

[54] **VARIABLE DOSAGE AMPOULE APPLICATOR**

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[58] Field of Search 128/218 D, 218 DA, 128/218 F, 218 R, 216, 173 H, 215, 218 P

[56] **References Cited**

UNITED STATES PATENTS

2,754,818	7/1956	Scherer	128/173 H
3,217,712	11/1965	Blumenstein et al	128/216
2,605,763	8/1952	Smoot	128/173 H
3,236,237	2/1966	Dunmire	128/216

FOREIGN PATENTS OR APPLICATIONS

1,205,551	9/1970	Great Britain	128/218 F
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Primary Examiner—Richard A. Gaudet

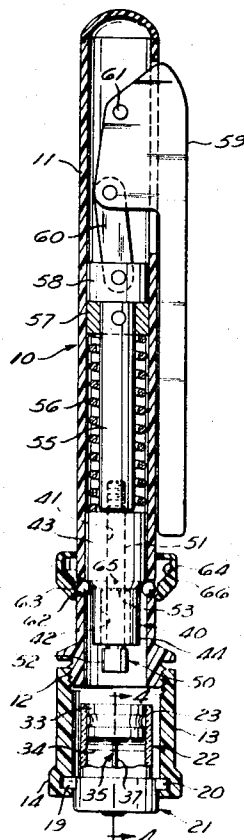
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[57] **ABSTRACT**

A variable dosage ampoule applicator having an external adjustment to vary the amount of medicament expressed from a medicament-containing ampoule contained within the applicator. The applicator has a hollow body with an ampoule mounting sleeve adjustably threaded to one end of the body. The ampoule is removably inserted within the sleeve and includes a cylindrical sidewall closed at one end by a slidable plunger and at the other end by a pierceable diaphragm. A hollow needle disposed within the medicament chamber is fixed to the plunger with its pointed end directed toward the pierceable diaphragm. The applicator includes a force-applying head to depress the ampoule plunger. The force-applying head has a fixed preselected stroke between a retracted position and an extended position. By adjusting the ampoule mounting sleeve, and therefore the ampoule, relative to the stroke of the force-applying head, the degree of depression of the ampoule plunger may be varied to thereby vary the volume of medicament injected into the patient by actuation of the force-applying head from its retracted position to its extended position.

5 Claims, 4 Drawing Figures



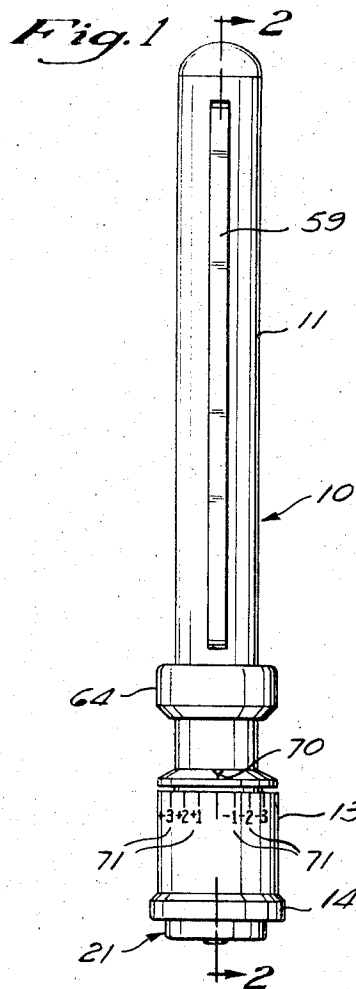
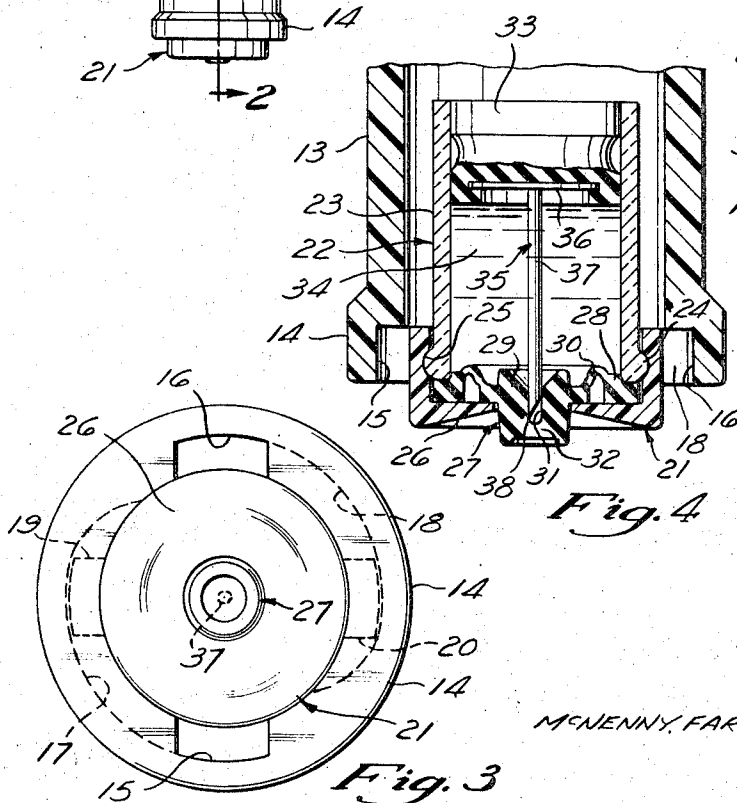
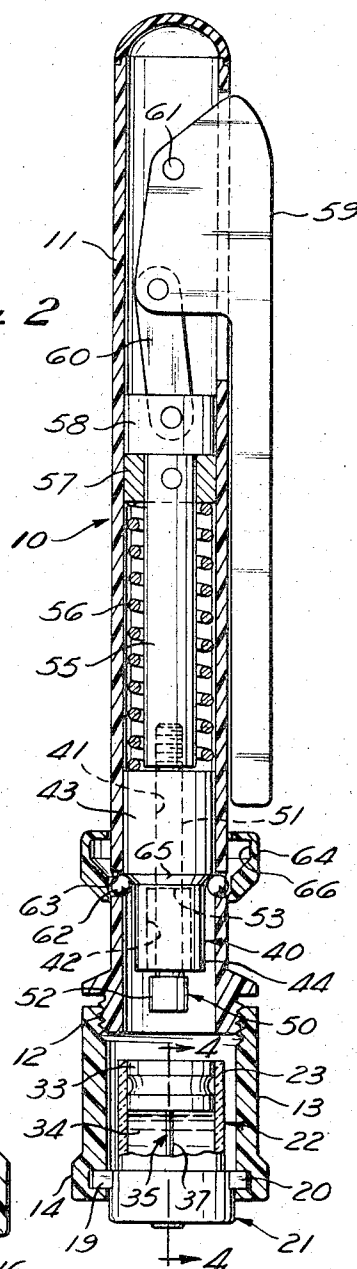


Fig. 2



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VARIABLE DOSAGE AMPOULE APPLICATOR

BACKGROUND OF THE INVENTION

In many instances, it is necessary to vary a standard medicament dosage depending upon the physical condition of the patient prior to an injection. For example, approximately 25 per cent of all diabetic patients using insulin therapy are considered to be so-called "stable diabetics." Under stable conditions of diet, physical and mental exertion, etc., such patients would normally require a regular schedule of uniform dosages of insulin to maintain a blood sugar balance. However, since they are generally unable to control their living habits with precision, the majority of these "stable diabetics" require minor variations up to plus or minus 15 per cent of their standard dosage to maintain the blood sugar balance. They commonly learn over a period of time to diagnose their own variations in insulin requirements, either by their own physical reactions to carelessness in dietary habits and/or over-exertion, or by use of urinalysis, and become capable of adjusting their insulin dosages accordingly. For example, a patient who is standardized on 20 units of insulin per day may vary his dosage between 17 and 23 units. Such a patient would purchase insulin in 10 cc. vials and use a reusable or disposable syringe calibrated in insulin units to make a subcutaneous injection. The type of syringe commonly employed required him to withdraw the proper insulin dosage from the vial and administer his injection.

Disposable ampoules adapted to perform subcutaneous injections are ideal devices for performing injections because of their convenience and low cost. However, such ampoules normally are pre-filled unit-dose devices and have not been widely accepted for insulin treatment because of the diabetic's required variations from standard dosages. Of course, it is possible to provide such unit-dose ampoules in a variety of different sizes for administering different dosages to cover normal variations from standard dosages. This, however, is impractical from the standpoint of the pharmaceutical manufacturer, since he would be required to carry a greatly enlarged inventory, and such a large inventory may present shelf-life problems for the drug contained therein. Furthermore, the diabetic himself would have to stock a variety of different sizes of the pre-filled ampoules.

In order to overcome these problems, it was proposed long ago to provide a single ampoule containing a quantity of medicament sufficiently in excess of a standard dosage to cover an expected maximum dosage requirement. For example, a patient standardized on 20 units of insulin per day would be provided with an ampoule containing 23 units of insulin. By use of an adjustable or variable dosage applicator, the desired amount of insulin from the expected maximum to the expected minimum may be injected by the patient. Such a variable applicator is set forth in U. S. Pat. No. 159,192 to Leiter, granted in 1875. The applicator according to Leiter may be adapted to inject different dosages by shortening or lengthening the stroke of an applicator plunger. This is accomplished by adjusting a nut on the plunger to limit the stroke of the plunger to a predetermined portion of its maximum stroke from a fixed starting position. However, in order to adjust the stroke of the plunger, one must disassemble the Leiter

device to gain access to the adjusting mechanism. Furthermore, the adjusting nut of Leiter is stopped by an end cap of the glass ampoule vial and, consequently, the full force of a driving spring is transmitted to the sidewall of the medicament-containing vial. Such force may tend to shatter a glass vial during an injection.

A later proposal involving a variable dose injector is set forth in U. S. Pat. No. 2,754,818 to Scherer. The Scherer patent relates to a hypojet or needleless injector having a housing for a force-applying member and an ampoule containing sleeve threaded onto one end of the housing. In its initial position, the force-applying member of Scherer contacts a head portion of the ampoule. In order to vary the dosage, the threaded sleeve is turned so that the force-applying member pushes the ampoule head toward a jet nozzle to expel a metered amount of fluid from the nozzle prior to the injection. After such an adjustment is effected, the force-applying member is triggered to expel the remaining contents of the ampoule into the patient to thus perform an injection. After such an adjustment is made, however, the stroke of the force-applying member of Scherer is limited by the end portion of the applicator adjacent the nozzle. Thus, substantial reinforcement must be provided at the jet end of the applicator to resist and limit the stroke of the force-applying member.

SUMMARY OF THE INVENTION

This invention overcomes many of the foregoing prior art problems relating to variable dosage applicators by providing a variable dosage applicator which permits preselected variations in dosages by a simple, externally located adjusting mechanism. To this end, the applicator is provided with a hollow body or sleeve having mounting means for retaining a medicament-containing hypodermic ampoule therein. The ampoule has a depressible plunger and a medicament-injecting means and is adapted to inject a volume of medicament into a patient as a direct function of the degree of depression of the plunger. The applicator also includes a spring-biased force-applying member mounted on the body for movement in the direction of the plunger for depressing the plunger. The force-applying member has a preselected stroke between a first retracted position and a second extended position relative to the hollow body. The position of the ampoule may be adjusted relative to the first and second positions of the force-applying means by a threaded connection between the ampoule mounting body and means mounting the force-applying member. The stroke of the force-applying member is limited in its second or extended position by a stop means which does not transmit force to the sidewall of the ampoule. Furthermore, the stop means limits the stroke of the force-applying member to prevent contact between the force-applying member and the medicament-injecting end of the ampoule so that that end of the ampoule need not be reinforced by portions of the applicator. This latter feature permits easy installation and removal of the ampoule.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is an elevational view of a variable dosage applicator according to this invention.

FIG. 2 is an enlarged, cross-sectional view of the applicator, the plane of the section being indicated by the

line 2—2 in FIG. 1, showing an ampoule mounted therein, partly in section.

FIG. 3 is a bottom end view of the applicator.

FIG. 4 is a cross sectional view, the plane of the section being indicated by the line 4—4 in FIG. 2.

DETAILED DESCRIPTION OF THE INVENTION

Referring now to the drawings, a variable dosage ampoule applicator 10 is illustrated. The applicator 10 includes a hollow body 11 having a threaded end portion 12. An ampoule mounting sleeve 13 is threaded onto the portion 12 and, as may be seen most clearly in FIG. 3, includes an enlarged end portion 14 having diametrically opposed slots 15 and 16 extending axially therethrough. The slots 15 and 16 respectively communicate with channels 17 and 18 in the enlarged end portion 14 and respectively receive lugs 19 and 20 extending radially from an annular retaining clip 21. The channels 17 and 18 extend in a clockwise direction from the slots 15 and 16 and taper radially inwardly toward the inner cylindrical sidewall of the sleeve 13. Thus, the clip may be removably retained in the sleeve 13 by inserting the lugs 19 and 20 into the slots 15 and 16 and turning the clip in a clockwise direction until the lugs frictionally engage the inwardly tapering sidewalls of the channels 17 and 18.

The retaining clip 21 is a component of an ampoule assembly 22 which is inserted into the open end of the applicator sleeve 13 with the lugs 19 and 20 moving through the slots 15 and 16. Turning the clip in a clockwise direction then moves the lugs 19 and 20 into the channels 17 and 18 to retain the ampoule assembly in the mounting sleeve 13.

The ampoule assembly 22 is more fully described as one embodiment of the copending application of Alfred A. Hirschman and Thomas P. Schiller, Ser. No. 114,493, filed Feb. 11, 1971, and includes a cylinder 23 which is preferably made from transparent glass tubing. One end of the cylinder 23 has a radially extending bead 24 which is received within an annular groove 25 in the clip 21 and which, together with a radially inwardly extending flange portion 26 of the clip 21, clamps a diaphragm 27 against the lower end of the cylinder 23.

The diaphragm 27 may be molded from rubber, and is preferably shaped to function in accordance with the teachings of U. S. Pat. No. 3,094,988, granted June 25, 1963, to Dunmire. The diaphragm 27 includes an outer annular portion 28, a thick, elongated, centrally located needle guiding and liquid sealing gland 29, and a relatively thin, flexible, corrugated, intermediate portion 30 connecting the gland 29 and the outer portion 28 to permit relative axial movement thereof. A needle passage 31 extends axially into the upper end of the gland 29 from the inside of the ampoule and terminates short of the opposite, lower end of the gland so as to leave a thin, easily puncturable wall 32 closing the bottom of the passage 31. Alternatively, preforming the needle passage 31 may be omitted during manufacture of the diaphragm 27, in which case the pointed end of the needle is forced into the gland 29 to the proper depth during assembly of the ampoule.

The other end of the cylinder 23 is closed by a rubber plunger 33 which, together with the diaphragm 27 and the cylinder 23, defines a medicament and needle chamber 34.

Entirely enclosed within the chamber 34 is a hypodermic needle 35, which preferably is of the type disclosed in U. S. Pat. No. 3,173,200 to Dunmire et al. A generally circular base or butt end 36 of the needle 35 is mounted on the plunger 33 so that the needle cannula 37 extends axially downwardly in the cylinder 23 with its pointed end 38 received within the axial recess 31 in the diaphragm gland 29 in position to be forced through the thin end wall 32 thereof. An opening (not shown) is provided in the butt end of the needle cannula 37, adjacent the base 36 of the needle, for free flow of medicament from the chamber 34 into the butt end of the needle cannula and through the cannula to the pointed discharge end 38 thereof. The chamber 34 is substantially completely filled with a fluid medicament.

As may be seen most clearly in FIG. 4, the inwardly extending flange portion 26 of the clip 21 forms a recessed, concave end surface which causes the skin of the patient to stretch and dome upwardly as the clip 21 is pressed against the skin of the patient. As is more fully described in U.S. Pat. No. 3,236,237 to Dunmire, it appears that the stretched skin, becoming tense, resists any substantial indentation by the gland 29 of the ampoule 22, and thereby forces the gland 29 axially inwardly toward the pointed end 38 of the needle 35 while the ampoule body is restrained against upward movement by the lugs 19 and 20.

The fluid medicament is injected into a patient by pressing the clip 21 and diaphragm gland 29 against the skin of a patient and forcing the ampoule plunger 33 downwardly toward the diaphragm 27 so that the needle 35 pierces the puncturable wall 32 to thereby force medicament from the chamber 34 through the needle and into the patient as the needle enters the patient and the volume of the chamber 34 is reduced.

In the illustrated embodiment of this invention, a force-applying means of the applicator for moving the ampoule plunger 33 includes a force-applying head 40 having a bore 41 and a counterbore 42 therethrough. The head 40 has an enlarged cylindrical portion 43 at one end and a reduced cylindrical portion 44 at its other end. The cylindrical portion 43 forms a loose sliding fit with the inner sidewall of the hollow applicator body 11. The reduced cylindrical portion 44 has an outside diameter which is adapted to be received within the ampoule cylinder 23 and is in axial alignment with that cylinder in the assembly.

The force-applying head 40 is slidably mounted on a retaining screw 50 which has a shank 51 extending through the bore 41 and counterbore 42 and a head portion 52 which is adapted to be received within the counterbore 42 and limit downward movement of the head 40 by engaging a shoulder 53 between the bore 41 and the counterbore 42. The retaining screw 50 is threaded into the end of a rod 55. Desirably, a locking insert (not shown) is provided on the threaded end of the screw 50 to insure a frictionally tight threaded fit between the screw 50 and the rod 55. A spring 56 surrounds the rod 55 between the force-applying head 40 and a bushing 57 which is pinned to the rod 55. The bushing 57 insures that the rod 55 is in a proper axially extending position. The rod 55 has an enlarged cylindrical portion 58 which is connected to a cocking lever 59 by a toggle link 60. The cocking lever 59 is pivotally connected to the applicator body 11 by a pin 61.

The force-applying head 40 is retained in a retracted position illustrated in FIG. 2 by a plurality of locking balls 62. The locking balls are retained in openings 63 in the hollow body 11 by a firing ring 64 so that the locking balls engage a shoulder 65 between the portions 43 and 44 of the head 40. To release the head 40 from its retracted position, the firing ring, which forms a sliding frictional fit with the body 11, is pushed downwardly toward the mounting sleeve 13 until the balls 62 are forced into an annular recess 66 in the ring 64 to thereby release the shoulder 65 and the head 40. The head 40 is thereupon driven downwardly by the spring 56, first into engagement with the ampoule plunger 33 and then on to an extended position. The extended position of the force-applying head 40 is determined by engagement of the head portion 52 on the screw 50 with the shoulder 53.

By driving the ampoule plunger 33 downwardly in this manner, the needle 35 pierces the diaphragm 27 and the chamber 34 is reduced in volume to force the medicament through the needle 35 and into the patient. The volume of medicament injected into the patient is a direct function of the degree of depression of the ampoule plunger 33 by the force-applying head 40. Since the stroke of the head 40 is constant, the degree of depression of the plunger 33 may be varied, to thereby vary the volume of medicament injected, by turning the ampoule mounting sleeve 13 in a clockwise direction to increase the dosage and by turning the sleeve 13 in a counterclockwise direction to decrease the dosage.

As may be seen in FIG. 1, the body 11 may be provided with a pointer mark 70 and the sleeve 13 may be provided with indicia 71 to indicate a standard dosage and plus or minus variations from standard. By pre-adjusting the retaining screw 50 in the factory, the stroke of the head 40 may be calibrated to, for example, a 20-unit standard dose when the sleeve 13 is in the position illustrated in the drawings.

After an injection has been effected, the applicator 10 may be reset for another injection by removing the spent ampoule, raising the cocking lever 59 so that the head 40 is drawn upwardly, reseating the locking balls 62 in their illustrated position by moving the firing ring 64 back to its illustrated position, and then compressing the spring 56 by moving the handle 59 back to its original position.

The invention is not restricted to the slavish imitation of each and every detail set forth above. Obviously, devices may be provided which change, eliminate, or add certain specific details without departing from the scope of the invention.

What is claimed is:

1. A variable dosage ampoule applicator comprising a hollow body and means for mounting thereon a medicament-containing hypodermic ampoule having a depressible plunger and medicament-injecting means adapted to inject a volume of medicament into a patient as a direct function of the degree of depression of said plunger, said applicator also comprising force-applying means including an axially movable force-applying head slidably mounted on a normally stationary shank, said force-applying head being mounted for movement in the direction of said plunger for depressing the plunger and having a pre-selected stroke

between a first retracted position and a second extended position relative to said hollow body and means for driving said force-applying means, said shank having stop means adjacent one end thereof for establishing said second position, and means for adjusting the position of said ampoule axially of said hollow body relative to both said first and second positions of said force-applying means and relative to said stop means to thereby vary the degree of depression of said plunger and the volume of medicament injected by movement of said force-applying means to its second position, and means for adjusting the position of said stop means relative to said body to thereby adjustably establish the stroke of said force-applying head.

2. A variable dosage ampoule applicator according to claim 1, wherein said means for adjusting the position of said stop means includes a threaded connection between said body and said stop means.

3. An ampoule and variable dosage ampoule applicator including a hollow cylindrical body, a mounting sleeve threaded onto one end of said body and being axially adjustable relative to said body, an ampoule mounted within said mounting sleeve for adjusting movement therewith; said ampoule having a cylindrical sidewall for a medicament chamber, a diaphragm closing said chamber at one end of said sidewall, a plunger initially slidably mounted in the other end of said sidewall for closing the other end of said chamber and having a hollow needle attached thereto so that a pointed end of said needle is directed toward said diaphragm, and a medicament contained within said ampoule; force-applying means including an axially movable force-applying head slidably mounted on a normally stationary shank which is, in turn, mounted on said cylindrical body, said force-applying head having a stroke in axial alignment with said plunger, spring means biasing said force-applying head axially toward said plunger, releasable latch means retaining said force-applying head in a first retracted position, said shank having stop means limiting the stroke of said force-applying head in a second extended position, said second extended position being axially beyond the initial position of said plunger and toward said diaphragm, whereby upon release of said latch means said force-applying head will push said plunger toward said diaphragm so that said needle will pierce said diaphragm and whereby said second extended position may be varied relative to said cylindrical sidewall by axially pre-adjusting the position of the threaded sleeve relative to said cylindrical body to thereby vary the amount of medicament expressed by said plunger through said hollow needle, and means for adjusting the position of said stop means relative to said body to thereby adjustably establish the stroke of said force-applying head.

4. The variable dosage ampoule applicator according to claim 3, wherein said means for adjusting the position of said stop means includes a threaded connection between said body and said shank.

5. The variable dosage ampoule applicator according to claim 4 wherein the stop means includes a screw having an enlarged head for abutting coaction with said force-applying head at the end of its stroke and the means for adjusting the position of said stop means includes a threaded shank of said screw threadedly engaged in a rod.