounted upon a spigot 32 projecting from the canister housing 4. The units dial 6 further includes a

concentric inner rim portion 34 protecting from an axial end face of the units dial 6. The tens dial 7 comprises an annular ring and is concentrically and rotatably mounted on the rim portion 34 of the units dial 6 so that the tens and units dials 6,7 can both rotate concentrically on the spigot 32, and also rotate relative to each other.

Numerals '0' to '9' are marked equispaced around a peripheral circumferential edge of the units dial 6. Additional numerals, in this embodiment from '1' to '20' and a blank space, are marked equi-spaced around a peripheral circumferential edge of the tens dial 7. When assembled these numerals marked on the peripheral circumferential edge of the dials 6,7 are arranged to be visible and read together through a corresponding viewing window 24 in the cover 9 as the dials 6,7 are rotated and as the inhaler is actuated.

Specifically the numerals on the units dial 6 indicate the units of the number of doses, and the numerals on the tens dial 7 indicate the tens of doses. In this embodiment shown the counter assembly 30 can accordingly indicate doses remaining from '200' to '0'. It will be appreciated however that different numerals can be marked on the tens dial 7 to indicated a different range of doses.

The dose counter assembly 30 is actuated, and the units dial 6 rotated when the inhaler is actuated and canister 2 depressed, by the two drive lugs 10a,10b accurately positioned on the body 1 with respect to the reference location for the valve 3, usually the end of the stem 11. These two lugs 10a,10b cause rotation of the units dial 6 by thirty six degrees for each actuation of the inhaler by their interaction with ten dial pins 17 located on the

units dial 6. It will be noted that 36 degrees is one tenth of a full rotation, and that the numerals on the units dial 6 are nought to nine, thus indicating the dispensing of one dose with each actuation.

The interaction between the units dial pins 17 and drive lugs 10a,10b is illustrated more clearly in Figures 14 and 15, while the dial pins 17 can also be seen in Figure 3. In particular the dial pins 17 and lugs 10a,10b are arranged as a reversed (modified Sully) escapement mechanism to rotate and control the incremental rotation of the units dial 6. Specifically, and as shown, ten dial pins 17 project from an axial end of the units dial 6 facing the body 1, and are equispaced, thirty six degrees apart, around the dial 6.

Each of the pins 17 are profiled so as to have first and second angled radially facing surfaces 34,36 which meet at a radially inwardly located apex 40, with an arcuate radially outward facing surface 38 extending between the angled radially facing surfaces and forming a base to the generally triangular shape formed by the angled radially facing surfaces 34,36. The drive lugs 10a,10b project from the body 1, and are spaced apart so as to engage the dial pins 17 as the canister 2 and canister housing 4 upon which the units dial is mounted, is depressed, and the units dial 6 moved relative to the body 1 and pins 17. As shown in Figure 14, as the units dial 6 is depressed the drive lugs move with at least partially radially with respect to the units dial 6 and drive pins 17. As the canister 2 and the units dial 6 is depressed an upper first, drive, surface 42 of the first drive lug 10a abuts against the arcuate base surface of one of the dial pins 17. The location and abutment of the drive lug 10, and angling of the respective

surfaces 42,38, is such that the dial 6 is then rotated (anti-clockwise as shown in Figure 14) as the canister 2, dial 6, and drive pin 17 is further depressed against the drive lug 10a. Specifically at least one of the drive surface 42,38 is at an angle to the radius of the units dial 6, and the drive lugs 10a is also moved relative to the units dial 6 at least partially in a tangential direction (i.e the movement of the drive lug 10a has a tangential component). At some point during this depression of the canister 2 an angled front face 44 of the second drive lug 10b abuts against, and slides over one of the radially inwardly facing angled surfaces 36 of one of the other drive pins 17 to control and prevent the units dial 6 from over rotating. The front face 44 of the second drive lug 10b and radially inwardly facing second angled surfaces 36 of the drive pin 17 accordingly define limit surfaces and their abutment provides a limit to the rotation of drive pins 17 and the units dial 6.

Once the canister 2 is fully depressed (and the medicament dispensed) the front face 44 of the second drive lug 10b slides beyond the apex 40 of the dial pin 17. Then, as the canister 2 is released and springs back upwardly out of the body 1 to its initial position, an angled rear drive face 46 (or at least portion thereof) of the second drive lug 10a abuts against the other radially inwardly facing first angled drive surface 34 of the dial pin 17 so as to continue to rotate the dial 6 (anti-clockwise as shown). At some point during the release and return rise of the canister 2 the arcuate base surface 38 of the other dial pin 17 abuts against and slides over an angled front face 44 of the first drive lug 10b to similarly control and prevent the dial 6 from over rotating. When the canister 2 is fully released and returns to its normal position the

arcuate base surface 38 of the dial pin 17 slides beyond the front face 44 and is adjacent the first surface 42 of the first drive lug 10a ready for the next actuation and depression of the canister 2. In this manner the dial 6 is incrementally rotated, one pin, and so by thirty six degrees at a time, by the engagement of the drive lugs with the respective pins 17.

In particular this arrangement converts the linear movement of the canister to incremental rotary motion of the units dial in a simple and reliable controlled manner, without the use of ratchets and pawls or other flexible components and using very few actual moving parts and components.

The escapement mechanism described copes with both over travel of the linear motion and under travel.

Within limits, defined by the construction of the canister valve, the canister may be depressed beyond the point at which drug is dispensed (over travel). Lug 10a will cause continued movement of the units dial in anticlockwise rotation, but when released, the lug 10b will still bring the units dial to the correct resting place.

If the user depresses the canister, but not far enough to dispense a dosage (under travel), then if the apex is between surfaces 44 and 46 and lug 10b has not moved past the apex 40 on the unit dial pins, the unit dial will be returned to its previous position by interaction between surface 36 and the dial pin and surface 44 or lug 10b.

The dose counter assembly 30 further includes an index and lock mechanism driven by the rotation of the units dial 6 and arranged to provide motion to the tens dial 7 to

incrementally rotate and move the tens dial 7 on every tenth actuation of the inhaler. The operation of the indexing mechanism is shown more clearly in figures 4 to 13 which show the progression and movement of the index mechanism as the dose counter assembly is operated and moves from indicating '191' doses to '188' doses. In Figures 4 to 13 only the units dial 6, tens dial 7 and indexer 8 of the dose counter 30 are shown with the other elements being omitted to more clearly illustrate the operation of the index mechanism.

Referring to Figures 2 and 3, and 4 to 13, the indexing mechanism comprises an eccentric 12 mounted on, or integral to, the units dial 6. The eccentric 12 comprises a cylindrical spigot projecting from the axial end face of the units dial 6 and located off centre such that the axis of the eccentric 12 is parallel, but spaced from the axis of the units dial 6. The eccentric 12 accordingly moves around the axis of the units dial 6 as the units dial 6 rotates. The indexer 8 is mounted on the eccentric 12. The eccentric imparts movement to, and is driven by the eccentric 12 around the axis of the dials 6,7 as the units dial 6 rotates.

The indexer 8 comprises an annular ring portion which is mounted on and around the eccentric 12, and a tail portion 52 extending radially outwardly from the annular ring portion 50. A first locking lug 14 projects in an axial direction from a distal end of the tail portion 52 and is slidingly engaged in a groove 15 in the inside of end face of the cover 9. The groove 15 extends generally radially with respect to the units dial 6 such that the locking lug 14 is thereby constrained to move radially with respect to the units dial 6 by the engagement in the groove 15 in the

cover 9.

The indexer 8 has an indexing tooth 13 projecting radially outwardly from the annular portion 50 and diametrically opposite the tail portion 52 of the indexer. An inner circumference of the tens dial 7 has a series of equispaced radially inwardly opening notches 16. These notches 16 are defined by walls forming corresponding teeth between the notches and which define drive faces and elements on the tens dial 7. The indexing tooth 13, corresponding to the notches 16, is moved into engagement with the notches 16 by means of a cam action between a cam lug 26 projecting radially outwardly from at one point around the circumference of the eccentric 12 and a first cam follower 18 which projects inwardly from the annular inside periphery of the annular portion 50 of the indexer 8.

Specifically, as shown in Figure 4 to 13, as the units dial 6 rotates, and the eccentric 12 moves around the axis of the units dial 6, the eccentric 12 rotates relative to and within the annular portion 50 of the indexer 8. As shown in Figures 6 to 9, the cam lug 26 on the eccentric 12 abuts against the inner periphery of the annular portion 50 of the indexer 8, and similarly the first cam follower 18 abuts against the periphery of the eccentric 12, to locate the indexer 8 on the eccentric 12. As the eccentric 12 moves the cam lug 26 then abuts and engages the cam follower 18 moving the indexer 8 both radially outwardly and tangentially (to the left as shown). The indexing tooth 13 is thereby pressed into engagement with one of the notches 16, and the tens dial 7 is incrementally rotated (anti-clockwise as shown) by one segment or notch 16. With continued rotation of the units dial 6 the cam lug 26 moves beyond the end of the cam follower 18 and the indexing

tooth 13 is disengaged from the notches 16. Since the units dial 6 and eccentric 12 only complete a full rotation after ten actuations of the inhaler, the indexing tooth 13 accordingly only engages the tens dial 7 and incrementally rotates the tens dial 7 by one segment every tenth actuation.

A second cam follower 21 on the indexer 8, diametrically opposite the first cam follower 18, projects radially inwardly from the annular inside periphery of the annular portion 50 of the indexer 8. The second cam follower 21 similarly to the first cam follower 18 also abuts against the periphery of the eccentric 12, to locate the indexer 8 on the eccentric 12. The eccentric 12 also has a recess 54 defining a second cam surface 22 in the periphery of the eccentric 12 and which is diametrically opposite the cam lug 26. As the eccentric 12 rotates, and the cam lug 26 engages the first cam follower 18 the second cam follower 22 engages and enters the recess 54 and abuts against the second cam face 22 to allow the indexer to mover radially with respect to the eccentric 12, whilst maintaining secure location of the indexer 8 on the eccentric 12.

A second lock pin 19 projects in an axial direction from a distal end of the tail portion 52 and oppositely to the first locking pin 14. The second locking pin 19 is normally engaged within radial locking grooves 20 in an axial end face of the tens dial 7. The second locking pin 19, and engagement in the locking grooves 20 thereby lock the tens dial 7 against rotating, with the first locking pin 14 holding the distal end of the tail portion 52 of the indexer 8 in a fixed radial position. However in use as the eccentric 12 rotates, and at the same time as the indexing tooth 13 is moved into engagement with the notches 16 on

the tens dial 7, the second lock pin 19 moves out of engagement with radial locking grooves 20 thus allowing the tens dial 7 to rotate. At the next actuation, the second cam follower 21 on the indexer 8, then pushes against the second cam face 22 and recess cut into the eccentric 12. This moves the indexing tooth 13 out of engagement with the notches 16 in the tens wheel 7. In addition it also forces the lock pin 19 into the next locking groove 20 in the tens wheel 7 thereby locking the tens dial 7. The locking pins 14,19 and their engagement in the locking grooves 15,20 thereby normally lock the tens dial 7 against accidental rotation, and ensure that the tens dial 7 only rotates when it should.

On the outer periphery of the tens dial 7 there is a shield 23. The shield 23 extends in a axial direction beyond the tens dial 7 and over the outside of the units dial 6. The shield 23 rotates with the tens dial 7 and is mounted at a point around the circumference of the tens dial 7 so that it is moved into a position under the viewing window 24 when the dose counter reaches zero. The shield 23 is sized to at least cover the inside of the viewing window 24 and so covers the numbers indicating that all doses have been dispensed, and when it is time to replace the canister 2. At a corresponding appropriate position around the inner periphery of the tens dial 7 there is a double notch 25, twice as wide as the other notches 16. The double notch 25 is in effect formed by omitting and removing a portion of one of the walls and drive faces of the notches 16. It will also be appreciated that the double notch 25 could be further enlarged and may comprise a triple of even large notch. Specifically, the double notch 25 is positioned around the inner periphery of the tens dial 7 such that when the shield 23 is positioned over the window 24 the

indexing tooth 13 engages and is moved into the double notch 25. When the indexing tooth 13 therefore engages the double notch 25, due to the size of the double notch 25, it simply moves within a double notch 25 created in the tens dial 7 and does not then rotate the tens dial 7 any further. The shield 23 therefore remains in place over the window 24 indicating that all the doses have been dispensed, but still allowing further actuation and depression of the inhaler and canister to dispense any remaining medicament that may remain in the canister if needed.

Various modifications to the specific embodiment described above can of course be made. In particular the dials 6,7 can be numbered and arranged to either (or both) indicate the number of doses dispensed and/or the number of doses remaining. In other embodiments of the invention, it is possible to arrange for the numerals to be read from other directions such as the front of the mechanism rather than the side as depicted in the Figures.

The reversed escapement mechanism comprising the described drive arrangement of the units dial 6 could also in other alternative embodiments be replaced by a ratchet and pawl or other means of converting from axial to radial movement to provide intermittent incremental rotation of the units dial 6.

Additional, and different numbers of indicator dials could also be used. For example three dials comprising a units, tens and hundreds dials could be used. These dials (for example units, hundreds and tens), could be indexed and rotated in a similar manner to that described above, with the tens dial for example including a further eccentric and

a further indexer being provided to drive the hundreds dial. In such an arrangement the tens dial would also only be numbered '0' to '9' and only ten notches would be provided to endure it makes a complete rotation every hundred actuation. In such a case the hundred dial would also include the shield, and double notch, rather than the tens dial, and the shield would extend over all the dials.

The dials 6 and 7 could also be concentrically rather than coaxially mounted and rotated with suitable modifications of the drive arrangement and indexer and eccentric.

The dose counter has also been described, and is particularly applicable for use with inhaler types medicament delivery devices. The dose counter could however be used in other types of medicament delivery devices which deliver repeated multiple discrete doses.

While the principle and mode of operation of this invention have been explained and illustrated in its preferred embodiments it must be understood that this invention may be practised otherwise than as specifically explained and illustrated without departing from its scope.

CLAIMS

1. A dose counter for a medicament delivery device comprising a rotatable indicator dial, and an index mechanism for incrementally rotating the indicator dial when, in use, the medicament is dispensed, wherein the index mechanism comprises an index element that selectively engages the indicator dial to incrementally rotate the indicator dial, and further comprises a locking element that is moveable from a first position in which it locks rotation of the indicator dial to a second unlocked position in which it allows rotation of the indicator dial when the index element engages the indicator dial.

2. A dose counter of claim 1 wherein the locking element comprises a locking pin that is selectively engaged within a locking groove.

3. A dose counter of claim 2 wherein the locking groove comprises a substantially radially extending groove in the indicator dial, and the locking pin is rotationally fixed and selectively radially moveable relative to the indicator dial.

4. A dose counter of any preceding claim wherein a plurality of drive elements are located around the indicator dial and the index mechanism comprises an indexer mounted on a eccentric to, in use rotate eccentrically relative to the indicator dial, the indexer having a drive element which is arranged to selectively engage the drive elements of the indicator dial when the indexer eccentrically rotates to an engagement position to incrementally rotate indicator dial.

5. A dose counter of claim 4 wherein the locking element is located on the indexer and selectively engages the indicator dial to prevent rotation as the indexer is eccentrically rotated, and selectively disengages the indicator dial when the indexer eccentrically rotates to the engagement position to allow the indicator dial to incrementally rotate indicator dial.

6. A dose counter of claim 4 or 5 wherein the indexer further comprises a second locking element that engages a body portion of the dose counter to constrain rotational movement of the indexer and indicator dial.

7. A dose counter of any one of claims 4 to 6 wherein the indicator dial is annular and the drive elements are defined in a inner annular periphery of the indicator dial, and wherein the indexer and eccentric are mounted within the annular indicator dial such that the indexer eccentrically rotates within the indicator dial to selectively engage the drive elements.

8. A dose counter of any preceding claim wherein the indicator dial comprises a second indicator dial, and the dose counter further comprises a first indicator dial rotatably mounted coaxially with the second indicator dial and which incrementally rotates when, in use, the medicament is dispensed, and which drives the index mechanism to incrementally rotate the second indicator dial when, in use, a predetermined number of doses of the medicament have been dispended.

9. A dose counter of any one of claims 4 to 7 wherein the indicator dial comprises a second indicator dial, and the dose counter further comprises a first indicator dial

rotatably mounted coaxially with the second indicator dial and which incrementally rotates when, in use, the medicament is dispensed, and wherein the eccentric is eccentrically mounted on the first indicator dial to eccentrically rotate the indexer.

10. A dose counter of claim 8 or 9 further comprising first and second drive lugs, and the first indicator dial has a plurality of spaced drive elements around the first indicator dial, and wherein the first indicator dial and drive lugs are mounted such that an actuator, in use, when the medicament is dispensed, reciprocally translates the first indicator dial relative to the drive lugs causing the first drive lug to selectively engage one of the drive elements and rotate the indicator dial when the first indicator dial is translated in a first direction, and then causes the second drive lug to selectively engage one of other drive elements and rotate the indicator dial in the same direction when the indicator dial is translated in a second return direction to thereby incrementally rotate the first indicator dial when, in use, the medicament is dispensed.

11. A dose counter of any preceding claim further comprising a viewing window to view the indicator dial, and a blanking element that is adapted to cover at least a portion of the indicator dial or window when the indicator dial, in use, is rotated to a zero position.

12. A dose counter for a medicament delivery device comprising a rotatable indicator dial which incrementally rotates when, in use, the medicament is dispensed, to indicate a number of doses, and viewing window to view the indicator dial, wherein the device further comprises a

blanking element that is adapted to cover at least a portion of the indicator dial or window when the indicator dial, in use, is rotated to a zero position.

13. A dose counter as claimed in claim 12 wherein the blanking element is mounted so as to remain in a fixed position when the indicator dial, in use, is rotated to the zero position.

14. A dose counter of any one of claims 12 to 13 wherein the indicator dial comprises a second indicator dial, and the dose counter further comprises a first indicator dial rotatably mounted coaxially with the second indicator dial and which incrementally rotates when, in use, the medicament is dispensed, to incrementally rotate the second indicator dial when, in use, a predetermined number of doses of the medicament have been dispended, and wherein the blanking element is mounted on the second indicator dial and extends over the first indicator dial to cover the first indicator dial and window when the indicator dials, in use, are rotated to the zero position.

15. A dose counter of claim 14 wherein the second indicator dial does not rotate once the indicator dials, in use, have been rotated to a zero position.

16. A dose counter of claim 15 wherein the first indicator dial continues to rotate once the second indicator dial, in use, has been rotated to the zero position.

17. A dose counter of any one of claims 14 to 16 further comprising an index mechanism driven by the first indicator dial and which incrementally rotates the second indicator

dial.

18. A dose counter of claim 17 wherein a plurality of drive elements are located around the second indicator dial and the index mechanism comprises an indexer mounted on a eccentric to, in use rotate eccentrically relative to the first indicator dial, the indexer having a drive element which is arranged to selectively engage the drive elements of the second indicator dial when the indexer eccentrically rotates to an engagement position to incrementally rotate indicator dial.

19. A dose counter of claim 18 wherein at least one of the drive elements on the second indicator dial to rotate the second indicator dial is missing such that the second indicator dial does not rotate when the indexer is eccentrically rotated to the position of the at least one missing drive element.

20. A dose counter for a medicament delivery device comprising a rotatable indicator dial having a plurality of spaced drive elements around the indicator dial, and first and second drive lugs, wherein the indicator dial and drive lugs are mounted such that an actuator, in use, when the medicament is dispensed, reciprocally translates the indicator dial relative to the drive lugs causing the first drive lug to selectively engage a drive element and rotate the indicator dial when the indicator dial is translated in a first direction, and then causing the second drive lug to selectively engage a drive element and rotate the indicator dial in the same direction when the indicator dial is translated in a second return direction to thereby incrementally rotate the indicator dial when, in use, the medicament is dispensed.

21. A dose counter of claim 20 wherein the first drive lug selectively engages one of the drive elements and the second drive lug selectively engages one of the other drive elements.

22. A dose counter of claim 20 or claim 21 wherein the drive lugs at least partially tangentially selectively engage the drive elements to rotate the indicator dial.

23. A dose counter of any one of claims 20 or 22 wherein the drive lugs are translated generally radially with respect to the indicator dial and drive elements.

24. A dose counter of any one of claims 20 or 23 wherein the drive elements have a first drive surface to selectively engage the first drive lug and rotate the indicator dial, and a second drive surface to selectively engage the second drive lug and rotate the indicator dial.

25. A dose counter of claims 24 wherein the first and second drive lugs have respective drive surfaces which, in use, abut against the corresponding first and second drive surface of the drive elements, and wherein at least one of the first and second drive surface of drive lugs or drive elements is at an angle to a radius of the indicator dial.

26. A dose counter of any one of claims 20 to 25 wherein at least one of the first and second drive lugs has a limit surface that selectively engages a corresponding limit surface on one of the drive elements to limit rotation of indicator dial when the indicator dial is being rotated by the other drive lug.

27. A dose counter of any preceding claim wherein the

medicament delivery device comprises an inhaler.

28. A medicament delivery device including dose counter of any one of claims 1 to 27.

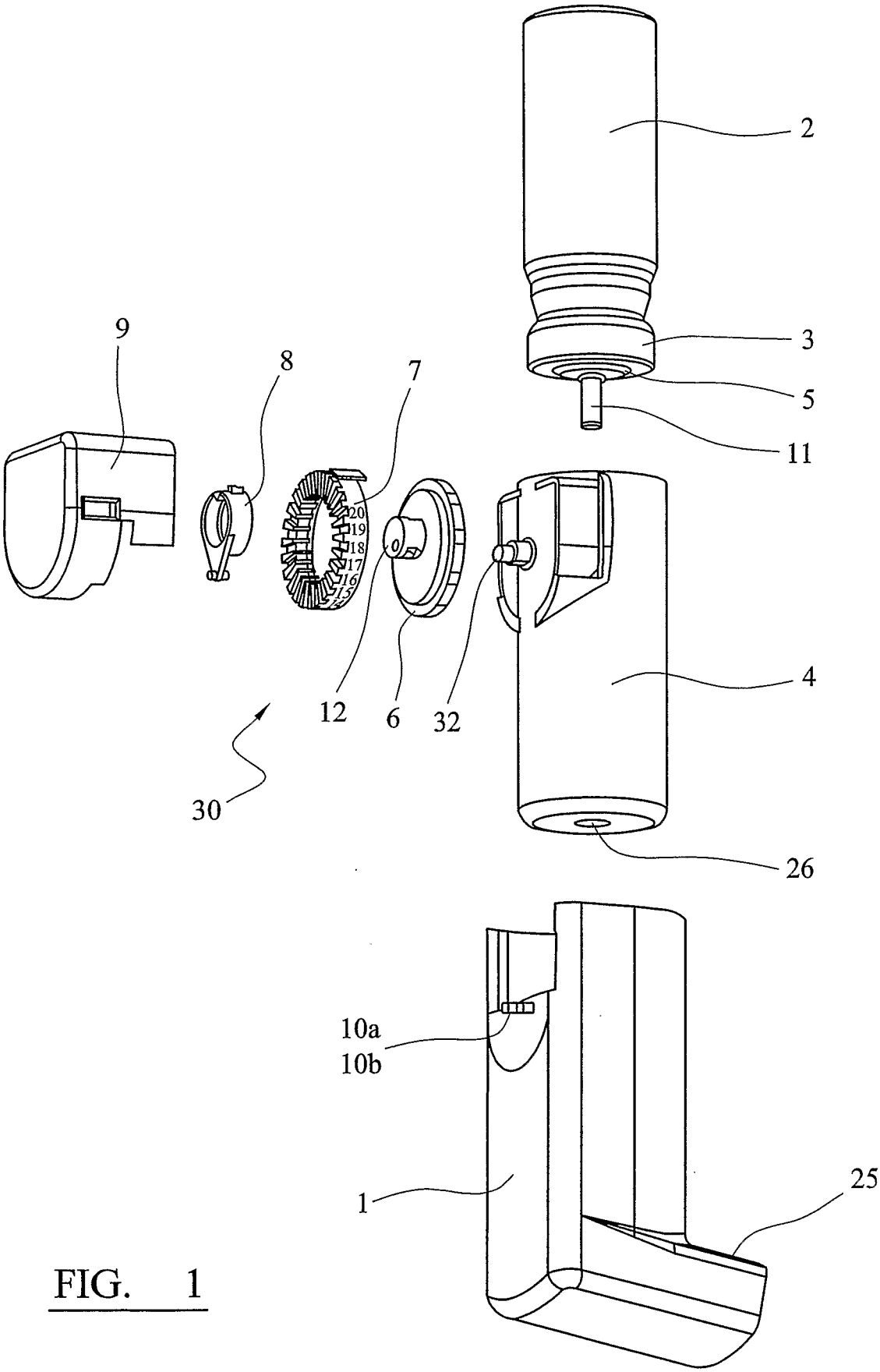

FIG. 1

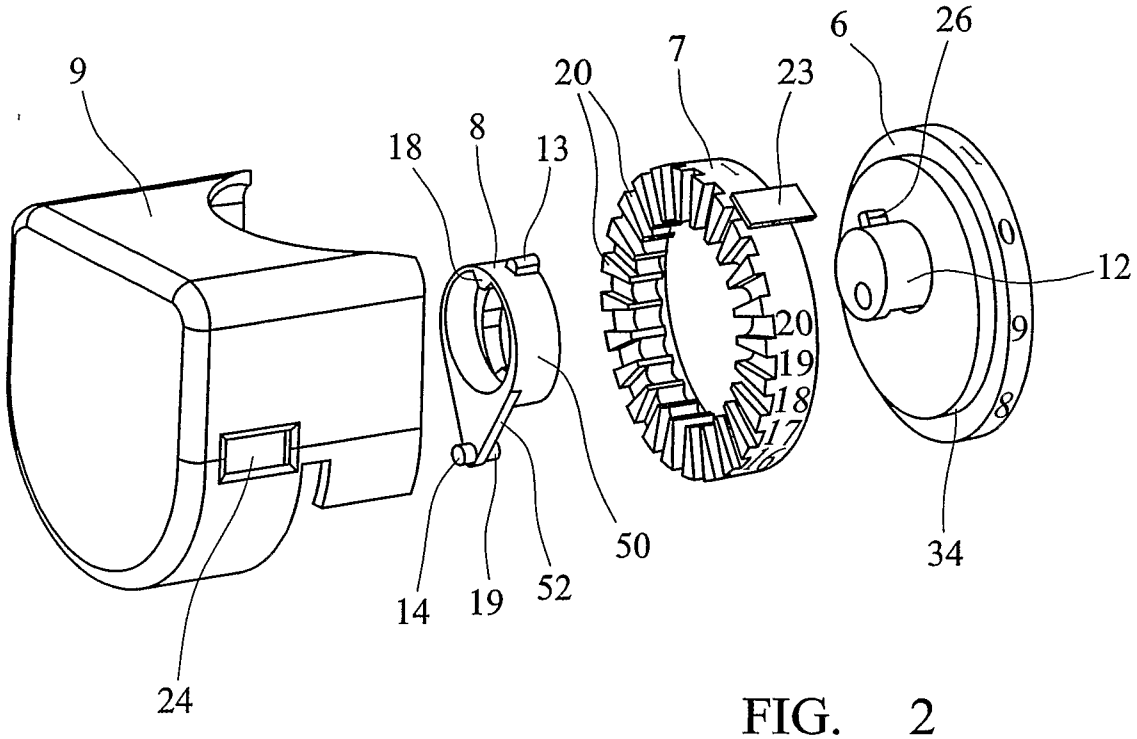
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FIG. 2

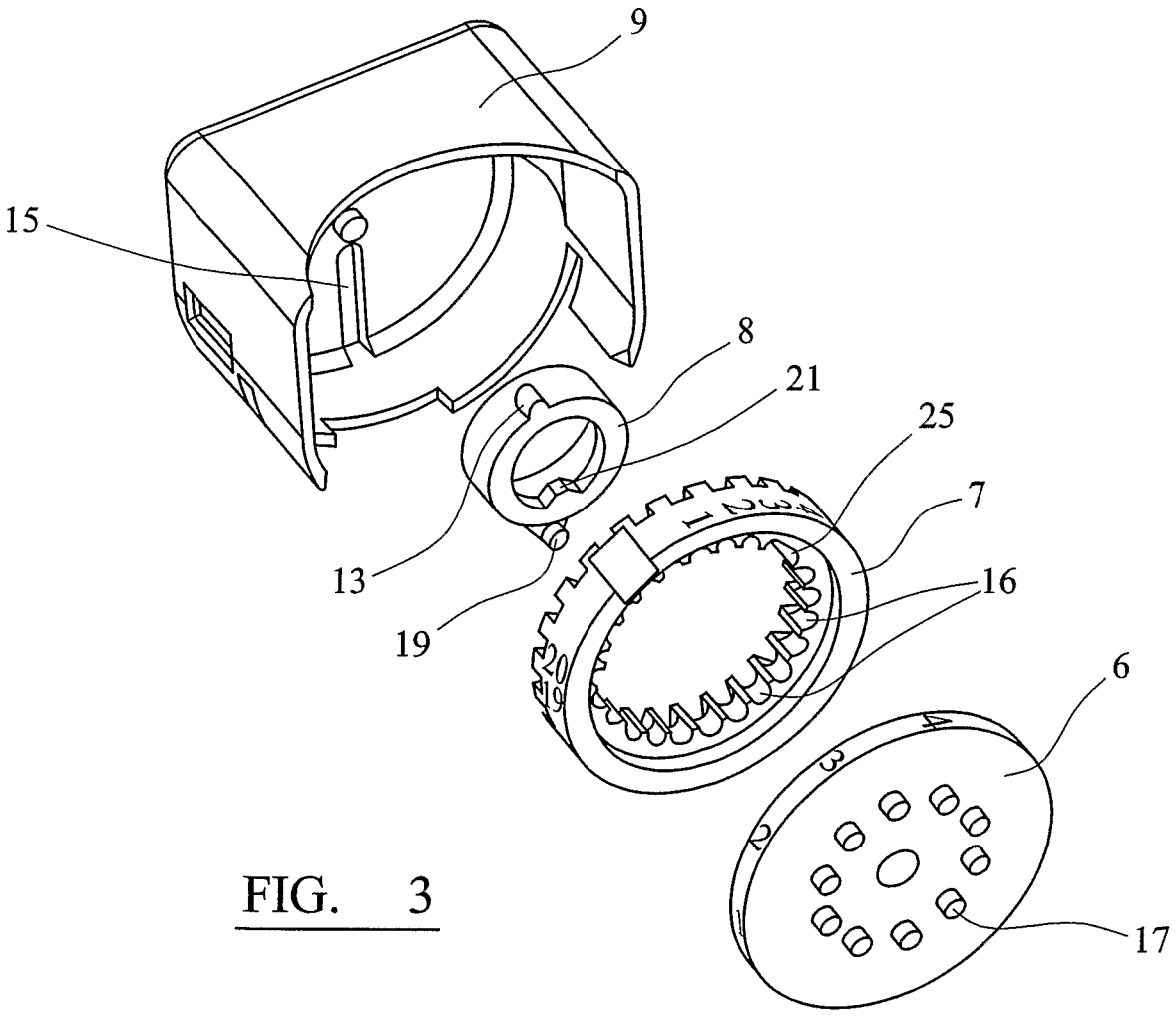
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FIG. 3

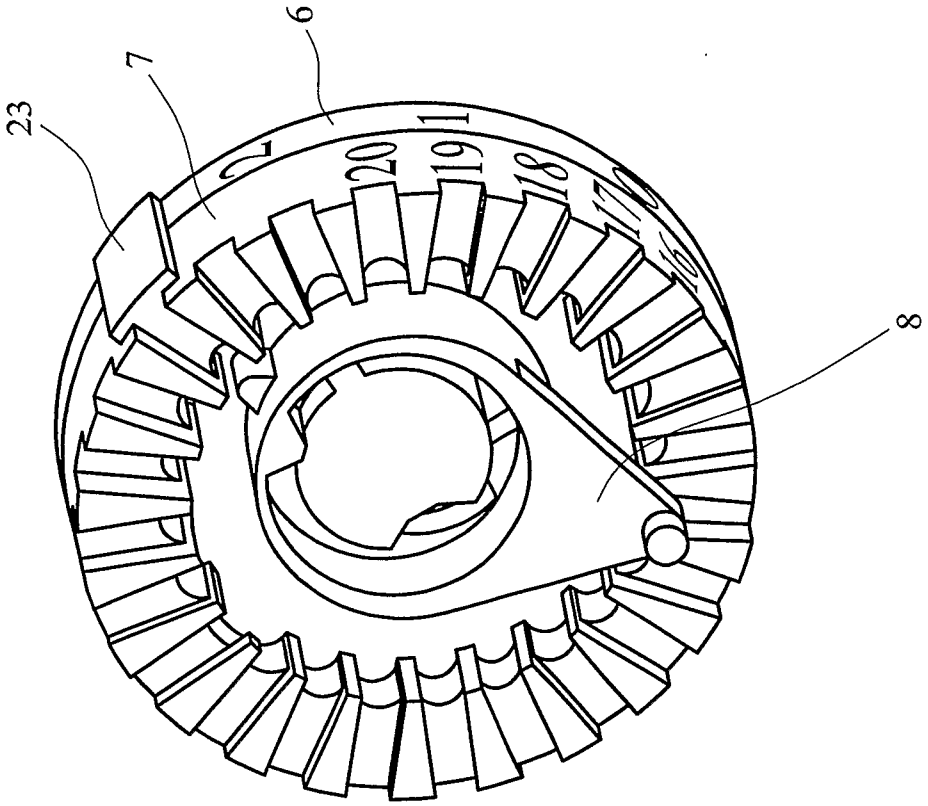

FIG. 5

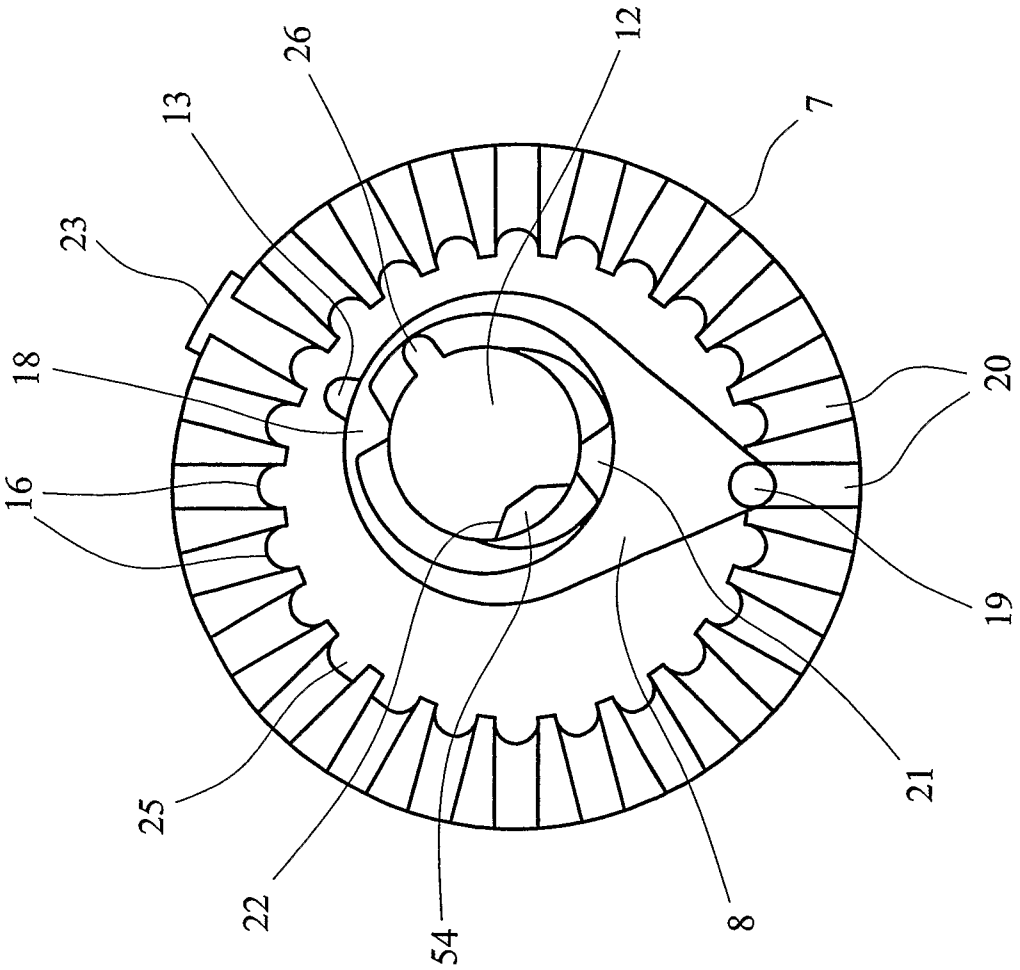

FIG. 4

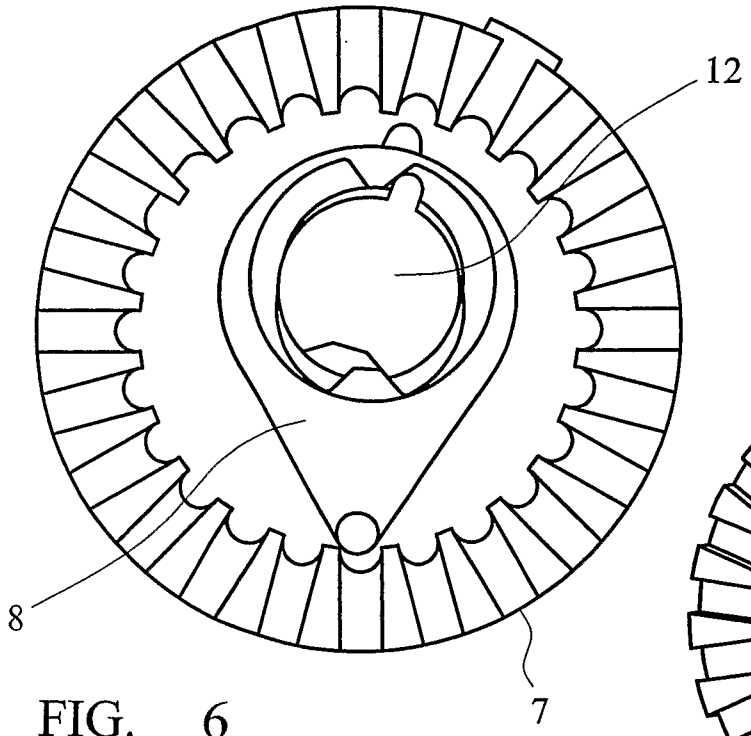

FIG. 6

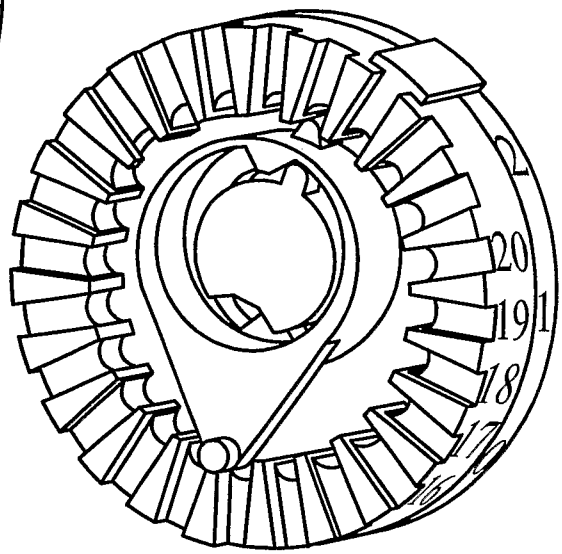

FIG. 7

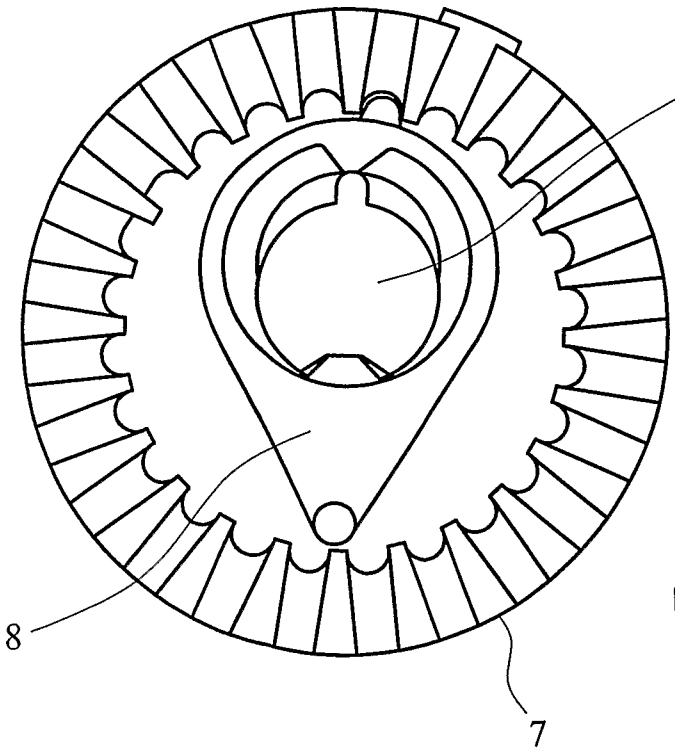

FIG. 8

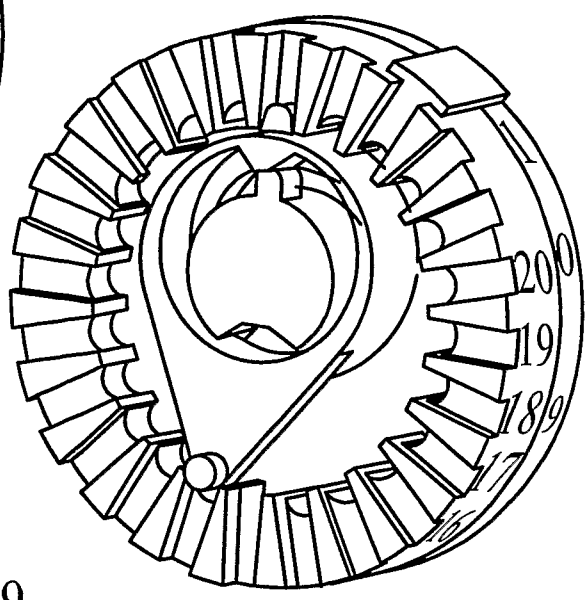

FIG. 9

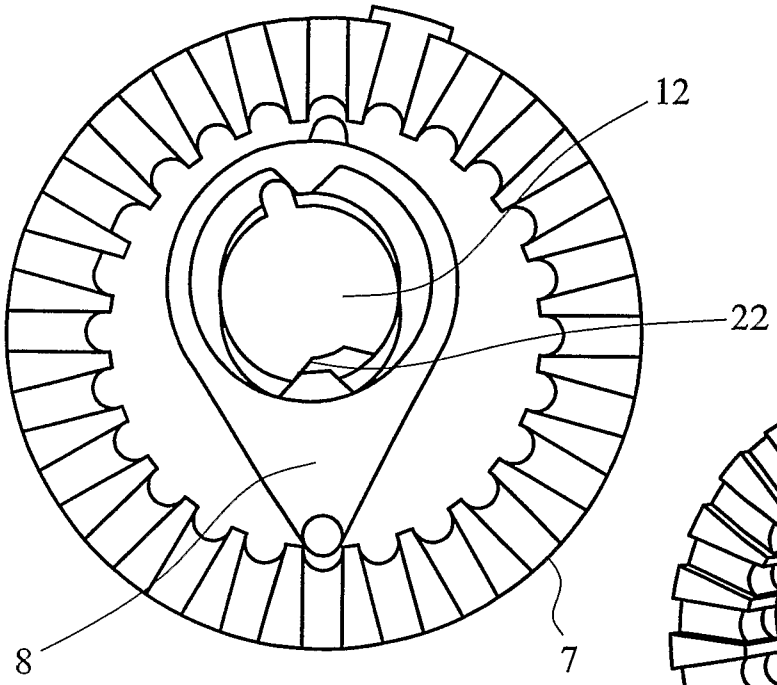

FIG. 10

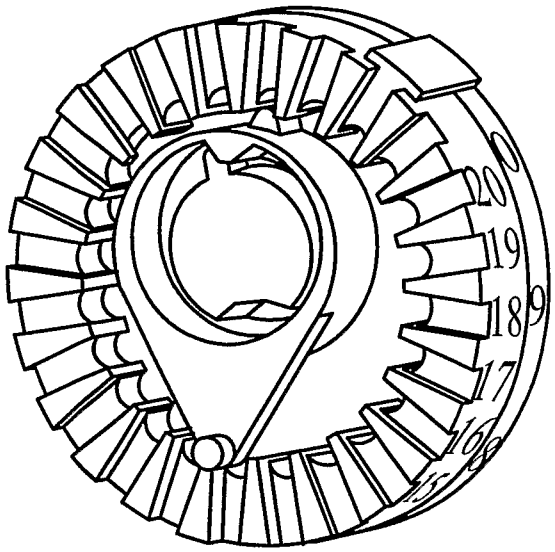

FIG. 11

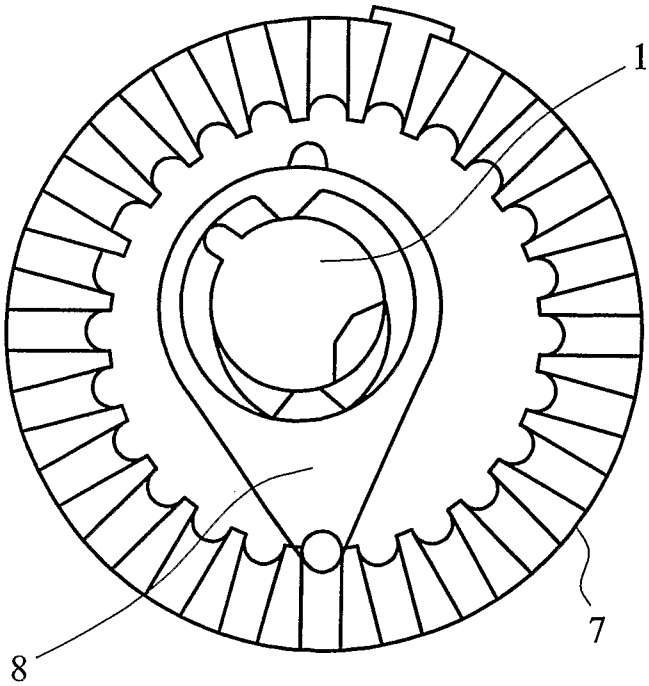

FIG. 12

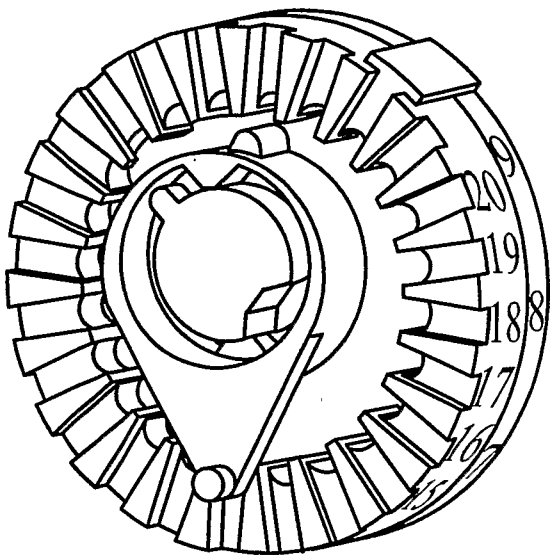

FIG. 13

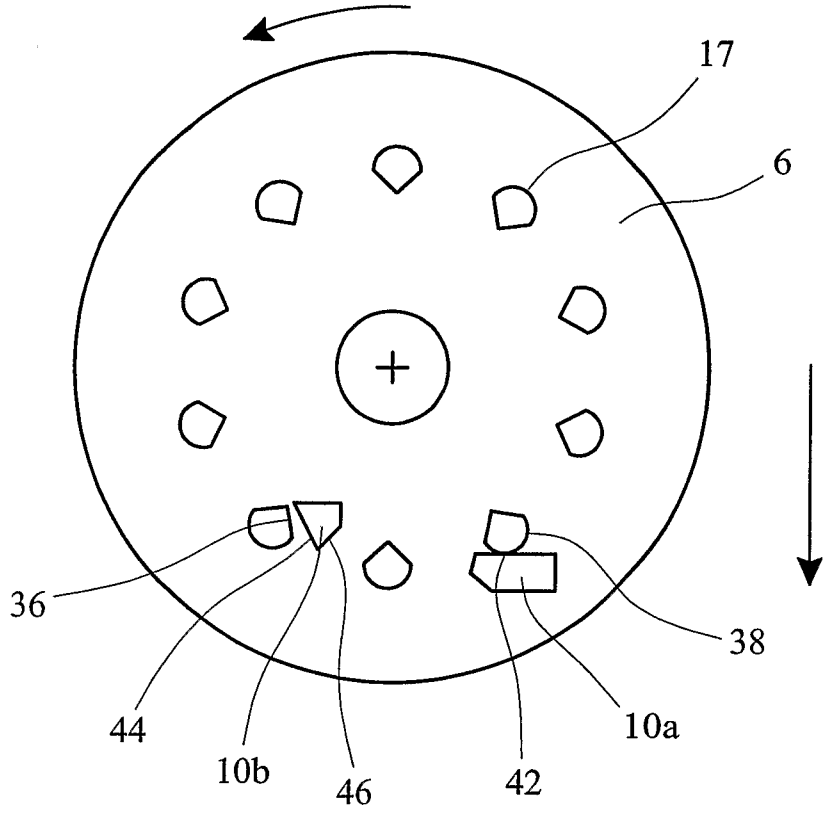

FIG. 14

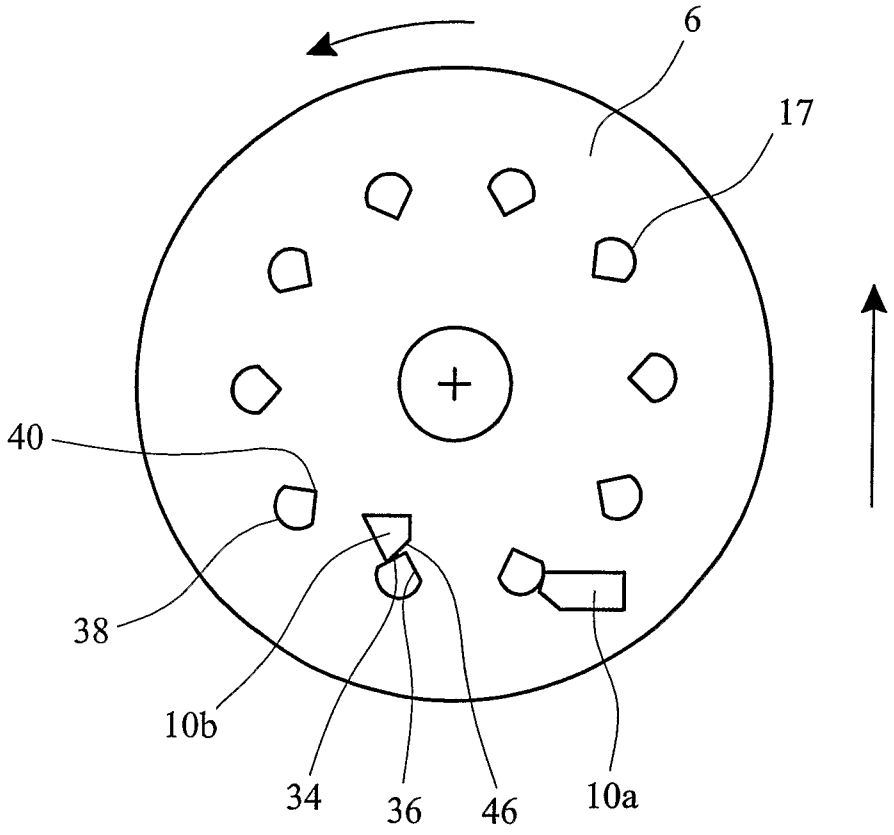

FIG. 15