

(19) World Intellectual Property Organization  
International Bureau



(43) International Publication Date  
27 September 2007 (27.09.2007)

PCT

(10) International Publication Number  
**WO 2007/108969 A2**

(51) International Patent Classification:  
A61M 5/14 (2006.01)

(74) Agent: GRAY, Richard, O., Jr.; Graybeal Jackson Haley  
LLP, 155 - 108th Ave NE, Suite 350, Bellevue, WA 98004-  
5973 (US).

(21) International Application Number:  
PCT/US2007/006115

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

(22) International Filing Date: 9 March 2007 (09.03.2007)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:  
60/782,941 16 March 2006 (16.03.2006) US  
11/705,814 12 February 2007 (12.02.2007) US

(84) Designated States (unless otherwise indicated, for every  
kind of regional protection available): ARIPO (BW, GH,  
GM, KE, LS, MW, MZ, NA, SD, SL, SZ, TZ, UG, ZM,  
ZW), Eurasian (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM),  
European (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI,  
FR, GB, GR, HU, IE, IS, IT, LT, LU, LV, MC, MT, NL, PL,  
PT, RO, SE, SI, SK, TR), OAPI (BF, BJ, CF, CG, CI, CM,  
GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

(71) Applicant (for all designated States except US): SEAT-  
TLE MEDICAL TECHNOLOGIES, INC. [US/US];  
1000 Second Avenue, Suite 1440, Seattle, WA 98104-3613  
(US).

(72) Inventors; and

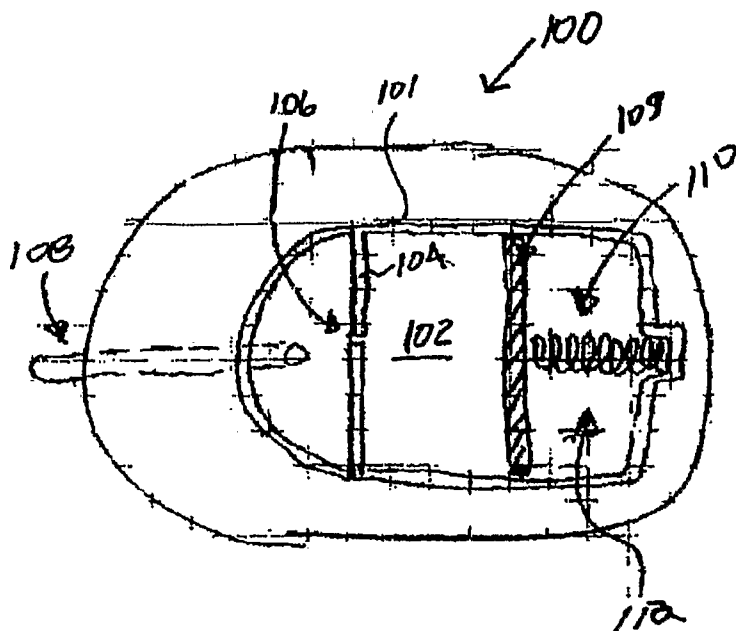
(75) Inventors/Applicants (for US only): ALFERNESS,  
Clifton, A. [US/US]; 5945 Marymac Dr.SW, Port Or-  
chard, WA 98367-7450 (US). ADAMS, John, M.  
[US/US]; 11420 NE 87th St., Kirkland, WA 98033-5744  
(US). HAWKINS, Daniel [US/US]; 15309 SE 82nd  
Street, Newcastle, WA 98059-9223 (US).

Published:

— without international search report and to be republished  
upon receipt of that report

For two-letter codes and other abbreviations, refer to the "Guid-  
ance Notes on Codes and Abbreviations" appearing at the begin-  
ning of each regular issue of the PCT Gazette.

(54) Title: INFUSION DEVICE WITH DOSAGE DIAL CONTROL



(57) Abstract: A disposable infusion device  
comprises a base arranged to adhere to a  
patient's skin, a cannula arranged to extend  
from the base to beneath the patient's skin to deliver  
a liquid medicament to the patient, and a source  
arranged to provide the cannula with a liquid  
medicament. The device further includes an  
actuator that actuates the source to provide the  
liquid medicament to the cannula. The source  
is arranged to provide, with each actuation, a  
fixed volume of medicament to the cannula. A  
control sets the fixed volume.

**INFUSION DEVICE WITH DOSAGE DIAL CONTROL****Claim Of Priority**

[1] This application claims priority to U.S. Provisional Application Serial No. 60/782,941, filed on 16  
5 March 2006, which is incorporated by reference.

**Background**

[2] Tight control over the delivery of insulin in both type I (usually juvenile onset) and type II (usually late  
10 adult onset), has been shown to improve the quality of life as well as the general health of these patients. Insulin delivery has been dominated by subcutaneous injections of both long acting insulin to cover the basal needs of the patient and by short acting insulin to compensate for meals  
15 and snacks. Recently, the development of electronic, external insulin infusion pumps has allowed the continuous infusion of fast acting insulin for the maintenance of the basal needs as well as the compensatory doses for meals and snacks. These infusion systems have shown to improve control  
20 of blood glucose levels, however, they suffer the drawbacks of size, cost, and complexity, which prevents many patients from accepting this technology over the standard subcutaneous injections. These pumps are electronically controlled and must be programmed to supply the desired  
25 amounts of basal and bolus insulin.

**Summary**

[3] In one embodiment, the invention provides a disposable infusion device comprising a base arranged to  
30 adhere to a patient's skin, a cannula arranged to extend from the base to beneath the patient's skin to deliver a

liquid medicament to the patient, a source arranged to provide the cannula with a liquid medicament, an actuator that actuates the source to provide the liquid medicament to the cannula, the source being arranged to provide, with each  
5 actuation, a fixed volume of medicament to the cannula, and a control that sets the fixed volume.

[4] The source may include a reservoir that holds the liquid medicament. The control may comprise a rotatable dial. The source may include a pump, the pump having a  
10 liquid medicament holding capacity, and the control may vary the amount of the pump holding capacity to be pumped to the cannula upon each actuation. The pump may comprise a compressible tube and the control may be arranged to control the portion of the compressible tube that is compressed with  
15 each actuation.

[5] The pump may include a disk having a circumferential surface that supports the compressible tube and a strap coupled to the actuator that compresses a portion of the compressible tube against the disk  
20 circumference. The disk may be provided with a groove within its circumferential surface, the groove having a depth that increases along the disk circumference. The groove may be arranged to receive the compressible tube, and the disk being rotatable to vary the length of the groove receiving  
25 the compressible tube to adjust the portion of the tube that is compressed and the volume of liquid medicament pumped to the cannula with each actuation of the actuator. The disk may be rotated by a rotatable dial. The source may further include a reservoir that holds the liquid medicament and the  
30 compressible tube communicates with the reservoir.

[6] In another embodiment, a disposable infusion device comprises a base arranged to adhere to a patient's skin, a cannula arranged to extend from the base to beneath

the patient's skin to deliver a liquid medicament to the patient and a source arranged to provide the cannula with a liquid medicament. The source includes a reservoir that holds the liquid medicament and a pump that pumps the liquid medicament from the reservoir to the cannula. The device further comprises an actuator that actuates the pump to cause the pump to provide the liquid medicament to the cannula. The pump is arranged to provide, with each actuation, a fixed volume of medicament to the cannula. The device still further comprises a control that varies the fixed volume.

#### **Brief Description Of The Drawings**

[7] The features of the present invention which are believed to be novel are set forth with particularity in the appended claims. The invention, together with further features and advantages thereof, may best be understood by making reference to the following description taken in conjunction with the accompanying drawings, in the several figures of which like reference numerals identify identical elements, and wherein:

[8] **FIG. 1** is a side view of an infusion port that may be used in practicing the invention;

[9] **FIG. 2** is a side view of an infusion port, loading membrane, and insulin reservoir according to one embodiment of the invention;

[10] **FIG. 2A** is a schematic diagram illustrating one potential manner of operation of the system of **FIG. 2**;

[11] **FIG. 2B** a schematic diagram illustrating another potential manner of operation of the system of **FIG. 2**;

[12] FIG. 3 is a side view, with portions cut away, of a disposable insulin infusion system including a mechanical timer according to another embodiment of the invention;

[13] FIG. 4 is a perspective view of a disposable  
5 insulin infusion system that provides for both basal delivery and bolus delivery of insulin according to an embodiment of the invention;

[14] FIG. 4A is a side view, with portions cut away, showing more particulars of the operation of the system of  
10 FIG. 4;

[15] FIG. 5 is a perspective view of a disposable insulin infusion system providing user basal delivery rate adjustment and bolus delivery of insulin;

[16] FIG. 6 is a side view of a disposable insulin  
15 infusion system including constant insulin delivery device and a separate mating bolus delivery device according to an embodiment of the invention;

[17] FIG. 7 is a top view, with portions cut away, of an insulin infusion system according to another embodiment  
20 of the invention having insulin delivery rate determined by a chamber pressure;

[18] FIG. 7A is a schematic diagram illustrating one potential manner of operation of the system of FIG. 7;

[19] FIG. 8 is a side view of an insulin infusion  
25 system having insulin bolus delivery volume controlled by peristaltic action according to an embodiment of the invention;

[20] FIG. 9 is an end view of the system of FIG. 8;

[21] FIG. 10 is a schematic diagram of a further system  
30 embodying the invention;

[22] FIG. 11 is a side view, with portions cut away, of a bolus pump embodying the invention prior to insulin delivery; and

[23] FIG. 12 is a side view, with portions cut away, of the bolus pump of FIG. 11 embodying the invention after  
5 insulin delivery.

### Detailed Description

[24] FIG. 1 shows an infusion port 10 into which a  
10 liquid medicament, such as insulin or incretins, can be injected manually using a standard syringe. The port 10 includes a funnel port 12, an insertion needle 14, and an injection membrane 16. The port 10 may be adhered to the skin 18 with adhesive tape 20. This system obviates the  
15 need for multiple daily percutaneous needle sticks to accomplish the provision of insulin dosage.

[25] The port 10 further includes a cannula 15. The cannula 15 is carried by the funnel port 12. As known in the art, once the needle 14 and cannula 15 are positioned  
20 beneath the skin 18 as shown, the needle 14 is removed leaving the cannula 15 in a deployed position and ready to deliver insulin to the patient.

[26] FIG. 2 shows a system 30 according to one embodiment of the invention. The system includes an infusion  
25 port 32 similar to port 10 for delivery of either long acting or short acting insulin. The port 32 is shown prior to the needle 39 being withdrawn from the cannula 41. The system includes a first source 31 including a reservoir 34 which may be filled with a fast acting insulin through a  
30 port 36 and a pump 38. A further reservoir may be provided as will be seen subsequently. The port allows for reservoir 34 to internally hold a first liquid medicament, such as a

fast acting insulin, for delivery at meals, for example, while the funnel port 33 of the port 32 forms a second source 43 and allows for a second liquid medicament, such as a slow acting insulin to be delivered as, for example, in the morning after awakening. The fast acting insulin may be delivered by the pump 38 which may be squeezed with the fingers.

[27] In the case when the system 30 includes multiple reservoirs, the system may have a mechanism for the selection of which insulin is infused at any given time. It also may provide control over how much of each particular insulin is determined to be delivered by having the patient depress the actuator 38 a desired number of times. For example, each activation might deliver 0.5 units of insulin. Therefore, if 3 units of insulin are desired, 6 depressions will deliver the desired amount.

[28] FIG. 2A shows one manner of operation of the system 30. Fast acting insulin may be loaded into reservoir 34 through loading port 36. The pump 38 may be a piston pump and more particularly, a fixed stroke piston pump which provides a predetermined volume of insulin upon each actuation. The number of depressions of pump 38 thus determines the amount of the fast acting insulin delivered from reservoir 34 to port 32 and cannula 41. When a slow acting insulin is to be delivered, such as in the morning upon awakening, the slow acting insulin may be delivered through funnel port 33. In that regard, it will be noted that the port 33 permits the slow acting insulin to be received from an instrument, such as syringe 39, from external to the system 30. It may further be noted that the infusion system 30 further includes one-way valves 45 and 47. Valve 45 is between the pump 38 and reservoir 34 and valve 47 is between port 32 and pump 38.

[29]        **FIG. 2B** shows another manner in which the system 30 may operate. Here, in addition to the reservoir 34 for the fast acting insulin, the system includes another reservoir 35 to contain slow acting insulin. The fast acting insulin is loaded into reservoir 34 through port 36. The slow acting insulin may be loaded into the reservoir 35 through port 37. A valve 40 controls which reservoir is selected as well as the rate in which the selected insulin is delivered. The pump 38, which again may be a fixed stroke piston pump, is used for pumping the selected insulin out to the patient through port 32. Valves 45 and 47 remain on opposite sides of the pump 38.

[30]        **FIG. 3** shows a system 50 for the constant delivery of a fixed amount of insulin per unit time. The insulin delivered over time is fast acting insulin, to meet the basal needs. This insulin is contained in a reservoir 52. An adjunctive port 54 for the injection of fast acting insulin for meals and snacks is also provided.

[31]        The insulin in reservoir 52 is constantly delivered under the control of a mechanical timer pump 56. The timer pump is of the type known in the art to include a winder 58, a wind-up spring 60, and gears 62. The gears 62 drive a worn gear 63 and lead screw 65 to drive a piston 67. The piston 67 thus pressurizes the reservoir 52 to provide a constant flow of insulin to the cannula 66. When a bolus of fast acting insulin is required, such as at meals, the port 54 is used to inject the fast acting insulin into the reservoir 52. When the reservoir is full, further injected insulin will displace a like quantity of insulin from reservoir 52 thereby injecting the same into and out of the cannula 66.

[32]        **FIG. 4** shows a device embodiment 70 with an infusion port for the delivery of a fixed amount of fast



acting insulin per unit time plus the mechanisms for delivery of boluses for meals and snacks. A slide 72 is provided to pressurize the insulin chamber (not shown). A filling membrane 74 permits the chamber to be filled. A trigger 76 may be depressed for each measured bolus of insulin to be delivered.

[33] Referring now to **FIG. 4A**, here it may be seen that the slide 72 performs an additional function after the patient has deployed the cannula 73. More specifically, the needle 71 may be retracted from the cannula 73 to leave the cannula 73 in a fully deployed position for delivering insulin to the patient. To this end, the slide 72 is coupled to the device needle 71 housed in the infusion tube 73. As the slide is slid back in the direction of the arrow 75, the needle 71 is retracted. Eventually, the needle is captured by a needle capture chamber 77. Further backward movement of slide 72 eventually causes the needle head 71a to be caught by a needle ejector 79. Upon further backward movement of slide 72, the needle ejector 79 is acted upon by a ramp 81 that causes the needle head to be displaced in the direction of arrow 79a. Such needle head displacement forces the needle off of the slide 72. At this point, the needle is dropped within the device 70 and cannot be reused. The device is now safe and ready for disposal after it has been fully used.

[34] **FIG. 5** shows a similar device 80 having a dial for the delivery of a user adjusted variable amount of fast acting insulin per unit time. This embodiment is particularly helpful for patients who may need a different amount of basal insulin support at different times during the day. The device 80 further includes mechanisms including a wind-up 84 and trigger 86 for delivery of boluses for meals and snacks. A filling membrane 88 is provided to

facilitate filling of the insulin reservoir (not shown) with the fast acting insulin.

[35] FIG. 6 shows an embodiment of infusion port 90 with an internal reservoir 92 to hold fast acting insulin for constant delivery of a fixed amount per unit time to meet the basal needs of the patient with an adjunctive bolus module 94 to provide separate bolus delivery. The module 94 is mated to the internal reservoir for the needs of meals and snacks. The module 94 may contain enough insulin to last considerably longer than the insulin contained in the reservoir 92. When reservoir 92 is exhausted, the module 94 may simply be mated with another reservoir like that of reservoir 92. Both the constantly fed insulin and the boluses may be delivered through the infusion tube 96. The device may be adhered to the skin with adhesive tape 98.

[36] FIG. 7 shows a disposable insulin infusion device 100 for delivery of a constant flow of insulin utilizing a substantially constant pressure source and a small, flow control orifice. More specifically, the device 100 includes a reservoir 101 including a chamber 102 for containing a fast acting insulin. A wall 104 of the chamber 102 includes a small orifice 106. Another wall 109 of the chamber 102 is moveable under the influence of a spring 110 within an expanding chamber 112. This pressurizes the reservoir 102 to control the flow of insulin through the orifice 106 and into the infusion tube or cannula 108. Hence, the device 100 of FIG. 7 is similar to the device of FIG. 3 in that a reservoir of insulin is pressurized to deliver a constant flow of insulin to a cannula.

[37] FIG. 7A is a schematic representation of the operation of another device 115 similar to the device 100 of FIG. 7. Here it may be seen that the insulin is pressurized by gas within the pressurized reservoir 102. The orifice 106

restricts the flow of insulin by a controlled amount to the infusion tube or cannula 108. In addition, the device 115 includes a bolus pump 114 to pump boluses of fast acting insulin from another reservoir (or the same reservoir) to the infusion tube or cannula 108. Again, the pump 114 may be a fixed stroke piston pump. Also, one-way valves 45 and 47 are positioned on opposite sides of the pump 114 as in previous embodiments.

**[38]**        **FIGS. 8 and 9** show another disposable insulin infusion device 120 embodying the invention. Here, a volume adjustment mechanism is provided to control the volume of insulin delivered with each actuation. This actuation may be manual to adjust boluses for meals and snacks or at specific timed intervals for an adjustable effective basal rate.

**[39]**        More specifically, the device 120 includes a reservoir 122 for containing a fast acting insulin. The device further includes disk 124 having a groove 126 that increases in depth along the circumference of the disk 124. A flexible tube 130 extends from the reservoir 122 around the disk 124 and within the groove 126. A strap 132 extends from a fixed tie point 134 along the tube 130 to an actuator 136. As the disk is rotated in the clockwise direction, an increasing length of the tube 130 will reside in the groove 126. Conversely, counter-clockwise rotation of disk 124 will cause a decreased length of the tube 130 to reside in the groove 126. When the actuator 136 is moved in the direction of arrow 138, the strap 132 acts upon (compresses) the portion of the tube 130 not in the groove 126 to cause a measured bolus of insulin to be delivered to the infusion tube 140. Hence, as more tubing is acted upon by the strap 132, a larger volume bolus is delivered by peristaltic action. The disk 124 may be rotated by a dial, such as the dial 82 of the device 86 of **FIG. 5**.

[40] **FIG. 10** schematically illustrates the operation of another disposable insulin infusion device 150 embodying the invention. Here there are separate reservoirs 152 and 154 for fast acting insulin and slow acting insulin respectively. Each reservoir is associated with its own respective pump. Reservoir 152 is associated with pump 156 and reservoir 154 is associated with pump 158. The pumps 156 and 158 may be fixed stroke piston pumps as shown. The reservoirs 152 and 154 deliver under the pumping action of pumps 156 and 158 their respective insulin to a common port 160 coupled to a cannula 162. Again, one-way valves 145 and 147 are on opposite sides of pump 156, and one-way valves 141 and 143 are on opposite sides of pump 158.

[41] **FIGS. 11 and 12** show a bolus pump 170 embodying the invention. The pump 170 takes the form of a dome pump as illustrated. **FIG. 11** shows the pump 170 prior to being depressed by the patient's finger 172 and **FIG. 12** shows the pump after being depressed and insulin delivery. The pump 170 may be arranged to deliver .5 units of insulin with each actuation and provide tactile feedback with each actuation of the pump.

[42] As may be noted, the pump includes a resilient membrane 174 sealed to a base 176 by a sealing ring 178. The base may be adhered to the patient's skin by adhesive tape (not shown). The pump 170 also includes an intake valve 180 which permits insulin to enter the inner cavity 184 formed by the membrane 174 and base 176 when the membrane returns to the configuration shown in **FIG. 11**. An output valve 182 permits insulin to flow from the cavity 184 when the membrane is depressed as shown in **FIG. 12**. The inner cavity may be arranged to displace a volume of .5 units of insulin for each depression of the pump 170. Hence, if 3 units of insulin are required for a meal, for example, the pump 170

may be depressed 6 times to deliver the desired amount of insulin to the patient.

[43] While particular embodiments of the present invention have been shown and described, modifications may  
5 be made, and it is therefore intended in the appended claims to cover all such changes and modifications which fall within the true spirit and scope of the invention as defined by those claims.

What is claimed is:

1. A disposable infusion device comprising:
  - a base arranged to adhere to a patient's skin;
  - 5 a cannula arranged to extend from the base to beneath the patient's skin to deliver a liquid medicament to the patient;
  - a source arranged to provide the cannula with a liquid medicament;
  - 10 an actuator that actuates the source to provide the liquid medicament to the cannula, the source being arranged to provide, with each actuation, a fixed volume of medicament to the cannula; and
  - a control that sets the fixed volume.
- 15 2. The device of claim 1, wherein the source includes a reservoir that holds the liquid medicament.
3. The device of claim 1, wherein the control comprises a rotatable dial.
4. The device of claim 1, wherein the source includes
  - 20 a pump, wherein the pump has a liquid medicament holding capacity, and wherein the control varies the amount of the pump holding capacity to be pumped to the cannula upon each actuation.
5. The device of claim 4, wherein the pump comprises a
  - 25 compressible tube and wherein the control controls the portion of the compressible tube that is compressed with each actuation.
6. The device of claim 5, wherein the pump further includes a disk having a circumferential surface that
  - 30 supports the compressible tube, a strap coupled to the actuator that compresses a portion of the compressible tube against the disk circumference, wherein the disk has a groove within its circumferential surface, the groove having

a depth that increases along the disk circumference, the groove being arranged to receive the compressible tube, and the disk being rotatable to vary the length of the groove receiving the compressible tube to adjust the portion of the tube that is compressed and the volume of liquid medicament pumped to the cannula with each actuation of the actuator.

7. The device of claim 6, wherein the control comprises a rotatable dial and wherein the disk is arranged to be rotated by the rotatable dial.

8. The device of claim 5, wherein the source further includes a reservoir that holds the liquid medicament and wherein the compressible tube communicates with the reservoir.

9. A disposable infusion device comprising:  
a base arranged to adhere to a patient's skin;  
a cannula arranged to extend from the base to beneath the patient's skin to deliver a liquid medicament to the patient;

a source arranged to provide the cannula with a liquid medicament, the source including a reservoir that holds the liquid medicament and a pump that pumps the liquid medicament from the reservoir to the cannula;

an actuator that actuates the pump to cause the pump to provide the liquid medicament to the cannula, the pump being arranged to provide, with each actuation, a fixed volume of medicament to the cannula; and

a control that varies the fixed volume.

10. The device of claim 9, wherein the control comprises a rotatable dial.

1/10

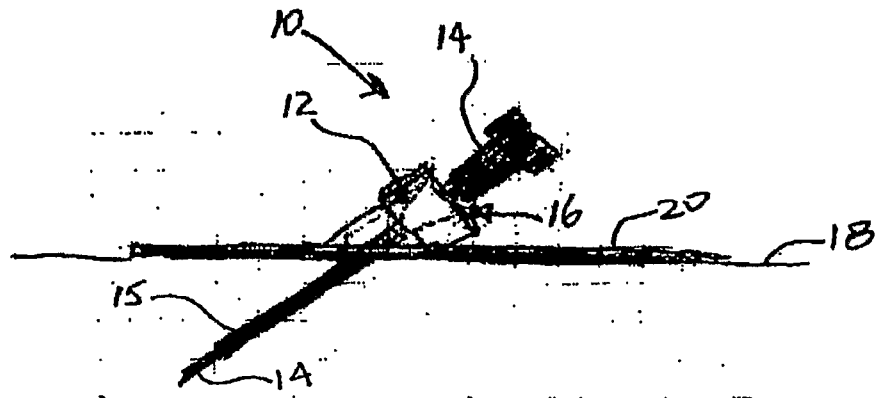


FIG. 1

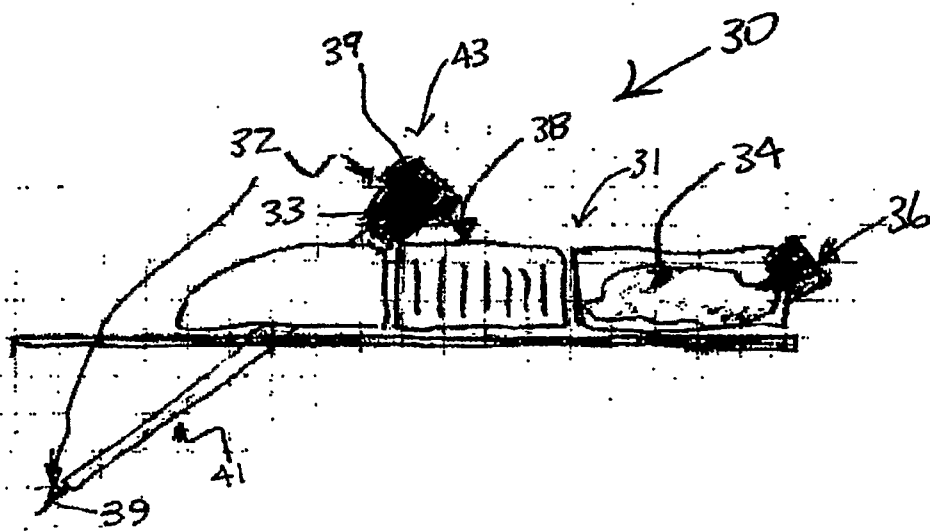
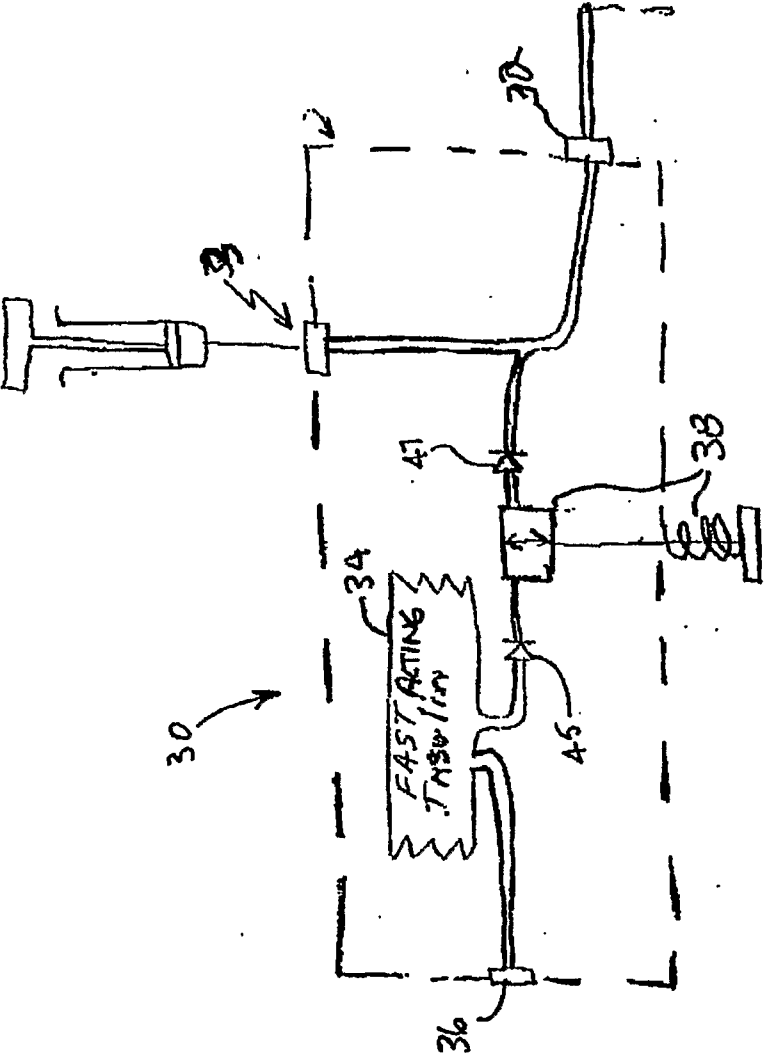


FIG. 2





: FIG. 2A

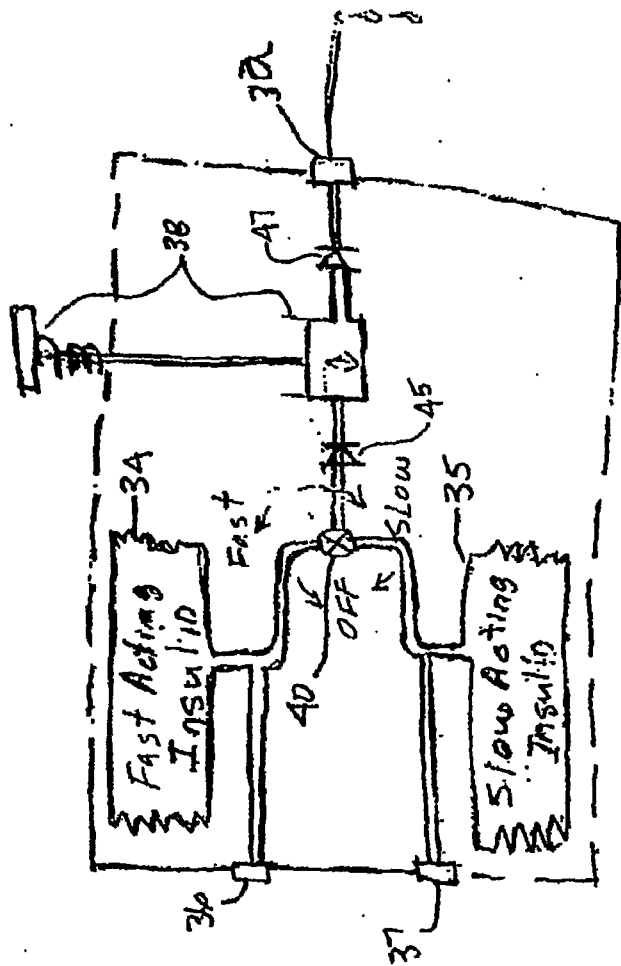
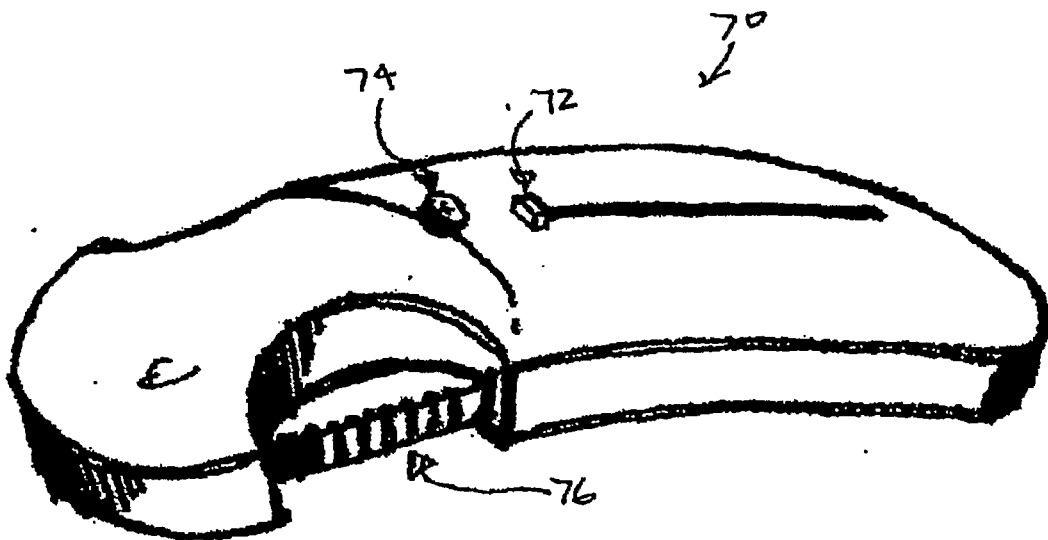
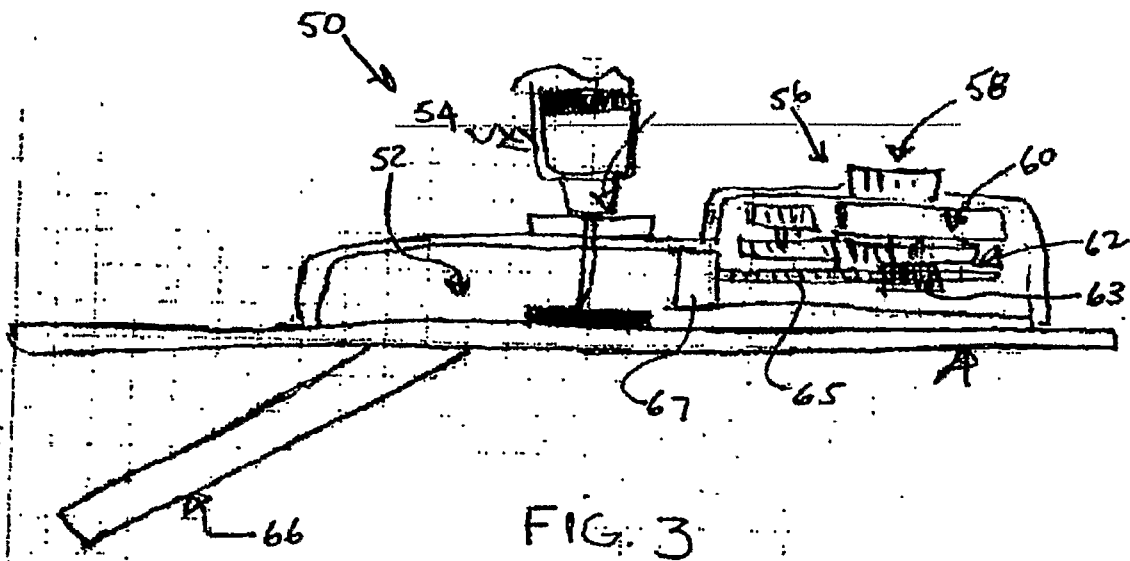
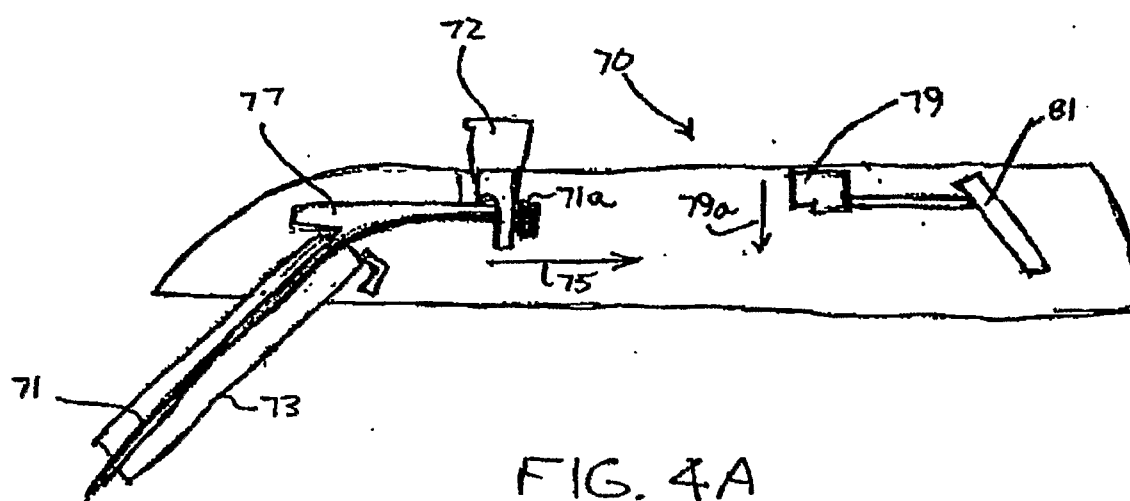


Fig. 2 M

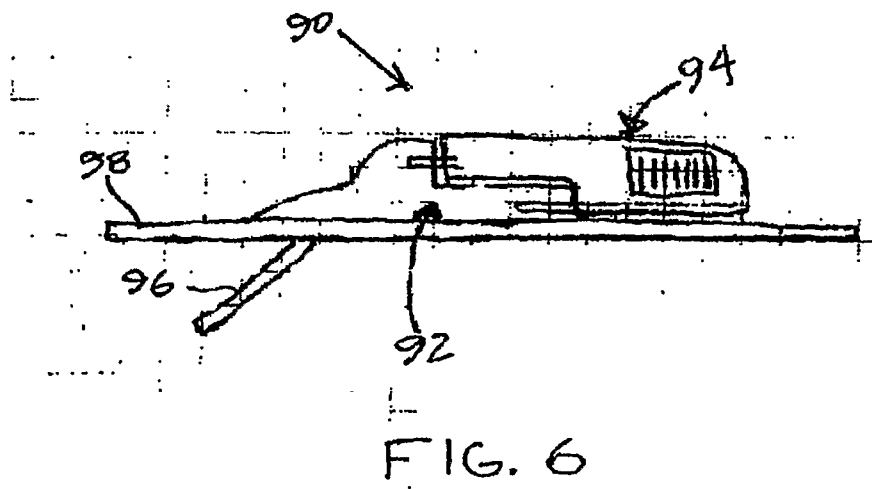
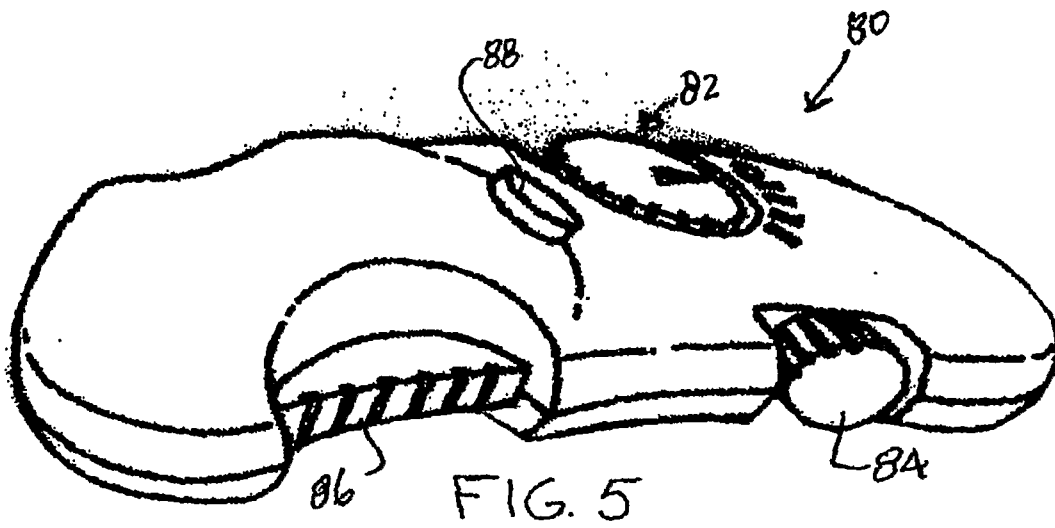
4/10



5/10



6/10



7/10

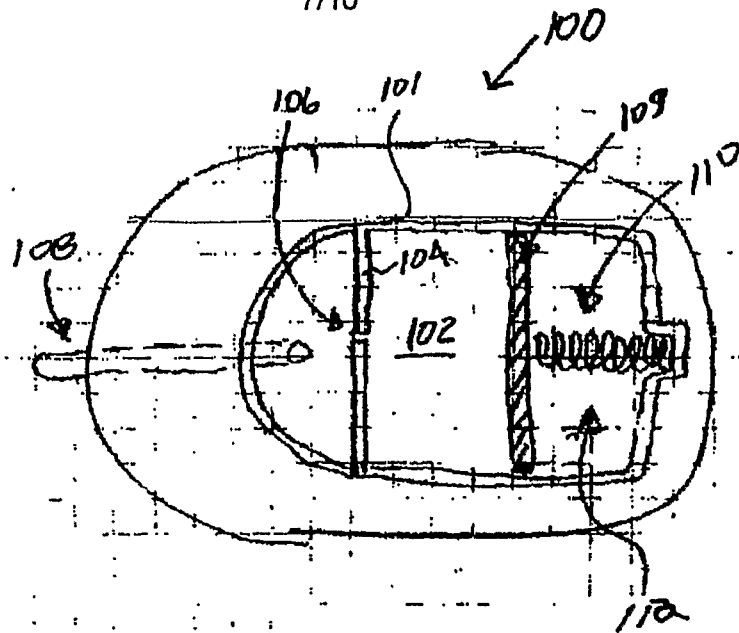


FIG. 7

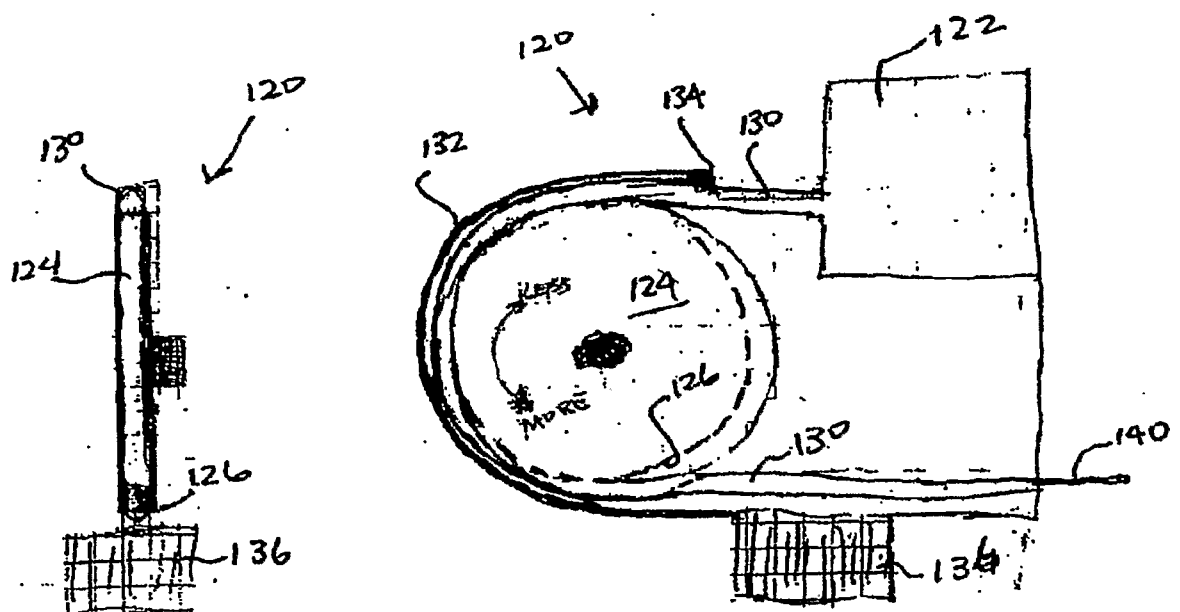


FIG. 9

FIG. 8

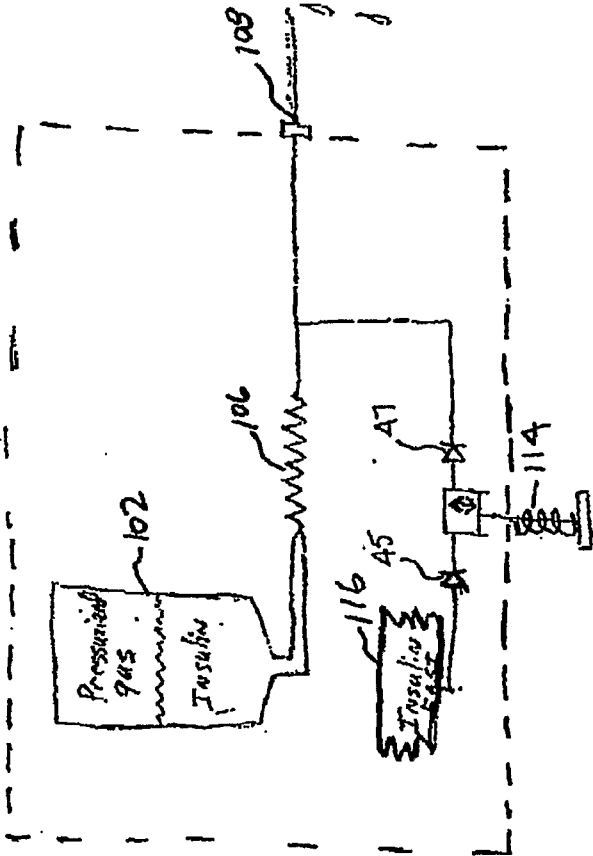


FIG. 7A

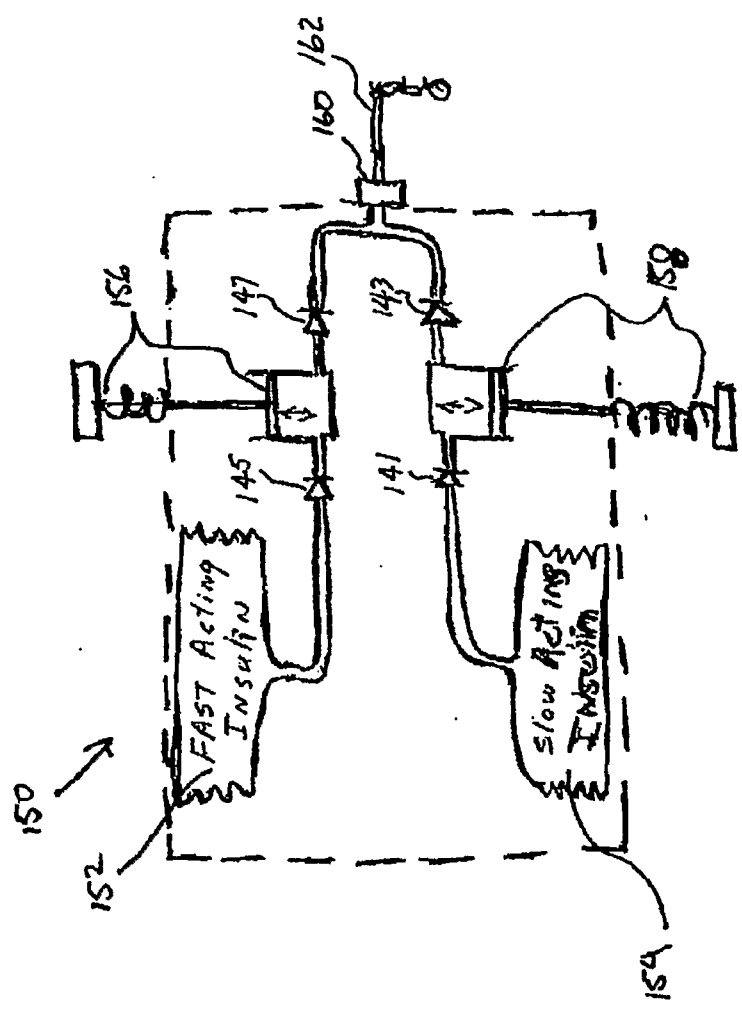


FIG. 10



10/10

