May 21, 1968 W. F. MULLER 3,384,080

PORTABLE SPRING POWERED INFUSION DEVICE HAVING ESCAPEMENT MEANS CONTROLLING SPEED OF INFUSION

Filed Oct. 16, 1964 3 Sheets-Sheet 1

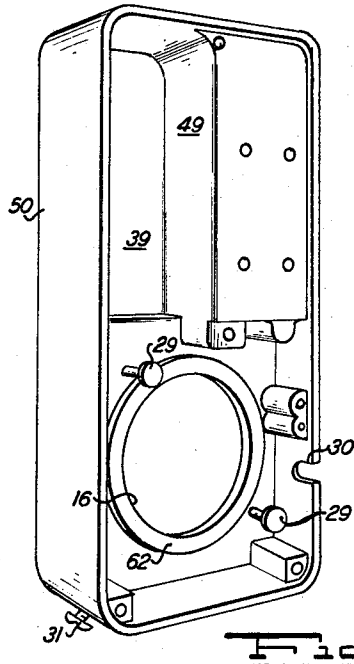

Fig. 1

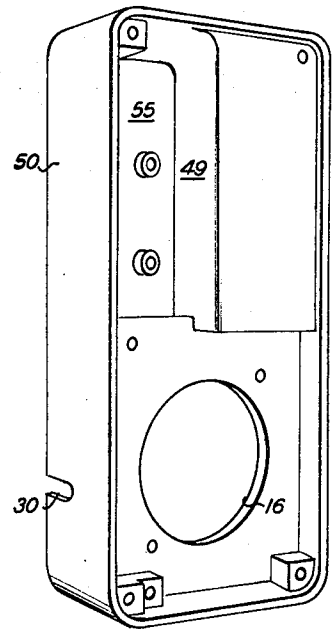

Fig. 2

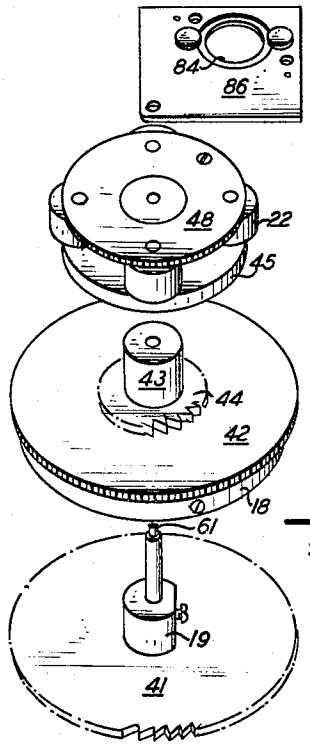

Fig. 6

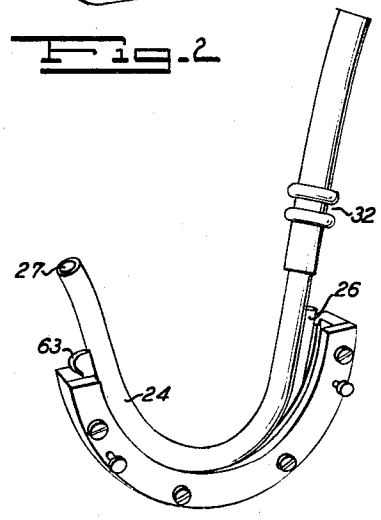

Fig. 7

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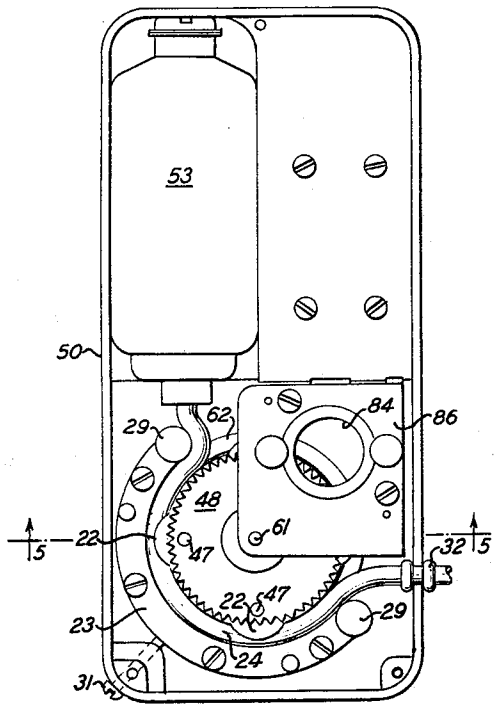

Fig. 3

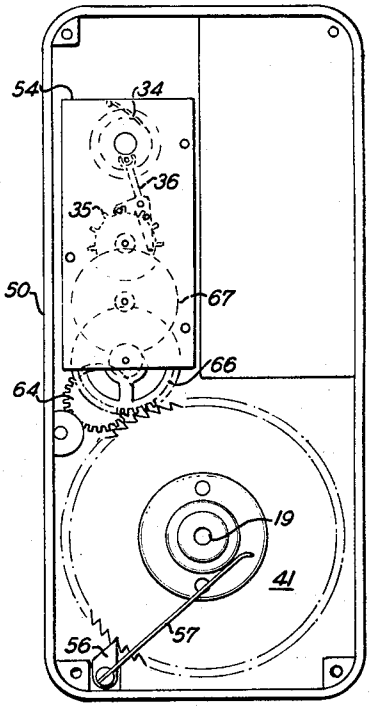

Fig. 4

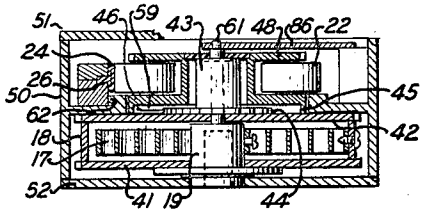

Fig. 5

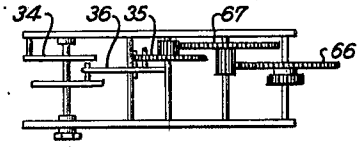

Fig. 6

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PORTABLE SPRING POWERED INFUSION DEVICE HAVING ESCAPEMENT MEANS CONTROLLING SPEED OF INFUSION

Filed Oct. 16, 1964 3 Sheets-Sheet 3

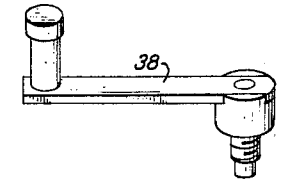

Fig. 9

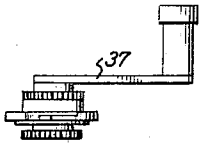

Fig. 10

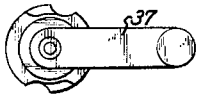

Fig. 10a

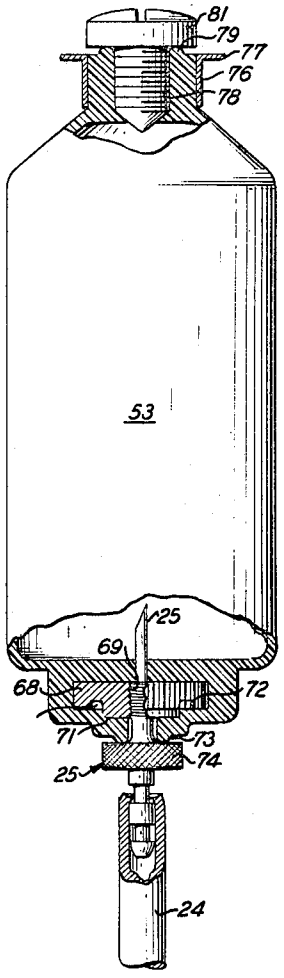

Fig. 11

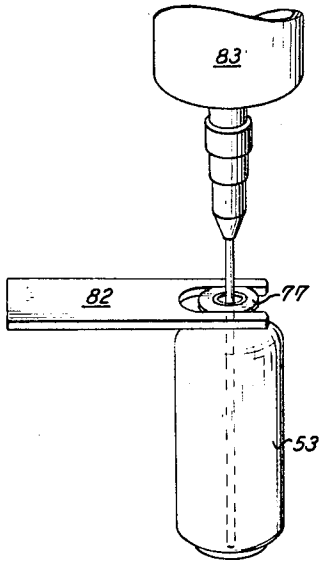

Fig. 12

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United States Patent Office 3,384,080 Patented May 21, 1968

3,384,080

PORTABLE SPRING POWERED INFUSION DEVICE HAVING ESCAPEMENT MEANS CONTROLLING SPEED OF INFUSION

Wolf F. Muller, New York, N.Y., assignor, by mesne assignments, to United States Catheter & Instrument Corporation, Glens Falls, N.Y., a corporation of Delaware

Filed Oct. 16, 1964, Ser. No. 404,425
4 Claims. (Cl. 128—214)

ABSTRACT OF THE DISCLOSURE

A portable infusion device for constantly injecting therapeutic fluids into the human body at low but positive pressures, which has a roller pump squeezing tubing containing medicaments for injection into the body. The pump is powered by a spring motor, the speed of which is controlled by a watch escapement unit connected by gearing to the spring motor.

This invention relates to new and useful improvements in portable infusion devices and more particularly seeks to provide a low pressure, positive force portable infusion device adapted especially for ambulatory intravascular drug therapy over an extended period of time, e.g. arterial infusion of antimetabolite drugs for regional chemical therapy of cancer.

A huge undertaking of cancer research is currently in progress to develop anticancer drugs for use in the management of neoplastic disease in man and an increasing number of compounds are becoming available for clinical use by the physician. Despite the prodigious efforts of these pre-clinical and clinical programs, progress has been slow and no chemical agents have been developed that are capable of inducing a general curative effect on disseminated forms of cancer. Nevertheless, over the past several years definite advances have been made in the introduction of new chemical compounds and special techniques and procedures of their administration for the chemical control of advanced cancer.

Methods of regional cancer chemotherapy have been developed to enhance the antitumor effect of compounds currently in use which, when given systemically, have been shown to have little practical value in the management of certain localized, yet uncontrolled, forms of cancer. A catheter is inserted into the accessible blood supply of the neoplasm and an antimetabolite is administered by continuous infusion for 1 week to 4 months or longer. For the most part, antimetabolites have been investigated by this method of administration, alone, and at times, combined with the appropriate metabolite administered systemically. The largest clinical experience has been with the antifolic compound, Methotrexate, and its antidote, citrovorum factor, as well as with the fluorinated pyrimidines, FU and FUDR. In general, when the disease has been limited to the area of infusion, the results have been good in terms of objective tumor regression and sustained clinical benefit. Antidote of the antimetabolite may be administered systemically to counteract distant toxic actions on bone marrow and intestine.

It is also apparent that these newer local techniques will become significant both in the research study of endocrine system function and in the therapy of endocrine disease. The ability to infuse a vascular bed bearing a target organ over a period of days gives one the ability to control the internal enviornment of that organ. Known concentrations of durgs can be introduced directly into vascular channels leading to the gland and chronic intermittent sampling of the venous drainage is possible.

It is desirable to prolong current forms of regional

cancer infusion therapy by the use of mechanism permitting, on ambulatory, outpatients basis, parenteral administration of fluid containing antimetabolite drugs Such a mechanism would also prove valuable in the animal laboratory since it would permit the continuous parenteral infusion of drugs into unrestrained large animals, such as dogs.

In developing a mechanism for vascular infusion o other medical purposes, the output must be accurate, a low pressure and volume but at sufficient positive pressure to prevent backflow on the high systolic point o the blood pressure. For ambulatory, out-patient use, th mechanism must be light, simple, durable, dependabl and entirely selfcontained including the driving mecha nism.

To maintain sterile conditions and maintain acceptabl surgical techniques, the unit must be operable on a mini mum of instructions to patients, not subject to break down, and readily transferrable to new patients withou danger of contamination. There must be high torque slow revolution but overdrive to fill the unit in the be ginning, and only uncostly disposable members that con tacts the medicament.

As disclosed hereinafter, the instant infusion devic meets all these demands and requirements. A small por table unit attachable to a catheter contains a replenish able drug supply, positive pump driving means at lo pressure and volume, easily and accurately measure output, and manual means for replenishing the powe means.

With these features in view, the nature of which wi be more apparent, the invention will be more fully under stood by reference to the drawings, the accompanyin detailed description, and the appended claims.

In the drawings:

FIG. 1 is a perspective view of the empty case fron the medicament side;

FIG. 2 is a perspective view of the empty case fron the driving side;

FIG. 3 is a plan view of the medicament side of th infusion device with all parts in position except the cove

FIG. 4 is a plan view from the opposed driving side

FIG. 5 is a section taken along line 5—5 of FIG. 3

FIG. 6 is a perspective exploded view of the drivin mechanism of FIG. 5;

FIG. 7 is a perspective view of the tubing partl mounted in the arcuate track segment;

FIG. 8 is a plan view with a plate removed of th watch braking mechanism;

FIG. 9 is a perspective view of the winding key;

FIG. 10 and 10*a* are side and plan views respectivel of the priming key;

FIG. 11 is a diagrammatic longitudinal section of th reservoir; and

FIG. 12 illustrates the filling of the reservoir.

As illustrated, this pump is designed primarily fo precisely injecting small volumes of parenteral fluid dur ing ambulatory intravascular therapy but obviously wit or without modification may be used for many othe purposes, including precise feeding during space flight precise feeding for animal experiments, etc.

A rectangular cast aluminum case **50** has an irregu lar partition **49** dividing a medicament chamber **39** cov ered by an inner cover not shown from a driving cham ber **55** covered by an outer cover not shown, the cas having dimensions of about 5" x 2.25" x 1.25" an weighing about 340 grams when completed as describe hereinafter. The drug reservoir **53** is located in medica ment chamber **39** and the clock escapement mechanism **54** is in driving chamber **55**, whereas the drive mecha nism is rotatably mounted in aperture **16** and is thu

positioned in both chambers. The covers are, of course, readily removable by screws or otherwise.

The drive mechanism includes a mainspring **17** mounted and secured within cylinder **18** and secured at the other end to the winding hub **19** which is integral with base ratchet plate **41** and spindle **61**. The base ratchet plate may be wound counterclockwise against the mainspring and is held from rotating clockwise by pawl **56** held in position by spring **57**. Accordingly, the mainspring drives the cylinder **18** and associated gear **42**. The gear **42** carries an enlarged hub **43** rotatably mounted on spindle **61** and a small ratchet **44**. Rotatably mounted on hub **43** is a rotor including a smooth plate **46** spaced from gear **42** by a cylindrical wall **45** to enclose ratchet **44** and to carry a pawl **59** so that plate **46** can move only in the direction of gear **42**. The rotor also includes four spindles **47** carried by plate **46** which terminate at their opposed ends in a priming gear **48**. Rotatably mounted between plate **46** and gear **48** on spindles **47** and extending beyond the periphery thereof, are four nylon rollers **22** which are spaced about 1/32" from segment **23** for about 180° of plate **46** and gear **48** circle.

This segment **23** holds a short segment of silastic tubing **24** which passes from the plastic drug reservoir **53** by the pump rollers to deliver fluid to the catheter attached to a subject. It may be provided at one end with a hypodermic needle connector for puncture of a rubber diaphragm of the silastic drug reservoir, e.g. of 25 ml. volume, and at the other end with a conventional male Luer-lok or other connector for a catheter or other member. The tubing is fabricated with a solid ridge **26** along its outer side with a bore **27** for passage of the drug. This solid ridge is clamped firmly into the semi-circular metal track segment **23** to prevent slippage of the tubing as the rotor revolves. The track is fabricated of two semi-circular segments of metal which are screwed together and held in accurate alignment by studs **29**, single screw **31**, and crown **62** on aperture **16**. Loosening of the holding screws permits slight separation of the two semi-circular segments and introduction of the solid ridge of the silastic tubing into the track.

The tubing **24** is provided with a grommet **32** that is secured to a notch **30** in the casing wall to prevent any external force from pulling the tube out of position. Starting slightly proximal to the grommet and extending to the peripheral end, the tubing is much thicker so that it will not reflect pulsations of the vascular system. At the proximal end of ridge **26** is located an enlarged bead **33** which is used to longitudinally position the tubing **24** relative to the track segment **23**. The track-retaining screw **31** of the housing may be loosened sufficiently to permit introduction of the tubing **24** and metal track **23**. The semi-circular metal track must pass beneath the upper flange of the retaining posts **29** at either end of the groove in the casing into which the semi-circular track fits. It should be possible to completely advance the track retaining screw so that the semi-circular metal track passes beneath each flange, thereby insuring that the pump will function by occlusive compression of the tubing by the pump rotors.

The rotor unit can rotate only counterclockwise under force of the mainspring or by positive force applied to the priming gear **48** as shown hereinafter. The rotor unit is driven ordinarily by the mainspring through gear **42**, the speed of which is controlled by the clock escapement mechanism. Gear **42** drives first spur gear **64** which drives second spur gear **66** which drives third spur gear **67**. The third spur gear drives the escapement wheel **35** controlled by the escapement arm **36** and the balance wheel **34**. This is a conventional clock escapement with two movements of the arm permitted per second. This is translated through appropriate gear reduction so that the rotor makes a complete 360° revolution every hour which means that the volume of fluid pumped per hour is four times the internal bore volume of 90° of the tubing. The tubing is carefully calibrated to give, for example, 0.05 cc. per 90°, or 0.2 cc. per hour or 4.8 cc. per day.

It will be obvious that the amount of drug to be pumped can be varied by changing speed of the watch mechanism, changing bore of the tubing or changing concentration of material in the bag, the latter being generally the most convenient.

The proximal end of tube **24** may be provided with a knurled and threaded penetrating needle **25** which is particularly adapted for a leak-proof connection with reservoir **53**. Various types of reservoirs could be used but that shown herein has been found preferable. This bag has molded within the outlet end a metal disc **68** with an internally threaded aperture **69** within an outwardly extending hub **71** and channel **72**. Into this channel and also bulging outwardly is an integral part of the bag plastic to form a sealing hub **73** whereby the needle flange **74** is threaded down to provide a leak-proof secondary seal, there being a primary seal inside the bag where the needle point penetrates the internal plastic layer of the bag. The inlet or filling end of the bag includes a metallic collar **76** with partly circular and partly straight flange **77**, a threaded aperture **78**, a sealing hub **79** extending beyond the collar **76** and a plastic screw cap **81** which threads down to make a positive seal with hub **79**.

It is desirable that the bag **53** be filled completely so that no air can be introduced into the system. This is done by holding the bag with holder **82** and introducing the medicament to the bottom with a syringe **83** as shown in FIG. 12. When the bag has been completely filled, the screw cap is threaded into aperture **78** before the bag is touched manually. If the bag is touched before closing, some squeezing will occur which diminishes the bag volume and subsequently draws air into the bag.

These filled bags may be provided to the patient as disposable units to be discarded after a single use or they may be returned for refilling. In either event, there should be no leakage into the housing or contamination thereof.

Once needle **25** has been properly inserted in bag **53**, it is necessary to fill the line through tubing **24** and an attached catheter or it may be necessary to flush the line with saline. Since the rotor unit rotates once per hour, this is not practical. However, priming key **37** is placed in aperture **84** of plate **86** to connect with priming gear **48** whereupon the rotor may be advanced at will for priming or flushing purposes.

The winding key **38** or stem threads into winding hub **19** to tighten the mainspring **17** to force gear **42** counterclockwise against the speed control of the clock escapement mechanism. Both the priming and winding keys are detachable. The mainspring is generally calculated to run twelve hours if completely wound. In any event, the patient can hear the ticking of the clock mechanism and will then know when the unit must be rewound.

The pump tubing (with attached metal track and adapters) and the disposable plastic drug reservoirs are the only parts of the device which need to be sterilized. Generally the tubing and reservoir will both be discarded when changing pumps from one patient to another so that the metal segment **23** is the only part that requires sterilization.

A harness is available so that the device can be strapped to the front of the chest. The winding hub **19** is directed outward so that the winding stem can be inserted without removal of the device from the harness case.

I claim:

1. A small-volume, positive-pressure, self-contained infusion device intended to be carried on the human body and adapted for constantly and slowly infusing desired liquids into the vascular system comprising a housing, an arcuate inflexible member secured inside said housing, an arcuate segment of flexible tubing mounted on the inner surface of said arcuate inflexible member and adapted

to be attached to a liquid reservoir and a catheter at the opposite ends thereof, a rotor mounted with its periphery parallel to and spaced from said arcuate inflexible member, a plurality of rollers mounted on the periphery of said rotor and extending outward to a point adjacent said inflexible member, a tooth gear operably engaged with said rotor, a convolute mainspring operably engaged to drive said gear, means to wind said spring, and a watch escapement unit driven by said gear to control the speed thereof.

2. The device of claim 1 additionally comprising said reservoir positioned within said housing.

3. The device of claim 1 wherein said rotor includes a ratchet mechanism permitting rotation of one portion manually in order to prime or flush said tube.

4. The device of claim 1 additionally comprising a primary crank for manual rotation of said rotor and a winding crank to wind said mainspring.

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