(54) Apparatus and system for the self-dosing of a liquid medicine
Gerät und System zum Selbstdosieren eines flüssigen Medikaments
Appareil et système pour se délivrer une dose d’un médicament sous forme liquide

(72) Inventor: Tsujikawa, Hajime
Otsu-shi, Shiga-ken (JP)

(74) Representative:
Kraus, Walter, Dr. et al
Patentanwälte Kraus, Weisert & Partner
Thomas-Wimmer-Ring 15
80539 München (DE)

(56) References cited:
EP-A- 0 483 759
FR-A- 2 588 757
WO-A- 90/12609
GB-A- 2 192 135
Description

The invention relates to an apparatus for the self-dosing of a liquid medicine, comprising:

- a casing formed with a chamber for receiving the liquid medicine and with an inlet port and an outlet port in fluid communication with the chamber, a piston liquid-tightly and slidably fitted in the chamber, a push button attached to the piston and capable of being pressed by a patient using the apparatus to move the piston from a home position to a pressed position, a one-way check valve communicating with said outlet port and a spring which cooperates with the push button and urge the piston towards its home position to enable rapid refilling of the chamber with fresh liquid medicine, wherein said check valve allows only a forward flow and inhibits a backward flow of the liquid medicine.

More particularly, the invention provides an apparatus of the above type which may be incorporated either in a system or used as an independent device so as to be operated by a patient himself or herself for the purpose of repeatedly dosing small amounts of analgesics to relieve postoperative pain or small amounts of an anticancer medicine to relieve cancerous pain, or one-shot dosing of other medicines.

It is becoming popular in the analgesic treatment to repeat or continue the dosing of small amounts of an analgesics for the control of postoperative or cancerous pain, wherein a certain device is used and an epidural catheter is inserted in patient's body. On the other hand, the conditions of patients are varied, and some patients may suffer an acute pain during the continued dosage of prescribed amounts of analgesics. Therefore, there have been proposed some kinds of apparatuses adapted for use by a patient himself or herself in the event of such an acute pain. Those apparatuses are designed to allow him or her to make the one-shot dosing of analgesics, as disclosed for example on the Domestic Re-publishing Gazette Sho. 63-501195 of an International Patent Application.

This apparatus for the patient-controlled delivery of a beneficial agent comprises, as shown in Fig. 5(a), a chamber 90 defined between a raised plateau 98 of a back plate 86 and a circular flexible sheet 96. The chamber 90 is connected to conduits, which are respectively attached to and communicate with a bladder or container of the agent and to a catheter or other medical devices. The flexible sheet 96 supports a floating plate 100 disposed thereon, and a button-like control switch 84 is located above the floating plate so as to be pushed thereto by the patient. A base portion of the control switch 84 is journaled on the back plate by a pivot pin 116, and a coiled spring 124 surrounds this pin. With the switch 86 being pushed by the patient, the chamber 90 will be compressed as shown in Fig. 5(b) and 5(c) so that the beneficial agent is supplied to him or her via one of the conduits. Upon retraction of the patient's finger from the button-like switch 84, the coiled spring 124 causes it to return to its home position shown in Fig. 5(d).

It is noted here that the flexible sheet 96 in the prior art apparatus remains pressed as illustrated in Fig. 5(d), even after the patient has removed his or her finger from the switch 84. Thus, the refilling of the chamber 90 with the beneficial agent is done only by a moderate compressive force imparted by the bladder to the beneficial agent therein. The elastomer bladder is however of such a nature that only small amounts of the agent can be dosed. Consequently, the beneficial agent is fed to the chamber at a slow speed (see the Gazette 63-501195, page 6, lines 13 - 19).

This feature of the prior art apparatus is problematic in that any prompt and rapid refilling of the agent for the next dose is not possible.

Further the patient cannot change or adjust the quantity of one dose, because only a limited volume of the agent can be discharged at a time by means of the conventional apparatus. Such a limited quantity and a slow refilling render it impossible for the patient to dose himself or herself a freely selected quantity of the agent at any desired speed.

It is also noted that, as will be seen in Figs. 5(a) to 5(d), this conventional apparatus is of a comparatively complicated structure which will be manufactured at a relatively high cost. In addition, the liquid agent is likely to leak from the periphery of the flexible sheet 96.

Moreover, an apparatus for the self-dosing of a liquid medicine of the type mentioned in the beginning is known from FR-A-2 588 757, upon which the preamble of claim 1 is based. In this apparatus the spring is provided on the top of the casing around the stem connecting the piston and the push button so that the spring extends between the top of the casing and the underside of the push button. Therefore, the height of the apparatus consists of the full height of the spring and the height of the casing and the height of the push button.

An object of the present invention is to provide an apparatus which is adapted for the self-dosing of a liquid medicine, is capable of being refilled rapidly with the agent and of adjusting the quantity of the dose at a time, and further is free from leakage of the agent, though it is of a comparatively simple structure manufactured at a reduced cost.

The invention provides an apparatus of the type mentioned in the beginning, which is characterized in that said spring surrounds a cylindrical portion of said casing, which defines said chamber so that the height of the apparatus is reduced and the apparatus therefore can be worn like a wrist watch.

In a desirable embodiment, the apparatus further comprises an upstream and a downstream conduit respectively connected to the inlet and outlet ports for
transportation of the liquid medicine, with the check valve disposed in the downstream conduit at its end so that only a forward flow of the liquid medicine is allowed, whereby a backward flow thereof is inhibited.

As one embodiment the present invention provides also a system for the self-dosing of a liquid medicine, the system including, in combination with the apparatus in the desirable mode, a continuous feeder "D" having a usual dosing line through which the liquid medicine continuously flows at a low flow rate, the dosing line being connected to the apparatus in parallel and in fluid communication therewith.

Alternatively, the system may include, in combination with the apparatus in the desirable mode, a medicine bag connected in series to the apparatus by a thin external tube of an extremely small inner diameter, through which tube the liquid medicine is fed to the apparatus.

In operation, the push button in the apparatus will be pressed by a patient in order to force the piston towards a bottom of the chamber, so that the liquid medicine flows out of the chamber through the output port, until the patient removes his or her finger(s) from the push button. Simultaneously with the retraction of the button, the spring elastically forces the piston towards its unactuated home position, whereby the chamber will be refilled with the liquid medicine which is automatically sucked due to a negative pressure produced in said chamber. The refilling of the chamber is effected in a short time in this manner. Therefore, a second and succeeding doses can be administered by the apparatus or the system employing same in the invention, without any significant delay. Thus, an amount of administrated medicine can be chosen easily relying on the number of repeated doses.

Because the device in the apparatus offered herein for the self-dosing of liquid medicine is composed of only four main parts, that is, the casing, the piston, the push button and the spring, its structure is so simple that it can be manufactured at a reduced cost. It is another important feature that the piston which is made of a gasket material is highly reliable in its sealing property, precluding the problem of leakage of the medicine.

BRIEF DESCRIPTION OF THE DRAWINGS

In the accompanying drawings showing embodiments of the present invention:

Fig. 1 is a cross-sectional view of an apparatus for the self-dosing of liquid medicine in a first embodiment;

Fig. 2 is a plan view of the apparatus;

Fig. 3 is a schematic view of a system for the self-dosing of liquid medicine in a second embodiment;

Fig. 4 is a schematic view of another system for the self-dosing of liquid medicine in a third embodiment; and

Figs. 5(a) to 5(d) illustrate a prior art apparatus for the self-dosing of liquid medicine.

THE PREFERRED EMBODIMENTS

As shown in Fig. 1 which is a cross-sectional view of an apparatus provided in the invention, and shown in Fig. 2 which is a plan view of a device or reservoir "A" included in the apparatus, it comprises a casing 1 composed of a base portion 2 and a cylindrical portion 3 integral therewith. The interior of the cylindrical portion 3 is formed as a chamber 4 in which a liquid medicine "m" is received. An aperture 5 opens through a bottom of the chamber 4 to the junction of an inlet and outlet ports 6 and 7 which are members of the apparatus and penetrate the base portion 2. Alternatively, those inlet and outlet ports 6 and 7 may be separated insofar as they are in fluid communication with the chamber 4. Secured to the top of cylindrical portion 3 is a stopper 12 for holding a piston 13 in the chamber, the piston being made of a gasket material such as referred to below. The casing may be made of a transparent plastics, for example ABS resin.

The casing 1 is substantially of a size of men's wrist watch, and may have slits 11 for fixing the ends of a pair of bands 10 and 11 so that this apparatus can be worn by a patient on his or her wrist. It is desirable that the periphery of casing 1 is graduated with a scale, for example 1 ml, 2 ml, 3 ml and so on, in proportion to the times of pressing a push button 14.

The piston 13 liquid-tightly fits in the cylindrical portion 3 of the casing 1. The push button 14 is attached to the piston 14, which is made of an elastic rubber such as a butyl rubber so that a sufficient sealing property is enhanced to the piston. The push button 14 comprises integral portions, that is, a disc 15 carrying the piston attached thereto, a rod 16 extending from the disc, and a head 17 formed at the top of rod 16. A recess 18 formed on the upper central surface of the head is for an easy pressing thereof by the patient. This push button 14 is made of a plastics such as polypropylene.

An annular seat 19 formed on the periphery of lower surface of the head 17 faces another annular seat 20 on the outer periphery around a bottom of the cylindrical portion 3 of the casing 1. A coiled spring 21 is held in place between the seats 19 and 20. This spring urges the push button 14 upwardly in Fig. 1 so that the button takes its uppermost position within the chamber 4 unless pressed by the patient.

If and when the patient presses the push button 14, the liquid medicine "m" will be compressed and discharged at the same time out of said chamber 4 through the output port 7. Upon removal of the patient's finger from the button 14, the piston returns promptly to its uppermost position, thereby producing a negative pressure in the chamber 4 and refilling it with the liquid medicine sucked through the inlet port 6. The chamber 4 is refilled again in this manner simultaneously with the return of button 14 to its home position.

Since instantaneous refilling of the chamber in the
apparatus with the liquid medicine "m" is effected every time when the push button 14 is pressed, a desired amount of the medicine can be supplied to the patient by the repeated pressing of said button. Only four parts, i.e., the casing 1, push button 14, piston 13 and spring 21, constitute the device or reservoir "A" as the principal member of the apparatus. Such a simplified structure of reservoir enables manufacture thereof at a reduced cost. The chamber's 4 sealing, which is realized by a close contact of the inner periphery of the cylindrical portion 3 with the outer periphery of piston 13, is of a high reliability because the piston is made of the gasket material which elastically and tightly engages with said inner periphery. Thus, there is no possibility of leakage of the medicine in the apparatus provided in the embodiment.

An upstream conduit 8 may be connected to the inlet port 6 of the apparatus as described above, with a downstream conduit 9 being connected to the outlet port 7. A "Luer-tapered" line connector 22 and a check valve 23 are connected to ends of the upstream and downstream conduits 8 and 9, respectively. The check valve 23 allows the medicine only to flow forwards in the direction indicated by the arrow "a", and inhibits it to flow in a reverse direction.

The apparatus "B" for the self-dosing of liquid medicine is constructed in a manner described above, and particularly comprises the check valve 23 so that the liquid medicine is sucked in the chamber only through the upstream conduit 8. By virtue of the line connector 22 and check valve 23, this apparatus "B" can be connected readily to a usual dosing line in a continuous dosing system or the like, without detaching said apparatus from the patient's arm or wrist.

Next, a system "C" for the self-dosing of liquid medicine will be described below, which system is provided in a second embodiment and in which system the apparatus "B" is employed.

As shown in Fig. 3, this system "C" comprises a continuous feeder "D" combined with the apparatus "B" and having a usual dosing line through which the liquid medicine continues to flow at a low flow rate. The feeder "D" is composed of: a medicine receptacle 30 having a dosing pump; a dosing tube 31 extending from the receptacle; and a flow control means 32 disposed on this tube between the pump and a terminal connector 33 attached to a free end of the tube 31. The connector 33 may be joined with a catheter or the like so that the medicine pumped out of the receptacle 30 is dosed to a patient at an extremely low flow rate, for example at 1 ml/hr, which flow rate is controlled by the control means 32.

In addition to the usual dosing line composed of the dosing tube 31 in this system, a bypass line is provided which comprises external tubes 35 and 35. One ends of those tubes 35 are connected to the usual dosing line, and the other ends of said tubes 35 are connected to the apparatus "B". Another flow control means 36 is also disposed on one of the external tubes 35, whereby the flow of medicine into the device or reservoir "A" is limited to for example 1 ml/hr.

In operation of such a system "C", the liquid medicine flowing out of the receptacle 30 diverges into the dosing tube 31 and external tube 35, wherein a fraction of the medicine travels through the control means 32 in the usual dosing line so as to be directly dosed to the patient to whom this system is applied. Another fraction flows through the bypass and advances beyond the other control means 36, so as to be received temporarily in the device "A" before dosed to the patient through the check valve 23. Thus, under a normal condition in this example, a total dose of 2 ml/hr is given to the patient. However, if and when this patient suffers an acute pain, he or she may press the push button 14 to one-shot dose himself or herself on the instant the medicine present in the reservoir "A".

Although an example of flow rate which is controlled respectively by the control means 32 and 36 is 1 ml/hr, it may be changed within a range of 0.5 - 2.5 ml/hr, taking into account the symptoms of patient and/or the concentration, i.e., dilution ratio, of liquid medicine. Since the volume of reservoir "A" is 2 - 3 ml in this example, the one-shot dose may be about 2.5 - 5.5 ml in its volume. A dose during the refilling of reservoir "A" after the emergency one-shot dose will be continued only through the usual dosing line at a flow rate controlled by the means 32 disposed on this line.

Fig. 4 illustrates a third embodiment wherein another system "E" is designed only for the one-shot doses.

A medicine bag 40 in this embodiment may usually have a capacity of 20 - 100 ml, or more preferably of 40 - 60 ml. A thin external tube 41, which connects the medicine bag 40 to the reservoir "A", is of a very small inner diameter, for example 50 - 200 μm. Since such a thin tube 41 per se regulates the flow rate of liquid medicine, a flow control means is dispensed with, thus rendering simpler the structure of this system. Another external tube 42 having a terminal connector 43 is connected to the outlet of the device or reservoir "A" so that the reservoir can be joined to a catheter or other medical device.

In operation, the push button 14 will be pressed and subsequently unpressed so that reservoir "A" automatically sucks an amount of liquid medicine from the bag 40. With the system being initially set in this state, the patient can press the button to dose himself or herself or the analgesics whenever he or she suffers a pain. Thus, this system is adapted in particular for the instantaneous one-shot dosing of the liquid medicine.

The time needed to refill the chamber or reservoir with the medicine will depend on the inner diameter and length of the thin external tube 41, and also depend on the reservoir capacity and the magnitude of negative pressure produced therein. A refilling time from 30 minutes to 1 hour is desirable from a practical point of view.

It will now be apparent that the apparatus comprising a device provided by the present invention for the
self-dosing of liquid medicine is advantageous not only in that the refilling time is relatively short, and the amount of doses can be selected freely, but also in that there is no possibility that the liquid medicine will leak, in spite of the simple structure manufactured at a reduced cost.

Further, the apparatus is useful either to cooperate with a slow continuous dosing system, or to construct a system which is specified only to effect the one-shot self-dosing of liquid medicine.

Claims

1. An apparatus for the self-dosing of a liquid medicine, comprising:
   a casing (1) formed with a chamber (4) for receiving the liquid medicine (m) and with an inlet port (6) and an outlet port (7) in fluid communication with the chamber (4),
   a piston (13) liquid-tightly and slidably fitted in the chamber (4),
   a push button (14) attached to the piston (13) and capable of being pressed by a patient using the apparatus to move the piston (13) from a home position to a pressed position, a one-way check valve (23) communicating with said outlet port (7) and a spring (21) which cooperates with the push button (14) and urges the piston (13) towards its home position to enable rapid refilling of the chamber (4) with fresh liquid medicine (m), wherein said check valve (23) allows only a forward flow and inhibits a backward flow of the liquid medicine (m),
   characterized in that said spring (21) surrounds a cylindrical portion of said casing (1), which defines said chamber (4) so that the height of the apparatus is reduced and the apparatus therefore can be worn like a wrist watch.

2. An apparatus as defined in claim 1, characterized in that the casing (1) is provided with slits (11) on opposite sides thereof wherein the ends of a pair of bands (10) are fixed for bearing the apparatus on the wrist of a patient.

3. An apparatus as defined in claim 1 or 2, characterized in that the apparatus is formed as an extracorporeal self-dosing apparatus.

4. An apparatus as defined in claim 1, 2 or 3, characterized by further comprising upstream and downstream conduits (8, 9) for transporting the liquid medicine (m), the conduits (8, 9) being connected to said inlet and outlet ports (6, 7), respectively, and wherein said check valve (23) is disposed in the downstream conduit (9) at its end.

5. An apparatus as defined in any one of claims 1 to 4, characterized in that said check valve (23) is a one-part check valve without ball and spring.

6. An apparatus as defined in any one of claims 1 to 5, characterized in that there is only provided said one check valve (23).

7. An apparatus as defined in any one of claims 1 to 6, characterized in that said chamber (4) is connected to a medicine bag (40) by a thin long tube (41) which per se regulates the flow rate of the liquid medicine (m) by pressure loss.

8. An apparatus as defined in claim 7, characterized in that said tube (41) has an inner diameter of 50 to 200 µm.

9. An apparatus as defined in claim 7 or 8, characterized in that said tube (41) regulates the refilling time of said chamber (4) from 30 minutes to 1 hour.

Patentansprüche

1. Vorrichtung für das Selbstdosieren einer flüssigen Medizin, umfassend:
   eine Gehäuse (1), das mit einer Kammer (4) zum Aufnehmen der flüssigen Medizin (m) und mit einem Einlaßkanal (6) und einem Auslaßkanal (7), die in Fluidverbindung mit der Kammer (4) sind, ausgebildet ist,
   einen Kolben (13), der flüssigkeitstüchtig und verschiebbar in der Kammer (4) angebracht ist,
   einen Druckknopf (14), der an dem Kolben (13) angebracht und fähig ist, von einem Patienten niedergedrückt zu werden, der die Vorrichtung benutzt, um den Kolben (13) aus einer Ausgangsposition in eine niedergedrückte Position zu bewegen, wobei ein Einweg-Rückschlagventil (23) mit dem Auslaßkanal (7) verbunden ist, und
   eine Feder (21), welche mit dem Druckknopf (14) zusammenwirkt und den Kolben (13) nach seiner Ausgangsposition zu drückt, um ein schnelles Wiederfüllen der Kammer (4) mit frischer flüssiger Medizin (m) zu ermöglichen, wobei das Rückschlagventil (23) nur eine Vorwärtsströmung ermöglicht und eine Rückwärtsströmung der flüssigen Medizin (m) verhindert,
   dadurch gekennzeichnet, daß die Feder (21) einen zylindrischen Teil des Gehäuses (1), welcher die Kammer (4) begrenzt, umgibt, so daß die Höhe der Vorrichtung vermindert ist und die Vorrichtung daher wie eine Armbanduhr getra-
gen werden kann.

2. Vorrichtung nach Anspruch 1, dadurch gekennzeichnet, daß das Gehäuse (1) mit Schlitzten (11) auf entgegengesetzten Seiten desselben versehen ist, worin die Enden eines Paars von Bändern (10) zum Tragen der Vorrichtung am Handgelenk eines Patienten befestigt sind.

3. Vorrichtung nach Anspruch 1 oder 2, dadurch gekennzeichnet, daß die Vorrichtung als eine extrakorporale selbstdösierende Vorrichtung ausgebildet ist.

4. Vorrichtung nach Anspruch 1, 2 oder 3, dadurch gekennzeichnet, daß sie weiter eine stromaufwär tige und stromabwär tige Leitung (8, 9) zum Transportieren der flüssigen Medizin (m) umfaßt, wobei die Leitungen (8, 9) mit dem Einlaß- bzw. Auslaßkanal (6, 7) verbunden sind und wobei das Rück schlagventil (23) in der stromabwär tigen Leitung (9) an deren Ende angeordnet ist.

5. Vorrichtung nach irgendeinem der Ansprüche 1 bis 4, dadurch gekennzeichnet, daß das Rück schlagventil (23) ein Ein-Teil-Rück schlagventil ohne Kugel und Feder ist.

6. Vorrichtung nach irgendeinem der Ansprüche 1 bis 5, dadurch gekennzeichnet, daß nur das eine Rück schlagventil (23) vorgesehen ist.

7. Vorrichtung nach irgendeinem der Ansprüche 1 bis 6, dadurch gekennzeichnet, daß die Kammer (4) mit einem Medizinbeutel (40) durch ein dünnes langes Rohr (41) bzw. einen dünnen langen Schlauch (41) verbunden ist, welches bzw. welcher per se die Strömungsraste der flüssigen Medizin (m) durch Druckverlust reguliert.

8. Vorrichtung nach Anspruch 7, dadurch gekennzeichnet, daß das Rohr (41) bzw. der Schlauch (41) einen Innendurchmesser von 50 bis 200 µm hat.

9. Vorrichtung nach Anspruch 7 oder 8, dadurch gekennzeichnet, daß das Rohr (41) bzw. der Schlauch (41) die Wiederfütterung der Kammer (4) von 30 Minuten bis 1 Stunde reguliert.

Revendications

1. Appareil pour l’auto-dosage d’un médicament liquide, comprenant :

   un boîtier (1) comportant une chambre (4) pour recevoir le médicament liquide (m), un orifice d’entrée (6) et un orifice de sortie (7) en communication de fluide avec la chambre (4),

   un piston (13) monté de façon étanche au liquide et de façon coulissante dans la chambre (4),

   un bouton-poussoir (14) attaché au piston (13) et pouvant être pressé par un patient qui utilise l’appareil, afin de déplacer le piston (13) d’une position de repos à une position pressée,

   un clapet unidirectionnel (23) en communication avec le dit orifice de sortie (7), et

   un ressort (21) qui coopère avec le bouton-poussoir (14) et qui pousse le piston (13) vers sa position de repos afin de permettre un nouveau remplissage rapide de la chambre (4) avec un médicament liquide neuf (m), le dit plateau (23) permettant seulement un écoul ement en sens direct et empêchant un écoul ement en retour du médicament liquide (m),

   caractérisé en ce que le dit ressort (21) entoure une partie cylindrique du dit boîtier (1), qui définit la dite chambre (4), de sorte que la hauteur de l’appareil est réduite et que l’appareil peut donc être porté comme une montre-bracelet.

2. Appareil suivant la revendication 1, caractérisé en ce que le boîtier (1) comporte des fentes (11) sur ses côtés opposés, dans lesquelles sont fixées les extrémités d’une paire de bandes (10) pour tenir l’appareil sur le poignet d’un patient.

3. Appareil suivant la revendication 1 ou 2, caractérisé en ce que l’appareil est sous la forme d’un appareil d’auto-dosage extracorporel.

4. Appareil suivant la revendication 1, 2 ou 3, caractérisé en ce qu’il comprend en outre des conduits amont et aval (8, 9) pour transporter le médicament liquide (m), les conduits (8,9) étant connectés aux dits orifices d’entrée et de sortie (6, 7), respectivement, et le dit clapet (23) est disposé dans le conduit aval (9) à son extrémité.

5. Appareil suivant une quelconque des revendications 1 à 4, caractérisé en ce que le dit clapet (23) est un clapet monobloc sans bille ni ressort.

6. Appareil suivant une quelconque des revendications 1 à 5, caractérisé en ce qu’il est prévu seulement le dit un clapet (23).

7. Appareil suivant une quelconque des revendications 1 à 6, caractérisé en ce que la dite chambre (4) est reliée à une poche de médicament (40) par un tube long et mince (41) qui régule lui-même le débit du médicament liquide (m) par perte de pression.

8. Appareil suivant la revendication 7, caractérisé en ce que le dit tube (41) a un diamètre intérieur de 50 à 200 µm.
9. Appareil suivant la revendication 7 ou 8, caractérisé en ce que le dit tube (41) règle la durée de remplissage de la dite chambre (4) de trente minutes à une heure.