Aug. 13, 1968 S. J. SARNOFF 3,396,726

HYPODERMIC SYRINGE AND CARTRIDGE FOR USE THEREWITH

Original Filed July 1, 1964

Fig. 1

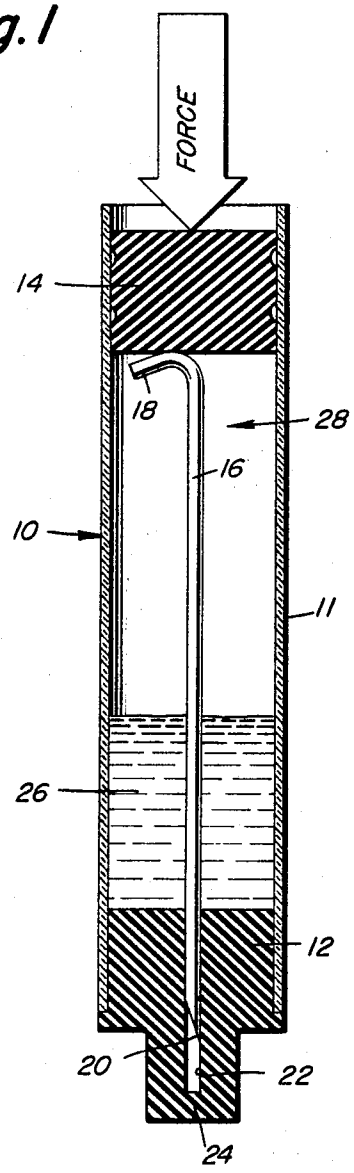
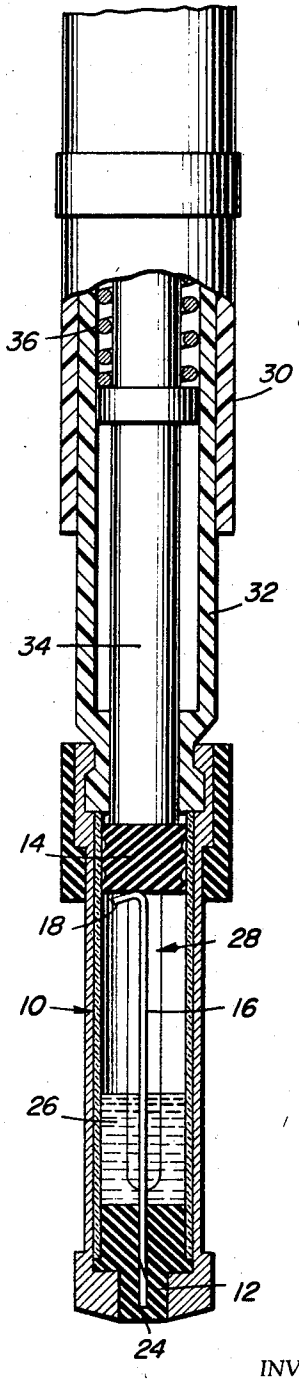


Fig. 2



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HYPODERMIC SYRINGE AND CARTRIDGE FOR USE THEREWITH

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Continuation of application Ser. No. 379,694, July 1, 1964. This application Jan. 25, 1968, Ser. No. 703,517
6 Claims. (Cl. 128—218)

ABSTRACT OF THE DISCLOSURE

A cartridge is comprised of a cylinder, a stopper at the front end thereof, a plunger at the rear end thereof, a hypodermic needle within the cartridge extending from the piston to the stopper with an opening to the needle at the end thereof adjacent the piston and a liquid within the cartridge only partially filling the cartridge, the remainder of the cartridge being occupied by air of such a column height as to allow full emergence of the needle from the stopper prior to ejection of liquid from the needle. This cartridge is utilized with a type of holder wherein a plunger under influence of a stressed spring applies a force to the piston when it is released to the action of the spring.

This application is a continuation of the application of Stanley J. Sarnoff, Ser. No. 379,694, filed July 1, 1964, now abandoned.

This invention pertains to hypodermic devices and to the administration of fluids hypodermically under diverse conditions of application of the hypodermic device to a subject under treatment. More specifically it relates to hypodermic devices having a retracted needle within a medicament chamber, the pointed end of which needle can spring with substantial speed, and force, a limited distance from a sheathed to an unsheathed position with provision to begin ejection of a fluid from the needle only after the needle has been advanced an initial predetermined distance.

An object of this invention is to provide a hypodermic device comprising a cartridge containing a sheathed needle therein, as well as a predetermined amount of medicament and gaseous fluid, together with a syringe of the type having a member capable of being driven, which member when driven for cooperation with the cartridge will drive the needle end out of the cartridge and, at a predetermined exposed position of the end of the needle relative to the end of the cartridge, initiate the expulsion of the medicament through the needle.

Another object of the invention is to provide a cartridge wherein there is a sheathed needle within a vial, said vial provided with a piston at one end, a needle penetratable stopper at the other end and a large volume of air compared to liquid within the vial between the piston and the stopper, the sharp end of the needle being at the stopper, the opening to the lumen of the needle being close to that end of the needle which is next to the piston.

The predeterminable advance of the needle prior to liquid ejection is desirable for many reasons, some of which are given in detail hereinbelow.

Intramuscular injections should deliver the medication deep within the muscle tissues for proper medical effectiveness, not near the skin surface. Some drugs cause chemical irritation when released near the skin surface causing patient discomfort.

Also, by premature ejection of a fluid into a subject, when the needle has not penetrated deep enough into the tissues, extra discomfort may result due to distension of the epidermal tissues; distension irritation is greater

near the skin surface because of the proliferation of nerve endings thereat.

A second major factor resulting in the need for controllable ejection of the needle prior to injection of medicament arises from the varying depth of the barrier layer which the needle must penetrate before its end has reached the desirable locus of medicament application. For example, in the field of veterinary medicine the thickness of hide and hair varies from one species of animal to another, and, within species, differs according to age and season.

Another major environment, of varying barrier thickness, requiring the control of the determinable advance of the needle beyond the stopper prior to initiation of medicinal ejection is the effective controllable use of the syringe in emergencies when there is no time to strip clothing from a subject, the cartridge dose being administered to the subject with the needle penetrating through his clothing. It has been found, for example, that the clothing of military personnel, dependent on their location and the time of year, may be quite thick and may vary in thickness, when measured under a given pressure, for example, twenty pounds per square inch. In one circumstance, the average thickness of clothing, measured as indicated, has been found to be one-eighth inch. In another circumstance, the average thickness has been found to be one-quarter inch. Were the depth of penetration of the needle prior to initiation of medicine ejection not taken into account, it is obvious that there could be considerable wetting of the clothing of the subject resulting in loss of medication as well as possible skin irritation. By loading the cartridge with a sufficient column of air as disclosed herein, proper administration of the medication, with no loss thereof, is assured. In case deep penetration of the needle is necessary, i.e., large displacement of the needle from the stopper prior to initiation of liquid ejection, the column of liquid becomes relatively small in a given cartridge, but the effectiveness of the medication can be maintained constant as by concentrating the medicinal substance in the solvent, enlarging the length or diameter of the cartridge, etc.

In the case of the thicker clothes mentioned above (one-quarter inch thick) it was found that when the cartridge was filled with 0.8 ml. of fluid and 0.3 ml. of air at just above atmospheric pressure (15 to 20 lbs.) there was considerable wetting of the clothing and a loss of .3 ml. of fluid. On the other hand, when the cartridge was filled with .5 ml. of fluid and 0.6 ml. of air under the same pressure, there was no wetting of the clothing and no loss of fluid. Where the clothing was thinner (i.e., one-eighth inch thick) penetration of the subject was deeper prior to initiation of ejection of the fluid.

With respect to the cartridge, it may be stated in another way that it is another object of this invention to provide a cartridge with a sufficient amount of gaseous fluid therein to cooperate with a syringe to enable proper administration of medicament to a subject. The syringe, for example, may be of the cocked spring type shown in the patent to Sarnoff 2,704,072 and in the patent to Sarnoff et al. 2,832,339, though it is preferred to utilize the easily reloadable syringe disclosed in the patent to Sarnoff and Balenger 3,330,279. The reloadable cartridge of the instant invention, however, contains a quantity of gas, preferably air, sufficient not only to enable the needle end to emerge from the stopper but to move to a predetermined distance therebeyond prior to initiation of expulsion of the liquid contents of the cartridge.

Furthermore, due to the positioning of the opening to the needle at the end of the needle adjacent the piston, it will be perceived that with the sharp point of the needle held downward, ejection of medicament will take place into the tissues of a patient while the needle is still pene-

trating deeper into the tissues, thus distributing the medicament throughout a thickness of tissues rather than administering the medicament in a localized area thereof and at a given depth below the entrance point of the needle into the tissues. This movement of the needle and spreading of the medicament through varying depths of tissues will take place even when the sharpened end of the needle end is held uppermost during administration of the medicament by reason of the viscosity of the medicament delaying its expulsion even though the liquid enters the needle lumen earlier than if the needle were held with the sharpened end downward.

For a fuller understanding of the invention, attention is directed to the following specification and accompanying drawings in which:

FIG. 1 is a drawing of a cartridge for use in explaining the principles of the invention, and

FIG. 2 is a partial view of the automatic ejector of the referred to patent to Sarnoff et al. 3,330,279, with the cartridge of this invention substituted for the cartridge shown in said earlier disclosure.

Referring to FIG. 1, a cartridge **10** is illustrated comprising a rigid cylindrical walled tube **11**, as of glass, plastic, or metal, a rubber stopper **12** at one end of the tube and a rubber piston **14** at the other end thereof. Within the cartridge is a hollow needle **16** preferably of the type having a bent end **18** against which the piston may be thrust and a needle point **20** within an obturated passageway **22** in the stopper, the needle being initially displaced, if desired, some distance from the obturating wall **24** of the stopper. The cartridge contains a liquid medication **26** and a compressible gaseous medium **28**, such as air, in the remaining space within the cartridge. When a force is applied to the piston, as indicated by the arrow, the piston moves toward the stopper, compressing the gas and applying pressure to the liquid medication. When the piston engages the non-pointed end of the hollow needle, in this illustration, the bend of the needle, the needle is thrust forward and, while the lower penetrating end of the needle is still within the cartridge, the air within the cartridge is being compressed. Once the needle has penetrated the wall **24**, however, the contents of the cartridge are free to be expelled. As assembled, the cartridge itself involves a closed pressure system including air as well as liquid. If no air were provided within the cartridge and with a stopped fixed against movement with respect to the rigid wall of the cartridge, the piston could not be moved.

Thus, the basic provision of some minor air space within the cartridge is necessary to render the piston and needle capable of movement. Activating the air-liquid medicament loaded cartridge by applying a force which moves the piston, results in a normal pressure-volume (P–V) relationship in the air space, pressure rising as volume decreases. This relationship holds until the needle emerges from the stopper and connects the interior of the cartridge with the exterior. This normal P–V relationship persists throughout the compression stroke, that is, the distance travelled by the plunger, until needle emergence.

It has heretofore been apparent that some minor amount of air must be present to attain needle emergence. A slightly longer column of air than is sufficient to permit emergence of the needle, must be present to allow for variations in the manufacture of the cartridge and its quantity of medication and to allow a reasonable force level of the driving member. What has not been realized in the prior art is that the penetrating end of the needle must advance a predetermined distance beyond the stopper and penetrate a desired distance into the injected subject before the medicament begins to be expelled from the needle. The means disclosed by the present invention for predetermining this expulsion of medicament relative to the distance the end of the needle must traverse beyond the stopper, is the predetermination of the column of air within the cartridge. The longer the column of air, the more will be the needle end movement beyond the stopper prior to medicament ejection.

It should be borne in mind that the type of medication applicator herein described generally involves the use of a suddenly released force as of a spring, and that there is in such cases an inherent delay in the flow of medication through the lumen of the needle dependent, at least in part, on the rapidity of movement of the plunger, the frictional drag on the flow of fluid through the needle, the inertia of the fluid and its viscosity. For any fixed size of cartridge, needle lumen, viscosity of fluid and rate of movement of the plunger under the influence of its driving spring or other force applied to it and the manner of use of the syringe, a predetermined volume of air or other gas is supplied within the cartridge sufficient to cause ejection of the liquid medicament only after the needle has advanced the predetermined distance beyond the stopper.

In a practical application of the syringe and its cartridge, the above referred to plunger driven mechanism of Sarnoff and Balenger was selected, of which only pertinent portions are illustrated in FIG. 2. For full information relative to the syringe, attention is directed to the Sarnoff and Balenger disclosure.

In FIG. 2 there is disclosed an outer sleeve **30** forming part of a syringe, a barrel **32** shiftable within the sleeve, and a plunger **34** which may be driven out of the barrel upon release of the compressed force of a spring **36**. The spring may be cocked to be under a compressive force and is released by manipulation of the outer sleeve relative to the barrel. Upon release, the free end of the plunger engages the piston **14** of the cartridge heretofore described and drives the piston into engagement with the needle **16**, if not already engaged therewith. Further movement of the plunger will drive the piston further into the tube **10** or cartridge cylinder, compressing the air therein, the column of air **28** being in accordance with the requirement of depth penetration of the needle prior to ejection of the liquid medication **26**. Continued movement of the plunger and piston will drive the pointed needle end through the rubber stopper **12**.

The column of air **28** in the cartridge is always in excess of that sufficient for enabling needle penetration of the stopper. The additional length of the column of air is that length which is compressed by the piston after the needle has penetrated the stopper and during the compression of which a delay is imposed on the flow of medicament **26** through the needle. Thus the needle moves a predeterminable distance beyond the end of the stopper before flow of liquid medicament from the pointed end occurs. When the medicament is administered with the cartridge so held that air is above the liquid and the bent end of the needle is exposed to the air, the penetrating end of the needle can move a distance beyond the end of the stopper while compressed air is expelled through the lumen of the needle. When the medicament is administered with the cartridge so held that air is below the medicament and the bent end of the needle is immersed in the medicament, the frictional drag of the medicament and its viscosity delay the ejection of the fluid while the extra volume of air is being compressed. It should now be clear that were it not for the additional column of air, pressure imposed on the liquid medication would result in expulsion of fluid substantially coincident with emergence of the needle from the stopper. Since the needle is still moving after the liquid medicament starts flowing, the medicament is administered to a patient at successively greater depths thereby distributing the liquid more effectively in the patient's body. As a matter of fact, in applying the hypodermic device to the body of the patient, the pressure applied to the skin of the patient by the wall **24** of the device, will compress the underlying tissues, and when pressure is removed, the tissues moving back to normal positions will further spread the administered medicament.

The length of the total column of air necessary within the cartridge to effect desired penetration of the needle into a subject prior to initiation of ejection of medication from the needle is a length in excess of a minimum length which the piston travels to bring the penetrating needle end to just beyond the stopper. In view, amongst other reasons, of the necessity of allowing a reasonable force level in the spring to exist to expel the contents of the cartridge, the air space length should desirably be designed to be about 50% greater than the minimum air column length referred to herein. Therefore the total length of the column of air within the cartridge should be in excess of that stroke of the piston just sufficient to cause needle penetration of the stopper, and desirably approximately one and one-half times that length, the additional length depending on the desired extent of the needle end beyond the stopper prior to initiation of medication ejection.

It will thus be seen that practice of the present invention results in the injection of medicament in the exact desired loci. Such predetermined fluid ejection is of particular benefit for mass medicament administration, since it allows effective emergency administration by personnel who are not as highly skilled medically as those required in the use of prior art hypodermic syringes.

Having thus described the invention, what is claimed is:

1. A syringe provided with a cartridge, said syringe having within it a plunger under potential energy and means to release the plunger to its driving force, said cartridge comprising an elongated hollow member having a piston adjacent one end thereof adapted to be engaged and driven by said plunger when said plunger is released, and a stopper adjacent the other end of the member, a hollow needle positioned longitudinally in said hollow member in position to be engaged by said piston in its movement toward the stopper and said needle having a stopper penetrating end initially within the hollow member, said member being filled with a column of fluid medicament and a column of a gas, the column of gas being of a length more than the length of piston travel necessary to just cause emergence of the needle from the stopper, under the force of said plunger, and of a predetermined distance therebeyond prior to issuance of said fluid medicament, the lumen in the needle communicating with the contents of the cartridge at the piston engageable end of the needle.

2. A syringe provided with a cartridge, as claimed in claim **1** wherein the column of gas is of a length more than one and one-half times the said necessary length of piston travel.

3. A cartridge for use with a syringe having a movable plunger, said cartridge having a piston adjacent one end thereof adapted to be engaged by said plunger and a stopper at the other end thereof, a hollow needle supported in said cartridge with one end adjacent the piston and the other end pointed and in position to penetrate the stopper, a fluid medication in said cartridge and a column of gas in said cartridge, said column of gas within the cartridge being more than that required for piston travel to cause emergence of the pointed end of the needle from the stopper, and sufficient to cause the emerged needle end to move a predetermined distance from the stopper prior to initiation of flow of said fluid medication from said needle, the lumen in the needle communicating with the contents of the cartridge at the end of the needle adjacent the piston, the hollow needle and its lumen extending through the length of the fluid and through substantially the entire column of gas.

4. The cartridge of claim **3** wherein the column of gas within the cartridge is more than one and one-half times that required for piston travel to cause needle emergence from the stopper.

5. A cartridge for use with a syringe having a driving member, said cartridge having a piston adapted to be driven by said member, and wherein said cartridge comprises an elongated tube having said piston near one end thereof and a stopper closing off the other end of said tube, a hollow needle supported with one end in position to be driven longitudinally of the tube by the piston and a second pointed end in position to pierce the stopper and move beyond the stopper, a fluid medicament in said cartridge, and a column of a gas in said cartridge, said column of gas being of a length which comprises the length the piston must be moved to allow compression of the gas and the member to move under the energy applied to it to cause point emergence from the stopper, plus a further additional length to predetermine the spacing of the point of the needle from the stopper prior to initiation of flow of medicament from the point of the needle, the lumen in the needle communicating with the contents of the cartridge at the piston driven end of the needle, the hollow needle and its lumen extending through the length of the fluid and through substantially the entire column of gas.

6. The cartridge of claim **5** wherein the additional length is approximately one-half times the first length.

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