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# DESCRIPTION

**[0001]** The invention relates to a new administration method, in particular one that uses a certain hand held medicine dosing and dispensing device.

**[0002]** The drug therapies used to treat or otherwise control a number of chronic diseases such as, but not limited to, Parkinson's disease, epilepsy, cancer, depression, schizophrenia, diabetes, arthritis and asthma and diseases requiring anti-coagulants, anti-arrhythmics and/or analgesia often have a narrow therapeutic window and produce significant side effects when dosing is non-optimal.

**[0003]** The timing of doses is therefore critical to maintain drug levels within desired levels and it is important that administered doses are as accurate as possible to reduce the effects that can otherwise arise from over or under dosing.

**[0004]** In order to administer as accurate a dose as possible EP 1 058 660 B1 describes a procedure for dosing a medicine for dispensing to a single patient from a supply of equally large units or partial doses of the medicine in the form of single tablets or pellets where each unit or partial dose contains from approximately 20 to approximately 2 weight percent of the therapeutic total dose to be administered to the patient on a single occasion.

**[0005]** This procedure allows the dispensing of highly variable doses of a medicine from a single supply of the medicine.

**[0006]** To render this procedure suitable for use by individual patients outside of a hospital environment it is desirable to provide a dosing and dispensing device that is portable and therefore considerably smaller than the dispensing devices typically used within hospitals and pharmacies to store and dispense medicines. It is also desirable to provide a dosing and dispensing device that is easily reusable in the sense that it is efficient, safe and hygienic to refill with units of medicine. Such devices would therefore lend themselves to be used in novel methods of administration.

**[0007]** The miniaturization associated with producing a portable dosing and dispensing device has been found to encourage the formation of bridges of tablets within the dosing and dispensing device, which impacts on the efficiency of any such device.

**[0008]** The formation of bridges of tables or pellets within funneled channel sections leading to outlets of tablet dispensing devices is known and is illustrated diagrammatically in Figure 1, which shows a bridge 1 of tablets 2 formed within a funneled channel 3 leading to an outlet 4 of a storage chamber 5.

**[0009]** EP 0 287 335 discloses a device that seeks to overcome the problems associated with the formation of bridges of tablets in a funneled channel of a tablet dispensing device.

**[0010]** The device disclosed in EP 0 287 335 includes a feed channel having a flexible wall to agitate tablets in the feed channel. However, in order to agitate tablets in the feed channel, the flexible wall must flex both outwardly and inwardly in order to provide the required vibration and therefore necessitates the provision of space in an outward direction into which the wall may flex. The requirement for this outward space results in a larger device than would otherwise be required in order to store the required number of units of medicine.

**[0011]** Unpublished international application PCT/EP2009/008253 discloses certain hand held dosing and dispensing devices, but does not disclose any administration method using that device.

**[0012]** In an aspect of the invention, there is provided a new administration method (or new dosing regime), in which a certain hand held dosing and dispensing device is employed to deliver the medicine in that method (or regime). Such a hand held dosing and dispensing device is as described herein.

**[0013]** More specifically, there is provided a medicament for use in the treatment of a disease wherein the medicament is orally administered on one to ten occasions daily using a hand held medicine dosing and dispensing device, and wherein:

the hand held medicine dosing and dispensing device comprises a housing including a storage chamber to store discrete units of medicine; a feed assembly located between the storage chamber and a dispenser to feed individual units of medicine from the storage chamber to the dispenser; and an impacter operably associated with the storage chamber to agitate units of medicine stored in the storage chamber, characterized in that the impacter includes a rigid element fixedly connected at or towards one end to a wall of the storage chamber and operably associated at or towards a second end with an actuating mechanism that deflects the second end of the impacter towards the wall of the storage chamber to strain the impacter such that, when released, the strained impacter moves towards the interior of the storage chamber and impacts against the units of medicine.

**[0014]** Hence, the invention relates to a medicament for use in an administration method, which is therefore referred to herein as "the method of the invention". The administration will be to a patient, preferably a human patient (e.g. one that is able to manage the hand-held device of the invention). In an aspect, the administration method of the invention may specify a certain frequency of administration of the relevant medicament, for instance it may relate to a certain dosing regime (i.e. administration on one to ten occasions daily is specified), and it may therefore be referred to herein as "the (dosing) regime of the invention". The hand held dosing and dispensing device used to administer the relevant medicament is referred to herein as "the device of the invention".

**[0015]** The term "medicament" when used herein refers to an active compound, which is

known to treat (including therapeutic and/or prophylactic treatment) a certain disease or condition. It may refer to the active component as such, e.g. an organic compound or a pharmaceutically acceptable salt, solvate or prodrug thereof. It may also refer to that active compound (or salt, solvate or prodrug thereof) as a component of a pharmaceutically acceptable composition/formulation, i.e. one that may further contain a pharmaceutically acceptable adjuvant, diluent or carrier (and/or other suitable ingredients of a composition/formulation).

**[0016]** For instance, pharmaceutically acceptable salts of active compounds that may be used as the medicament (or as a component of the medicament) in the method/regime of the invention include acid addition salts and base addition salts. Such salts may be formed by conventional means, for example by reaction of a free acid or a free base form of the relevant active compound with one or more equivalents of an appropriate acid or base, optionally in a solvent, or in a medium in which the salt is insoluble, followed by removal of said solvent, or said medium, using standard techniques (e.g. *in vacuo,* by freeze-drying or by filtration). Salts may also be prepared by exchanging a counter-ion of a compound of the invention in the form of a salt with another counter-ion, for example using a suitable ion exchange resin.

**[0017]** Although active compounds that may be used as the medicament (or as a component of the medicament) in the method/regime of the invention may possess pharmacological activity as such, certain pharmaceutically-acceptable (e.g. "protected") derivatives of the relevant active compound may exist or be prepared which may not possess such activity, but may be administered and thereafter be metabolised in the body to form the relevant active compound. Such compounds (which may possess some pharmacological activity, provided that such activity is appreciably lower than that of the active compounds to which they are metabolised) may therefore be described as "prodrugs" of compounds of the invention.

**[0018]** The term "prodrug" includes compounds that form the relevant active compound in an experimentally-detectable amount, within a predetermined time (e.g. about 1 hour), following administration. All prodrugs of the relevant active compounds may be the active compound in the medicament (or a component of the medicament).

**[0019]** As stated hereinbefore the medicament that may be administered may be the active compound (i.e. including salts, solvates or prodrugs thereof) as such or it may be a pharmaceutically acceptable composition/formulation comprising that active compound, for instance in admixture with one or more adjuvant, diluent or carrier.

**[0020]** The active compound (including salts, solvates or prodrugs thereof) may also be a component of a pharmaceutically acceptable composition, which has a sustained and/or controlled release characteristic (and therefore doses may need to be taken relatively less frequently), for instance it may comprise another component which, in combination with the active component, provides for the sustained and/or controlled release characteristic. The further component may be a distinct component (e.g. a certain excipient or a swelling agent, such as hydroxypropyl methylcellulose or the like; such a component may comprise from about

5% to about 50% parts by weight, per 100 parts by weight of the formulation) or the active compound may be embedded in a matrix of insoluble substance, the active ingredient being released as a result of its solubility. Other standard sustained and/or controlled release formulations are included within the scope of the invention. Also, the sustained and/or controlled may be an inherent property of the active ingredient.

**[0021]** By "sustained release", we include formulations/compositions, which when administered (e.g. orally administered), the active ingredient will be released for absorption into the blood stream over a period of time (that is longer than the period that the active ingredient would normally be released into the blood if it did not have the sustained (or controlled) release properties or characteristics).

**[0022]** It is stated herein that a medicament may be administered as hereinbefore defined, for instance once daily or more, i.e. up to ten times daily. However, conveniently, the medicament may be administered even more frequently using the device of the invention, if the disease to be treated requires. Preferably, the route of administration is oral and the active compound is taken as a unit consisting of a tablet or capsule (or multiple units, i.e. several tablets or capsules). It is also understood that the active compound may be a component of a pharmaceutically acceptable formulation as hereinbefore defined (which includes a sustained and/or controlled release formulation).

**[0023]** Advantageously, the hand held medicine dosing and dispensing device of the invention (i.e. "the device of the invention") is used to administer the medicament (i.e. the active compound, or formulation containing it) orally on a distinct number of occasions per day. On each occasion, the medicament may be taken by the administration of several partial doses or units (e.g. microtablets) that together make up the total dose to be administered on each single occasion. Advantageously, the device of the invention allows for the dose on each occasion to be fine-tuned, depending on the requirements of the disease/patient.

**[0024]** When the medicament (i.e. the active compound or formulation containing it) is administered, then it may be once daily (by which we mean that the entire recommended daily dose is taken on one occasion, or in one batch, in a 24 hour period) or more than once daily, for instance two, three or four times daily (i.e. the recommended daily dose is administered on two, three or four occasions, or in two, three or four batches, in a 24 hour period). When it is taken on more than one occasion (or in more than one batch) in a 24 hour period, then preferably (and advantageously) each batch is spread over the 24 hours in a manner appropriate to the disease or condition to be treated. That is, when the daily dose is administered on more than one occasion daily, then the quantity taken on each occasion in the 24 hour period may be the same or different. Advantageously, the device of the invention lends itself to be able to allow the patient or user to be able to administer the medicament in any predetermined dosing regime, i.e. in any quantity on any given number of occasions.

**[0025]** When the medicament (i.e. the active compound or formulation containing it) that is to be administered is not a sustained or controlled release formulation (for instance, if the active

ingredient is released into the blood stream over a period of 6 hours or less), then the number of doses is preferably 3 or more (e.g. 4 or more, such as 5 to 10 doses) daily. The device of the invention advantageously lends itself to such administration methods (or dosing regimes), given that it allows for the dispensing of highly variable doses of a medicine, including such spreading of a daily dose over the 24 hour period.

**[0026]** However, when the medicament (i.e. active compound, or formulation containing it) that is to be administered is a sustained and/or controlled release formulation (which may preferably be the case, for instance if the active ingredient is released into the blood stream over a period of more than six hours, e.g. between 6 and 24 hours; which includes the situation where the active ingredient itself has a long half life and therefore has inherent sustained-release properties), then the number of doses will be less frequent, for instance 4 or less daily (e.g. 3 or less, such as 2 and most preferably once daily, if the formulation allows). Preferably, with a once daily dosing regime, the dose is taken before sleep (e.g. before night-time, before the patient sleeps) or after sleep (e.g. in the morning, after the patient awakes). Advantageously, the device of the invention may also be employed to deliver such daily doses (in particular once, twice or three times daily).

**[0027]** Most importantly, the number of occasions that the medicament will need to be taken in a 24 hour period will depend on the disease and the patient to be treated. For instance, if the medicament is a sustained release formulation (or the disease to be treated is one in which the daily frequency is low regardless of the type of formulation), then the frequency of administration in a 24 hour period will be relatively less (e.g. three or less occasions daily), but if the disease to be treated is one where a higher daily frequency is necessary e.g. Parkinson's, then the number of occasions may be relatively more, e.g. three or more (e.g. three to ten, such as five to ten, occasions daily).

**[0028]** A daily dose refers to the amount of active compound required by the patient in a 24 hour period, to treat a certain disease or condition. The actual daily dose (i.e. quantity of medicament or active compound) will depend on the patient and will also vary according to the disease or condition to be treated.

**[0029]** For instance, oral dosages may range from between about 0.01 mg/kg of body weight per day (mg/kg/day) to about 100 mg/kg/day, preferably about 0.01 to about 10 mg/kg/day, and more preferably about 0.1 to about 5.0 mg/kg/day. A typical total daily dose may therefore correspond to 100 to 2500 mg (however, more specific daily doses are mentioned hereinafter). For e.g. oral administration, each unit or partial dose typically contains between about 0.01 mg to about 500 mg, and preferably between about 1 mg to about 100 mg, of the active ingredient. Typically, when the device of the invention uses partial doses (which is preferably the case), then a partial dose (or unit/microtablet) may be between about 1 mg and 25 mg (e.g. about 5 mg). Advantageously, compounds may be administered in a once daily dose, or the total daily dose may be administered two, three or four times daily, i.e. in two, three or four batches in a 24 hour period (on two, three or four occasions in a 24 hour period).

**[0030]** In any event, the physician, or the skilled person, will be able to determine the actual dosage which will be most suitable for an individual patient, which is likely to vary with the route of administration, the type and severity of the condition that is to be treated, as well as the species, age, weight, sex, renal function, hepatic function and response of the particular patient to be treated. The above-mentioned dosages are exemplary of the average case; there can, of course, be individual instances where higher or lower dosage ranges are merited, and such are within the scope of this invention.

**[0031]** Where, the dose of medicament is administered more than once daily, then the quantity given on each occasion may or may not be divided equally. For instance, if the total daily dose should be 100 mg (which is typically the lower limit of the total daily dose), and the administration method requires twice daily oral intake, then each dose may be 50 mg each or, equally, one dose may be 75 mg and the second dose may be 25 mg. The actual quantity of the medicament administered to the patient on each occasion, and the frequency of administration, will depend on the disease or condition to be treated (and on the patient himself). However, advantageously, the device of the invention allows (or alerts) the patient or user to take the appropriate dose on the relevant number of occasions (e.g. once daily or more frequently, up to ten times daily; the daily dose being divided up equally or not, when the administration is more than once daily). It is stated herein that each unit of medicine contains from approximately 20% to 2% of the weight of the total dose to be administered on each specific occasion. Hence, the medicament may consist of several individual units, i.e. partial doses (e.g. tablets or capsules) contained within the device of the invention, and the total number of units to be administered on a single occasion may be 5 to 50 individual units. Hence, if such a medicament is taken on more than one occasion in a 24 hour period, then the total number of individual units to be taken daily may be 5 (x the number of occasions) to 50 (x the number of occasions), i.e. when the units are taken on three occasions daily, then 15 to 150 individual units may be administered in that 24 hour period.

**[0032]** Any number of individual units may be taken on a given occasion, provided that the total daily dose is respected. For instance, if the total daily dose of the medicament is 100 mg (which is typically the lower limit of the total daily dose), and it has to be taken once daily, then this may consist of 5 individual units of 20 mg taken on that one occasion. If the daily dose is taken on 2 occasions, and the dose is administered as 10 individual units, each unit being 10 mg, then this may be taken on two occasions (i.e. in two batches) in a 24 hour period, which may be 1 to 9 units (e.g. 4 to 6) on the first occasion and 9 to 1 (e.g. 6 to 4) units on the second occasion, making the total 10 units, thereby making up the total daily dose.

**[0033]** A quantity of medicament taken on one occasion refers to the intake of a medicament within a period of less than 30 minutes, preferably less than 10 minutes and most preferably less than 5 minutes (e.g. less than 2 minutes). Where the number of occasions that a daily dose is administered is greater than one in a 24 hour period, then the number of occasions may be spread out over the 24 hour period appropriately, such that there is preferably anywhere between 6 and 18 hours between each occasion. This is especially the case when the number of occasions per day is 2, 3 or 4. The number of occasions may be spread out

evenly over a period of 24 hours, i.e. it is most preferably 24 divided by the number of occasions. Hence, when a daily dose is taken on two occasions in a 24 hour period, then the second dose is preferably about 8 and 16 hours after the first, and most preferably about 12 hours after the first). As stated hereinbefore, the quantity of medicament taken on each occasion (when the number of occasions is greater than one) may or may not be divided equally between those number of occasions. Preferably, in an embodiment of the invention, the quantity of medicament in a daily dose may be divided up equally (i.e. daily dose divided by the number of occasions; hence 100 mg daily may be administered in two 50 mg batches in 24 hours), or about equally (i.e. within a variation of less than 50%, preferably less than 25%, e.g. less than 10%; hence a total of 100 mg taken twice daily may be administered in one batch of <75 mg and >25 mg, preferably <62.5 mg and >37.5 mg, e.g. <55 mg and >45 mg, with the second batch making up the total daily dose), by the number of occasions (if greater than once daily) on which the medicament is taken in that 24 hour period.

**[0034]** The disease or condition that may be treated by the method (or regime) of the invention includes:

1. (1) Parkinsons disease (PD)
   In this instance, the medicament preferably contains levodopa/carbidopa or levodopa/benserazide as the active ingredient. Preferably, the daily dose is 100 - 2500 mg for a typical adult patient and it is preferably administered in the method of the invention four or more times daily (i.e. four to ten times daily, preferably four to six times).
   It is well established that stable plasma concentrations of the dopamine precursor levodopa is favorable in all stages of PD and hence this is obtained by the frequent dosing using the device of the invention;
2. (2) Chronic severe pain
   In this instance, the medicament preferably contains morphine, oxikodone or methadone as the active ingredient. Preferably, the daily dose of morphine is 30-200 mg, of oxikodone is 15-120 mg and of methadone is 5-40 mg. Such medicaments are preferably administered three or more (i.e. three to ten, preferably three to six, e.g. 3 to 5) times daily.
   All opioid drugs are characterised by large inter-individual variation in pharmacokinetics. Further, the level and background of pain (cancer, trauma etc.) differs. Tolerance might develop and the classification of the drugs as narcotics means that there is a demand for dosing control. Dosing giving high concentration peaks are considered to induce addiction. Depot preparation are on the market but they are not easy to dose and unfavorable in events of overdose. Frequent dosing (i.e. more than 3 times daily) using the device of the invention therefore offers a new and unique possibility for individualized optimized therapy in severe chronic pain. The built-in electronic diary of pain level and side-effects will guide the dosing. Moreover, the units of medicament (e.g. micro-tablets) are locked within the cassette and their administration is registered - hence, important functions with regard to a risk of abuse as their administration may be monitored;
3. (3) Neuropathic pain, acute anxiety disorder, fibromyalgia and epilepsy

In this instance, the medicament preferably contains pregabaline as the active ingredient. Preferably, the daily dose is 100-600 mg and it is also preferred that the medicament is administered three or more (i.e. three to ten, preferably three to six, e.g. 3 to 5) times daily.

The active ingredient Pregabaline, primarily an antiepileptic drug, is presently registered for the other above-mentioned indications. There is a rapidly growing use of the drug especially in the therapy of neuropathic pain and anxiety, which are the two indications primarily in need for a new dosing strategy. Due to the need of individualized dosing 25, 50, 75, 100, 150, 225 and 300 mg capsules are available. There are some reports on abuse of the drug and the Medical Product Agency in Sweden has started an investigation on the use of pregabaline. Without doubt the drug is a valuable new option in the therapy of neuropathic pain and acute anxiety (recently approved in US also for fibromyalgia). It seems very important in these indications to use the device of the invention and the administration method of the invention, to divide the daily dose into at least 3 doses a day, to utilize the diary report for individualized, optimal, dosing and to register the use.

4. (4) Anxiety and panic disorders and detoxication programs

   In this instance, the medicament preferably contains diazepam (daily dose preferably 5-30 mg daily), oxazepam (daily dose preferably 15-100 mg), alprazolam (daily dose preferably 6-30 mg). Preferably such medicaments are administered four or more (i.e. four to ten, e.g. four to six) times daily. Repeated smaller doses of the above-mentioned medicaments are regarded as less prone to induce addiction. With the device of then invention several, more than four, individualized, low doses can be administered and the utilization is exactly controlled. Further, the units (e.g. microtablets) are locked within the cassette - an important hindrance to abuse.

5. (5) Diabetes (type 2)

   In this instance, the medicament preferably contains acarbose (daily dose preferably 150-300 mg), metformine (daily dose preferably up to 3000 mg), glibenclamide (daily dose preferably 1.75-10.5 mg), glipizide (daily dose preferably 2.5-15 mg)

   These oral antidiabetic drugs are characterized by great inter-individual variation in dose and a risk of hypoglycemia upon relative overdose. The need for individualized and age-related dosing is presently not properly met. The device of the invention will permit suitable dosing in connection with the different meals of a day. Further the blood glucose levels obtained by self-test can be recorded in the diary of the dose automat.

6. (6) Attention Deficit Hyperactivity Disorder (ADHD)

   In this instance, the medicament preferably contains atomoxetine (daily dose preferably up to 100 mg). Preferably, this medicament is administered once or twice daily (although the device of the invention allows for a greater frequency). This drug seems to offer a new valuable therapy in ADHD. However, dosing and titration to optimal effect is complex. The age group is heterogenous and dosing is calculated by bodyweight, starting in children with 0.5 mg/kg. Although no more than two doses a day are presently recommended the device of the invention would facilitate individualized dosing and documentation of drug utilization and clinical effect.

7. (7) Intestinal and gastric cancer, advanced breast cancer

In this instance, the medicament preferably contains capecitabine (daily dose preferably up to 2500mg/body surface). Preferably, this medicament is administered once or twice daily.

The therapy means a complex balance between effect and side-effects and the dose is calculated based on body surface. Although no more than two daily doses are presently recommended the device of the invention would facilitate individualized dosing

8. (8) Myastenia gravis (MG)

   In this instance, the medicament preferably contains pyridostigmine (daily dose preferably 180-1200mg). Preferably, this medicament is administered three or more (e.g. at least 3 and up to 6 times) daily.

   Most patients need at least 3, sometimes up to 6 doses daily of this choline esterase inhibitor to keep muscle power. Doses are very individual and changing over the course of the disorder. The device of the invention would offer a great advantage and the patients experience of power can be registered in the diary of the automate.

9. (9) Prophylaxis of thrombembolic events

   In this instance, the medicament preferably contains warfarin (daily dose preferably 5-15 mg)

   A controlled balance between effect and side-effects (risk of serious bleeding) is of utmost importance. Several factors (genetic, age, other drugs) influence optimal dosage. Dosage is based on regular estimation of the prothrombin complex according to International Normalized Ratio (INR). Today, patients often have to divide tablets into halves or even quarters. Adoption of the device of the invention with units (e.g. microtablets) would generate a secure and convenient dosing. Further, the INR values could be stored within the diary of the automate as a guide for dosage.

10. (10) Epilepsy and bipolar psychosis

    In this instance, the medicament preferably contains valproate (daily dose preferably 20-3000 mg). Preferably, this medicament is administered two or three times daily

    There is a great inter-individual variation in daily dose, commonly divided into 2-3 doses daily. As an antiepileptic agent the drug is used from childhood to advanced age. Therapeutic plasma concentration intervals have been defined for epilepsy (40-100 mg/l) and for prophylaxis of manic episodes (50-125 mg/l). The device of the invention would improve optimal dosage.

11. (11) Schizophrenia

    In this instance, the medicament preferably contains quetiapine (daily dose preferably 50-800 mg. Preferably, this medicament is administered two times daily (e.g. less than five times daily).

    Inter-individual variation in optimal dose is considerable and optimal dose titration important. Two doses a day is presently recommended. The device of the invention would facilitate dosing and titration and symptoms could be evaluated by means of the electronic diary.

**[0035]** The skilled person will therefore appreciate the large variation between the disease or

condition to be treated, the medicament to treat it and the preferred frequency of administration of the relevant medicament.

**[0036]** In the device of the invention, the provision of an impacter in the form of a rigid element fixedly connected at or towards one end to a wall of the storage chamber results in a means for agitating units of medicine stored within the storage chamber that requires minimal space in an outward direction to operate. It therefore allows the amount of useful storage space within the dosing and dispensing device in percentage terms to be maximized.

**[0037]** To allow for efficient, safe and hygienic refilling of the dosing and dispensing device, the storage chamber is preferably provided in a removable cassette that is releasably engageable within the housing.

**[0038]** This allows the use of cassettes that are refilled within a pharmacy and delivered to a patient in a sealed condition.

**[0039]** In embodiments of the invention in which the storage chamber is provided in a removable cassette, the cassette and the housing preferably include mutually engageable latch members that interengage on insertion of the cassette into the housing to retain the cassette within the housing. In such embodiments, the dosing and dispensing device also preferably includes an ejection mechanism that is selectively operable to disengage the latch members and allow removal of the cassette from the housing.

**[0040]** The provision of an ejection mechanism means the cassette and housing can be formed such that any outer surfaces of the cassette are flush with adjacent outer surfaces of the housing when the cassette is inserted into the housing, which enhances the outer appearance of the dosing and dispensing device.

**[0041]** According to a further aspect of the invention there is provided a medicament for use in the treatment of a disease wherein the medicament is orally administered on one to ten occasions daily using a hand held medicine dosing and dispensing device, and wherein: the hand held medicine dosing and dispensing device comprises a housing including a storage chamber to store discrete units of medicine; and a feed assembly located between the storage chamber and a dispenser to feed individual units of medicine from the storage chamber to the dispenser, wherein the storage chamber is provided in a removable cassette that is releasably engageable within the housing and characterised in that the cassette and the housing include mutually engageable latch members that engage on insertion of the cassette into the housing to retain the cassette within the housing, and the dosing and dispensing device further includes an ejection mechanism that is selectively operable to disengage the latch members and allow removal of the cassette from the housing.

**[0042]** In this aspect of the invention, the medicament, disease and administration method are as hereinbefore defined.

**[0043]** In embodiments where it is important to prevent illegitimate or otherwise unauthorized access to the units of medicine, the ejection mechanism may be adapted so that it is only operable to disengage the latch members and allow removal of the cassette from the housing when the storage chamber of the cassette is empty.

**[0044]** In such an embodiment, the provision of a cassette having outer surfaces that are flush with adjacent outer surfaces of the housing when the cassette is inserted into the housing may reduce the risk of someone being able to force the cassette out of the housing in order to gain unauthorized access to the units of medicine.

**[0045]** To determine whether the storage chamber of a cassette is empty, the dosing and dispensing device preferably includes one or more sensors.

**[0046]** One of the cassette and the housing may include latch members in the form of elongate projections engageable, when the cassette is received within the housing, with latch members in the form of corresponding openings provided in the other of the cassette and the housing. In such embodiments, the dosing and dispensing device preferably includes one or more biasing members to bias each of the elongate projections into engagement with the corresponding opening when the cassette is received within the housing.

**[0047]** Preferably the dispenser includes a dispensing chamber to collect and hold individual units of medicine fed from the storage chamber via the feed assembly, the dispensing chamber including a dispensing outlet selectively openable to dispense units of medicine held in the dispensing chamber.

**[0048]** In order to effect opening of the dispensing outlet, the dispensing chamber may be movable between a first position in which the dispensing outlet is closed and a second position in which the dispensing outlet is open. In such embodiments the dispenser may further include a motor to effect movement of the dispensing chamber between its first and second positions.

**[0049]** It is envisaged that in other embodiments the dispenser may omit the dispensing chamber and the feed assembly may communicate directly with a dispensing outlet.

**[0050]** Regardless of whether or not the storage chamber is provided in a cassette, the feed assembly preferably includes a feed wheel defining a plurality of feed pockets about its circumference. The feed wheel is rotatable in a first direction to move the feed pockets sequentially into alignment with a feed channel of the storage chamber to each receive a unit of medicine. On further rotation of the feed wheel in the first direction, the feed pockets are moved sequentially into alignment with the dispenser so as to feed the received units of medicine sequentially to the dispenser.

**[0051]** In embodiments where the storage chamber is provided in the form of a cassette, the feed wheel is preferably located in the cassette. Such an arrangement results in the provision of a sealed feed assembly and therefore minimizes the risk of the introduction of contaminants

into the feed assembly during replacement of the cassette, for example.

**[0052]** The dispenser may also form part of the cassette, the feed wheel being located between the storage chamber and the dispenser, and thereby also minimizing the risk of the introduction of contaminants into the dispenser during replacement of the cassette.

**[0053]** The dosing and dispensing device preferably includes a motor to drive the feed wheel, the drive motor preferably being controllable to drive the feed wheel to rotate in the first direction so as to feed a predetermined number of units to the dispenser.

**[0054]** Where the storage chamber is provided in a cassette and an ejection mechanism is provided to eject the cassette from the housing, the drive motor also preferably forms part of the ejection mechanism and is controllable to drive the feed wheel to rotate in a second direction to disengage the latch members and allow removal of the cassette from the housing.

**[0055]** In such embodiments, the feed wheel may include a drive shaft and the drive motor may include a drive gear engageable with an end of the drive shaft. The end of the drive shaft defines a pair of sloped contact surfaces, each contact surface terminating in a shoulder against which the drive gear engages on rotation in a first direction and the sloped contact surfaces defining cam surfaces along which the drive gear travels causing movement of the cassette relative to the housing on rotation of the drive motor in the second direction to disengage the latch members.

**[0056]** The dosing and dispensing device may further include a biasing member to expel the cassette on disengagement of the latch members.

**[0057]** In preferred embodiments, the feed wheel defines the actuating mechanism and the impacter is operably associated at or towards its second end with the feed wheel.

**[0058]** In order to effect deflection of the impacter, the feed wheel may include a plurality of equidistantly spaced fins protruding outwards from its outer circumference, adjacent fins defining the feed pockets therebetween. Rotation of the feed wheel in the first direction moves each of the fins sequentially into engagement with a front face of the second end of the impacter. Continued rotation of the feed wheel causes deflection of the second end of the impacter towards the wall of the storage chamber as the respective fin is moved across the front face of the second end of the impacter and out of engagement therewith.

**[0059]** This arrangement effects the movement required to cause repeated agitation of the units of medicine stored in the storage chamber during dispensing of a number of units of medicine and therefore assists in ensuring that units of medicine stored in the storage chamber do not form a bridge during dispensing. It therefore assists in improving the efficiency of the dosing and dispensing device.

**[0060]** In embodiments where the storage chamber is provided in a removable cassette and

the feed wheel is located in the cassette, rotation of the feed wheel in the second direction preferably moves an adjacent one of the fins into engagement with a second face of the second end of the impacter such that the second end of the impacter blocks further rotation of the feed wheel in the second direction.

**[0061]** In other embodiments, the impacter may be formed from a magnetic material and the actuating mechanism may include an electro-magnet selective operable to cause deflection of the second end of the impacter towards the wall of the storage chamber.

**[0062]** The dosing and dispensing device preferably includes a controller to control operation of the dosing and dispensing device, and such controller preferably being programmable to prompt a user to activate the dosing and dispensing device to dispense a predetermined number of units of medicine at one or more predetermined times.

**[0063]** The dosing and dispensing device may includes a display to display information to a user, which allows the dosing and dispensing device to display, for example, time, medication and/or dosage size.

**[0064]** The dosing and dispensing device also preferably includes a data input device to enter data into the controller and effect operation of the dosing and dispensing device in accordance with the input data.

**[0065]** The provision of a data input device allows a user to influence operation of the dosing and dispensing device in dependence on the user's symptoms, for example.

**[0066]** Preferably the display and the data input device are provided in the form of a touch-sensitive screen.

**[0067]** In such embodiments a visual analogue scale (VAS) may be selectively displayed on the screen to facilitate the input of data, and the visual analogue scale (VAS) may be displayed on the screen when the dosing and dispensing device dispenses one or more units of medicine.

**[0068]** In particularly preferred embodiments, the dosing and dispensing device includes a memory to store times of dosing and dose sizes provided and thereby maintain an electronic log function. This in turn can be used to monitor dosage compliance. In such embodiments the dosing and dispensing device may not necessarily require the provision of an input device.

**[0069]** The dosing and dispensing device may include a settable alarm that emits sound or light, and/or causes the dispensing device to vibrate at one or more predetermined times. This helps to ensure that the user dispenses the required number of units of medicine and takes his or her dose of the medicine within the therapeutic window associated with the medicine.

**[0070]** In order to prevent illegitimate or otherwise unauthorized dosing and dispensing of

units of medicine, the dosing and dispensing device may include a lock. This reduces the risk of children, for example, dosing and dispensing units of medicine from the dispensing device.

**[0071]** In embodiments where the storage chamber is provided in the form of a cassette, the cassette may include a readable marker and a controller in the device may include a reader to read the marker on the cassette and thereby allow the controller to identify the medicine contained in the cassette.

**[0072]** This arrangement permits the controller to be pre-programmed to function in a number of predetermined modes of operation, each mode of operation being specific to a particular medicine, and to then select the mode of operation applicable to the medicine contained in the cassette once it has identified the medicine contained in the cassette.

**[0073]** A preferred embodiment of the dosing and dispensing device of the invention will now be described, by way of a non-limiting example, with reference to the accompanying figures in which:

Figure 1 illustrates the formation of a bridge of tablets within a funneled channel section;

Figures 2 and 3 show a hand held medicine dosing and dispensing device according to an embodiment of the invention;

Figure 4 shows a cross-sectional view of a cassette of the hand held medicine dosing and dispensing device of Figures 2 and 3;

Figures 5 to 8 illustrate operation of an impacter of the hand held medicine dosing and dispensing device of Figures 2 and 3;

Figures 9 and 10 show internal controls of the hand held medicine dosing and dispensing device of Figures 2 and 3;

Figure 11 shows a rear face of the cassette of Figure 4;

Figures 12A and 12B illustrate operation of a dispensing chamber of a dispenser of the cassette of Figure 4; and

Figures 13 and 14 show front and rear perspective views of a drive motor of the hand held dosing and dispensing device of Figures 2 and 3.

**[0074]** A hand held medicine dosing and dispensing device 10 according to an embodiment of the invention is shown in Figures 2 and 3.

**[0075]** The dosing and dispensing device 10 is comparable in size with other hand held devices such as, for example, mobile telephones, thereby rendering the dosing and dispensing device 10 suitable for use as a hand held device. It is envisaged that in other embodiments the

size and shape of the dosing and dispensing device 10 may be varied to render the dosing and dispensing device 10 suitable for users having limited dexterity, for example.

**[0076]** The dosing and dispensing device 10 includes a housing 12 including a storage chamber 14 to store discrete units of medicine 16 and a feed assembly 18 located between the storage chamber 14 and a dispenser 20. The dosing and dispensing device 10 also includes an impacter 22 (Figure 4) that is operably associated with the storage chamber 14 to agitate units of medicine 16 stored in the storage chamber 14.

**[0077]** As can be seen from Figure 4, the impacter 22 includes a rigid element 24 fixedly connected at one end 26 to a wall 28 of the storage chamber 14. The impacter 22 is operably associated at a second end 30 with an actuating mechanism 32 that deflects the second end 30 of the impacter 22 towards the wall 28 of the storage chamber 14 to strain the impacter 22 such that, when released, the strained impacter 22 moves towards the interior 34 of the storage chamber 14 and impacts again units of medicine 16 stored therein.

**[0078]** In the embodiment shown in Figures 2 and 3, the dosing and dispensing device 10 includes a storage chamber 14 provided in a removable cassette 36 that is releasably engageable with the housing 12.

**[0079]** In other embodiments of the invention it is envisaged that the storage chamber 14 may be permanently located within the housing 12, the housing 12 including an opening to permit access to the storage chamber 14 to permit refilling thereof.

**[0080]** The housing 12 and cassette 36 include mutually engageable latch members that interengage on insertion of the cassette 36 into the housing 12 to retain the cassette 36 within the housing 12. The dosing and dispensing device 10 also includes an ejection mechanism that is selectively operable to disengage the latch members and allow removal of the cassette 36 from the housing 12.

**[0081]** This allows the provision of a cassette 36 that, when received in the housing 12, has an external surface 38 that sits flush with an adjacent outer surface 40 of the housing 12, which enhances the appearance of the dosing and dispensing device 10.

**[0082]** The latch members include elongate projections 42 provided on an upper face 44 of the cassette 36 and extending in the direction in which the cassette 36 is inserted into and withdrawn from the housing 12.

**[0083]** The latch members also include correspondingly shaped and sized openings 46 (Figures 9 and 10) provided on an inner surface 48 of an upper face 50 of the housing 12. The openings 46 are located on the inner surface 48 so as to be aligned with the projections 42 provided on the cassette 36. Accordingly, when the cassette 36 is fully inserted into the housing 12, the elongate projections 42 are received within the respective openings 46. This engagement prevents sliding withdrawal of the cassette 36 from the housing 12.

**[0084]** In the embodiment shown in Figures 2 and 3, first and second leaf springs 52a,52b are provided on an inner surface 54 of the lower face 56 of the housing 12. The first and second leaf springs 52a,52b are located within an internal cavity 58 of the housing 12 in which the cassette 36 is received and act on the cassette 36 to bias the cassette 36 towards the inner surface 48 of the upper face 50 of the housing 12. The leaf springs 52a,52b thereby bias the projections 42 into engagement with the respective openings 46.

**[0085]** On insertion of the cassette 36 into the internal cavity 58 of the housing 12, a leading end face 60 of each of the projections 42 contacts the inner surface 54 of the lower face 56 of the housing 12. To assist sliding movement of this leading end 60 over the inner surface 54, the leading end 60 of each projection 42 is beveled as shown in Figures 11 and 12.

**[0086]** On continued sliding movement of the cassette 36 into the internal cavity 58, the leading end 60 engages the respective opening 46 in the inner surface 48 of the upper face 50 of the housing 12, this engagement serving to guide and locate the remainder of the projection 42 into the respective opening 46. Consequently, as well as acting to retain the cassette 36 within the housing 12, engagement of the projections 42 in the openings 46 during insertion of the cassette 36 into the housing 12 acts to guide and locate the cassette 36 in the internal cavity 58 of the housing 12.

**[0087]** On insertion of the cassette 36 into the internal cavity 58, a spring support 62 (Figure 9) provided on an end wall 64 of the cassette 36 engages against an engagement surface 66 of a biasing member 68, which is moveably mounted on the inner surface 48 of the upper face 50 of the housing 12.

**[0088]** Engagement of the spring support 62 against the engagement surface 66, on insertion of the cassette 36 into the internal cavity 58, causes displacement of the biasing member 68 towards an opposed wall (not shown) of the housing 12. This in turn causes engagement of an opposite side of the engagement surface 66 against a coiled spring (not shown) located within the biasing member 68. The coiled spring is fixed at an end remote from the engagement surface 66 such that displacement of the biasing member 68 towards the opposed wall causes compression of the coiled spring such that the coiled spring acts on the engagement surface 66 so as to bias the biasing member 68 away from the opposed wall. As a result the biasing member 68 biases the cassette 36 in an outward direction relative to the internal cavity 58 of the housing 12.

**[0089]** The biasing force provided by the coiled spring located within the biasing member 68 may be adjusted by adjusting the degree of compression present within the coiled spring prior to engagement of the spring support 62 against the engagement surface 66. The greater the degree of compression present in the coiled spring prior to such engagement the greater the biasing force provided on engagement of the spring support 62 against the engagement surface 66, and vice versa. This is advantageous in that it allows adjustment of the force applied to the cassette 36 during ejection of the cassette 36 from the housing 12, which is

described below.

**[0090]** Engagement of the projections 42 within the openings 46 retains the cassette 36 within the internal cavity 58 of the housing 12 against the bias provided by the compression spring via the biasing member 68.

**[0091]** In the embodiment shown in Figures 2 and 3, the dispenser 20 includes a dispensing chamber 72 (Figures 12A and 12B) to collect and hold individual units of medicine 16 from the storage chamber 14 via the feed assembly 18. The dispensing chamber 72 includes a dispensing outlet 74 that is selectively openable to dispense units of medicine 16 held in the dispensing chamber 72.

**[0092]** The dispenser 20 forms part of the cassette 36 and the dispensing chamber 72 is movable between a first position (Figure 12A) in which the dispensing outlet 74 is closed and a second position (Figure 12B) in which the dispensing outlet 74 is open.

**[0093]** In the first position of the dispensing chamber 72 the dispensing outlet 74 is aligned with a base wall 76 of the cassette 36, the base wall 76 thereby closing the dispensing outlet 74.

**[0094]** In the second position of the dispensing chamber 72 the dispensing outlet 74 is aligned with an opening 78 provided in the base wall 76 of the cassette 36, the opening 78 thereby opening the dispensing outlet 74.

**[0095]** Movement of the dispensing chamber 72 between its first and second positions is effected by means of a first drive motor 80 (Figure 10) that is operable to drive linear movement of a drive member 82 (Figures 9 and 10) in first and second directions. The drive member 82 defines a recess 84 at a free end 86 to receive a peg 88 protruding from the dispensing chamber 72 through a slot 90 provided in a side wall 92 of the cassette 36. Through engagement of the drive member 82 with the peg 88, movement of the drive member 82 causes movement of the peg 88 from one end of the slot 90 to the other and back, and thereby results in movement of the dispensing chamber 72 from its first position to its second position and back to its first position.

**[0096]** In other embodiments it is envisaged that the dispenser 20 may not include a dispensing chamber 72, and the feed assembly 18 may feed the units of medicine 16 direct to a permanently open dispensing outlet 74 of the dispenser 20.

**[0097]** The feed assembly 18 includes a feed wheel 94 (Figure 4) defining a plurality of feed pockets 96 about its circumference. In the embodiment shown in Figures 2 and 3 the feed wheel 94 is located in the cassette 36 between the storage chamber 14 and the dispenser 20.

**[0098]** The feed wheel 94 is mounted to rotate so that rotation in a first direction, which is depicted by arrow A in Figure 4, moves the feed pockets 96 sequentially into alignment with a

feed channel 98 of the storage chamber 14 to each receive a unit of medicine 16.

**[0099]** On further rotation of the feed wheel 94 in the first direction, the feed pockets 96 are moved sequentially into alignment with an inlet of the dispensing chamber 72 of the dispenser 20 to feed the respective units of medicine 16 into the dispensing chamber 72 dispenser 20.

**[0100]** The dosing and dispensing device 10 includes a second drive motor 100 (Figures 9, 10, 13 and 14) to drive the feed wheel 94 to rotate, the second drive motor 100 being mounted on the inner surface 48 of the upper face 50 of the housing 12.

**[0101]** On insertion of the cassette 36 into the internal cavity 58 of the housing 12, a drive gear 102 (Figure 13) engages a drive shaft 104 (Figures 11, 12A and 12B) that protrudes from the upper face 44 of the cassette 36.

**[0102]** The drive shaft 104 is formed to define sloped edges 106,108 that terminate in shoulders 110,112 (Figures 12A and 12B).

**[0103]** The drive gear 102 includes an elongate lug 114 that engages the shoulders 110,112 and, on rotation of the second drive motor 100 in a first direction, drives the drive shaft 104 to rotate. This in turn causes the feed wheel 94 to rotate in the first direction.

**[0104]** As can be seen from Figures 9, 10, 13 and 14, the second drive motor 100 includes electrical contacts 116. These electrical contacts 116 engage corresponding contacts (not shown) on the cassette 36 on insertion of the cassette 36 into the internal cavity 58 of the housing 12.

**[0105]** In the embodiment shown in Figures 2 and 3, the drive shaft 104 is operable by hand to effect rotation of the feed wheel 94 in the first direction when the cassette 36 is removed from the housing. Such operation allows a user to feed units of medicine 16 from the storage chamber 14 of the cassette 36 in the event, for example, that a fault occurs within the dosing and dispensing device 10 that prevents a user from operating the dosing and dispensing device 10 to prepare and dispense a dose of the medicine contained within the storage chamber 14.

**[0106]** In other embodiments, where it is desirable to prevent unauthorized or illegitimate access to the units of medicine 16, the drive shaft 104 may be locked against manual rotation so that units of medicine 16 may only be accessed when the cassette 36 is mounted within the housing 12 of the dosing and dispensing device 10. In such embodiments the cassette 36 may also be sealed so as to prevent unauthorized access to any units of medicine 16 stored in the storage chamber 14 of the cassette 36.

**[0107]** The dosing and dispensing device 10 also includes a sensor in the form of a photocell 117 (Figure 14) arranged relative to the inlet of the dispensing chamber 72 to detect movement of units of medicine 16 from feed pockets 96 of the feed wheel 94 into the

dispensing chamber 72.

**[0108]** The sensor monitors the movement of units of medicine 16 moving from the feed pockets 96 of the feed wheel 94 into the dispensing chamber 72. The information provided by the sensor allows movement of the second drive motor 100 to be controlled to drive the feed wheel 94 in the first direction so as to feed a predetermined number of units of medicine 16 to the dispenser 20.

**[0109]** The sensor also allows the dosing and dispensing device 10 to determine when the storage chamber 14 is empty.

**[0110]** More specifically, in use, the second drive motor 100 drives the feed wheel 94 to rotate so as to feed units of medicine 16 from the storage chamber 14 of the cassette 36, via the feed pockets 96, to the dispensing chamber 72.

**[0111]** During this movement, the photocell 117 is located relative to the inlet of the dispensing chamber 72 so as to enable the dosing and dispensing device 10 to be able to determine the number of units of medicine 16 that are fed into the dispensing chamber 72.

**[0112]** The second drive motor 100 is controlled to continue to drive rotation of the feed wheel 94 until the dosing and dispensing device 10 determines via the photocell 117 that the required number of units of medicine 16 have been fed into the dispensing chamber 72, at which point the second drive motor 100 stops driving rotation of the feed wheel 94.

**[0113]** This arrangement means that the feed wheel 94 continues to turn to deliver units of medicine 16 into the dispensing chamber 72 until the required number of units of medicine 16 is fed into the dispensing chamber 72. It thereby ensures that the required number of units of medicine 16 is fed into the dispensing chamber 72 regardless of whether or not one of the feed pockets 96 fails to receive and feed a unit of medicine 16 from the storage chamber 14 to the dispensing chamber 72 during rotation of the feed wheel 94.

**[0114]** If the photocell 117 identifies a number of consecutive empty feed pockets 96 exceeding a predetermined number during rotation of the feed wheel 94, the dosing and dispensing device 10 determines that the storage chamber 14 is empty.

**[0115]** Preferably the dosing and dispensing device 10 determines that the storage chamber 14 is empty if the photocell 117 identifies more than six consecutive empty feed pockets 96 being aligned with the inlet of the dispensing chamber 72 during rotation of the feed wheel 94.

**[0116]** In other embodiments, depending on the nature of the units of medicine 16, and the ease with which the units of medicine 16 move from the storage chamber 14 into the feed pockets 96, the predetermined number of consecutive empty feed pockets required to determine whether the storage chamber 14 is empty may increase or decrease.

**[0117]** In order to eject the cassette 36 once the storage chamber 14 is empty, or early if the patient wishes to replace the cassette 36 with a cassette 36 containing a different medicine or to gain direct access to the units of medicine contained within the cassette 36, the second drive motor 100 may be driven in a second, opposite, direction.

**[0118]** Rotation of the second drive motor 100 in the opposite direction causes the lug 114 to travel along the sloped edges 106,108 on the drive shaft 104. Since the drive gear 102 is fixe d relative to the upper face 50 of the housing 12, movement of the lug 114 along the sloped edges 106,108 causes movement of the cassette 36 away from the inner surface 48 of the upper face 50 of the housing 12. This movement in turn moves the projections 42 out of engagement with the openings 46 and the bias provided by the compressed spring located within the biasing member 68 pushes the cassette 36 in an outward direction and thereby ejects the cassette 36 from the housing 12.

**[0119]** Once the cassette 36 is ejected, a user may insert a replacement cassette 36 into the dosing and dispensing device 10 in order to replenish or change the supply of medicine contained within the dosing and dispensing device 10.

**[0120]** In other embodiments it is envisaged that the second drive motor 100 may only be driven in the second, opposite, direction once the sensors have determined that the storage chamber 14 of the cassette 36 is empty. In such embodiments, controlled operation of the ejection mechanism prevents unauthorized or otherwise illegitimate access to the units of medicine 16 stored within the storage chamber 14 of the cassette 36.

**[0121]** In such embodiments the provision of an external surface 38 of the cassette 36 that is flush with the adjacent outer surface 40 of the housing 12 is advantageous in that it reduces the possibility of someone seeking to prise the cassette 36 out of the housing 12.

**[0122]** In the embodiment shown in Figures 2 and 3, the feed wheel 94 defines the actuating mechanism 32 with which the second end 30 of the impacter 22 is operably associated.

**[0123]** In particular, the feed wheel 94 includes a plurality of equidistantly spaced fins 118 protruding outwardly from its outer circumference, adjacent fins 118 defining the feed pockets 96 therebetween.

**[0124]** The length of each of the fins 118 is such that rotation of the feed wheel 94 in the first direction moves each of the fins 118 sequentially into engagement with a front face 120 of the second end 30 of the impacter 22, as shown in Figure 5. Continued rotation of the feed wheel 94 causes deflection of the second end 30 of the impacter 22 towards the wall 28 of the storage chamber 14 as the respective fin 118 is moved across the front face 120 (Figures 6 and 7) until the fin 118 moves out of engagement with the second end 30 of the impacter 22 (Figure 8).

**[0125]** Once the respective fin 118 moves out of engagement with the front face 120 of the

second end 30 of the impacter 22, the strained impacter 22 moves towards the interior 34 of the storage chamber 14 and impacts against units of medicine 16 stored therein.

**[0126]** The free end of each fin 118 that contacts the second end 30 of the impacter 22 is shaped so as to present a curved face 122 to the front face 120 of the second end 30 of the impacter 22 so as to facilitate movement over the front face 120.

**[0127]** The curved face 122 terminates in a shoulder 124 that is brought into engagement with a rear face 126 of the second end 30 of the impacter 22 in the event the feed wheel 94 is driven to rotate in a second, opposite, direction. This engagement together with the relative positions of the second end 30 of the impacter 22 and the free end of the fin 118 when the impacter 22 is in its unstrained condition means that the second end 30 of the impacter 22 blocks further rotation of the feed wheel 94 in the second direction.

**[0128]** In other embodiments of the invention it is envisaged that movement of the second end 30 of the impacter 22 towards the wall 28 of the storage chamber 14 may be effected by other means.

**[0129]** In one other such embodiment the impacter 22, or at least the second end 30 of the impacter 22, is formed from, or coated with, a magnetic material and an electro-magnet is provided in the storage chamber 14.

**[0130]** On the application of a current to the electro-magnet, the magnetic field produced by the electro-magnet causes deflection of the second end 30 of the impacter 22 towards the wall 28 of the storage chamber 14 so as to strain the impacter 22.

**[0131]** In such an embodiment, the electro-magnet may be mounted on the wall 28 of the storage chamber 14 and the magnetic field produced by the electro-magnet may attract the second end 30 of the impacter 22 towards the wall 28 of the storage chamber 14.

**[0132]** The second end 30 of the impacter 22 is released, allowing the strained impacter 22 to move towards the interior 34 of the storage chamber 14, on removal of the current to the electro-magnet.

**[0133]** As can be seen from Figures 5 to 8, the dosing and dispensing device 10 includes a separating element 128 located above the feed wheel 94 and adjacent the impacter 22 so as to prevent units of medicine 16 becoming jammed between a feed pocket 96 in the feed wheel 94 already containing a unit of medicine 16 and the impacter 22. The separating element 128 presents a sloped face 130 towards the interior 34 of the storage chamber 14 so as to direct the units of medicine towards the feed channel 98 of the storage chamber 14. The separating element 128 also presents a curved face 132 to the feed wheel 94 so as to allow the tips of the fins 118 to travel past the separating element 128.

**[0134]** The dosing and dispensing device 10 shown in Figures 2 and 3 includes a

programmable controller to prompt a user to dispense units of medicine 16 at one or more pre-determined times throughout the day.

**[0135]** At the or each predetermined time, the controller activates an alarm provided in the dosing and dispensing device 10 to emit sound or light and/or causes the dosing and dispensing device 10 to vibrate so as to alert the user to dispense units of medicine 16 and take his or her dose of the medicine within a therapeutic window associated with the medicine.

**[0136]** In the event the user does not respond to an initial alarm, the controller may be programmed to emit one or more further alarms within a predetermined time from the first alarm.

**[0137]** When the user is alerted to the need to dispense units of medicine 16, a message delivered on a display 134 provided on an outer surface 136 of the upper face 50 of the housing 12 prompts the user to enter a code into the dosing and dispensing device 10 via a data input device.

**[0138]** In the embodiment shown in Figures 2 and 3, the display 134 is provided in the form of a touch-sensitive screen, which also functions as the data input device.

**[0139]** On entry of the correct code, the dosing and dispensing device 10 is unlocked and a message delivered on the display 134 prompts the user to activate the dosing and dispensing device 10 to feed either a predetermined number of units of medicine 16 into the dispensing chamber 72 or prompts the user to identify the dose of medicine he or she requires.

**[0140]** In other embodiments it is envisaged that the data input device may be provided in the form of a keypad mounted on the outer surface 136 of the upper face 50 of the housing 12.

**[0141]** It is also envisaged that in other embodiments the lock may be omitted.

**[0142]** Following the required response from the user, the controller operates the second drive motor 100 to operate the feed wheel 94 to feed the number of units of medicine 16 into the dispensing chamber 72 that will provide the required dose of medicine to the user.

**[0143]** During operation of the feed wheel 94 to feed units of medicine 16 into the dispensing chamber 72, a sensor, preferably provided in the form of a photocell, senses the movement of each unit of medicine 16 that passes from the feed wheel 94 into the dispensing chamber 72. This allows the controller to count the number of units of medicine 16 that are fed into the dispensing chamber 72.

**[0144]** Once the sensor has counted the required number of units of medicine 16 being fed into the dispensing chamber 72, the controller ceases operation of the second drive motor 100 and thereby ceases operation of the feed wheel 94.

**[0145]** The first motor 80 is then operated to cause movement of the dispensing chamber 72 from its first position to its second position so as to open the dispensing outlet 74 of the dispenser 20 and dispense the dose of medicine held in the dispensing chamber 72 to the user.

**[0146]** In other embodiments, it is envisaged that the dosing and dispensing device 10 will automatically feed a predetermined number of units of medicine 16 to the dispensing chamber 72 once the dosing and dispensing device 10 is unlocked.

**[0147]** The controller may display further messages before, during or after operation of the second drive motor 100 to prompt the user to respond to questions concerning the nature of any symptoms he or she may be experiencing via the data input device.

**[0148]** In the embodiment shown in Figures 2 and 3, where the display 134 is a touch-sensitive screen, responses to these questions may be input via a visual analogue scale (VAS) displayed on the display 134. This allows a user to provided information concerning pain levels, for example, via the use of a straight line scale extending from zero, meaning no pain, to ten, meaning intolerable pain.

**[0149]** The information provided by the patient to the questions posed, via the data input device, is stored within a memory provided in the dosing and dispensing device 10 and may be accessed on the display 134 of the dosing and dispensing device 10 or by connecting the dosing and dispensing device 10 to a computer via a USB port, for example.

**[0150]** This facility allows a user and his or her physician to monitor the user's symptoms at the time of drug intake, for example, which may be particularly beneficial for the user and the physicial in the dose-finding process.

**[0151]** As well as storing data input by the user, the memory provided in the dosing and dispensing device 10 may record the times at which the dosing and dispensing device 10 is activated to prepare a dose of medicine and dispense that dose. It may also record the dose prepared and dispensed each time in terms of the number of units of medicine 16. This information provides an electronic log, which may be accessed by connecting the dosing and dispensing device 10 to a computer, and provides a means for monitoring dosage compliance.

**[0152]** In embodiments not shown in the figures, the cassette 36 includes a readable marker (not shown) identifying the medicine contained within the storage chamber 14 of the cassette 36. A reader provided within the inner cavity 58 of the housing 12 of the dosing and dispensing device 10 reads the readable marker is read on insertion of the cassette 36 into the inner cavity 58, and allows the controller within the dosing and dispensing device 10 to identify the medicine.

**[0153]** In such embodiments, the controller may be programmed to function in a number of predetermined modes of operation, each mode of operation being specific to a particular

medicine, and to then select the mode of operation applicable to the medicine contained in the cassette 36 once it has identified the medicine contained in the cassette 36.

**[0154]** The provision of a readable marker is advantageous in circumstances where there are insufficient units of medicine contained within a cassette to allow the dosing and dispensing device 10 to feed the required number of units of medicine 16 to the dispensing chamber 72 in a single operation. In such circumstances the dispensing outlet 74 of the dispenser 20 may be opened to dispense the units of medicine 16 held in the dispensing chamber 72 and the empty cassette 36 is replaced with a replacement cassette 36. The controller may check that the replacement cassette 36 contains the same medicine before operating the second drive motor 100 to continue to feed the units of medicine 16 to the dispensing chamber 72 required to complete the dose. Preferably in such circumstances the display 134 displays a message to the user clearly identifying that the units of medicine 16 dispensed from the dispensing chamber 72 prior to replacement of the empty cassette 36 is an incomplete dose.

**[0155]** In other embodiments it is envisaged that the dispenser 20 forms part of the housing 12 instead of the cassette 36. In such embodiments the location of the dispensing chamber 72 in the housing 12 renders it unnecessary for an incomplete dose to be dispensed prior to replacement of an empty cassette 36.

**[0156]** The number of units of medicine 16 to be dispensed from the dosing and dispensing device 10 is determined by the size of the total dose required and is therefore determined by the amount of active ingredient or medicine contained in each unit of medicine 16.

**[0157]** The amount of active ingredient contained in each unit of medicine 16 may be chosen depending on the nature of the medicine and the side effects that arise from over or under dosing. For example, the amount of active ingredient contained in each unit of a medicine for which the side effects arising from over or under dosing are minimal may be greater than that for a medicine for which the side effects are more pronounced. This is because the greater the amount of active ingredient contained in each unit of medicine, the less possible it is to fine tune the total dose.

**[0158]** Consideration must also however be made of the consequences of having to store in the storage chamber 14 a relatively large number of partial doses in the form of individual units of medicine in the event each unit of medicine contains a very low amount of active ingredient.

**[0159]** Preferably therefore each unit of medicine contains from approximately 20% to 2% of the weight of the total dose to be administered and dispensed from the dosing and dispensing device 10 at any one time.

**[0160]** The units of medicine may be provided in the form of tablets or pellets, and preferably have convex or iso-diametrical surfaces so as to define a spherical or near spherical shape produced through the use of a punch having a concave surface.

**[0161]** In circumstances where the units of medicine are provided in the form of tablets, the tablets preferably have a diameter in the range of 1-13mm, more preferably in the range of 2-8mm and most preferably in the range of 2-5mm.

**[0162]** In circumstances where the units of medicine are provided in the form of pellets, the pellets preferably have a size in the range of 1-8mm and most preferably in the range of 1-4mm.

# REFERENCES CITED IN THE DESCRIPTION

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**Patent documents cited in the description**


- EP1058660B1 **[0004]**
- EP0287335A **[0009]** **[0010]**
- EP2009008253W **[0011]**

PATENTKRAV

1. Håndholdt lægemiddeldoserings- og –dispenseringsindretning (10) omfattende et hus (12), der inkluderer et lagerkammer (14) indeholdende separate enheder af lægemiddel (16); et fødeaggregat placeret mellem lagerkammeret og en dispenser (20) til at sende individuelle enheder af lægemiddel fra lagerkammeret til dispenseren; og en impaktor (22), der kan samvirke med lagerkammeret til omrøring af enheder af lægemiddel opbevaret i lagerkammeret, **kendetegnet ved**, at impaktoren omfatter et stift element (24), der er fast forbundet ved eller mod én ende (26) til en væg af lagerkammeret og kan betjenes tæt ved eller mod en anden ende (30) med en aktiveringsmekanisme (32), der afbøjer impaktorens anden ende mod lagerkammerets væg til at spænde impaktoren således, at når den løsnes, bevæger den spændte impaktor sig mod det indre af lagerkammeret og støder mod lægemiddelenhederne;
hvor lagerkammeret er tilvejebragt i en udtagelig kassette (36), der er i løsbart indgreb med huset, og hvor lægemiddelenhederne omfatter et medikament, som er eller indeholder levodopa/carbidopa eller levodopa/benserazid, morfin, oxikodon eller metadon, pregabalin, diazepam, oxazepam eller alprazolam, acarbose, metformin, glibenclamid eller glipizid, atomoxetin, capecitabin, pyridostigmin, warfarin, valproat eller quetiapin.

2. Kassette (36), der er konfigureret til at gå i løsbart indgreb med en håndholdt lægemiddeldoserings- og –dispenseringsindretning (10), hvilken kassette omfatter et lagerkammer (14), et fødeaggregat placeret mellem lagerkammeret og en dispenser (20) til at sende individuelle lægemiddelenheder fra lagerkammeret til dispenseren; og en impaktor (22), der kan samvirke med lagerkammeret, for at omrøre lægemiddelenheder, som er lagret i lagerkammeret, **kendetegnet ved**, at impaktoren omfatter et stift legeme (24), der er fast forbundet ved eller mod én ende (26) til en væg af lagerkammeret og kan betjenes tæt ved eller mod en anden ende (30) med en aktiveringsmekanisme (32), der afbøjer impaktorens anden ende mod lagerkammerets væg til at spænde impaktoren således, at når den løsnes, bevæger den spændte impaktor sig mod det indre af lagerkammeret og støder mod lægemiddelenhederne;

hvor lægemiddelenhederne omfatter et medikament, som er eller indeholder levodopa/carbidopa eller levodopa/benserazid, morfin, oxikodon eller metadon, pregabalin, diazepam, oxazepam eller alprazolam, acarbose, metformin, glibenclamid eller glipizid, atomoxetin, capecitabin, pyridostigmin, warfarin, valproat eller quetiapin.

3. Håndholdt lægemiddeldoserings- og –dispenseringsindretning (10) ifølge krav 1 eller en kassette (36) ifølge krav 2, hvor doserings- og –dispenseringsindretningen eller kassetten yderligere omfatter én eller flere sensorer til bestemmelse af, hvornår lagerkammeret er tomt.

4. Håndholdt lægemiddeldoserings- og –dispenseringsindretning eller kassette ifølge ethvert foregående krav, hvor dispenseren eller kassetten omfatter et dispenseringskammer (72) til at opsamle og indeholde individuelle lægemiddelenheder sendt fra lagerkammeret via fødeaggregatet, og hvor dispenseringskammeret omfattende et dispenseringsudløb (74) kan åbnes selektivt til at dispensere lægemiddelenheder opbevaret i dispenseringskammeret.

5. Håndholdt lægemiddeldoserings- og –dispenseringsindretning eller kassette ifølge krav 4, hvor dispenseringskammeret (72) kan bevæges selektivt mellem en første position, hvori dispenseringsudløbet (74) er lukket, og en anden position, hvori dispenseringsudløbet (74) er åbent.

6. Håndholdt lægemiddeldoserings- og –dispenseringsindretning eller kassette ifølge krav 5, hvor dispenseren (20) yderligere omfatter en motor til at udvirke bevægelse af dispenseringskammeret mellem dets første og anden position.

7. Håndholdt lægemiddeldoserings- og –dispenseringsindretning eller kassette ifølge ethvert foregående krav, hvor fødeaggregatet omfatter et fødehjul (94), som definerer et antal fødelommer (96) langs sin omkreds, hvor fødehjulet (94) kan dreje i en første retning for at bevæge fødelommerne (96) sekventielt ind på linje med en fødekanal (98) i lagerkammeret, så hver modtager en lægemiddelenhed (16), og for ved yderligere drejning af fødehjulet (94) i den

første retning at bevæge fødelommerne (96) sekventielt ind på linje med dispenseren (20), så de modtagne lægemiddelenheder sendes sekventielt til dispenseren.

8. Håndholdt lægemiddeldoserings- og –dispenseringsindretning eller kassette ifølge krav 7, hvor fødehjulet (94) befinder sig i kassetten (36).

9. Håndholdt lægemiddeldoserings- og –dispenseringsindretning ifølge ethvert af kravene 4 til 6 og 8, hvor dispenseren (20) udgør en del af kassetten, og fødehjulet (94) er placeret i kassetten (36) mellem lagerkammeret og dispenseren (20).

10. Håndholdt lægemiddeldoserings- og –dispenseringsindretning ifølge ethvert af kravene 7 til 9, hvor doserings- og dispenseringsindretningen omfatter en drivmotor til at bringe fødehjulet til at dreje.

11. Håndholdt lægemiddeldoserings- og –dispenseringsindretning ifølge krav 10, hvor drivmotoren kan styres til at drive fødehjulet (94) til at dreje i den første retning for derved at sende et forudbestemt antal lægemiddelenheder til dispenseren (20).

12. Håndholdt lægemiddeldoserings- og –dispenseringsindretning eller kassette ifølge ethvert af kravene 1 og 7 til 11, hvor fødehjulet (94) definerer aktiveringsmekanismen (32), og impaktoren (22) kan styres tæt ved eller mod sin anden ende med fødehjulet.

13. Håndholdt lægemiddeldoserings- og –dispenseringsindretning eller kassette ifølge krav 12, hvor fødehjulet omfatter et antal ækvidistant adskilte finner (118), som rager udad fra dets ydre omkreds, idet hosliggende finner definerer fødelommerne (96) imellem sig, så drejning af fødehjulet (94) i den første retning vil bevæge hver af finnerne (118) sekventielt i indgreb med en forside af den anden ende af impaktoren (22), og fortsat drejning af fødehjulet (94) medfører afbøjning af den anden ende af impaktoren (22) mod lagerkammerets væg,

efterhånden som den enkelte finne bevæger sig tværs over forsiden af den anden ende af impaktoren (22) og ud af indgreb dermed.

14. Håndholdt lægemiddeldoserings- og –dispenseringsindretning eller kassette ifølge krav 13, hvor drejning af fødehjulet i den anden retning bevæger en hosliggende én af finnerne (118) i indgreb med en anden flade af den anden ende af impaktoren (22), således at den anden ende af impaktoren (22) blokerer for yderligere drejning af fødehjulet i den anden retning.

15. Håndholdt lægemiddeldoserings- og –dispenseringsindretning eller kassette ifølge ethvert af kravene 1 til 11, hvor impaktoren (22) er fremstillet af et magnetisk materiale, og aktiveringsmekanismen (32) omfatter en elektromagnet, der kan betjenes selektivt til at fremkalde afbøjning af den anden ende af impaktoren mod lagerkammerets væg.

# DRAWINGS

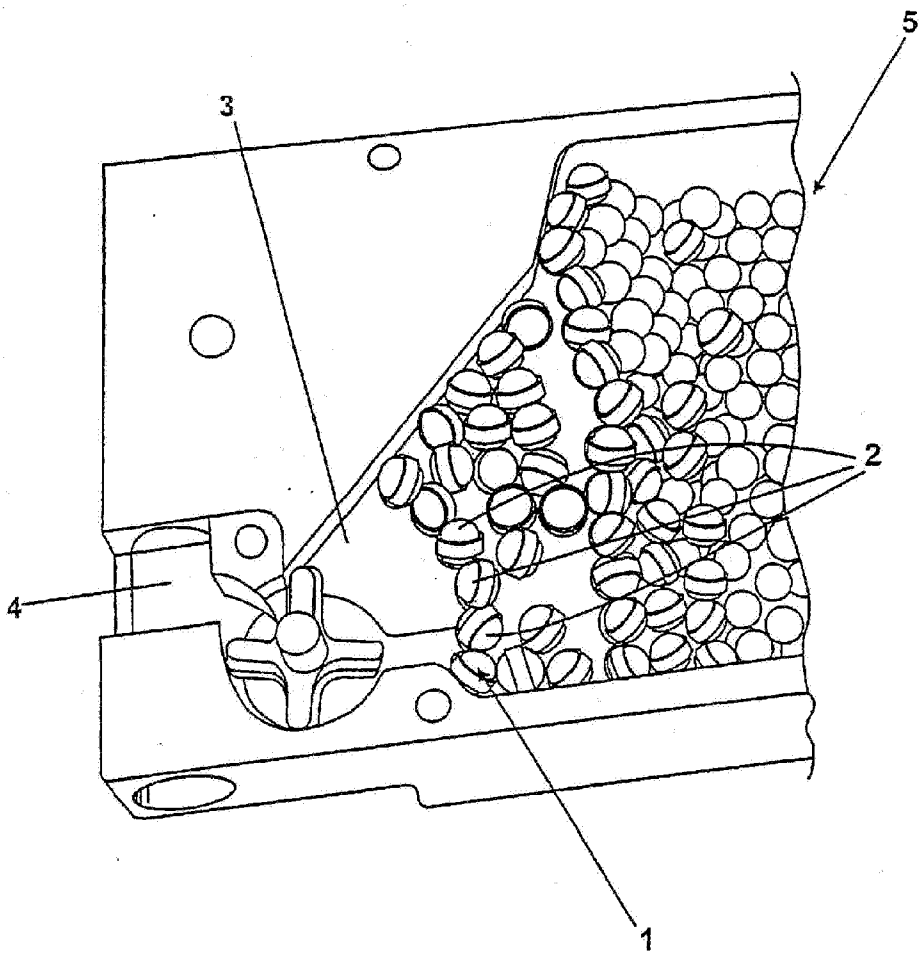


*Figure 1*

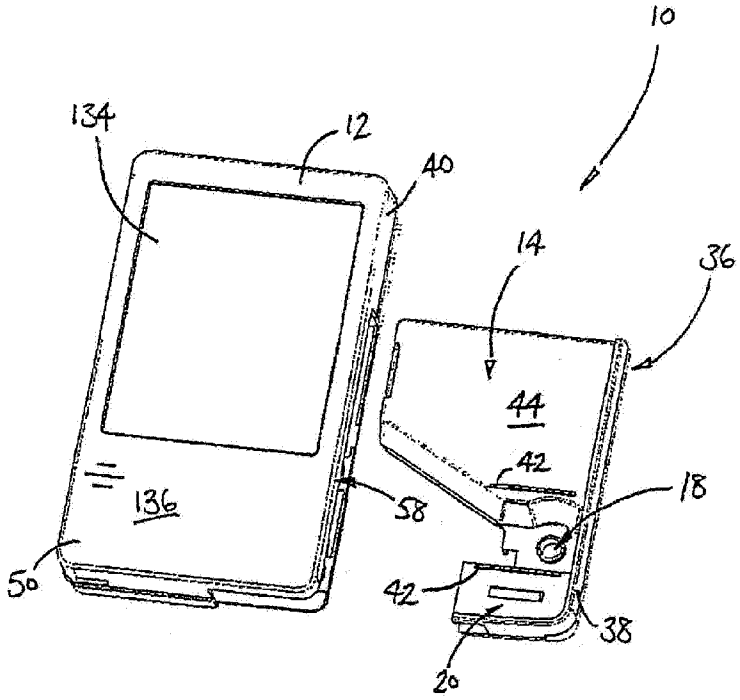


Figure 2

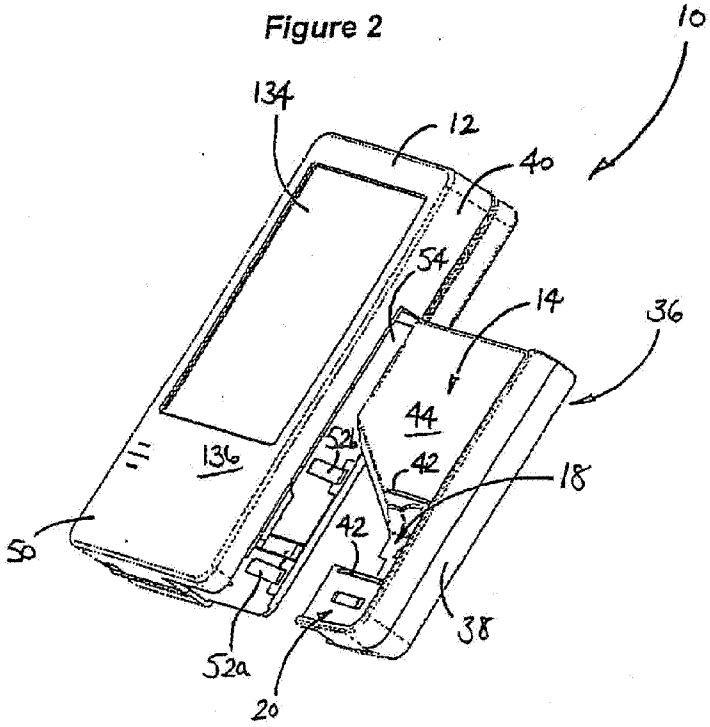


Figure 3

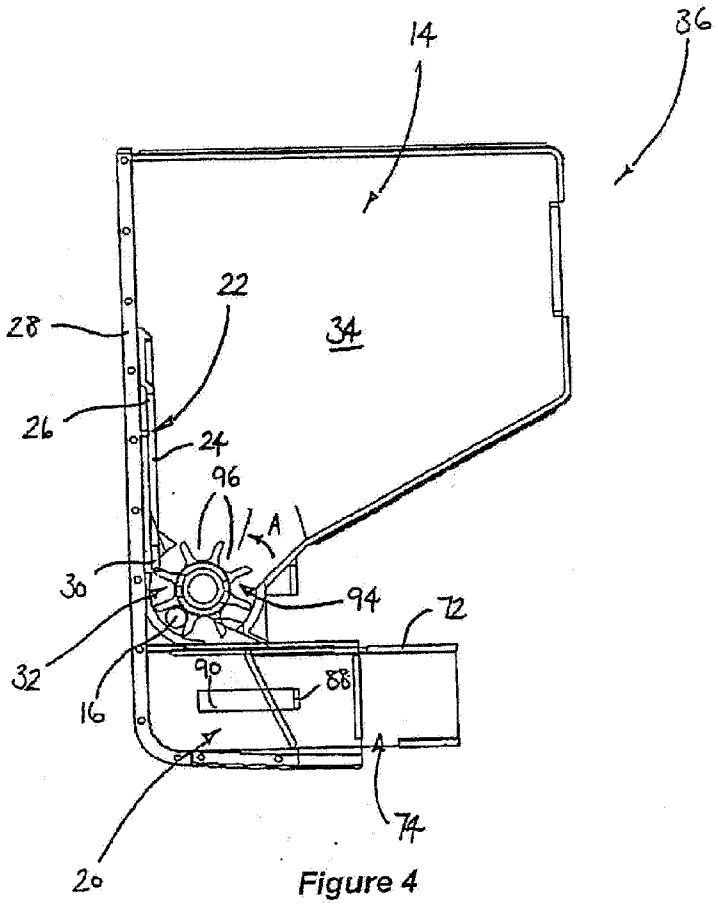


Figure 4

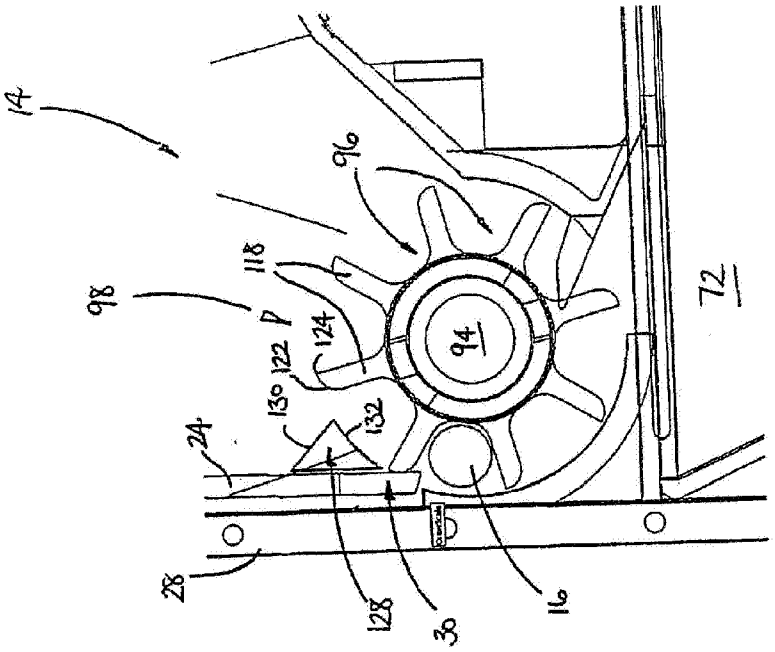


Figure 6

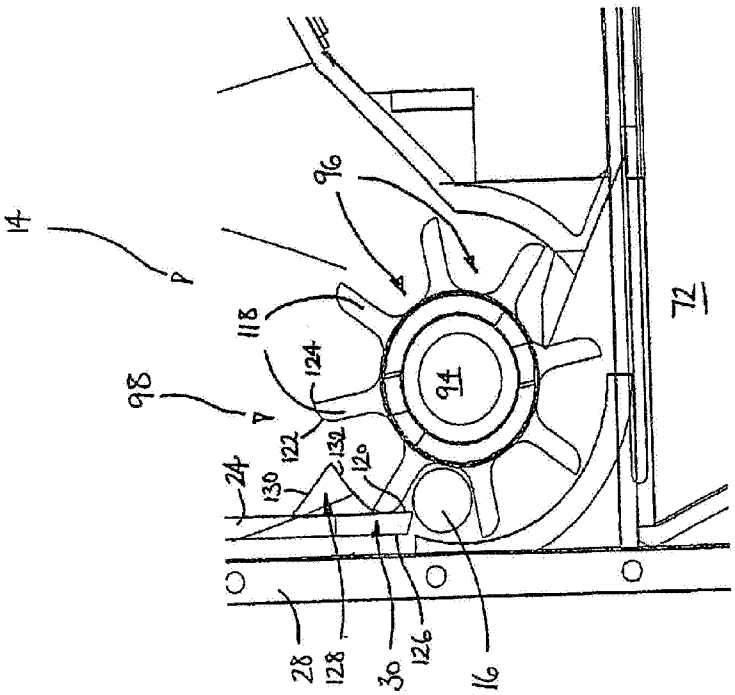


Figure 5

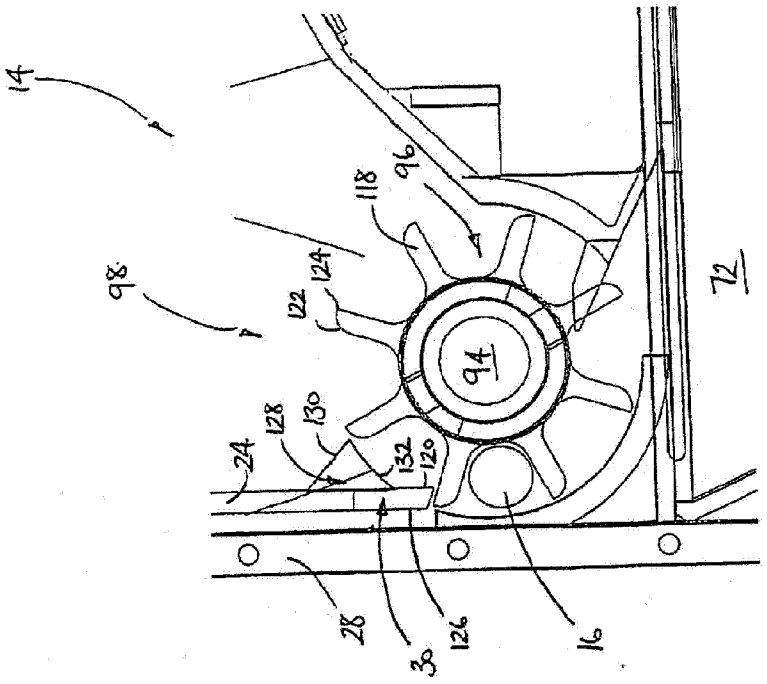


Figure 8

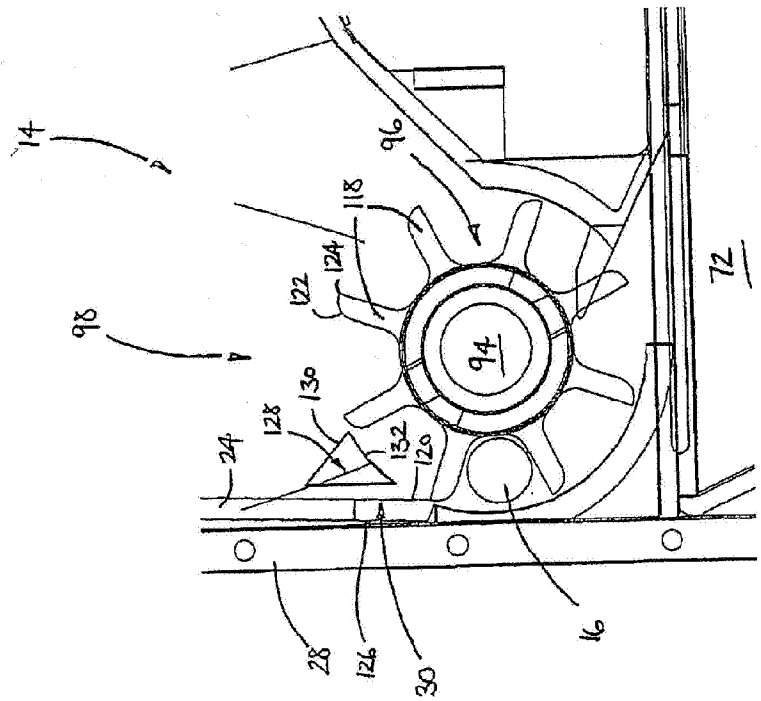


Figure 7

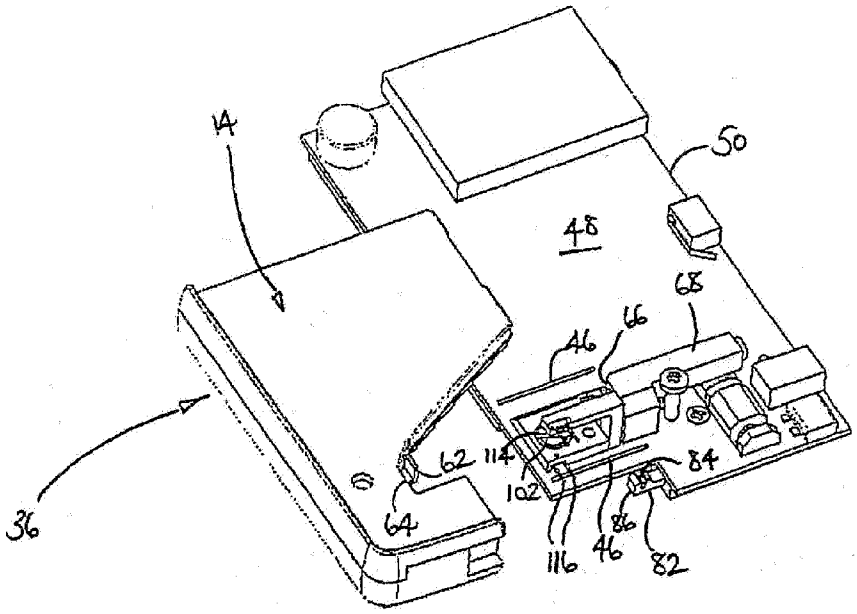


Figure 9

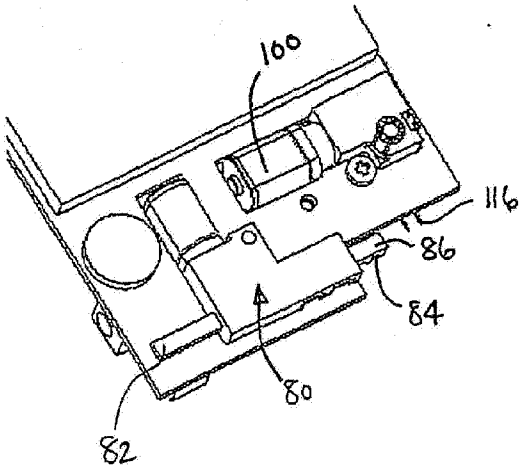


Figure 10

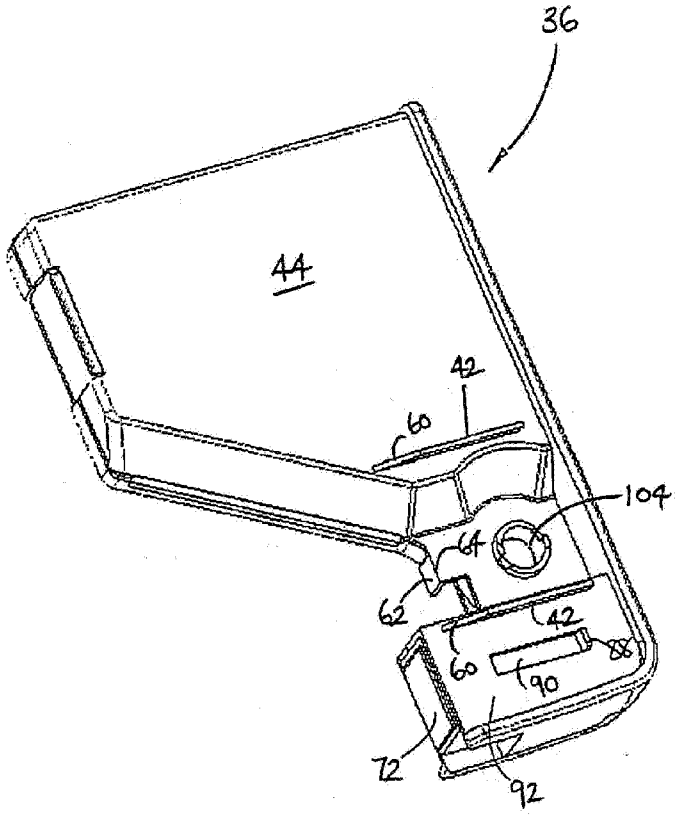


*Figure 11*

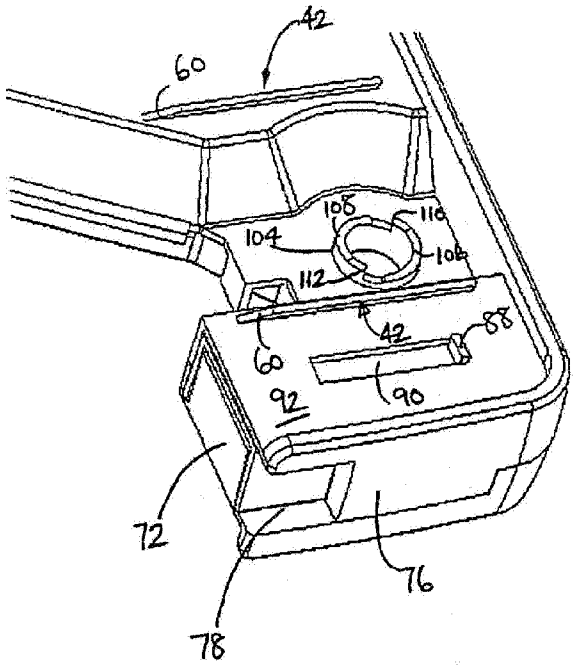


Figure 12A

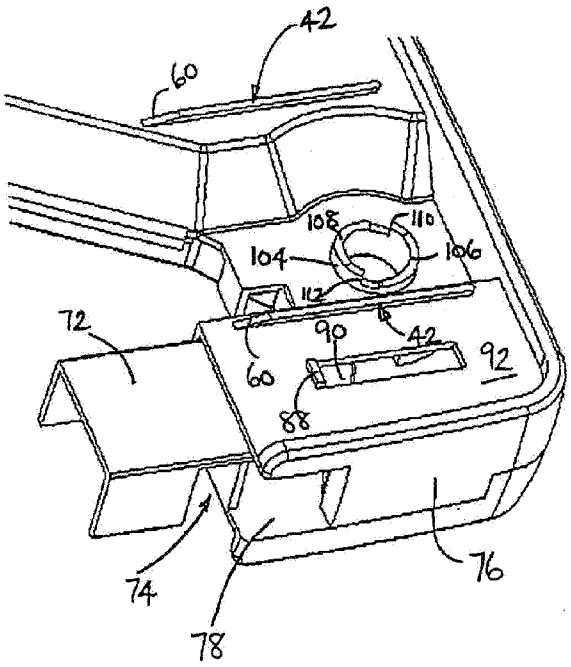


Figure 12B

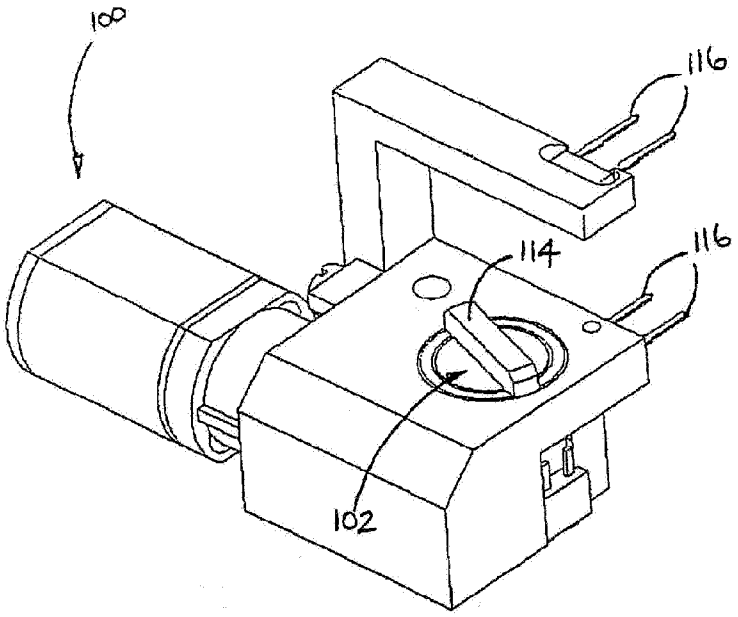


Figure 13

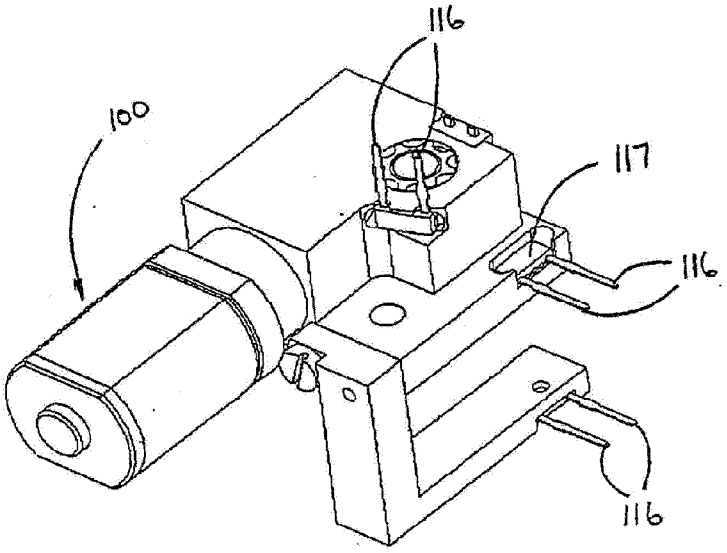


Figure 14