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DESCRIPTION

FIELD OF THE INVENTION

[0001] This invention generally relates to counters and in particular to counters for use with dispensers and to dispensers comprising said counters. More particularly the present invention relates to counters for use with metered-dose dispensers, such as metered-dose inhalers (MDIs).

BACKGROUND TO THE INVENTION

[0002] Counters are useful in a wide variety of applications, and are especially important in the field of medical dispensers where an accurate determination of the number of doses of medicament remaining in a medicament container might otherwise be difficult to obtain. An example of such a medical dispenser is a metered-dose inhaler.

[0003] Metered-dose inhalers (MDIs) are devices for dispensing medicaments, e.g. in aerosol form, to the lungs. Broadly speaking dispensers such as MDIs are comprised of two components: a container and a delivery device. The container holds the medication, e.g. dissolved or suspended in a propellant under high pressure to maintain a liquid phase. Additionally the container often comprises an internal metering valve, which is designed to release a precisely measured, reproducible dose of medicament when the valve is actuated. The delivery device typically includes an actuator and a mouthpiece. The actuator, which can be triggered by the user, for example by inhalation or manual operation, typically interacts with the metering valve of the container to induce release of a dose. The mouthpiece serves to direct the medication towards the user. Figure 1 provides a view of a breath actuated dispenser and will be discussed in more detail below.

[0004] As medicament containers are typically made of an opaque material such as aluminium, and may be housed entirely within a delivery device, it is generally not possible for a user to gauge effectively how many doses of medicament remain therein. This may result in a user prematurely discarding a MDI still containing doses of medicament or worse using the MDI beyond its recommended lifetime. Neither situation is desirable - the former is wasteful while the latter is potentially dangerous. Users sometimes shake MDIs to try to obtain a measure of whether any medicament is present therein, but this only provides a very crude qualitative measure of the container contents. It would not, for example, enable a user to distinguish between a container comprising enough medicament and propellant to form a dose and one comprising a quantity of medicament and propellant that is less than that needed to fill the metering valve. In other words, there is a risk that users overestimate the amount of medicament present in a container and mistakenly conclude that there is sufficient medicament remaining for another dose when in fact there is not. Additionally a user may not be provided

with sufficient warning to obtain a replacement medicament container prior to the one in use running out.

[0005] It is therefore desirable to provide dispensers, e.g. inhalers, with a counter mechanism that enables a user to track how many doses have been dispensed therefrom and, complementarily, how many doses remain. Indeed, regulatory bodies such as the Food and Drug Administration (FDA) of the United States and the European Medicines Agency (EMA) have issued guidelines encouraging the implementation of dose-counters (Food and Drug Administration, "Guidance for industry: integration of dose counting mechanisms into MDI drug products", 2003; European Agency for Evaluation of Medicinal Products, "Final guideline on the quality of inhalation and nasal products", 2005).

[0006] Dose counters can generally be classified according to the manner by which a 'count' is registered, these being mechanical counters comprised of a series of moving parts that respond to a movement or mechanical force resulting, for example, in a displacement of the container/housing; electronic counters having electrical circuitry to sense an event associated with an actuation such as sound, temperature or pressure change; and electro-mechanical counters which combine electrical and mechanical parts.

[0007] Some background prior art relating to dose counters includes: EP1169245 Dispensing Apparatus Comprising a Dosage Counting Device; PCT/GB97/03480 Inhaler Dose Counter; PCT/US1996/008418 Indicator Device Responsive to Axial Force; PCT/FR2004/001844 Improved Dose Indicator for Fluid Product Dispensing Device; GB2372542 Dosage Counting Device; PCT/CA04/001884 Indicating Device with Warning Dosage Indicator; PCT/US04/039926 Dose Counter for Dispensers; US7047964 Dispenser for Medicament; and WO2007/107431 Dose Information Device.

[0008] Although such devices have provided the advantage of being able to provide some measure of the number of doses of medicament dispensed from a container and/or the number of doses remaining therein, there remains room for improvement. In particular it has proven difficult to provide dose counters that reliably "count" the release of medicament doses from containers. The difficulty encountered is that a relatively small movement, typically of the metering valve stem, needs to be detected and translated into a count. This difficulty is exacerbated by the fact that manufacturing tolerances in the length of medicament containers means they do not have a consistent length. At the same time, it is highly undesirable for any movements to not be counted since this will lead to the counter indicating a higher number of doses remaining than is actually the case. Moreover there is also regulatory pressure to minimise the number of false counts.

[0009] Additionally it is desirable that a counter, especially a medicament dose counter, display the count information in an easy to read form so it may be used by children and the elderly as well as adults. Naturally there is also a need that the counter can be manufactured at low cost.

SUMMARY OF THE INVENTION

[0010] Viewed from a first aspect the present invention provides a counter comprising:

a first member disposed in at least a partial helical turn about a longitudinal axis of an entity whose movements and/or contents are to be counted, said first member having an indicium or indicia indicative of a count;

a second member extending generally in the direction of said longitudinal axis, said second member being operatively disposed in overlapping relationship under and over one or more portions of said at least partial helical turn of said first member; and

means to effect relative movement between said first and second members, said movement comprising a relative incremental rotation about said longitudinal axis.

[0011] In a preferred embodiment of the present invention the entity is a medicament container for a dispenser having a body for receiving the medicament container and a dispensing mechanism for dispensing a dose of medicament from the container.

[0012] In a further preferred embodiment of the present invention, the movement is performed in a relative incremental rotation in response to the dispenser being actuated.

[0013] In a still further preferred embodiment of the present invention, the indicium or indicia is or are indicative of the number of doses of medicament dispensed from, or remaining in, the container.

[0014] Thus viewed from a further aspect the present invention provides a dose counter for use with a dispenser having a body for receiving a medicament container and a dispensing mechanism for dispensing a dose of medicament from said container, the dose counter comprising:

a first member disposed in at least a partial helical turn about a longitudinal axis of said medicament body and having an indicium or indicia indicative of the number of doses of medicament dispensed from, or remaining, in said container;

a second member extending generally in the direction of said longitudinal axis, said second member being operatively disposed in overlapping relationship under and over one or more portions of said at least partial helical turns of said first member; and

means to effect relative movement between said first and second members when said dispensing mechanism is actuated, said movement comprising a relative incremental rotation about said longitudinal axis.

[0015] In preferred embodiments of the present invention the first member is disposed in a plurality of helical turns (e.g. two or more) about said longitudinal axis of said dispenser

[0016] In further preferred embodiments of the present invention the second member extends in a direction substantially parallel (e.g. parallel) to said longitudinal axis. Preferably the second member extends in a direction that is within 10°, still more preferably within 7°, e.g. within 5° or 1° of being parallel with said longitudinal axis.

[0017] In further preferred embodiments of the present invention, the relative incremental rotation about said longitudinal axis changes said overlapping relationship between said first and second members.

[0018] Viewed from a further aspect the present invention provides a dispenser comprising a counter as hereinbefore described.

[0019] More specifically the present invention provides a dispenser comprising:

a body for receiving a medicament container;

a medicament container;

a dispensing mechanism for dispensing a dose of medicament from said container; and

a counter as hereinbefore described.

[0020] In preferred embodiments, the counter comprises a dose counter for use with a dispenser having a body for receiving a medicament container and a dispensing mechanism for dispensing medicament from said container, wherein said container comprises a certain number of doses of medicament. As such, where reference is made to these features, it will be understood that they are only preferred and not essential to the invention.

[0021] The first member of the counter of the present invention preferably comprises a rigid, resilient or flexible material. The first member may be in the form of a helix per se or may be capable of being formed into a helix. The helix may or may not have a constant pitch. Regardless of the form of the first member, its helical shape readily lends itself to arrangement around cylindrical entities (e.g. containers) and thereby addresses the internal space constraints of, e.g. dispenser devices having such containers, without unduly increasing their bulkiness, i.e. diameter and length. For example, where the first member of the counter is to rotate during use without hindrance in a forward direction between an outer housing of the dispenser and an internal container, the first and second members may fit in a radial gap of less than about 5.0 mm, e.g. in a gap of 0.5 to 5 mm.

[0022] Furthermore, helical configurations may have a large ratio of total height to turn height, which provides increased display capacity. Helical configurations that may be useful in the counter of the present invention may comprise a partial turn (i.e. less than one complete helical turn), one or more complete helical turns or a combination of complete and partial helical turns. Broadly speaking, a complete helical turn comprises a 360-degree twist about an axis. The number of turns in the helix may depend on the indicia to be included thereon. The number of turns may therefore be in the range $\frac{1}{2}$ to 12, preferably 1 to 8, e.g. 3 to 6.

[0023] In a preferred counter of the present invention, either the first member rotates and the second member is fixed or the second member rotates and the first member is fixed. Particularly preferably the second member is fixed and the first member rotates.

[0024] The second member of the counter may comprise a strip of flexible, resilient or rigid material. Thus, one or both of the first and second members may flex or bend to slide under and over each other. Preferably, one or both of the first and second members is comprised of a low friction coefficient material, for ease of sliding. Exemplary materials include acetal and PTFE-loaded acetal.

[0025] The first and second members are operatively disposed in an overlapping relationship. More specifically the second member is operatively disposed in overlapping relationship under and over one or more portions of said partial turn or turns of said first member. A preferred overlapping relationship is illustrated in Figure 2, in which a dotted line indicates an imaginary boundary between two turns, and the arrow indicates the direction of rotation.

[0026] In Figure 2(a) the second member 202 is under a portion of the first turn of the first member 201 and over portions of the second and third turns of the first member. Such an overlapping relationship therefore presents a portion 201 a of the first turn, e.g. through a window indicated approximately by the dashed line. This serves to highlight the indicium on the portion 201a of the first turn of the first member while occluding from view the indicia on the other corresponding portions. In Figure 2(b) there has been relative movement between the first and second members, which in operation may be caused by actuation of a dispensing mechanism. In Figure 2(b) the second member is still under a portion 201 b of the first turn of the first member and over portions of the second and third turns of the first member. A different indicium on the portion 201 b of the first turn of the first member is, however, highlighted. In Figure 2(c) there has been a number of relative movements between the first and second members which in operation may be caused by actuation of a dispensing mechanism. Thus in Figure 2(c) the second member is now under a portion 201 c of the second turn of the first member and over portions of the first and third turns of the first member.

[0027] In a preferred counter, the end of the first member that is displayed first is fed under the second member after one turn is completed. This may be achieved by biasing the first member to curl inwards or by using a means to feed the first member under the second member.

[0028] The afore-going describes a preferred overlapping relationship between the first and second members of the counter. Thus in a preferred counter said overlapping relationship is such that only a portion of one partial turn or turn of said first member lies over or under, preferably over, said second member. It will, however, be understood that other overlapping relationships are also possible.

[0029] Preferably the indicium or indicia is or are provided on, in or through the portion of said one partial turn or turn of said first member that is over or under, preferably over, said second member. Preferably the indicium or indicia is or are provided by a shape of the first member and/or indicia comprising one or more of: numbers, colours, letters or symbols. Symbols could include arrows or other pointing representations. Indicia may be oriented upright or horizontal with respect to the longitudinal axis of the dispenser, but are preferably upright.

[0030] Preferably the indicia at least comprise numbers. In particularly preferred counters, numeric indicia provide a quantitative measure of the amount of counts (e.g. doses released or, more preferably remaining in the dispenser). Preferred counters may, for example, provide a number resolution to the nearest half, one, two, ten, twenty, fifty, and/or a hundred, e.g. one or two. Fractions are of use, for example, when one dose of medicament corresponds to two or more actuations of a dispensing mechanism (e.g. 'puffs') by the user.

[0031] Where every other integer is represented this allows an increased font size to be used, thereby providing better legibility while having minimal or no effect in practice on a user's ability to track the count. In an alternative embodiment, the number resolution may increase as the count approaches its maximum (e.g. when the number of doses in a medicament container is becoming exhausted). This is beneficial for medicament containers containing hundreds of doses, where greater precision close to exhaustion is desirable. Alternatively, or additionally, colour coding may indicate whether the remaining amount of doses in the medicament container is 'high' (e.g. green) or 'low' (e.g. red). The indicia may be printed, cut out from, embossed, molded, adhered, incorporated, painted or otherwise marked (e.g. laser marked) on one or both of the first and second members.

[0032] In a further preferred embodiment of the counter and dispenser of the present invention, indicia may be provided on a window of the housing of the dispenser. This is preferably in addition to the indicia provided on the first member.

[0033] In preferred counters of the present invention, the first member helically disposed about the longitudinal axis of the entity, e.g. medicament container, has a substantially constant pitch and/or width along its length. However, in other counters these may vary along its length, e.g. in one or more discrete sections of different pitch/width along its length. It will be appreciated that a range of parameters of the first member, including the radius, height, number of turns, width and pitch (or equivalently helical angle), may be varied according to the preferences or requirements for a particular counter.

[0034] In a preferred embodiment of the counter of the present invention, there is provided a

tubular sleeve around which the first member is disposed. The sleeve preferably surrounds the entity whose movements and/or contents are to be counted (e.g. the medicament container). For configurations in which the first member is rotated, there may be a tendency for the first member to contract inwards, particularly where the first member is disposed in a plurality of helical turns. This may eventually affect the ability of the first member to correctly rotate. The sleeve serves to counteract this contraction and helps the first member to maintain its shape.

[0035] In a further preferred embodiment of the counter of the present invention, there is provided a spine (e.g. a rigid spine) along at least a portion of the length of the first member. Alternatively, or additionally, the counter may comprise a guide element for guiding the first member. The guide element may therefore comprise a track mounted on, or integral with, another part of the dispenser or counter, e.g. the outer housing of the medicament or the afore-mentioned sleeve. The spine and/or guide element may help to correct any distortion experienced by the first member, such as a compression in an axial direction thereof, thereby minimising counting inaccuracies. However, the first member may correct itself naturally without the need for such a spine.

[0036] In a preferred counter of the present invention, the means to effect a relative rotation comprises a drive mechanism having a pawl-bearing member to releasably engage a teeth-bearing member. Broadly speaking, the drive mechanism translates vertical movements, e.g. of a junction member or medicament container, into rotational movements of a counter, e.g. of the first member. A relative rotation between the first and second members may be allowed in a forward direction but substantially prevented in a reverse direction. In this way, the counter cannot be improperly 'reset' (accidentally or deliberately), to provide a false indication of the count (e.g. number of doses) in the dispenser. This minimises the possibility of user abuse, and is of particular use for medicament dispensers. The counter may, however, be alternatively designed to allow for it to be rewound and/or for it to be reset by a manufacturer upon replacement with a fresh entity (e.g. medicament container).

[0037] In a further preferred counter, the drive mechanism biases the first, generally helical member in a rotational direction about the longitudinal axis responsive to a force in a direction parallel to the longitudinal axis. Such a force could be provided by a dispensing mechanism of a dispenser device. Preferably, a count is at least initiated before a corresponding unit of product comprising medicament is released, e.g. for inhalation.

[0038] It will be appreciated from the afore-going that the relative movement between the first and second members may be achieved by fixing the first member to the entity whose movement and/or contents are to be counted (e.g. a medicament container or tubular sleeve) and rotating the second member around said entity. Preferably, however, the second member is fixed to said entity (e.g. medicament container or tubular sleeve). Correspondingly it is also preferred that said first member rotates about said longitudinal axis of said entity. In this configuration, vertical movement of the first member per se does not cause a count to be made.

[0039] Rotation of the first or second member about the entity (e.g. medicament container) is preferably achieved by driving said first or second member by the drive mechanism, e.g. by fixing the first or second member to the pawl-bearing member or the tooth-bearing member, whichever one is rotating. Preferably said first member is driven by (e.g. attached to) said drive mechanism.

[0040] The dispenser may include a housing having a window in substantial superimposed alignment with the second member, with the overlapping relationship being such that only one portion of said at least a partial helical turn of said first member is exposed to the window. The window may be a hole in the housing or may be a transparent area of the housing. This allows a precise reading of the quantity of unit product, such as metered doses of medicament, remaining in the container or dispensed therefrom. Where the second member comprises a rigid strip of material, this could be mounted internally on, or be integral with, the housing.

[0041] It will be apparent from the afore-going discussion that the present invention finds particular application in dispensers, especially metered dose dispensers. Nevertheless, the present invention may be implemented in conjunction with any suitable device.

[0042] The counters of the present invention may be used with a conventional dispenser comprising a body for receiving a medicament container and a dispensing mechanism for dispensing a dose of medicament from the container. Preferably the dose counter is used with a metered dose inhaler. Particularly preferably the dose counter is used with a breath actuated metered dose inhaler. Such inhalers are known in the art, e.g. from WO1998/41254 (US 6422234), WO2002/11802 (US 7036505), WO2002/058772 (US6866038) and WO2004/073776 (US 2007 062522).

BRIEF DESCRIPTION OF THE DRAWINGS

[0043] These and other aspects of the invention will now be further described, by way of example only, with reference to the accompanying figures in which:

Figure 1 is a cross-sectional view of a conventional dispenser to which a counter according to the present invention may be attached;

Figures 2(a) to 2(c) schematically illustrate an overlapping relationship between members of the counter according to the present invention;

Figure 3 is a cross-sectional view of the dispenser of Figure 1 to which a counter according to a first embodiment of the present invention has been attached;

Figure 4 is a cross-sectional view of the dispenser of Figure 1 to which a counter according to a first embodiment of the present invention has been attached;

Figures 5 illustrates a drive mechanism for use with the counter of the present invention;

Figures 6a to 6d are schematic diagrams showing a part of the principle of operation of the drive mechanism for use with a counter of the present invention;

Figures 7a to 7d are schematic diagrams showing another part of the principle of operation of the drive mechanism for use with a counter of the present invention;

Figure 8 is a perspective internal view of a dispenser including a counter according to the present invention;

Figure 9 is a perspective external view of the dispenser of Figure 8;

Figure 10 is a perspective view of a counter according to one embodiment of the present invention;

Figure 11 is a perspective view of a counter according to another embodiment of the present invention;

Figure 12 schematically illustrates an overlapping relationship between members of the counter according to the present invention;

Figure 13 schematically illustrate another overlapping relationship between members of the counter according to the present invention; and

Figure 14 schematically illustrates a guide element for guiding a first member.

DETAILED DESCRIPTION OF PREFERRED EMBODIMENTS

[0044] To explain the invention, a brief overview of some features and operating principles of exemplary dispensers is initially provided. As used herein the term "dispenser" is intended to mean any device suitable to receive a container holding a product (e.g. medicament), and which will also dispense the product from the container upon actuation.

[0045] Figure 1 shows in partial cross section an example of a breath-actuated, kink valve dispenser. The dispenser 100 comprises a body 102 with a mouthpiece 104 and a pivoted mouthpiece cover 106. The mouthpiece cover is pivotable about an axis, A, low in the body and carried on a cam arrangement comprising two cam lobes (only one cam lobe 108 is shown), together with a central finger 110. The body has an opening 112 for receiving a medicament container 114. The container may be held fixedly in place at the upper end of the body, at a location where the body extends completely around a metering valve assembly of the container (not shown). The metering valve assembly comprises a metering chamber 116 and an outlet stem 118. Alternatively, or additionally, if the container is housed entirely within the dispenser, the container may be held at an end distal of its metering valve assembly, for example by a cap portion of an outer housing. In a preferred dispenser for use with the counter of the present invention, the dispenser comprises a tolerance adjustment mechanism (e.g. an

abutment feature) as described in WO2007/029019 (US application no. 11/991,680).

[0046] Moulded inside the body, inwards of the opening 112 are internal grooves (not shown). A junction member 120 is slidably accommodated in the body with the grooves engaged by ribs in its periphery. The junction member has a pair of pivot clips (not shown) for pivotally locating the flap 122 in the junction member 120. Centrally, the junction member has a socket 124 for an outlet stem 118 of the container. The socket is continued by a passage 126, which has a thin wall, kinkable portion and a nozzle end. The nozzle end is in a movable part of the junction member. The main part and the movable part of the junction member are connected by a living hinge.

[0047] The moving part of the junction member 120 also carries a pair of sears (not shown) that are arranged to engage with latches on the underside of flap 122 as described below. The movable part of the junction member also carries a finger for engagement with the cam arrangement.

[0048] Initially when the dispenser is closed the flap is unlatched and the movable part of the junction member is in its lower position. The kinkable portion, sometimes referred to herein as a kinkable valve, is open. On opening of the mouthpiece cover 106, the central finger of the cam arrangement acts on the movable part of the junction member to close the kink valve. The movement of the movable part of the junction member also serves to engage the sears of the movable member with the latches of the flap, thereby fixing the flap in an upper position. The junction member 120 is also lifted by the main cam lobes 108 against an internal spring (not shown) of the metering valve assembly, with displacement of the stem 118 inwards of the container. Further lifting of the mouthpiece cover 106 opens the container valve and a metered dose is released into the upper part of the tube, the dose being retained by the closed kink valve acting as a closed valve.

[0049] Breathing in through the mouthpiece causes an air flow through the dispenser and impinges on flap 122. This causes release of the sears and the kink tube tends to straighten under the action of its own resilience and the pressure of the retained dose. The dose is thus released through the nozzle into the mouthpiece for inhalation. The flap may also carry a finger (not shown) that can act on the moveable part of the junction member to ensure that the kink valve is opened when the flap is breath actuated.

[0050] These and other features of exemplary dispensers are described in more detail in Clinical Designs Limited's prior PCT applications WO1998/41254 (US 6422234); WO2002/11802 (US 7036505); WO2002/058772 (US6866038) and WO2004/073776 (US 2007 062522).

[0051] The following description of exemplary embodiments of the invention is presented in the context of metered-dose inhalers, in particular the dispenser illustrated in Figure 1. However, as stated previously, it will be appreciated that this is but one example of a suitable application.

[0052] Referring to Figure 3, the dispenser 100 may be provided with a teeth-bearing member 302 of a pawl-and-tooth drive mechanism 300. The term "drive mechanism" is to be interpreted broadly as any means by which the dispensing of a dose is linked to a counter being made by the counter. In described embodiments the dispensing of a dose will involve a vertical movement, e.g. of junction member 120, as described earlier with reference to Figure 1. In the described preferred embodiment this vertical movement is translated into an incremental rotation that is counted.

[0053] The teeth-bearing member has a collar 304, which extends around the container just above the metering valve assembly, with a ring of moulded teeth 306 on an outwardly facing surface. A pair of arms 308 (only one is depicted in Figure 3) extends downwardly from the collar on either side of the metering chamber 116. The arms can be spring-loaded against, or affixed to, an upper portion of junction member 120. An annular, pawl-bearing member 312 (depicted only in part in Figure 3 for clarity) is configured and arranged to fit around the collar 304, for engagement with the teeth.

[0054] The junction member moves vertically, e.g. when a mouthpiece cover is opened. The action of lifting the junction member 120 (which causes the release of a dose from a pressurised medicament container) imparts an upward force on the teeth-bearing member in a direction parallel to a longitudinal axis 316 of the dispenser. The resulting upward displacement of the teeth-bearing collar leads to an engagement with pawl-bearing member 312, which is rotatably driven. Once a dose is released and the mouthpiece cover is rotated to a closed position, the junction and teeth-bearing members are able to move downwards to their original positions by means of, for example, an internal spring (not shown) of the container. This downward movement also leads to an engagement between teeth-bearing member 302 and pawl-bearing member 312, resulting in a further rotation.

[0055] Taken together, these two increments of rotation define a "complete" incremental rotation of the pawl-bearing member.

[0056] Figure 4 illustrates an alternative exemplary embodiment in which a dispenser is provided with a pawl-bearing inner sleeve 402 coupled to an upper end of junction member 120 by an interlocking connecting rod 404. A ring of teeth is moulded on an inner surface of outer housing 406, which comprises a teeth-bearing member. The mode of operation is similar to that described above.

[0057] Figure 5 illustrates an exemplary drive mechanism 300 in which the ring of teeth 306 is disposed on an inwardly facing surface of the teeth-bearing member 302, with the pawl-bearing member 312 being disposed within its bore.

[0058] Two pawls 502a, 502b, are borne integrally by pawl-bearing member 312, being defined by a cutaway portion thereof. Viewed from this perspective, each pawl extends toward the ring of teeth 306 in an annular plane of the pawl-bearing member 312, at about the same

(but opposite) angle α , β . The second (lower) pawl 502b is offset in a circumferential direction relative to the first (upper) pawl 502a. The pawls each have a root end and a free end. A tip 508a, 508b protrudes radially outwardly from each of the free ends, to operatively engage with the teeth.

[0059] The outlet stem 118 of the metering valve assembly (hidden from view) inserts down through the clearance hole of the base of the pawl-bearing member 312 to rest on a shelf 510 in a stem block 512. This differs from the preferred configuration shown in Figure 3. It will be appreciated that this difference, in itself, is not of particular significance in the context of the drive mechanism.

[0060] In operation, and viewed from this perspective, the pawl-bearing member 312 moves up and down, and rotates, relative to the teeth-bearing member 302 when the stem block is moved upwards to depress 118 and release a dose. For convenience, the upward and downward movements of the pawl-bearing member 312 will be referred to as the 'count stroke' and 'return stroke', respectively.

[0061] Figures 6a to 6d show a sequence of cross-sectional views of the drive mechanism during the count stroke. In Figure 6a, the pawl-bearing member is at rest on the teeth by means of a protruding block 610. An upwardly directed force on the pawl-bearing member initially results in frictional engagement between the tip 508a of the first (upper) pawl 502a and a vertical face 612 of tooth 602. This action guides the pawl-bearing member substantially vertically upwards, until such a time as the tip 508b of the second (lower) pawl 502b engages with a lower, sloped face 614 of tooth 606 (Figure 6b). This effects an upward diagonal movement, which proceeds until tip 508b reaches, and then surpasses, the apex 616 of tooth 606 (Figures 6c and 6d, respectively). At the same time, the first (upper) pawl 502a flexes slightly inwards to allow tip 508a to pass over tooth 602 (Figure 6c). Dashed arrows indicate the direction of movement.

[0062] Figures 7a to 7d show a sequence of cross-sectional views of the drive mechanism during the return stroke. Like elements to those of Figure 6 are indicated by like reference numbers.

[0063] In Figure 7a, which corresponds substantially to Figure 6d, the tip 508a of the first (upper) pawl 502a moves vertically downwards until it frictionally engages with an upper, sloped face 618 of tooth 602, resulting in a downward diagonal movement. In Figure 7b, the tip 508a has proceeded further down face 618, and block 610 now engages an upper, sloped face 620 of tooth 604. This time the second (lower) pawl 502b flexes slightly inwardly to allow tip 508b to pass over tooth 604. This proceeds until the pawl-bearing member again comes to rest on the teeth (Figures 7c and 7d). Figure 7d corresponds substantially to Figure 6a, but rotated by one tooth, i.e. from tooth 606 to tooth 604.

[0064] Although the foregoing discussion has described the case where the pawl-bearing member rotates about an axis (i.e. rotates relative to the dispenser as a whole), it is equally

possible that the teeth-bearing member rotates.

[0065] It will also be appreciated that a rotational displacement need not be performed by way of two engagements (though this may be beneficial), nor need it comprise vertical and rotational movement. For example, a mechanism providing purely rotational motion, in other words without vertical movement, could also be used. However, the drive mechanism should effect a relative rotation between the first and second members of the counter about a longitudinal axis of the counter.

[0066] In the specific embodiment of a dose counter shown in Figure 8, a cantilever 802 extends upwardly from an upper edge of the collar 304 of a teeth-bearing member 302 and integrally connects to a second member 202 of the dose counter. The second member extends substantially vertically. In this particular configuration, the second member 202 is spatially fixed relative to the teeth-bearing member 302, which oscillates between a lower position and an upper position. The cantilever 802 allows the teeth-bearing member to move unobstructed and exerts a downward spring force on the collar 304 of the teeth-bearing member, causing it to return to its lower position. The dose counter also includes a generally helical first member 201 forming multiple turns around the container. The first member 201 is coupled to pawl-bearing member 312 (shown only in part). The second member 202 overlaps under and over the first member 201.

[0067] In operation, the rotation of pawl-bearing member 312, caused by the upward and subsequent downward displacements of the teeth-bearing member 302, acts to rotate the first member 201. For this particular drive mechanism, these displacements taken together define a rotation of the helical member from a first to a second position.

[0068] With reference to Figure 9, the depicted dispenser 900 has an outer housing 902 attached to or integral with the body of the dispenser. The second member 202 is superimposed under a window 904 of the outer housing. The teeth-bearing member, which is hidden from view, fixes the second member 202 positionally (here offset by approximately 90 degrees compared to its position in Figure 8) in relation to the window. As can be readily ascertained from Figure 9, the first member 201 and the second member 202 of the dose counter overlap such that only a portion (shown with the indicium "41") of one turn of the first member 201 is exposed to the window.

[0069] An exemplary overlapping relationship is detailed in Figure 10. The first member 201 exhibits numeric indicia 1002, and is arranged in multiple turns (three in this case) about an axis 316. In this particular example, the numbers of the set $\{0, 1, \dots, 60\}$ decrease in integer steps of one from a base portion 1004 to a tip portion 1006 of the member, but in other arrangements the numbers may decrease from the tip portion to the base portion. A second member 202 extends over a portion of each of the turns except one, such that only a single numeric integer ('41') is displayed across its width. Numbers (and other indicia) may alternatively be oriented in other directions relative to those shown here, such as rotated by 90 degrees.

[0070] In addition to different indicia, many of the structural characteristics associated with the first member 201 may be varied, including the pitch p , the strip width W , the height h , and the radius of curvature R , depending on the shape, number of held doses and configuration of the container and dispenser. To give but one example, the first member 201 could be a triangular strip, i.e. broad at one end and tapering to the other end. Further, the material of either or both of the first and second members 201, 202 may be selected from a range of available materials such as papers and plastics.

[0071] In an alternative overlapping relationship of the dose counter, shown in Figure 11, a dose counter comprising a rigid outer element 1102 and a rigid second member 202 define a recess 1106 (e.g. for a container) and a channel 1108. A first end 1110 of a flexible first member 201 is threaded into the channel between the outer element 1102 and the second member 202, gradually winding through the channel 1108 as the contents of the container are dispensed.

[0072] In Figure 12, the first member 201 makes one complete helical turn. A suitably windowed outer housing 902 of the dispenser is superimposed over the second member 202. The window 904 is configured such that only a portion 201 a of the first member is presented. The second member comprises an element within the diameter of the first member.

[0073] In Figure 13, the first member 201 comprises a triangular strip wrapped within the housing 902 and having at least an upper edge 201 b making a complete helical turn, with the second member 202 being behind the first member when viewed through the window 904. As the first member is rotated, the ratio between the visible portion 202a of the second member 202 and the visible portion 201 a of the first member increases. Suitable colouring, such as green for the first member and red for the second member, provides a fuel-gauge type counter. Alternatively or additionally indicia may be provided on the housing 902.

[0074] In Figure 14, the first member 201 is provided with a guide element G for guiding first member 201. The guide element G shown in Figure 14 comprises a track which extends along the entire length of the first member 201. In other embodiments, however, the guide element G may only extend along portions of the length of the first member 201. The guide element G helps to ensure that the first member 201 does not compress as it rotates.

[0075] While a dose counter should accurately track the number of doses released from/remaining in a medicament container, it is also desirable that a count is registered before a corresponding dose is released to the user. This reduces the possibility of user abuse. Thus, where the dispenser includes a drive mechanism and a retaining mechanism such as a kinked-valve, an irreversible count may be initiated by the first engagement, which coincides with a release of a dose into the kinked valve, and completed by the second engagement, which coincides with reset after the release from the kinked valve to the user.

REFERENCES CITED IN THE DESCRIPTION

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- Final guideline on the quality of inhalation and nasal products European Agency for Evaluation of Medicinal Products, 2005, [\[0005\]](#)

TÆLLER

Patentkrav

1. Tæller, der omfatter:

et første element 201, som er anbragt i mindst en delvis helisk kurve omkring en længdeakse af en enhed, hvis bevægelser og/eller indhold skal tælles, idet det første element har et indeks eller indekser 1002 til angivelse af en optælling; et andet element 202, der generelt strækker sig i retningen af længdeaksen, idet det andet element er operativt anbragt i overlappende forhold under og over én eller flere dele af den mindst delvis heliske kurve af det første element; og midler 300 til fremkaldelse af relativ bevægelse mellem det første og det andet element, idet bevægelsen omfatter en relativ inkrementel rotation omkring længdeaksen.

2. Tæller ifølge krav 1, hvor enheden er en medikamentbeholder til en dispenser 900, der har en krop til modtagelse af medikamentbeholderen og en dispenseringsmekanisme til dispensering af en medikamentdosis fra medikamentbeholderen.

3. Tæller ifølge krav 2, hvor bevægelsen foretages i en relativ inkrementel rotation som reaktion på, at dispenser 900 aktiveres.

4. Tæller ifølge krav 2 eller krav 3, hvor indekset eller indekserne 1002 angiver det antal medikamentdoser, som er dispenseret fra eller fortsat befinder sig i beholderen.

5. Dosistæller til anvendelse med en dispenser 900, der har en krop til modtagelse af en medikamentbeholder og en dispenseringsmekanisme til dispensering af en medikamentdosis fra beholderen, hvilken dosistæller omfatter:

et første element 201, som er anbragt i mindst en delvis helisk kurve omkring en længdeakse af medikamentbeholderen og har et indeks eller indekser 1002, der angiver det antal medikamentdoser, som er dispenseret fra eller fortsat befinder sig i beholderen;

et andet element 202, der generelt strækker sig i retningen af længdeaksen, idet det andet element er operativt anbragt i overlappende forhold under og over én eller flere dele af de mindst delvis heliske kurver af det første element; og midler 300 til fremkaldelse af relativ bevægelse mellem det første og det andet element, når dispenseringsmekanismen aktiveres, idet bevægelsen omfatter en relativ inkrementel rotation omkring længdeaksen.

6. Tæller ifølge et hvilket som helst foregående krav, hvor det første element 201 er anbragt i en flerhed af heliske kurver omkring længdeaksen.

7. Tæller ifølge et hvilket som helst foregående krav, hvor det andet element 202 strækker sig i en retning, som er parallel med længdeaksen.

8. Tæller ifølge et hvilket som helst foregående krav, hvor den relative inkrementelle rotation omkring længdeaksen ændrer det overlappende forhold mellem det første 201 og det andet element 202.

9. Tæller ifølge et hvilket som helst foregående krav, hvor det overlappende forhold er således, at kun en del af én delvis kurve eller en kurve af det første element 201 ligger over eller under det andet element 202.

10. Tæller ifølge krav 9, hvor indekset eller indekserne 1002 er anbragt på det første element 201 med henblik på at være lokaliseret over eller under det andet element 202.

11. Tæller ifølge et hvilket som helst foregående krav, hvor det andet element 202 omfatter en strimmel af fleksibelt, elastisk eller stift materiale.

12. Tæller ifølge et hvilket som helst foregående krav, hvor det første element 201 omfatter et stift, elastisk eller fleksibelt materiale.

13. Tæller ifølge et hvilket som helst foregående krav, hvor ét af det første 201 og det andet element 202 eller begge to består af et materiale med lav friktionskoefficient.

14. Tæller ifølge et hvilket som helst foregående krav, hvor indekset eller indekserne 1002 er tilvejebragt via en form af det første element og/eller indekser, der omfatter én eller flere af: tal, farver, bogstaver og symboler.

15. Tæller ifølge krav 14, hvor indekserne 1002 omfatter en talmængde, der er sekventiel i inkremitter af én eller flere af: en brøkdel af én, én, to, fem, ti, tyve, halvtreds og et hundrede.

16. Tæller ifølge krav 14 eller krav 15, hvor indekserne 1002 er påtrykt, udskåret fra, præget, støbt, påhæftet, inkorporeret og/eller påmalet på ét af det første og det andet element eller begge to.

17. Tæller ifølge et hvilket som helst foregående krav, hvor det første element 201, som er helisk anbragt omkring en længdeakse af dispenserens krop har en i det væsentlige konstant stigning P og/eller bredde W langs med længden.

18. Tæller ifølge et hvilket som helst af kravene 1 til 16, hvor det første element 201, som er helisk anbragt omkring en længdeakse af dispenserens krop, har en variabel stigning P og/eller bredde W, der omfatter én eller flere adskilte afsnit med forskellig stigning P og/eller bredde W langs med længden.

19. Tæller ifølge et hvilket som helst foregående krav, hvor de midler, der fremkalder en relativ rotation, omfatter en drevmekanisme 300 med et med en spærreklinke forsynet element 312, som er anbragt og konfigureret til udløseligt at gå i indgreb med et med tænder forsynet element 302.

20. Tæller ifølge krav 19, hvor drevmekanismen forspænder det første element 201 i en rotationsretning omkring længdeaksen som reaktion på en kraft i en retning, som i det

væsentlige er parallel med længdeaksen.

21. Tæller ifølge krav 20, hvor en rotation af det første element 201 fra en første position til en anden position initieres inden en dispensering af produktet.

22. Tæller ifølge et hvilket som helst foregående krav, hvor det andet element 202 er fastgjort i forhold til dispenseren.

23. Tæller ifølge et hvilket som helst foregående krav, hvor det første element roterer omkring længdeaksen af dispenseren.

24. Tæller ifølge et hvilket som helst af kravene 19 til 23, hvor det første element 201 drives af drevmekanismen 300.

25. Tæller ifølge et hvilket som helst foregående krav, hvor dispenseren 900 indbefatter et hus 902 med et vindue 904, der i det væsentlige flugter med det andet element 202, og hvor det overlappende forhold er således, at kun én del af den mindst delvis heliske kurve af det første element 201 eksponeres for vinduet.

26. Dispenser 900, der omfatter tælleren ifølge et hvilket som helst af kravene 1 til 25.

27. Dispenser, der omfatter:

- en krop til modtagelse af en medikamentbeholder;
- en medikamentbeholder;
- en dispenseringsmekanisme til dispensering af en medikamentdosis fra beholderen; og
- en tæller ifølge et hvilket som helst af kravene 1 til 25.

28. Dispenser ifølge krav 26 eller krav 27, der er en tællerstyret dosisinhalator under tryk (pMDI).

DRAWINGS

Figure 1
PRIOR ART

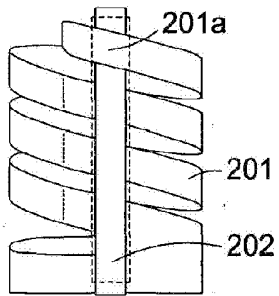
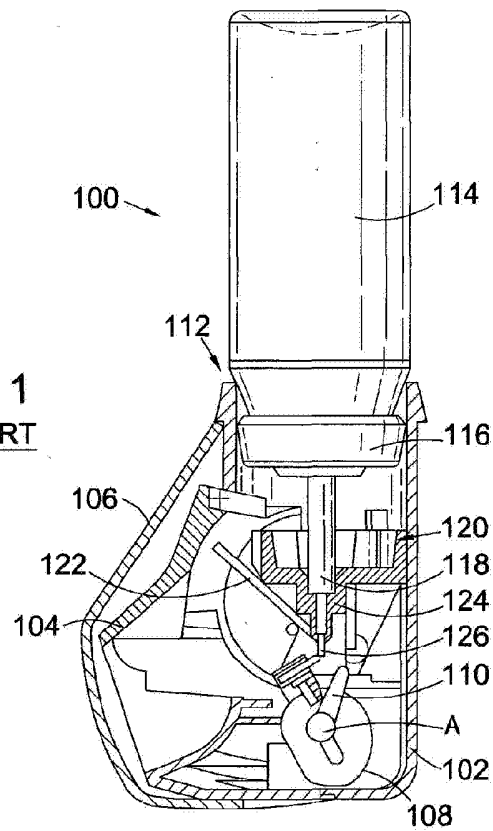


Figure 2(a)

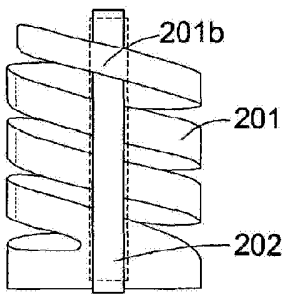
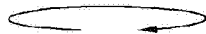


Figure 2(b)

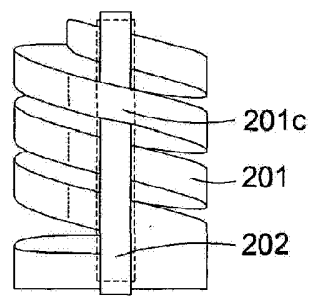
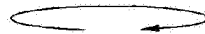


Figure 2(c)

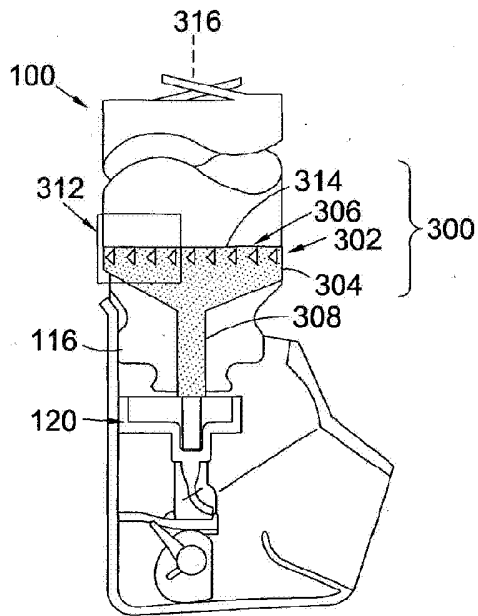


Figure 3

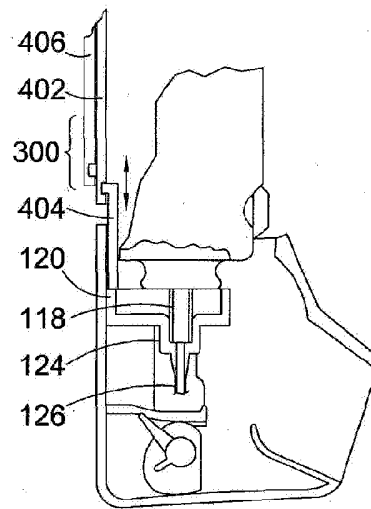


Figure 4

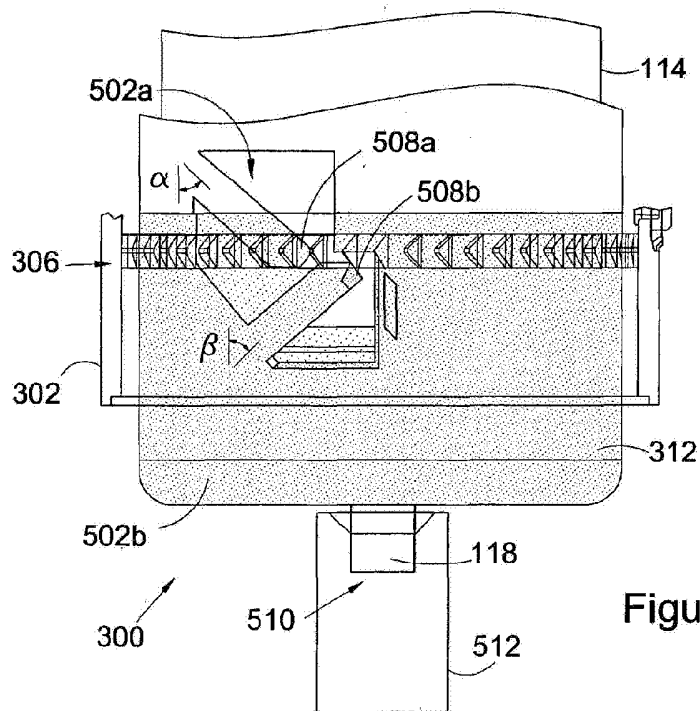


Figure 5

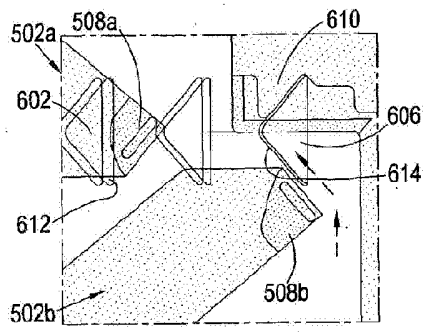


Figure 6A

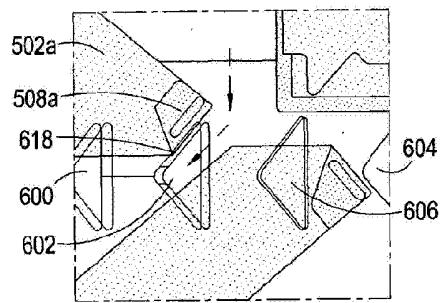


Figure 7A

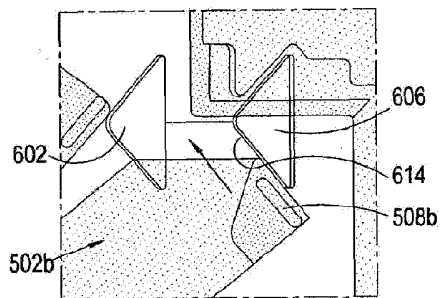


Figure 6B

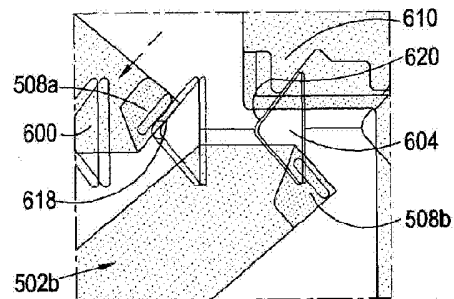


Figure 7B

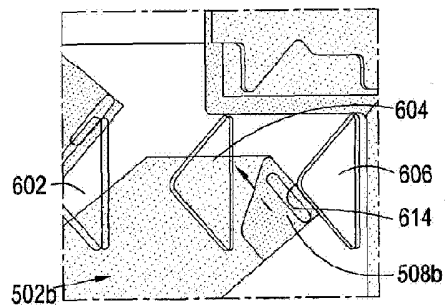


Figure 6C

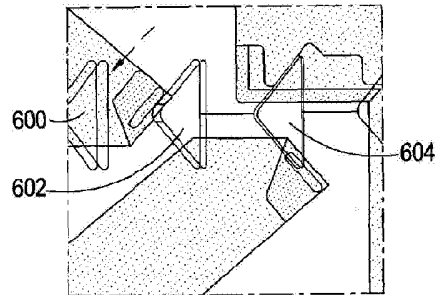


Figure 7C

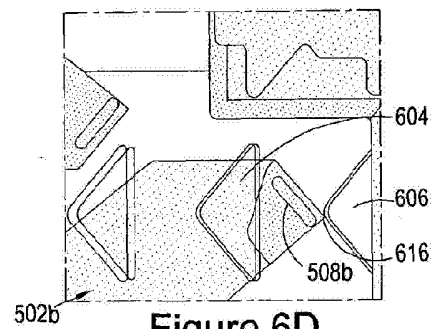


Figure 6D

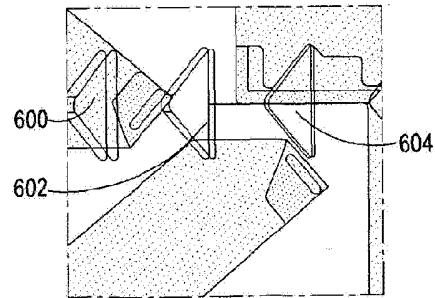


Figure 7D

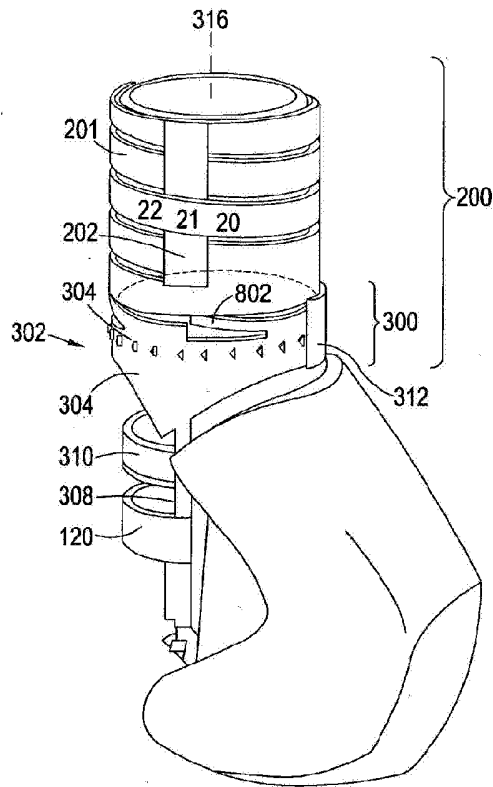


Figure 8

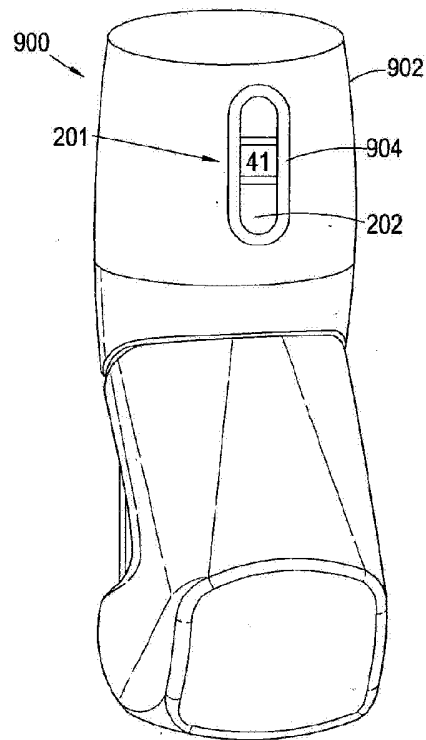


Figure 9

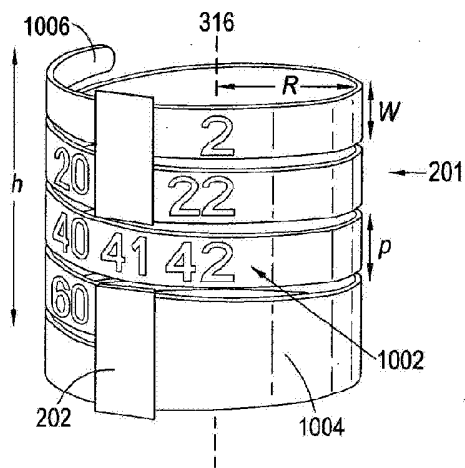


Figure 10

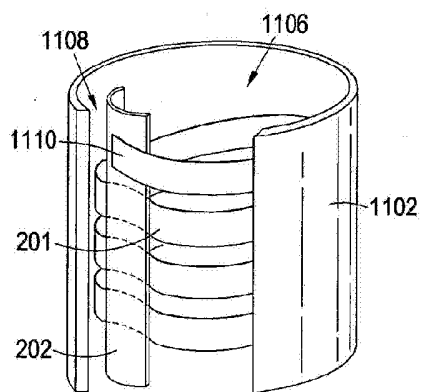


Figure 11

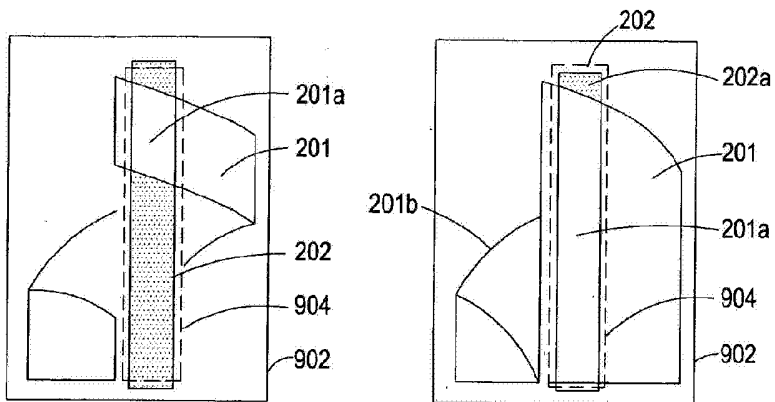


Figure 12

Figure 13

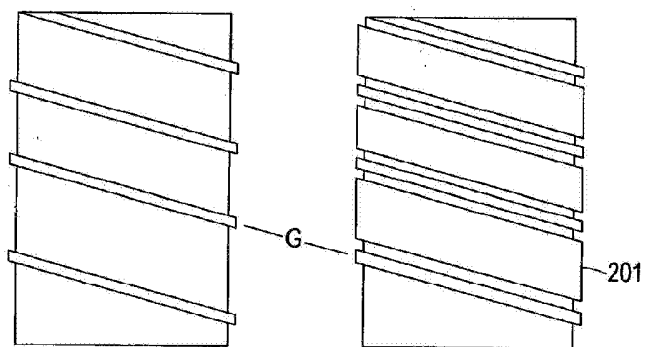


Figure 14