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(54) **DISPENSING DEVICE**

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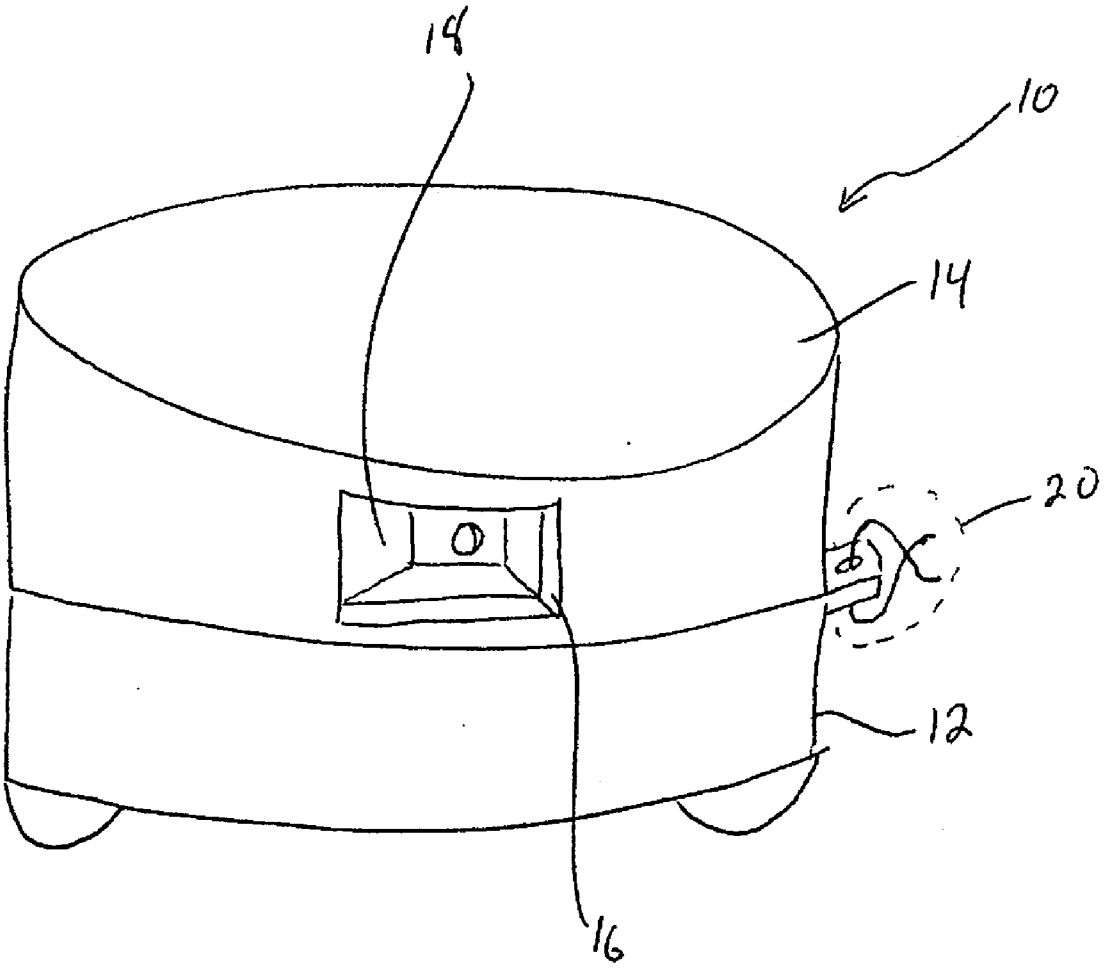
(57) **ABSTRACT**

The invention relates to a device for the time-controlled dispensing of pharmaceutical compositions to a patient. The device is intended to allow multiple doses of pharmaceutical compositions to be delivered to a patient over a predetermined or programmable dosing schedule.



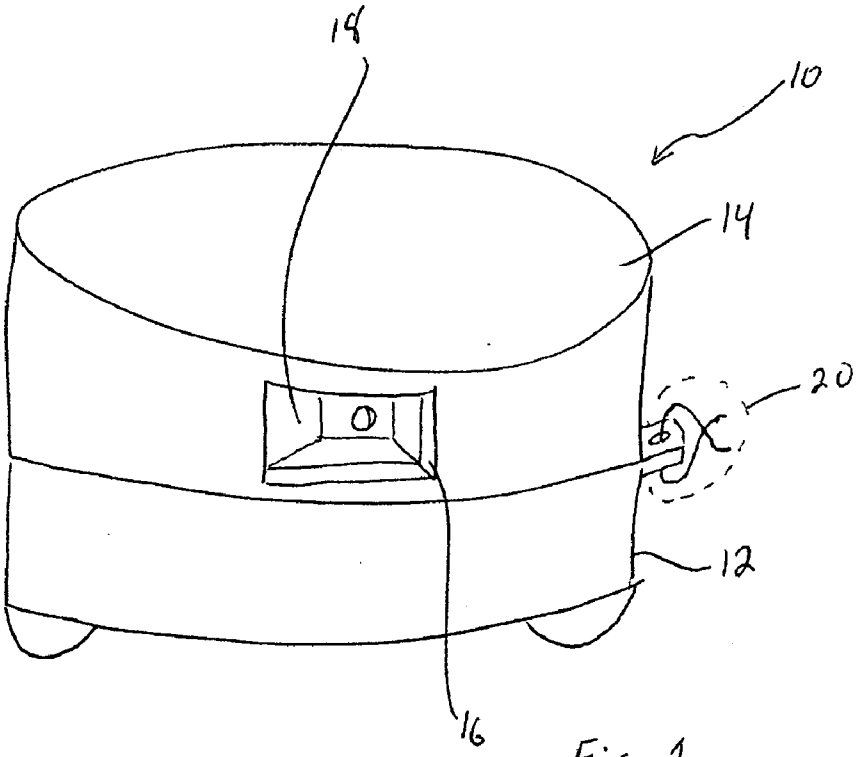


Fig. 1

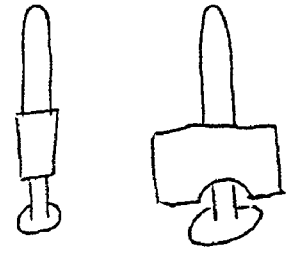


Fig 2(a)

Fig 2(b)

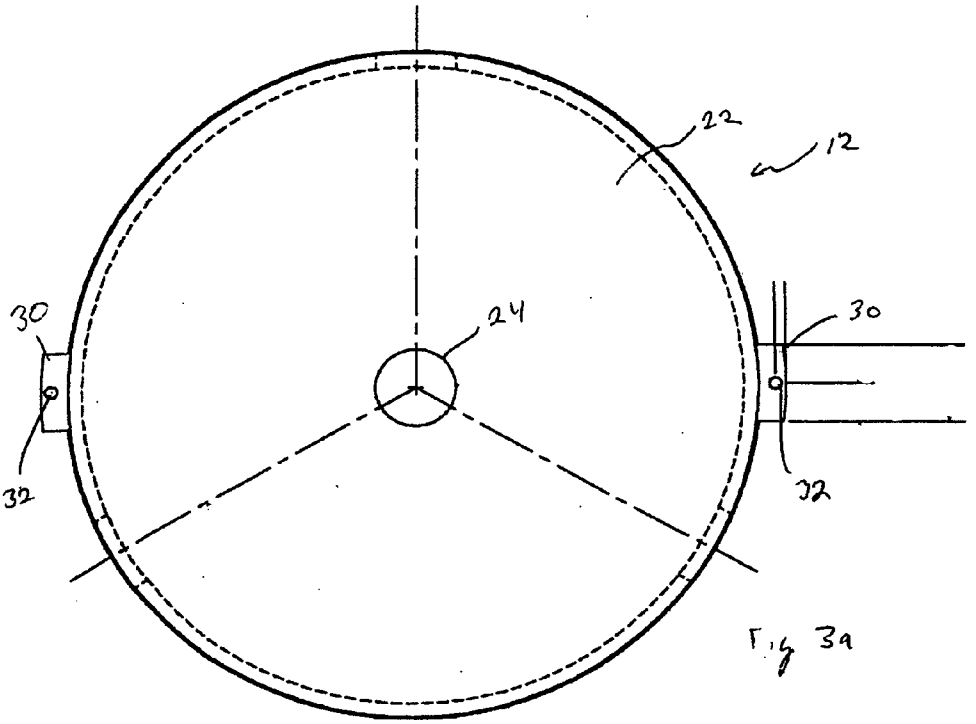


Fig 3a

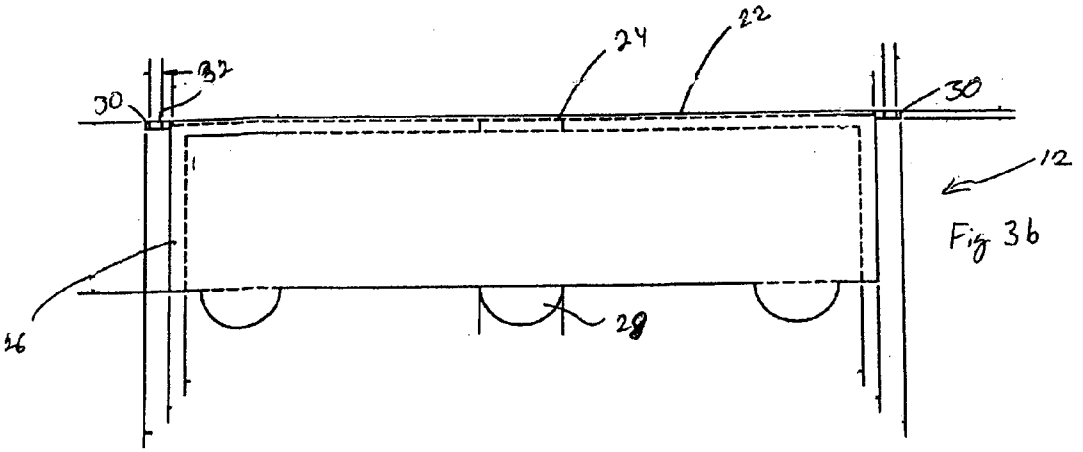


Fig 3b

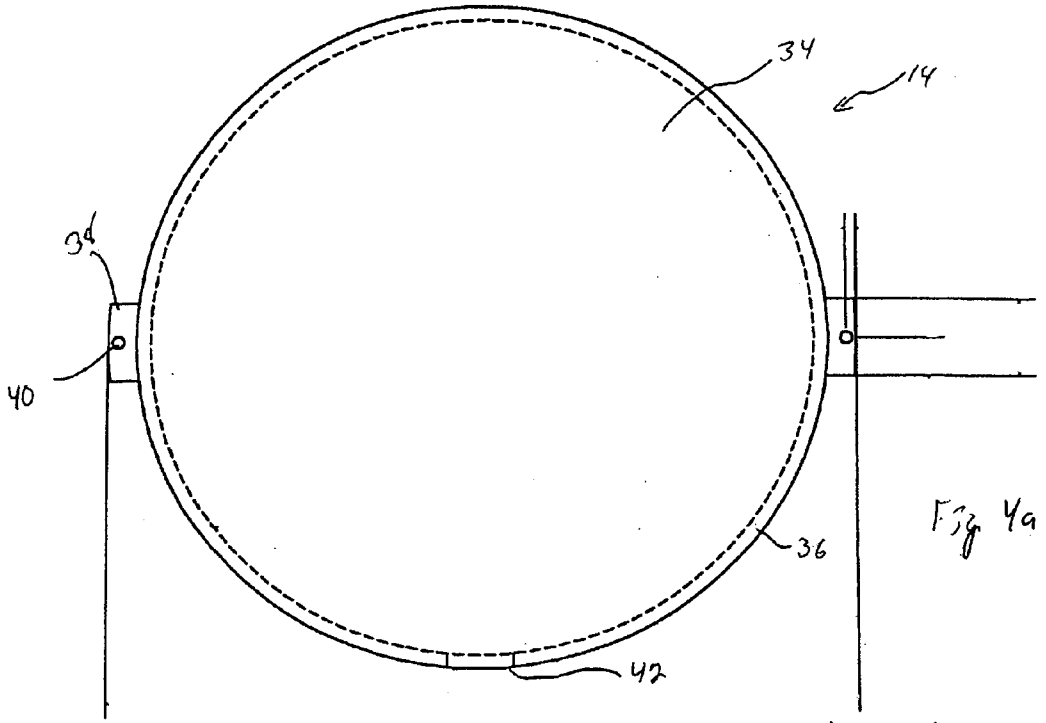


Fig 4a

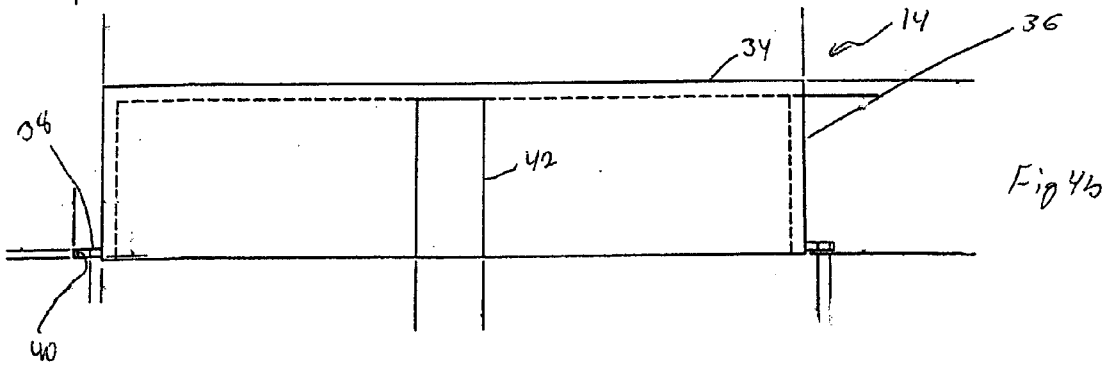


Fig 4b

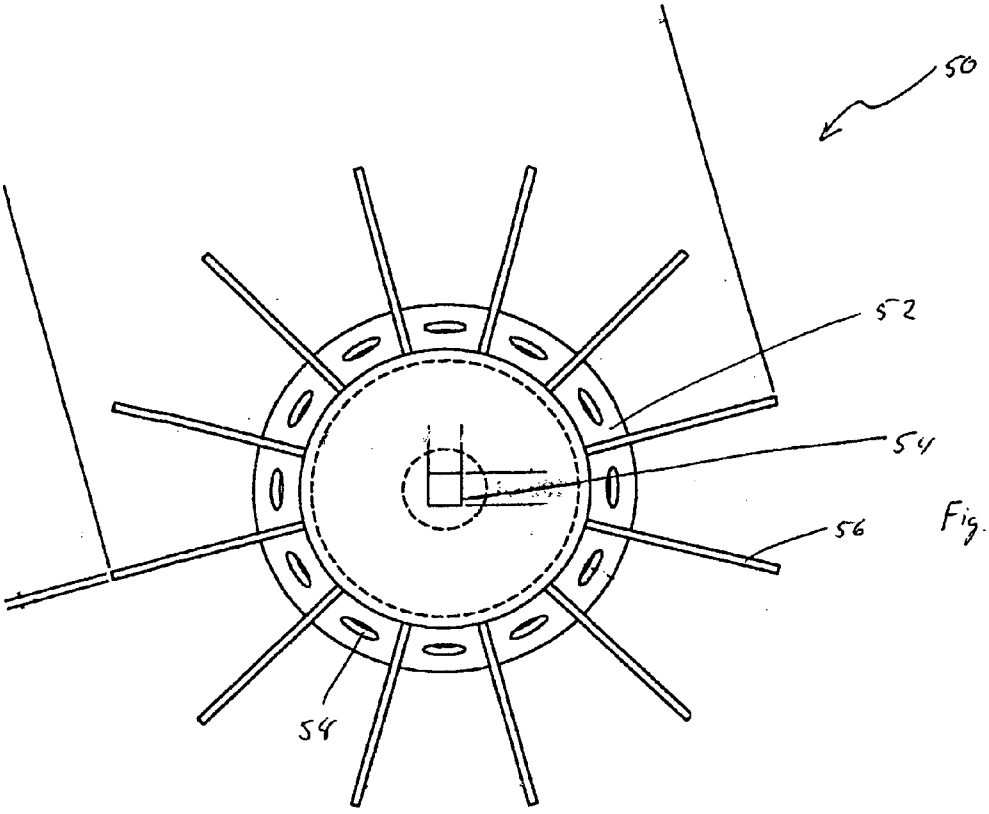


Fig. 5a

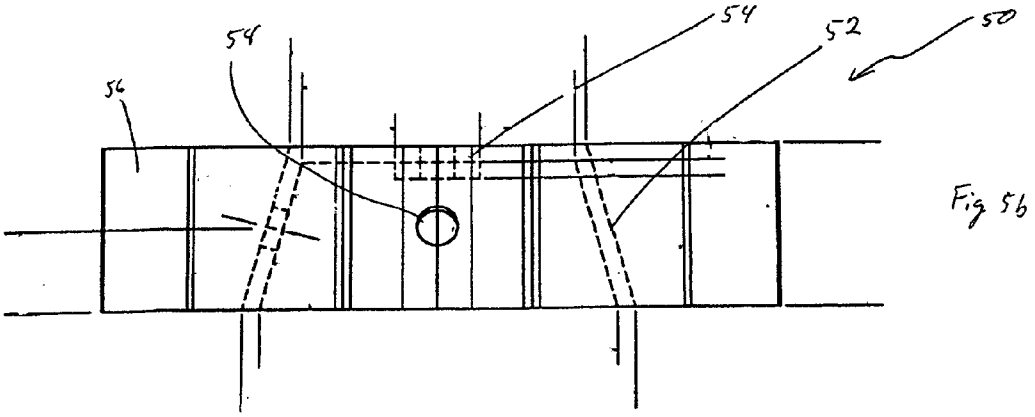


Fig 5b

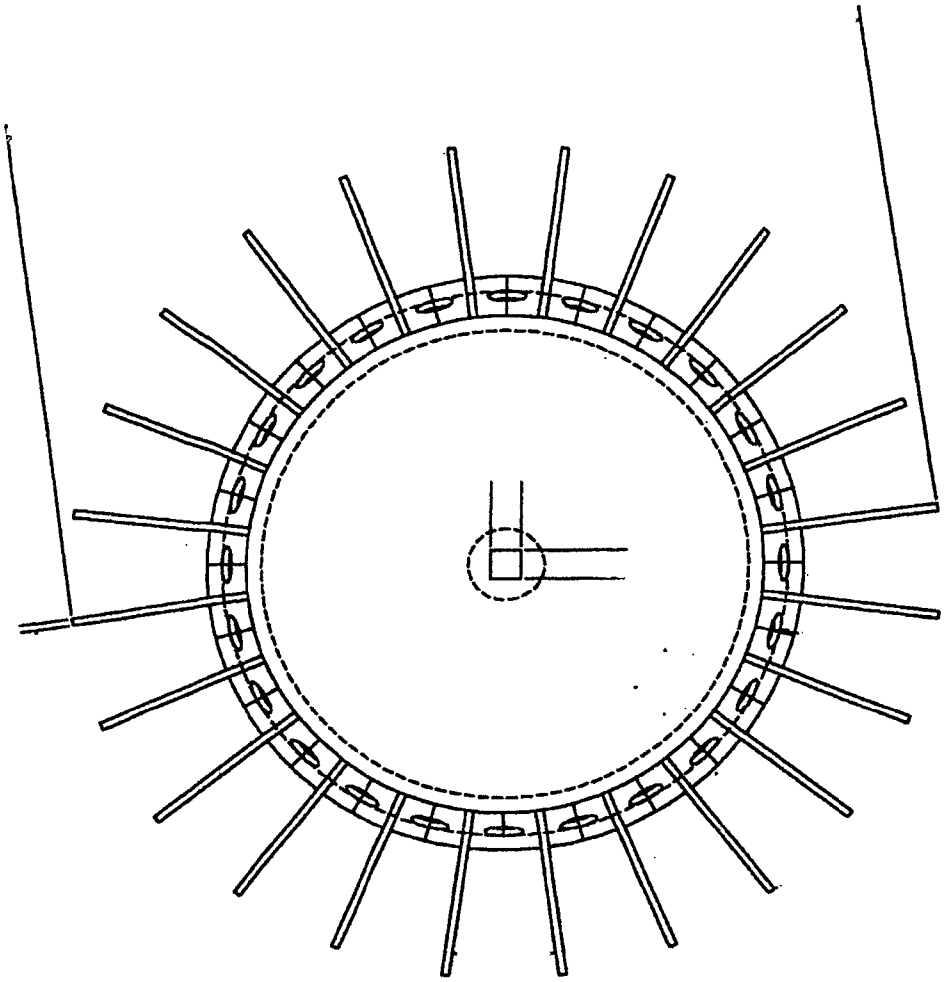
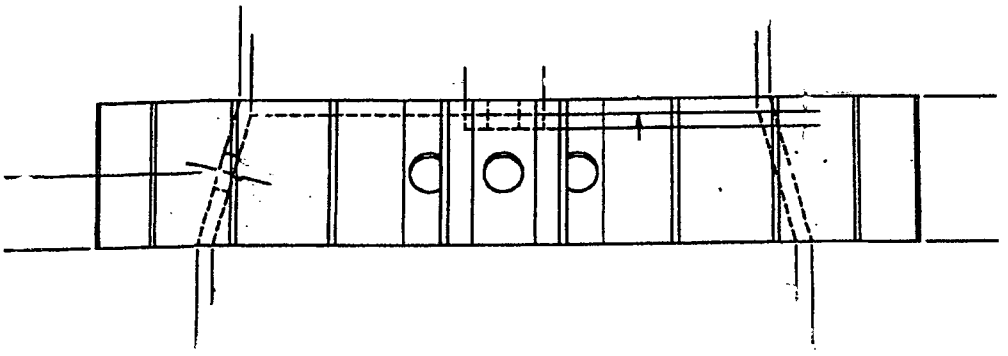


Fig 5c



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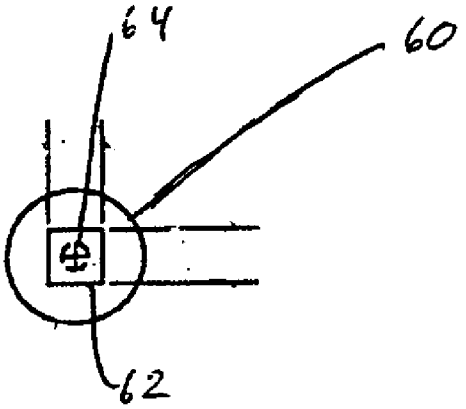

Fig 6a

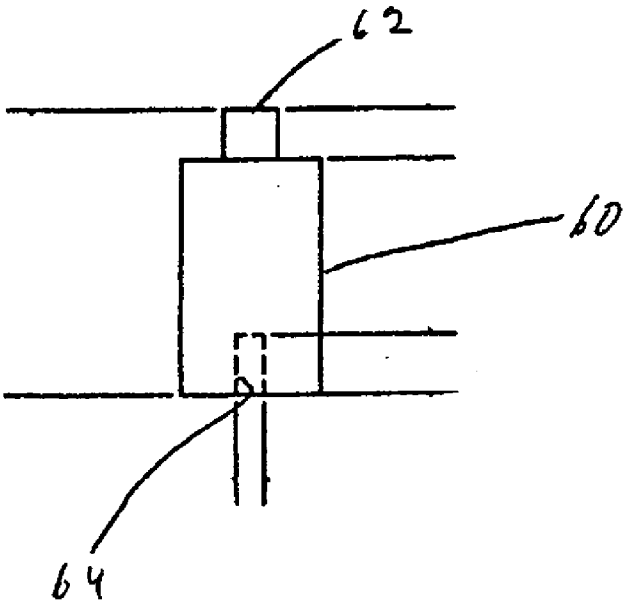

Fig 6b

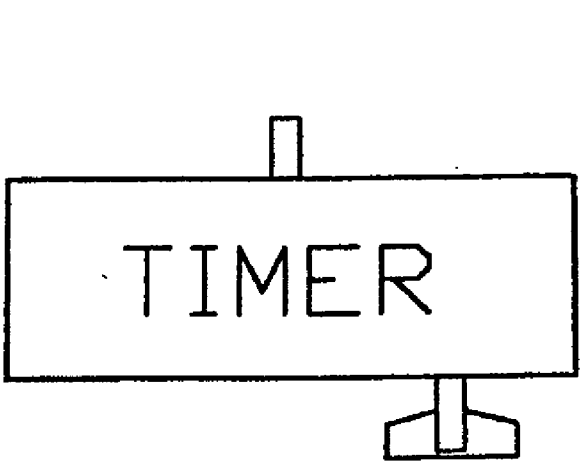

Fig 7.

DISPENSING DEVICE

FIELD OF THE INVENTION

[0001] The present invention relates to devices used for dispensing pharmaceutical compositions to patients in a time-controlled manner.

BACKGROUND

[0002] Dispensing pharmaceutical compositions to patients is often complicated by the need to limit the delivery to specific dosing regimens over specific time periods. In the case of many pharmaceuticals, delivery times must be controlled to provide adequate and effective dosing over time, while at the same time preventing inadequate dosing as well as overdosing.

[0003] The problem is particularly acute with drugs that demand patient compliance to optimize safety, while maximizing efficacy. Drugs that fall into this class may have strict administration schedules and stringent dosing amounts as exemplified by such classes of molecules to include, but not limited to analgesics, cardiovascular agents, metabolic disorder treatments, and drugs used to treat certain cancers. Such drugs may be subject to overdosing as patients often seek medication prior to the recommended or allowable prescribed dose and schedule, leading to the possibility of adverse events, abuse or fatality.

[0004] In supervised healthcare settings, i.e., hospitals, nursing homes, hospices, clinics, and the like, the problem is addressed by enabling healthcare practitioners to dispense fixed amounts of medication for patients at prescribed times in a controlled fashion. In addition, dosing requires the presence of a practitioner to determine, monitor, and sometimes adjust the dosing regimen of the required drug or drugs delivered to the patient in order to optimize efficacy and safety. Such necessary oversight places a large burden on the healthcare provider, as it requires personnel and detailed record-keeping for each patient. Likewise, in less controlled settings, supervision is still required to ensure adequate treatment and to prevent either under or overdosing and/or abuse. A relevant example includes the home healthcare setting, where visiting nurses are often required to be present for the delivery of individual drug doses to patients.

[0005] Therefore, a need exists for a user-friendly, simple drug-dispensing device that may contain several doses of a drug, provide individual doses available to a patient at prescribed time intervals, and which moderates some degree of protection to the patient, both by deterring potential over dosage and by making diversion by a family member or other visitor obvious.

SUMMARY AND OBJECTS OF THE INVENTION

[0006] One object of the present invention is to provide a simple device for storing and dispensing prescription drugs.

[0007] A further object of the present invention is to provide a simple device for storing and dispensing drugs which are administered to a patient via intranasal means.

[0008] A further object of the present invention is to provide a simple drug dispensing device that would allow a patient to receive drug doses at prescribed time intervals.

[0009] Another object of the present invention is to provide a drug dispensing device that is suitable for use in supervised, semi-supervised, and unsupervised healthcare settings.

[0010] Another object of the present invention is to provide a drug dispensing device having indicia thereon to indicate tampering or other attempts to gain unauthorized access to the drugs contained therein.

[0011] Still another object of the present invention is to provide a drug dispensing device that can be programmed by a healthcare practitioner to dispense drugs to a patient at prescribed intervals.

[0012] Still another object of the present invention is to provide a drug dispensing device that can be programmed by a healthcare practitioner to prevent dispensing drugs to a patient at less than prescribed time intervals.

[0013] Yet another object of the present invention is to provide a drug dispensing device that would allow patients to self-administer drugs over a prescribed time period.

[0014] It is another object of the present invention is to provide a drug dispensing device that would allow patients to self-administer such drugs as analgesics, cardiovascular drugs, drugs used to treat metabolic disorders, and drugs used to treat certain cancers when desired, but no earlier than at prescribed intervals.

[0015] It is another object of the present invention to provide a drug dispensing device that can dispense a prescribed drug regimen to a patient at prescribed time intervals.

[0016] The above and other objects may be achieved by providing a device for the controlled release of drug delivery units which comprises a magazine for containing a plurality of drug delivery units, a housing containing the magazine having an aperture allowing drug delivery units to be removed through the housing, a link by which the magazine may be moved relative to the housing, and a timing mechanism in communication with the link, for causing the magazine to be moved relative to the housing, thereby periodically allowing removal of individual drug delivery units through the aperture at pre-selected intervals. The device may be configured to allow dispensing of a specified number of drug delivery units over an extended time period, for example 12 or 24 hours or more, or it may be configured to allow dispensing of individual drug delivery units as desired by the patient, provided that the minimum interval between each delivery is of a pre-specified length. The various timing and delivery issues may be controlled by a healthcare provider during loading of the device or at some time thereafter.

[0017] The above objects and summary of the invention will be more fully set forth in the Figures and detailed description of the invention below.

DESCRIPTION OF THE DRAWINGS

[0018] FIG. **1** is a schematic depiction of the device of the present invention.

[0019] FIGS. **2***a* and **2***b* are schematic depictions of intranasal drug delivery units delivered by one embodiment of the present invention.

[0020] FIGS. **3***a* and **3***b* are schematic top and side views of the base of one embodiment of the present invention.

[0021] FIGS. **4***a* and **4***b* are schematic top and side views of the housing of one embodiment of the present invention.

[0022] FIGS. **5***a*-**5***d* are schematic top and side views of the magazine of two embodiments of the present invention.

[0023] FIGS. **6***a* and **6***b* are schematic top and side views of the link of one embodiment of the present invention.

[0024] FIG. **7** is a schematic depiction of the timing mechanism of one embodiment of the present invention.

DETAILED DESCRIPTION

[0025] The invention relates broadly to a device for the controlled dispensing of drug delivery units. As used herein, the term "drug delivery unit" is intended to refer to a unit dose of a pharmaceutical composition or an applicator for providing a unit dose of a pharmaceutical composition. Thus, while the term "drug delivery unit" may refer to a pill, tablet, capsule, caplet, etc., (i.e., a unit dose of a pharmaceutical composition) which is ingested by a patient, the term is also intended to refer to a device for delivering a unit dose of a pharmaceutical composition to a patient. Examples herein include, but are not limited to, intranasal applicators, such as applicators designed to deliver a single unit or bidose or multiunit dose of a pharmaceutical composition to a patient. Thus, as will become apparent, the present device may be used to dispense compositions which are ingestible as well as devices for delivering compositions which are administered by means other than ingestion. In one preferred embodiment, the invention is configured to dispense intranasal applicators (such as those manufactured by Ing. Erich Pfeiffer GmbH, Radofzell, Germany; Pfeiffer of America, Princeton, N.J.), each loaded with a unit dose of intranasal ketamine, intranasal morphine, or mixtures thereof, either with or without other constituents. Likewise, the invention may be configured to dispense more than one drug delivery unit at any given time, or it may be configured to dispense a drug delivery unit in the form of, for example, a capsule at one or more time intervals and a drug delivery unit in the for of, for example, an intranasal applicator at one or more different time intervals.

[0026] While the device is intended to be used to dispense any of a wide variety of drug delivery units, it is particularly adapted for dispensing controlled, scheduled drugs in a manner that prevents or provides indicia of overdosing. As noted above, the device is well-suited for the delivery of intranasal applicators, each loaded with a unit dose of intranasal ketamine, intranasal morphine, or mixtures thereof, either with or without other constituents; however, other drug delivery units are contemplated as well. These include, but are not limited to, the following drugs listed on DEA Schedules II, III, IV and V:

SCHEDULE II

Substance	DEA Number
1-Phenylcyclohexylamine	7460
1-Piperidinocyclohexanecarbonitrile	8603
Alfentanil	9737
Alphaprodine	9010
Amobarbital	2125
Amphetamine	1100
Anileridine	9020
Benzoylecgonine	9180
Bezitramide	9800
Carfentanil	9743

-continued

SCHEDULE II

Substance	DEA Number
Coca Leaves	9040
Cocaine	9041
Codeine	9050
Dextropropoxyphene, bulk (non-dosage forms)	9273
Dihydrocodeine	9120
Diphenoxylate	9170
Diprenorphine	9058
Ecgonine	9180
Ethylmorphine	9190
Etorphine HCl	9059
Fentanyl	9801
Glutethimide	2550
Hydrocodone	9193
Hydromorphone	9150
Isomethadone	9226
Levo-alphacetylmethadol	9648
Levomethorphan	9210
Levorphanol	9220
Meperidine	9230
Meperidine intermediate-A	9232
Meperidine intermediate-B	9233
Meperidine intermediate-C	9234
Metazocine	9240
Methadone	9250
Methadone intermediate	9254
Methamphetamine	1105
Methylphenidate	1724
Metopon	9260
Moramide-intermediate	9802
Morphine	9300
Nabilone	7379
Opium extracts	9610
Opium fluid extract	9620
Opium poppy	9650
Opium tincture	9630
Opium, granulated	9640
Opium, powdered	9639
Opium, raw	9600
Oxycodone	9143
Oxymorphone	9652
Pentobarbital	2270
Phenazocine	9715
Phencyclidine	7471
Phenmetrazine	1631
Phenylacetone	8501
Piminodine	9730
Poppy Straw	9650
Poppy Straw Concentrate	9670
Racemethorphan	9732
Racemorphan	9733
Remifentanil	9739
Secobarbital	2315
Sufentanil	9740
Thebaine	9333

SCHEDULE III

Substance	DEA Number
Amobarbital & noncontrolled active ingred.	2126
Amobarbital suppository dosage form	2126
Anabolic steroids	4000
Aprobarbital	2100
Barbituric acid derivative	2100
Benzphetamine	1228

-continued

SCHEDULE III

Substance	DEA Number
Boldenone	4000
Buprenorphine	9064
Butabarbital	2100
Butalbital	2100
Chlorhexadol	2510
Chlorotestosterone (same as clostebol)	4000
Chlorphentermine	1645
Clortermine	1647
Clostebol	4000
Codeine & isoquinoline alkaloid 90 mg/du	9803
Codeine combination product 90 mg/du	9804
Dehydrochlormethyltestosterone	4000
Dihydrocodeine combination product 90 mg/du	9807
Dihydrotestosterone (same as stanolone)	4000
Dronabinol in sesame oil in soft gelatin capsule	7369
Drostanolone	4000
Ethylestrenol	4000
Ethylmorphine combination product 15 mg/du	9808
Fluoxymesterone	4000
Hydrocodone & isoquinoline alkaloid 15 mg/du	9805
Hydrocodone combination product 15 mg/du	9806
Ketamine	7285
Lysergic acid	7300
Lysergic acid amide	7310
Mesterolone	4000
Methandienone (see Methandrostenolone)	4000
Methandranone	4000
Methandriol	4000
Methandrostenolone	4000
Methenolone	4000
Methyltestosterone	4000
Methyprylon	2575
Mibolerone	4000
Morphine combination product/50 mg/100 ml or gm	9810
Nalorphine	9400
Nandrolone	4000
Norethandrolone	4000
Opium combination product 25 mg/du	9809
Oxandrolone	4000
Oxymesterone	4000
Oxymetholone	4000
Pentobarbital & noncontrolled active ingred.	2271
Pentobarbital suppository dosage form	2271
Phendimetrazine	1615
Secobarbital & noncontrolled active ingred	2316
Secobarbital suppository dosage form	2316
Stanolone	4000
Stanozolol	4000
Stimulant compounds previously excepted	1405
Sulfondiethylmethane	2600
Sulfonethylmethane	2605
Sulfonmethane	2610
Talbutal	2100
Testolactone	4000
Testosterone	4000
Thiamylal	2100
Thiopental	2100
Tiletamine & Zolazepam Combination Product	7295
Trenbolone	4000
Vinbarbital	2100

SCHEDULE IV

Substance	DEA Number
Alprazolam	2882
Barbital	2145
Bromazepam	2748
Butorphanol	9720
Camazepam	2749
Cathine	1230
Chloral betaine	2460
Chloral hydrate	2465
Chlordiazepoxide	2744
Clobazam	2751
Clonazepam	2737
Clorazepate	2768
Clotiazepam	2752
Cloxazolam	2753
Delorazepam	2754
Dexfenfluramine	1670
Dextropropoxyphene dosage forms	9278
Diazepam	2765
Dichloralphenazone	2467
Diethylpropion	1610
Difenoxin 1 mg/25 ug AtSO4/du	9167
Estazolam	2756
Ethchlorvynol	2540
Ethinamate	2545
Ethyl loflazepate	2758
Fencamfamin	1760
Fenfluramine	1670
Fenproporex	1575
Fludiazepam	2759
Flunitrazepam	2763
Flurazepam	2767
Halazepam	2762
Haloxazolam	2771
Ketazolam	2772
Loprazolam	2773
Lorazepam	2885
Lormetazepam	2774
Mazindol	1605
Mebutamate	2800
Medazepam	2836
Mefenorex	1580
Meprobamate	2820
Methohexital	2264
Methylphenobarbital (mephobarbital)	2250
Midazolam	2884
Modafinil	1680
Nimetazepam	2837
Nitrazepam	2834
Nordiazepam	2838
Oxazepam	2835
Oxazolam	2839
Paraldehyde	2585
Pemoline	1530
Pentazocine	9709
Petrichloral	2591
Phenobarbital	2285
Phentermine	1640
Pinazepam	2883
Pipradrol	1750
Prazepam	2764
Quazepam	2881
Sibutramine	1675
SPA	1635
Temazepam	2925
Tetrazepam	2886
Triazolam	2887
Zaleplon	2781
Zolpidem	2783

SCHEDULE V

Substance	DEA Number
Codeine preparations - 200 mg/100 ml or 100 gm	
Difenoxin preparations - 0.5 mg/25 ug AtSO4/du	
Dihydrocodeine preparations 10 mg/100 ml or 100 gm	
Diphenoxylate preparations 2.5 mg/25 ug AtSO4	
Ethylmorphine preparations 100 mg/100 ml or 100 gm	
Opium preparations - 100 mg/100 ml or gm	
Pyrovalerone	1485

[0027] Apart from the above-noted intranasal applicators, each loaded with a unit dose of intranasal ketamine, intranasal morphine, or mixtures thereof, other preferred drug delivery units include unit doses of prescription drugs such as digoxin, β-blockers, α_2-antagonists, thyroid replacement drugs, drugs to treat specific diseases (Alzheimer's, AIDS, diabetes, etc.), anticoagulants, vitamins having potentially toxic overdosages, and any other ingestible, inhalable, injectable or topical drug that is provided according to a scheduled regimen. Other representative drugs include, but are not limited to: betamethasone, budesonide, cortisone, dexamethasone, hydrocortisone, methyl-prednisolone, prednisolone, triamcinolone, capecitabine, chlorambucil, cyclophosphamide, etoposide, hydroxyurea, imatinib, mercaptopurine, methotrexate, buprenorphine, butorphanol, codeine, hydrocodone, hydromorphone, levorphanol, meperidine, methadone, morphine, opium, oxycodone, pentazocine, oxymorphone, anisindione, dicumarol, warfarin, isocarboxazid, phenelzine, tranylcypromine, amitriptyline, amoxaphine, clomipramine, desipramine, doxapin, imipramine, nortriptyline, protriptyline, trimipramine, olanzapine, risperidone, quetiapine, ziprasidone, aripiprazole, clozapine, chlorpromazine, fluphenazine, trifluoperazine, perphenazine, thioridazine, haloperidol, thiothixene, molindone, loxapine, apomorphine, benztropine mesylate, entacapone, levodopa/carbidopa/entacapone, carbidopa/levodopa, pergolide, ropinirole Hcl, amantadine Hcl, and selegiline Hcl.

[0028] Broadly, in one embodiment, the device is intended to be loaded with multiple doses of one or more drug delivery units and programmed to allow the drug delivery units to be dispensed at predetermined time intervals. In another embodiment, the device is intended to be loaded with multiple doses of one or more drug delivery units and programmed to allow the drug delivery units to be dispensed to a patient when desired, provided that a minimum time interval has passed between dispensing cycles. In another embodiment, patients requiring a regimen of several different drugs over an extended time period may use the device to dispense the particular prescribed multi-drug regimen at specified time periods.

[0029] One necessary element of the present invention is a controllable timing mechanism which is in operable communication with a delivery system within the device. While the timing mechanism will be discussed in greater detail below, it is noted that it may be either an electrical or mechanical timing mechanism. Although both offer desired utility, mechanical timing mechanisms offer the advantage of employing the device in the absence of an electrical source.

[0030] For dispensing of drug delivery units over a scheduled time period, it is contemplated herein that the timing mechanism may be controlled either by the device manufacturer or at the time it is loaded with the desired drug delivery units. Thus, in one non-limiting example, in which the devise is intended to dispense drug delivery units hourly over a 12 hour time period, the timing mechanism may be preprogrammed by the manufacturer. In a further embodiment, the timing mechanism may include a user interface through which a particular dosing and time period may be input. One such non-limiting example would allow a healthcare practitioner to load the device with, for example, 12 doses of intranasal ketamine, and then program the timing mechanism to allow the devise to provide one dose every 2 hours.

[0031] Likewise, it is also contemplated that the device may include an interface through which a patient may self-administer drugs on an interval-limited basis. In this embodiment, the device may include a patient dosing interface through which the patient requests a drug delivery unit to be dispensed. The timing mechanism may be programmed by either the manufacturer or a healthcare practitioner to allow drug delivery units to be dispensed freely, provided a minimum interval has passed between each dispensing.

[0032] In one embodiment, the device may be used to simplify a complicated dosing regimen required by a patient. For example, many patients, particularly elderly patients, require doses of several different drugs one or more times per day. Selecting the particular drugs required at particular times can often be complicated or confusing. In one embodiment, the present invention provides a means by which proper dosing may be simplified. In particular, the device may be loaded in a manner which allows several drug delivery units to be dispensed at one time. As one example, consider the case of a patient requiring drugs A, B, and C every morning, and drugs B and D every evening. The chambers in the magazine of the device may be loaded with alternating combinations of drugs A, B and C and drugs B and D, and the device may be set to dispense the alternating combinations to the patient at twelve hour intervals.

[0033] In a preferred embodiment, it is contemplated that the entire device, loaded with the required drug delivery units, may be provided to a patient. This configuration is best applied in situations where the device will be used for short periods, such as for acute post-surgical pain relief. Upon termination of pain medication, the device may be cleaned, loaded with drug delivery units for a different patient, sealed and re-used. Alternatively, in applications in which the device will be used for longer periods, a patient may be provided with a version of the device in which the magazine used to contain drug delivery units is absent. In this case, a healthcare practitioner, pharmacist, or other authorized person may provide a magazine loaded with the appropriate drug delivery units to the patient. Depleted magazines may be either refilled, or replaced with fully loaded units.

[0034] The device may be best understood from the description below with reference to the accompanying Figures.

[0035] In one embodiment, shown in FIG. **1**, the device **10** comprises a base **12**, a housing **14** having an aperture **16** which provides access to the interior of the housing, a magazine **18** for containing drug delivery units and at least one tamper indicia **20**. Each of these elements, as well as other device components (not shown in FIG. **1**) is described

in detail below. The device is well-suited for use with individual (FIG. **2***a*) and multiple (FIG. **2***b*) intranasal drug delivery units, however, it is not intended to be limited in this manner. Rather, it is contemplated that any of a wide variety of delivery units, including but not limited to, intranasal applicators, pills, capsules, caplets, syringes, inhalers, patches, vials, and the like may be used in connection with the device.

[0036] The base **12** of the device is depicted schematically as a top view in FIG. **3***a* and side view in FIG. **3***b*. In FIGS. **3***a* and **3***b*, the base **12** comprises a substantially circular platform **22** containing a central aperture **24**. A wall **26** extends downward from the platform **22** periphery to define an interior space below the platform. The interior space communicates with the central aperture **24**. Optionally, a plurality of feet **28** may extend from portions of the wall **26** to support the device. In some embodiments, it is desirable to provide the device **10** with tamper indicia **20** which provide evidence of attempts to open the device by unauthorized individuals. While such tamper indicia **20** will be described in greater detail below, in one embodiment, the base **12** may include one or more flanges **30** extending outwardly from the platform. These flanges may contain a bore **32** adapted to mate with similar structures on the housing **14** to provide a means for securing the housing **14** to the base **12** in a manner which would evidence attempts to separate these elements and gain unauthorized access to the device interior.

[0037] The housing **14** of the device is depicted schematically as a top view in FIG. **4***a* and side view in FIG. **4***b*. In FIGS. **4***a* and **4***b*, the housing comprises a substantially circular enclosure having a top **34** and a wall **36** extending therefrom. As with the base **12**, the housing **14** may include one or more flanges **38** extending outwardly from the housing. These flanges may contain a bore **40** adapted to mate with similar structures on the base **12** to provide a means for securing the housing **14** to the base **12** in a manner which would evidence attempts to separate these elements and gain unauthorized access to the device interior. The wall **36** includes an aperture **42** allowing access to the interior of the housing. The aperture **42** may comprise simply a region on the circumference of the top **34** from which the wall **36** does not extend, or it may be formed as a separate opening in the wall. An optional door, not shown, may cover the aperture to prevent dust and other unwanted substances from entering the device interior. The door may include a simple mechanism that allows it to be opened when a drug delivery unit is available, and closes and optionally locks it when a drug delivery unit is not available. The aperture **42**, with or without the optional door, must be large enough to allow a drug delivery unit to be removed from the device when it is positioned within the housing **14** adjacent to the aperture **42**.

[0038] Positioned within the device in the chamber formed between the base **12** and the housing **14** is a magazine **50**, shown in FIGS. **5***a*-**5***d*. The magazine **50** comprises a hub **52** having a link interface **54** and a plurality of partitions **56** extending therefrom. When positioned within the device in the chamber formed between the base **12** and the housing **14**, the link interface **54** mates with a link (described below) and a timing mechanism (described below) to allow the magazine **50** to be rotated within the device. The partitions **56** define storage regions for the drug delivery units and serve to move the units through the device, toward the aperture **42**, as the magazine **50** is rotated in a controlled manner. The hub **52** may contain a drug delivery unit aperture **58** in the regions formed between the partitions to assist in positioning each drug delivery unit within the device. The number of partitions used depends on the particular anticipated dosing regimen with which the device will be used, as well as the particular timing mechanism selected. For example, if the device is intended to dispense 12 drug delivery units over a 24 hour period, the device could have 12 partitions and a 24-hour timing mechanism. As will be apparent from FIGS. **5***a* and **5***b*, a magazine having 12 partitions defines 12 storage regions between them. Likewise, in another non-limiting embodiment, shown in FIGS. **5***c* and **5***d*, the magazine may include 24 partitions to define 24 storage regions. Such a device could be used to deliver 24 drug delivery units hourly over the course of a day when used with a one-day timing mechanism, or 12 drug delivery units daily over the course of two days when used with a two-day timing mechanism. Numerous other combinations of timing and dosing regimens will be apparent to those of ordinary skill in the art.

[0039] The magazine **50** is rotated within the device using a link **60** shown in FIGS. **6***a* and **6***b*. The link **60** comprises, generally, an axle having a magazine interface **62** and a timing mechanism interface **64**. The magazine interface **62** mates with the link interface **54** on the magazine **50** to allow the link, when rotated, to rotate the magazine. The timing mechanism interface mates with a timing mechanism, described below, which rotates the link and the magazine in a controlled manner.

[0040] The timing mechanism **70** is depicted schematically in FIG. **7**. It is anticipated that any of a wide variety of timing mechanisms may be embodied in the present invention. For example, the timing mechanism may be an electrical timer that is driven by AC current, or it may be an electrical timer that is driven by battery power. In one preferred embodiment, however, the timing mechanism is a mechanical timer. Mechanical timers are preferred because they are simple, durable, reliable and do hot require a current source to operate. Thus, the use of a mechanical timer allows the device to be employed in a wide variety of environments where electrical timers would offer little or no usefulness. For example, the device of the present invention is well suited for military applications where AC current may be unavailable. Likewise, the device is suitable for civil defense applications where it may be stored for extended periods of time prior to use. Mechanical timers are unaffected by such storage, whereas batteries may not be reliable in such circumstances.

[0041] The timing mechanism **70** is selected such that it provides the magazine with one complete rotation over a predetermined dosing period. Thus, a "one-day" timing mechanism is one that provides the magazine with one complete rotation over a 24 hour period, a "two-day" timing mechanism is one that provides the magazine with one complete rotation over a 48 hour period, a "half-day" timing mechanism is one that provides the magazine with one complete rotation over a 12 hour period, etc. The timing device includes a rotating rod that mates with the link via the timing mechanism interface **64**. As such, as the rod on the timing mechanism is rotated, it rotates the link, which, in turn, rotates the magazine.

[0042] The timing mechanism **70** may optionally include an audible and/or visual indicator that provides an indication when a drug deliver unit is available for withdrawal from the

device. The audible indicia may be, for example, a bell that rings when a dose is available, and the visual indicia may be, for example, a colored segment that becomes visible through the aperture **42** when a dose is available. Thus, in the case of a 12 dose regimen over the course of one day, an audible indicia would sound every two hours.

[0043] As noted in FIGS. **3***a* and **3***b* and FIGS. **4***a* and **4***b*, the device may include tamper indicia. In the embodiments shown, the tamper indicia **20** comprises flanges on the base and the housing each having a bore through which a seal may be inserted. In one preferred embodiment, the seal comprises an electrical tie-wrap which can be formed into a loop using a one-way ratchet mechanism thereon. By inserting tie wraps through the flanges on the base and housing, the base and housing are secured together in a manner that prevents unauthorized access to the interior of the device unless the tie wraps are cut.

[0044] The device is not intended to be tamper-proof. Rather, the device is intended to provide an indication to a healthcare practitioner that unauthorized access, or attempts at unauthorized access, to the device interior have occurred. It should be understood as well, that any of a wide variety of devices may be used to secure the housing to the base via the flanges. These include dial locks, keyed locks, scored labels and tapes, etc.

[0045] In one embodiment of the assembled device, a mechanical timing mechanism is mounted to the underside of the base in a manner such that rotating rod extends through the center of the base and mates with the timing mechanism interface on the link. The magazine, selected for the particular dosing regimen and loaded with drug delivery units is positioned on the base in a manner such that it mates with the magazine interface on the link. The housing is positioned over this assembly and the tamper indicia is employed to hold the housing to the base. In one preferred embodiment, the drug delivery units comprise intranasal dispensers of analgesic medications intended to be dispensed every two hours over the course of a full day. As such, a one-day timer and a magazine having 12 partitions is employed.

[0046] The device above could be stored until needed, and then employed simply by providing it to a patient and activating the mechanical timing mechanism, such as by winding. The timing mechanism will begin to rotate the magazine within the device in a manner such that a patient can withdraw one drug delivery unit from the aperture in the housing every two hours. Once a drug delivery unit is removed from the device, another one will not be available until the magazine has rotated sufficiently to make another drug delivery unit available. If the patient attempts to accelerate the dosing by gaining access to the interior of the device, this attempt will be evident via the tamper indicia. If the dosing is intended to be continued over the course of a second day, a healthcare practitioner can open the device, and either reload the magazine or replace it with a preloaded magazine.

[0047] In other embodiments of the present invention, individuals may use the device at home to dispense medications according to their particular needs. Thus, a patient taking multiple medications over the course of one or more days may load the magazine, or obtain personalized preloaded magazines, to provide the appropriate medications at the appropriate times.

[0048] The individual elements of the device may be made of any of a wide variety of materials. In one preferred embodiment, the base, housing, link and magazine are fabricated from a cast or thermoformed polymer. It is anticipated that the device may be employed in a manner where the elements are reusable, and thus, durable plastics are preferred. In one embodiment, however, the base, housing, timing mechanism and link are intended to be made available as a packaged unit, and the magazine, loaded with the appropriate drug delivery units is obtained separately. In this case, the magazine may be returned during the process of refilling, or it may be discarded. In the latter case, it is preferred that the magazine be formed of a biodegradable or recyclable material.

[0049] The device of the present invention offers a simple, durable alternative to conventional patient controlled analgesia (PCA) devices. Unlike common PCA systems, a preferred embodiment the present invention can operate in the absence of electrical power, while providing periodic doses of analgesics in a manner that is tamper evident and self-accounting.

[0050] The device lends itself to use in hospitals, semi-supervised care environments, and independent supervised care environments. In post operative patients, the device reduces the cost of care as there is no need for a healthcare practitioner to periodically administer the dispensed medications. For end-of-life care, the device can be used to deliver analgesic medications at a greatly reduced cost and improved safety. For settings where the patient needs assistance with determining when to take the medications, i.e., nursing homes, the device reduces the needs for a healthcare practitioner at each dosing event. Finally, in natural disaster or military situations, the device provides a durable means of dispensing medications in environments where electrical power may be unavailable.

Equivalents

[0051] The present invention is not intended to be limited in scope by the specific embodiments described herein, each of which is presented by way of example only. Various modifications of the invention in addition to those described herein will become apparent to those skilled in the art from the foregoing description and the accompanying figures. Such modifications are intended to fall within the scope of the claims.

1. A device for the controlled release of drug delivery units, which comprises:

a) a magazine for containing a plurality of drug delivery units;

b) a housing containing the magazine, said housing having an aperture allowing drug delivery units to be removed therethrough;

c) a link by which the magazine may be moved relative to the housing; and

d) a mechanical timing mechanism in communication with the link, for causing the magazine to be moved relative to the housing, thereby periodically allowing removal of individual drug delivery units through the aperture.

2. The device of claim **1**, wherein the magazine is configured to hold 12 drug delivery units.

3. The device of claim **1**, wherein the magazine is configured to hold 24 drug delivery units.

4. The device of claim **1**, further including at least one tamper detection element.

5. The device of claim **4**, wherein the tamper detection element provides an indication of at least one condition selected from the group comprising: opening the housing, adjusting the timing mechanism, movement of the magazine by other than the timing mechanism, and attempts of each.

6. The device of claim **1**, wherein the magazine moves relative to the housing via rotation.

7. The device of claim **6**, wherein the link comprises an axle upon which the magazine may be rotated.

8. The device of claim **7**, wherein the timing mechanism communicates with the axle in a manner such that drug delivery units may be removed at pre-selected time intervals.

9. The device of claim **1**, wherein the combined plurality of drug delivery units in the magazine comprises a daily drug dose for a patient.

10. The device of claim **1**, wherein each of the drug delivery units comprises a single unit dispenser for delivering a drug selected from the group comprising intranasal ketamine, intranasal morphine, and mixtures thereof.

11. The device of claim **10**, wherein each of the drug delivery units comprises a Pfieffer intranasal applicator.

12. The device of claim **1**, wherein the aperture is accessed via a door.

13. The device of claim **1**, further including a patient dosing interface.

14. The device of claim **13**, wherein the patient dosing interface includes a lock-out to prevent removal of drug delivery units at time intervals less than a pre-selected minimum interval.

15. The device of claim **1**, further including an indicator to alert a patient that a drug delivery unit is available.

16. The device of claim **15**, wherein the indicator is an audible alarm, a visual indication, or a combination of both.

17. The device of claim **1** wherein the drug delivery units are intranasal, ingestible, topical or injectable drug delivery units.

18. A device for the controlled release of drug delivery units, which comprises:

a) a magazine for containing a plurality of drug delivery units;

b) a housing containing the magazine, said housing having an aperture allowing drug delivery units to be removed therethrough;

c) a link by which the magazine may be moved relative to the housing; and

d) a mechanical timing mechanism in communication with the link, for causing the magazine to be moved relative to the housing, the device having a time-based lock-out to prevent access to the magazine except at pre-selected time intervals, thereby allowing removal of individual drug delivery units through the aperture only at pre-selected time intervals.

19-34. (canceled)

35. A system for the controlled delivery of drugs, the system comprising:

a) at least one drug delivery unit;

b) a magazine constructed and arranged to contain a plurality of drug delivery units, the magazine containing said at least one drug delivery unit;

c) a housing containing the magazine, said housing having an aperture allowing said at least one drug delivery unit to be removed therethrough;

d) a link by which the magazine may be moved relative to the housing; and

e) a mechanical timing mechanism in communication with the link, for causing the magazine to be moved relative to the housing, thereby periodically allowing removal of individual drug delivery units through the aperture.

36-51. (canceled)

52. A method for providing drug delivery units to a patient at pre-selected time intervals, the method comprising the steps of:

a) providing a system for the controlled delivery of drugs, the system comprising:

i) at least one drug delivery unit;

ii) a magazine constructed and arranged to contain a plurality of drug delivery units, the magazine containing said at least one drug delivery unit;

iii) a housing containing the magazine, said housing having an aperture allowing said at least one drug delivery unit to be removed therethrough;

iv) a link by which the magazine may be moved relative to the housing; and

v) a mechanical timing mechanism in communication with the link, for causing the magazine to be moved relative to the housing, thereby periodically allowing removal of individual drug delivery units through the aperture;

b) providing the timing mechanism with data indicative of the dosing schedule for the patient;

c) activating the timing mechanism to thereby allow the patient to withdraw drug delivery units from the system according to the dosing schedule.

53-68. (canceled)

69. A device for the controlled release of drug delivery units, which comprises:

a magazine containing a plurality of drug delivery units, wherein the magazine is intended to operate with a device comprising:

a) a housing for containing the magazine, said housing having an aperture allowing drug delivery units to be removed therethrough;

b) a link by which the magazine may be moved relative to the housing; and

c) a mechanical timing mechanism in communication with the link, for causing the magazine to be moved relative to the housing, thereby periodically allowing removal of individual drug delivery units through the aperture.

70-78. (canceled)

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