(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
28 August 2014 (28.08.2014)

WIPO | PCT

(10) International Publication Number
WO 2014/130766 A1

(51) International Patent Classification:
A61M 5/168 (2006.01) *A61M 5/315* (2006.01)

(21) International Application Number:
PCT/US2014/017578

(22) International Filing Date:
21 February 2014 (21.02.2014)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
61/767,306 21 February 2013 (21.02.2013) US
61/815,776 25 April 2013 (25.04.2013) US

(71) Applicant: **THE JOHNS HOPKINS UNIVERSITY** [US/US]; 3400 N. Charles Street, Baltimore, Maryland 21218 (US).

(72) Inventor: **BHALALA, Utpal**; 2415 Crest Road, Baltimore, Maryland 21209 (US).

(74) Agent: **RYAN, Louisa**; 100 N. Charles Street, 5th Floor, Baltimore, Maryland 21201 (US).

(81) Designated States *(unless otherwise indicated, for every kind of national protection available)*: AE, AG, AL, AM, AO, AT, AU, AZ, BA, BB, BG, BH, BN, BR, BW, BY, BZ, CA, CH, CL, CN, CO, CR, CU, CZ, DE, DK, DM, DO, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN, HR, HU, ID, IL, IN, IR, IS, JP, KE, KG, KN, KP, KR, KZ, LA, LC, LK, LR, LS, LT, LU, LY, MA, MD, ME, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM, PA, PE, PG, PH, PL, PT, QA, RO, RS, RU, RW, SA, SC, SD, SE, SG, SK, SL, SM, ST, SV, SY, TH, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, ZA, ZM, ZW.

(84) Designated States *(unless otherwise indicated, for every kind of regional protection available)*: ARIPO (BW, GH, GM, KE, LR, LS, MW, MZ, NA, RW, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, RU, TJ, TM), European (AL, AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HR, HU, IE, IS, IT, LT, LU, LV, MC, MK, MT, NL, NO, PL, PT, RO, RS, SE, SI, SK, SM, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, KM, ML, MR, NE, SN, TD, TG).

Published:

— *with international search report (Art. 21(3))*

(54) Title: DEVICE FOR DELIVERING RESUSCITATIVE DOSING OF EPINEPHRINE

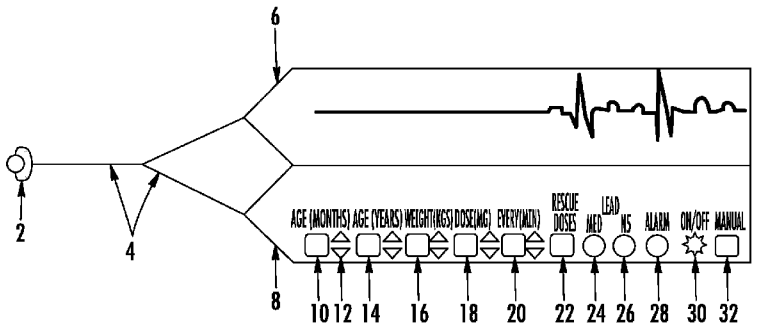


FIG. 1

(57) Abstract: A device and method of the present invention provides rescue doses of medication to a patient. The device can be used in conjunction with other traditional methods of resuscitation such as CPR, in order to deliver timed, metered rescue doses of medication, such as epinephrine. The device includes a syringe filled with the rescue medication and a syringe filled with saline. The device also includes a control unit for timing the delivery of the rescue medication. The control unit can also be used to program the amount of medication or saline dispensed and can be configured to sound a beep to alert medical professionals caring for the patient that another dose of medicine will be administered within 10 seconds.

WO 2014/130766 A1

DEVICE FOR DELIVERING RESUSCITATIVE DOSING OF EPINEPHRINE

CROSS REFERENCE TO RELATED APPLICATION

[0001] This application claims the benefit of U.S. Provisional Patent Application No. 61/767,306 filed on February 21, 2013, and U.S. Provisional Patent Application No. 61/815,776 filed on April 25, 2013, both of which are incorporated by reference, herein, in their entirety.

FIELD OF THE INVENTION

[0002] The present invention relates generally to medical devices. More particularly, the present invention relates to a device for providing resuscitative dosing of medicine.

BACKGROUND OF THE INVENTION

[0003] Epinephrine is an endogenous catecholamine with both alpha- and beta-adrenergic activity. Epinephrine's potent alpha1-and alpha2-adrenergic effects improve cerebral and myocardial blood flow by preventing arterial collapse and by increasing peripheral vasoconstriction. For these reasons, Epinephrine is the vasopressor of choice for use during CPR. In some instances, epinephrine is administered once and the patient is revived. In other instances, the epinephrine must be administered in multiple doses over a period of time. For example, during cardiac arrest, the American Heart Association (AHA) recommends a rescue dose of epinephrine every 3-5 minutes.

[0004] In one such method of providing timed, rescue doses, the rescue dose is drawn up manually into a syringe from a container of medication. There is potential for a medication error, such as drawing up the wrong dose of medication. Administering the wrong dose of medication can result in failure of the medication, in

the case of a dose that is too small, or adverse or fatal effect in the case of a dose that is too large.

[0005] In another such method of providing timed, rescue doses, the rescue dose in a syringe is connected to an intravenous (IV) or intraosseous (IO) line of the patient. In this method, there is potential for blood stream infection due to repeated access for multiple rescue doses. In yet another such method for delivering timed, rescue doses to the patient, the rescue dose is pushed manually from the syringe into the patient's IV or IO line. Here, there is potential for medication error and timing error in a life threatening condition like cardiac arrest.

[0006] It would therefore be advantageous to provide a device that provides rescue doses of a parenteral medication like epinephrine at a set time interval, followed by a normal saline flush through an IV/IO line.

SUMMARY

[0007] The foregoing needs are met, to a great extent, by the present invention, wherein in one aspect a device for delivery of a series of metered doses of a medication to a patient includes a first syringe configured to hold a predetermined amount of the medication for delivery of the series of metered doses. The device also includes a second syringe configured to hold a predetermined amount of saline for delivery after each one of a dose in the series of metered doses and a connector configured to connect the first syringe and the second syringe to a vein of a patient. Additionally, the device includes a control unit for the timing and delivery of the medication. The control unit is programmed to deliver the predetermine amount of the medication to the patient and follow with the delivery of the predetermined amount of saline.

[0008] In accordance with an aspect of the present invention, the medication further takes the form of one selected from a group consisting of epinephrine, vasopressin, and anesthetic. The device is configured for use during one selected from a group consisting of CPR and procedural sedation. The device further includes a display screen for information relevant to the delivery of the metered doses. The relevant information can be at least one selected from a group consisting of patient age, height, weight, predetermined dose of medication, and dose interval. The device further includes buttons configured to allow a medical professional to adjust the information relevant to the delivery of the metered doses.

[0009] In accordance with another aspect of a present invention, the device includes a non-transitory computer readable medium programmed to determine the predetermined dose of the medication and the dose interval of the medication. The non-transitory computer readable medium is further programmed to determine the predetermined dose of the medication and the dose interval of the medication based on CPR guidelines. The device also includes a strap for holding the device to an appendage of the patient. An alarm for alerting a medical professional that a dose of the medication is going to be administered is included and an alarm to indicate that at least one of the medication or saline is at a predetermined low level can also be included. The non-transitory computer readable medium is also programmed to allow delivery of a rescue dose of epinephrine and/or vasopressin based on physiological parameters. The physiological parameters take the form of at least one of a group consisting of end-tidal carbon dioxide levels and blood pressure of the patient. The device further includes a y-shaped tubing having an internal one-way valve system

configured to allow delivery of parenteral drugs and fluids in one direction from the device to the patient.

BRIEF DESCRIPTION OF THE DRAWINGS

[0010] The accompanying drawings provide visual representations which will be used to more fully describe the representative embodiments disclosed herein and can be used by those skilled in the art to better understand them and their inherent advantages. In these drawings, like reference numerals identify corresponding elements and:

[0011] FIG. 1 illustrates a top down view of a device for administering rescue medication, according to an embodiment of the present invention.

[0012] FIG. 2 illustrates a sectional view of the device for administering rescue medication, illustrated in FIG. 1.

[0013] FIG. 3 illustrates a back view of the device according to an embodiment of the present invention.

[0014] FIG. 4 illustrates a sectional view of a syringe tube, according to an embodiment of the present invention.

[0015] FIG. 5 illustrates a y-shaped tubing according to an embodiment of the present invention.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

[0016] The presently disclosed subject matter now will be described more fully hereinafter with reference to the accompanying Drawings, in which some, but not all embodiments of the inventions are shown. Like numbers refer to like elements throughout. The presently disclosed subject matter may be embodied in many

different forms and should not be construed as limited to the embodiments set forth herein; rather, these embodiments are provided so that this disclosure will satisfy applicable legal requirements. Indeed, many modifications and other embodiments of the presently disclosed subject matter set forth herein will come to mind to one skilled in the art to which the presently disclosed subject matter pertains having the benefit of the teachings presented in the foregoing descriptions and the associated Drawings. Therefore, it is to be understood that the presently disclosed subject matter is not to be limited to the specific embodiments disclosed and that modifications and other embodiments are intended to be included within the scope of the appended claims.

[0017] A device and method of the present invention provides rescue doses of medication to a patient. The device can be used in conjunction with other traditional methods of resuscitation such as CPR, in order to deliver timed, metered rescue doses of medication, such as epinephrine. The device includes a syringe filled with the rescue medication and a syringe filled with saline. The device also includes a control unit for timing the delivery of the rescue medication. The control unit can also be used to program the amount of medication or saline dispensed and can be configured to sound a beep to alert medical professionals caring for the patient that another dose of medicine will be administered within 10 seconds.

[0018] FIG. 1 illustrates a top down view of a device for administering rescue medication, according to an embodiment of the present invention. The device for administering rescue medication 1 includes a hub 2 for coupling to a IV or IO line of the patient. Alternately, the device 1 can include a needle or other means known to or conceivable by one of skill in the art to transmit the medication and saline into the patient's bloodstream. A first syringe tube 6 and a second syringe tube 8 are coupled

to the hub 2 with a y-shaped tubing 4. The first syringe tube 6 can be configured to hold the rescue medication, such as epinephrine or vasopressin. The second syringe tube 8 can be configured to hold the saline. The first and second tubes 6, 8 can be cylindrical in shape and are in fluid communication with the y-shaped tubing 4 and also with the hub 2. The y-shaped tubing 4 can have a one way valve system positioned within each branch of the y-shaped tubing 4. This prevents mixing of the medication and the saline in the first and second syringe tubes 6, 8. The one way valve system is further described with respect to FIG. 5, below.

[0019] Also as illustrated in FIG. 1, a control unit can be coupled to the first and second syringe tubes 6, 8. The control unit includes a series of small screens, buttons and alarms. A first age screen 10 displays an age of the patient in months, and a second age screen 14 displays the age of the patient in years. Weight screen 16 displays the weight of the patient in kilograms. Dosing of medication in mg is displayed on dose screen 18. Time interval screen 20 displays the time interval between rescue doses in minutes, and total screen 22 displays the total number of rescue doses already delivered to the patient at any given time.

[0020] Further, FIG. 1 illustrates buttons 12 that are positioned beside each of screens 10, 14, 16, 18, 20, and 22. Buttons 12 allow for increase and/or decrease of parameters displayed on the screen. Only the parameters that must be determined by a medical professional are able to be changed on the screens using the buttons 12. Therefore, for instance, total screen 22 cannot be changed with the buttons 12. In a preferred embodiment the buttons 12 can take the form of arrowhead buttons. In each paired arrowhead button system beside each screen, pushing the arrowhead button that points up allows an increase in the parameter displayed on the screen and pushing

the arrowhead button that points down allows a decrease in the parameter displayed on the screen. For example, if a medical professional wanted to increase the time interval between the rescue doses, it could be changed by pushing on the upward pointing arrowhead button positioned adjacent to screen 20. While the buttons have been described as separate sets for each screen, it is possible that only one set of buttons is included along with a separate mode button to cycle through the different screens with parameters that can be changed.

[0021] FIG. 1 also illustrates alarms 24 and 26. Alarms 24 and 26 preferably take the form of lights that start blinking every second, when either the first or second syringe tubes 6, 8 are about to be empty. The alarms 24 and 26 can take the form of an LED or other suitable means of indication known to or conceivable by one of skill in the art. Alarm 28 is an alert light that starts blinking every second for 10 seconds prior to release of the recue dose from the device. Alarms 24, 26, and 28 can take the form of different colored lights in order to provide a distinction between the alarms for the medical professional. The alarms 24, 26, 28 can also take the form of sound alerts for the medical professional.

[0022] FIG. 2 illustrates a sectional view of the device for administering rescue medication, illustrated in FIG. 1. First and second syringe tubes 6, 8 are configured to hold rescue medication and saline respectively, as described above. Further, first and second syringe tubes 6, 8 can include a first lid cover 34 disposed on the first syringe tube 6 and a second lid cover 36 disposed on the second syringe tube 8. When opened, the first lid cover 34 reveals a first 60 mL syringe 38 filled with rescue medication within the first syringe tube 6. The second lid cover 36 reveals a second 60 mL syringe 40 filled with saline within the second syringe tube 8. Each syringe 38, 40 has

a plunger 42, 48 and a plunger top holder 44, 46. The plungers 42, 48 fit snugly into plunger top holders 44, 46. Each plunger top holder 44, 46 is also capable of pushing the syringe plunger 42, 48 at a set interval, as programmed by the control unit. The components of the device can be formed from plastic, acrylic, or any other suitable material known to or conceivable by one of skill in the art.

[0023] FIG. 3 illustrates a back view of the device according to an embodiment of the present invention. The syringe tubes 6, 8 are covered partially by a strap system to restrain the device to an upper or lower extremity of the patient. The strap can include a securement device such as hook and loop, snap, button, tab and loop, or any other suitable securement device known to or conceivable by one of skill in the art. Additionally, the strap can be formed from any suitable material known to one of skill in the art. The strap can be formed from an elastic material in order to allow adjustability or adjustability can be facilitated with choice and placement of the securement device. Also illustrated in FIG. 3, a groove 54, 56 can be included for batteries. Each battery groove 54, 56 can also include a cover 52.

[0024] FIG. 4 illustrates a sectional view of a syringe tube, according to an embodiment of the present invention. As illustrated in FIG. 4, syringe 64 fits between syringe holders 66. Additionally, a system of wires 58 connects the screens, buttons, and alarms to internal software, that will be described in further detail below, as well as to the syringe plunger holders.

[0025] FIG. 5 illustrates a y-shaped tubing according to an embodiment of the present invention. Y-shaped tubing 4 includes a one-way valve in each limb of the y-shaped tubing 4. The stem of the y-shaped tubing 4 includes hub 2 that is configured to connect to an IV or IO line. The two limbs of the y-shaped tubing 4 pass through an

opening on each of the first and second syringe tubes 6, 8 to be connected to syringes 38 and 40. The one-way valve allows for the passage of medication and saline only in one direction, from the syringe to the patient.

[0026] The device includes software, which would allow a programmed delivery of rescue dose of epinephrine and/or vasopressin every 3-5 minutes based on current CPR guidelines. Based on growing scientific evidence, it is possible that AHA may recommend rescue dose epinephrine and/or vasopressin based on physiologic parameters like end-tidal carbon dioxide levels and/or blood pressure in certain cases of cardiac arrest in which physiologic monitoring is available to guide the CPR. The device software can therefore allow delivery of rescue dose epinephrine and/or vasopressin based on physiologic parameters like end-tidal carbon dioxide levels and/or blood pressure. For example, if goal end-tidal carbon dioxide level is more than 20 mm Hg, then our future prototype would be able to detect a drop in end tidal carbon dioxide level below 20 mm Hg and provide rescue dose epinephrine in response to the drop in end tidal carbon dioxide level.

[0027] It should be noted that the software is fixed on a non-transitory computer readable medium that can be read and executed by any computing device, such as a microprocessor, a PC computer, a tablet, a phablet, a smartphone, or any other suitable computing device known to or conceivable by one of skill in the art. The non-transitory computer readable medium can take any suitable form known to one of skill in the art. The non-transitory computer readable medium is understood to be any article of manufacture readable by a computer. Such non-transitory computer readable media includes, but is not limited to, magnetic media, such as floppy disk, flexible

disk, hard, disk, reel-to-reel tape, cartridge tape, cassette tapes or cards, optical media such as CD-ROM, DVD, blu-ray, writable compact discs, magneto-optical media in disc, tape, or card form, and paper media such as punch cards or paper tape.

[0028] While the present invention was described relative to delivery of epinephrine for rescue and CPR, the device can also be used to deliver other rescue drugs such as vasopressin. Additionally, the device could be used for delivery of anesthetics during procedural sedation. Although the present invention has been described in connection with preferred embodiments thereof, it will be appreciated by those skilled in the art that additions, deletions, modifications, and substitutions not specifically described may be made without departing from the spirit and scope of the invention as defined in the appended claims.

CLAIMS

1. A device for delivery of a series of metered doses of a medication to a patient comprising:

a first syringe configured to hold a predetermined amount of the medication for delivery of the series of metered doses;

a second syringe configured to hold a predetermined amount of saline for delivery after each one of a dose in the series of metered doses;

a connector configured to connect the first syringe and the second syringe to a vein of a patient; and

a control unit for the timing and delivery of the medication, wherein the control unit is programmed to deliver the predetermine amount of the medication to the patient and follow with the delivery of the predetermined amount of saline.

2. The device for delivery of a series of metered doses of a medication to a patient of claim 1 wherein the medication further comprises one selected from a group consisting of epinephrine, vasopressin, and anesthetic.

3. The device for delivery of a series of metered doses of a medication to a patient of claim 1 wherein the device is configured for use during one selected from a group consisting of CPR and procedural sedation.

4. The device for delivery of a series of metered doses of a medication to a patient of claim 1 further comprising a display screen for information relevant to the delivery of the metered doses.

5. The device for delivery of claim 4 wherein the relevant information further comprises at least one selected from a group consisting of patient age, height, weight, predetermined dose of medication, and dose interval.

6. The device for delivery of claim 4 further comprising buttons configured to allow a medical professional to adjust the information relevant to the delivery of the metered doses.

7. The device for delivery of claim 1 further comprising a non-transitory computer readable medium programmed to determine the predetermined dose of the medication and the dose interval of the medication.

8. The device for delivery of claim 7 wherein the non-transitory computer readable medium is further programmed to determine the predetermined dose of the medication and the dose interval of the medication based on CPR guidelines.

9. The device for delivery of claim 1 further comprising a strap for holding the device to an appendage of the patient.

10. The device for delivery of claim 1 further comprising an alarm for alerting a medical professional that a dose of the medication is going to be administered.

11. The device for delivery of claim 1 further comprising an alarm to indicate that at least one of the medication or saline is at a predetermined low level.

12. The device for delivery of claim 1 further comprising a non-transitory computer readable medium programmed to allow delivery of a rescue dose of epinephrine and/or vasopressin based on physiological parameters.

13. The device for delivery of claim 12 wherein the physiological parameters comprise at least one of a group consisting of end-tidal carbon dioxide levels and blood pressure of the patient.

14. The device for delivery of claim 1 wherein the device further comprises a y-shaped tubing having an internal one-way valve system configured to allow delivery of parenteral drugs and fluids in one direction from the device to the patient.

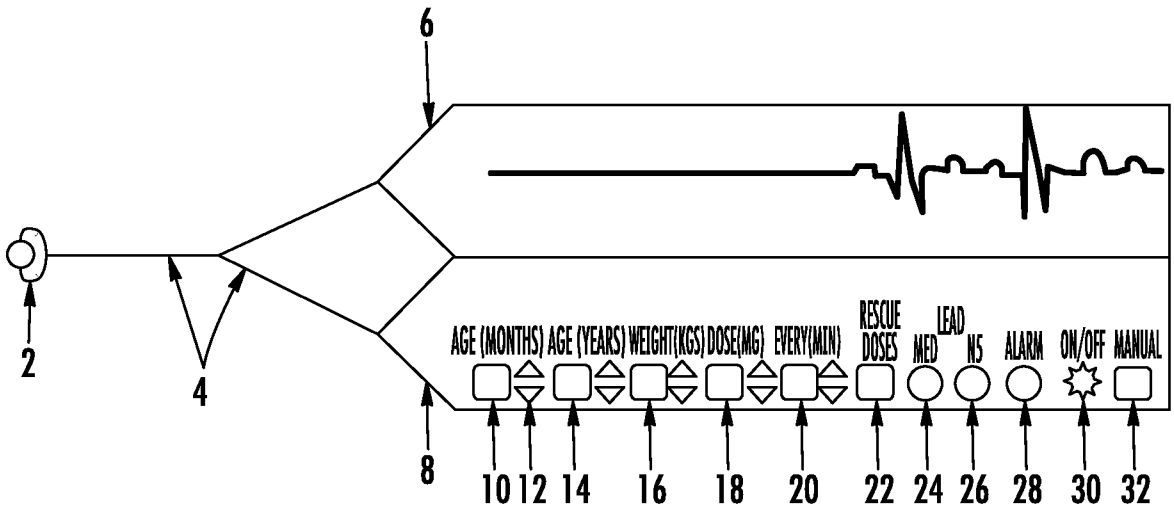

6
2
4
8
AGE (MONTHS)
AGE (YEARS)
WEIGHT(KGS)
DOSE(MG)
EVERY(MIN)
RESCUE DOSES
MED
LEAD
N5
ALARM
ON/OFF
MANUAL
10 12 14 16 18 20 22 24 26 28 30 32

FIG. 1

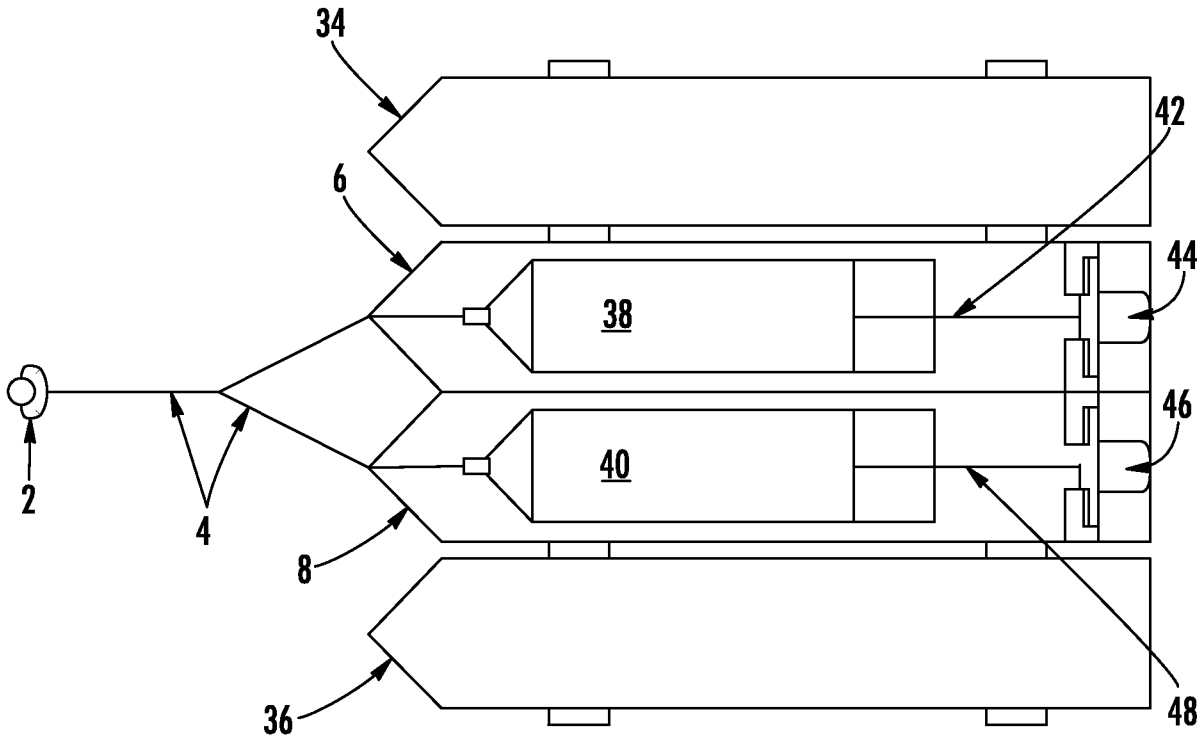


FIG. 2

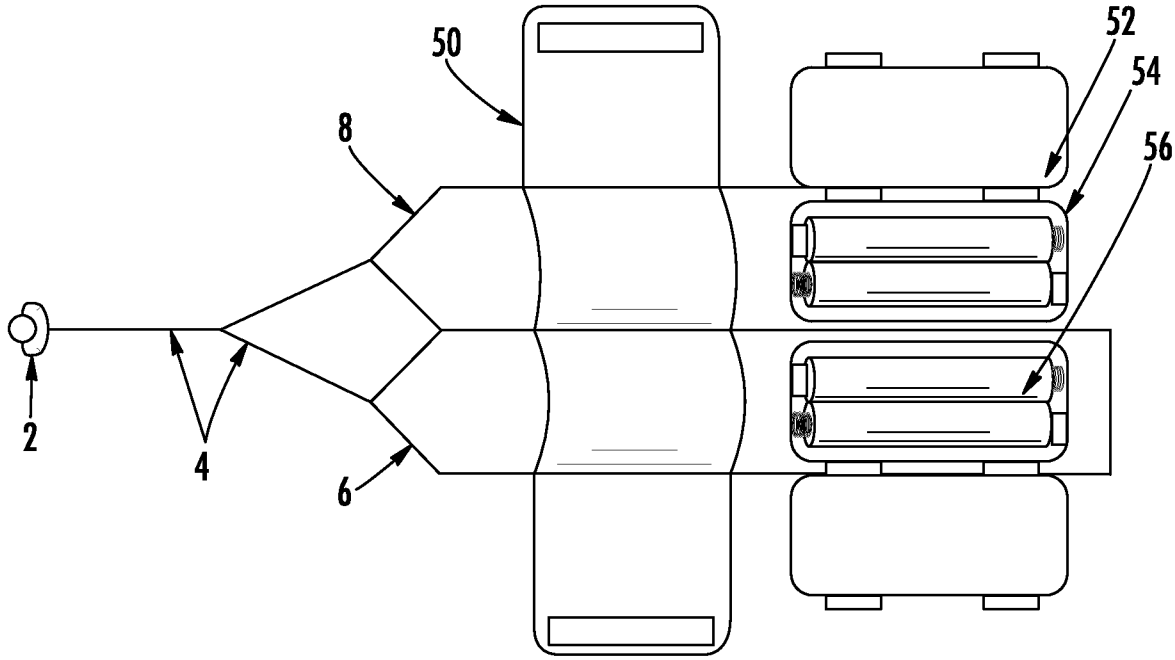


FIG. 3

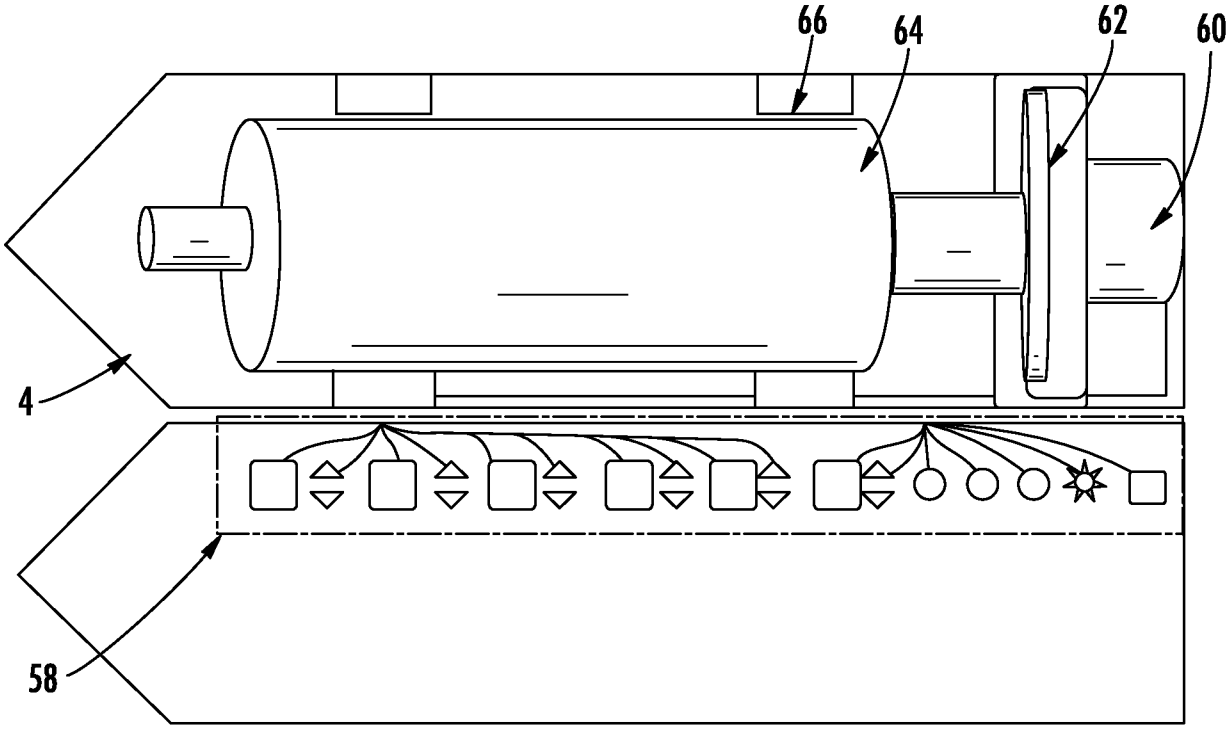


FIG. 4

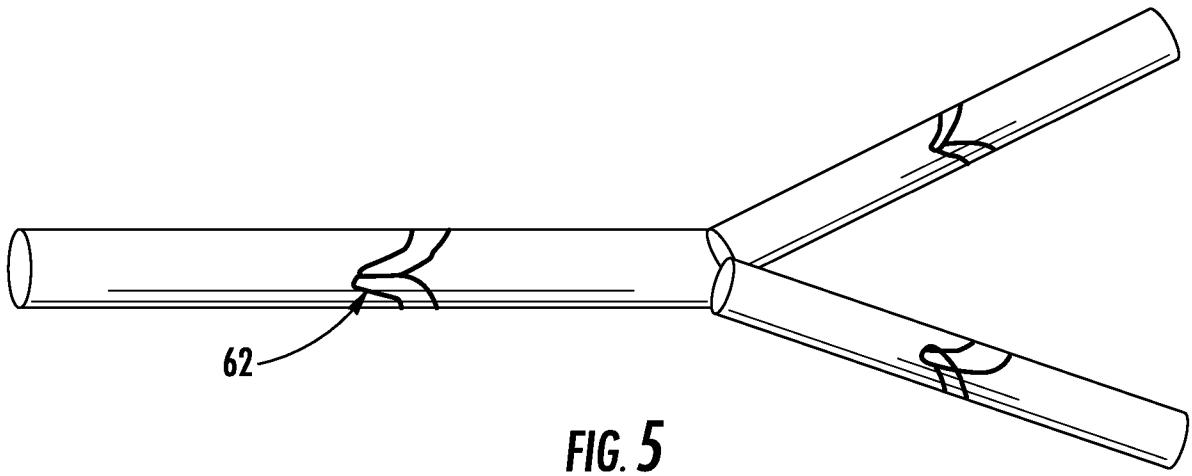


FIG. 5

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2014/017578

A. CLASSIFICATION OF SUBJECT MATTER

A61M 5/168(2006.01)i, A61M 5/315(2006.01)i

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
A61M 5/168; A61M 5/00; B65B 1/04; A61M 5/315

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched
Korean utility models and applications for utility models
Japanese utility models and applications for utility models

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
eKOMPASS(KIPO internal) & keywords: delivery, metered dose, syringe, saline, control

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2007-0093712 A1 (NEMOTO, S. et al.) 26 April 2007 See abstract; paragraph [0005]; claims 1-12; figure 2.	1-14
A	US 4529401 A (LESLIE, J. E. et al.) 16 July 1985 See abstract, and claims 1, 2.	1-14
A	US 4731051 A (FISCHELL, R. E.) 15 March 1988 See abstract, and claim 1.	1-14
A	US 4865583 A (TU, H. C.) 12 September 1989 See abstract, and claim 7.	1-14
A	US 2012-0273087 A1 (STAVSKY, M. et al.) 1 November 2012 See abstract, and claims 1-10.	1-14

☐ Further documents are listed in the continuation of Box C.

☒ See patent family annex.

* Special categories of cited documents:
"A" document defining the general state of the art which is not considered to be of particular relevance
"E" earlier application or patent but published on or after the international filing date
"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
"O" document referring to an oral disclosure, use, exhibition or other means
"P" document published prior to the international filing date but later than the priority date claimed
"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents,such combination being obvious to a person skilled in the art
"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
02 May 2014 (02.05.2014)	**07 May 2014 (07.05.2014)**

Name and mailing address of the ISA/KR
International Application Division
Korean Intellectual Property Office
189 Cheongsa-ro, Seo-gu, Daejeon Metropolitan City, 302-701, Republic of Korea
Facsimile No. +82-42-472-7140

Authorized officer
MOON, Sun Heup
Telephone No. +82-42-481-8242

Form PCT/ISA/210 (second sheet) (July 2009)

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No.
PCT/US2014/017578

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 2007-0093712 A1	26/04/2007	CN 100484580 C	06/05/2009
		CN 1871041 A	29/11/2006
		EP 1681069 A1	19/07/2006
		EP 1681069 A4	12/09/2007
		JP 04786344 B2	05/10/2011
		WO 2005-039675 A1	06/05/2005
US 4529401 A	16/07/1985	US 4665184 A	12/05/1987
		US 4942227 A	17/07/1990
US 4731051 A	15/03/1988	CA 1207871 A1	15/07/1986
		DE 3390462 C2	29/07/1993
		DE 3390462 T	24/01/1985
		EP 0137789 A1	24/04/1985
		EP 0137789 A4	10/09/1987
		EP 0137789 B1	01/07/1992
		GB 2146460 A	17/04/1985
		GB 2146460 B	24/06/1987
		GB 8424624 D0	07/11/1984
		IT 1219342 B	03/05/1990
		IT 8323311 D0	14/10/1983
		JP 06-059315 B	10/08/1994
		JP 60-501293 A	15/08/1985
		WO 84-03218 A1	30/08/1984
US 4865583 A	12/09/1989	US 4791916 A	20/12/1988
		US 4865583 A	12/09/1989
US 2012-0273087 A1	01/11/2012	US 2009-0198208 A1	06/08/2009
		WO 2009-095904 A1	06/08/2009