



- (51) International Patent Classification: Not classified
- (21) International Application Number: PCT/IB2012/001835
- (22) International Filing Date: 17 September 2012 (17.09.2012)
- (25) Filing Language: English
- (26) Publication Language: English
- (30) Priority Data: 13/196,136 2 August 2011 (02.08.2011) US
- (71) Applicants (for all designated States except US): **BAXTER HEALTHCARE S.A.** [CH/CH]; Thurgauerstrasse 130 (opfikon), CH-8152 Glattpark (CH). **BAXTER INTERNATIONAL INC.** [US/US]; One Baxter Parkway, Deerfield, IL 60015 (US).
- (72) Inventors; and
- (75) Inventors/Applicants (for US only): **HUNGERFORD, Roger, L.** [US/US]; 711 Park Avenue, Medina, NY 14103 (US). **BUI, Tuan** [US/US]; 4131 Stonegate Ln., Buffalo, NY 14221 (US).

- (74) Agent: **MALISZEWSKI, Chester, Paul;** Simpson & Simpson, PLLC, 5555 Main Street, Williamsville, NY 14221-5406 (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, IS, JP, KE, KG, KM, 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, 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,

[Continued on next page]

(54) Title: INFUSION PUMP WITH INDEPENDENTLY CONTROLLABLE VALVES AND LOW POWER OPERATION AND METHODS THEREOF

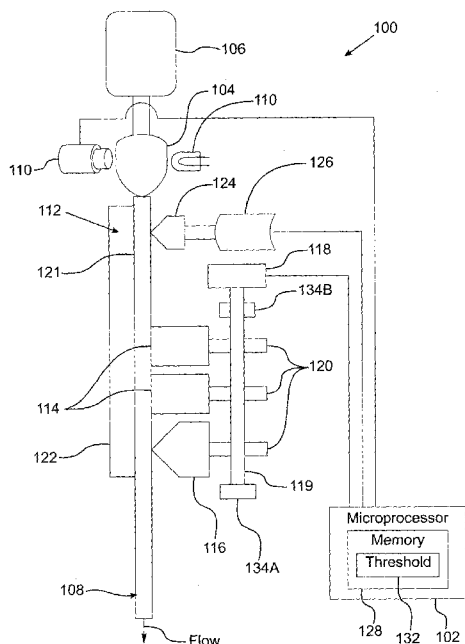


Fig. 1

(57) Abstract: An infusion pump, including: a specially programmed microprocessor; a drip chamber for connection to a source of fluid and to an output tubing; a pumping section including a plurality of fingers and a first actuator, controllable using the microprocessor, for sequentially displacing the plurality of finger to compress a first portion of the output tubing to displace fluid from the drip chamber through the output tubing; an inlet valve disposed between the drip chamber and the pumping section and arranged to compress the output tubing to restrict or block flow through the output tubing; and a second actuator, controllable using the microprocessor, for opening or closing the inlet valve independent of the displacement of the plurality of fingers; or for operating the inlet valve to control a rate of flow of fluid from the drip chamber to the portion of the output tubing.

WO 2013/017949 A2

TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

**Published:**

— without international search report and to be republished upon receipt of that report (Rule 48.2(g))

— with information concerning request for restoration of the right of priority in respect of one or more priority claims; the decision of the receiving Office regarding the request for restoration is pending and will be published separately once available (Rules 26bis.3 and 48.2(j))

INFUSION PUMP WITH INDEPENDENTLY CONTROLLABLE VALVES AND LOW  
POWER OPERATION AND METHODS THEREOF

5

TECHNICAL FIELD

[0001] The present disclosure relates to an infusion pump with an independently controllable inlet valve. The present disclosure also relates to an infusion pump with an inlet valve for controlling flow from a drip chamber. The present disclosure further relates to an infusion pump switchable between gravity-feed operation and active pumping operation.

10

BACKGROUND

[0002] Figure 9 is a schematic representation of prior art peristaltic pump 10. Pump includes drip chamber 12 connected to source of fluid 14, tubing 16 connected to the drip chamber, upstream valve 18 to block or allow fluid flow from the drip chamber to the tubing, and a plurality of fingers 20 to create a moving zone of occlusion along the tubing and to push the fluid downstream past downstream valve 22. The downstream valve is used to block or enable fluid output, for example, blocking fluid output when the upstream valve is opened. The upstream valve, fingers and downstream valves are typically engaged with cam lobes 24 on cam shaft 26 and rotated by motor and associated gears 28. Different shapes for the cam lobes determine the timing of opening and closing of the upstream and downstream valves and peristaltic function of the fingers. In general a pumping cycle for the pump is as follows: a first cam lobe operates the upstream valve to fully open the upstream valve to admit a volume of fluid while a second cam lobe operates the outlet valve to close the downstream valve; the first cam lobe operates to close the inlet valve and the second cam lobe operates to fully open the downstream valve; a set of cam lobes operates on the fingers such that the fingers expel fluid past the downstream valve; the second cam lobe operates on the downstream valve to close the downstream valve; and, the preceding sequence is repeated.

[0003] A typical maximum volume for the tubing between the upstream and downstream valves is 0.160 milliliter. Often the maximum volume is reduced due to the fingers partially compressing the tubing, for example, the maximum volume is reduced to 0.080 milliliter. Since the upstream and downstream valves and fingers are all mounted on a single cam shaft, it is not possible to control the amount of fluid entering the tubing independently from the movements of the fingers. The amount of fluid entering the tubing from the drip chamber is controlled by the opening and closing of the upstream valve, thus is

30

not possible to control the amount of fluid entering the chamber, independently from the movements of the fingers. That is, for each pump cycle, the upstream valve is fully opened and an amount of fluid equal to the maximum volume flows to the tubing from the drip chamber. Therefore, the minimum amount of fluid entering the pumping chamber at each  
5 pumping cycle is 0.080 milliliter in this case.

[0004] Certain infusion regimens require very low flow rates, for example, 0.1 microliter/hour. Pump 10 has difficulty in maintaining flow continuity at such low flow rates.

[0005] Cam shaft 26 is supported proximate each end by respective bearings 30. The bearings hold the shaft in a position that is fixed except for rotation of the shaft. The fixed  
10 position is such that cam lobes 24 are able to operate fingers 14 and to open and close the upstream and downstream valves. In general, the cam lobes are positioned such that one of the upstream or downstream valves is closed at all times. One possible mode of failure for pump 10 is the failure of some or all of bearings 30. For example, the bearings can fail such that the shaft is no longer held in the fixed position noted above and one or both of the ends  
15 of the shaft are further from body. In this case, the cam lobes may be far enough from the fingers and/or the upstream or downstream valves such that the cam lobes are no longer able to close the upstream and/or downstream valves. Thus, for failure of some or all of the bearings, pump 10 is unable to control flow from the drip chamber. For example, in the sequence noted above, when the upstream valve is opened it is presumed that the downstream  
20 valve is closed. However, if the bearing failure results in the cam shaft being unable to close the downstream valve, an uncontrolled flow from the drip chamber results when the upstream valve is opened. An uncontrolled flow condition can be extremely hazardous to a patient receiving an infusion via pump 10, for example, resulting in a dangerously high dosage of a drug being infused with pump 10.

[0006] Figure 10 is a schematic representation of a prior art gravity-feed infusion arrangement. In some clinical applications, fluid delivery by gravity, as shown in Figure 10, is acceptable. For delivery by gravity, gravity force is strong enough to cause fluid to flow from container 32 hung on pole 34 through tubing 36 to the patient. However, the flow rate from container 32 cannot be automatically controlled and it is difficult to accurately control the  
30 flow rate. For example, roller clamp 38 is used to manually control the flow. The clamp is equipped with roller 40 that may be rolled by hand to contract tubing 14 to compress the

tubing to control the flow through the tubing from container 32. Such manual control is not accurate and is very susceptible to human error.

#### SUMMARY

[0007] According to aspects illustrated herein, there is provided an infusion pump, including: a specially programmed microprocessor; a drip chamber for connection to a source of fluid and to an output tubing; a pumping section including a plurality of fingers and a first actuator, controllable using the microprocessor, for sequentially displacing the plurality of finger to compress a first portion of the output tubing to displace fluid from the drip chamber through the output tubing; an inlet valve disposed between the drip chamber and the pumping section and arranged to compress the output tubing to restrict or block flow through the output tubing; and a second actuator, controllable using the microprocessor, for opening or closing the inlet valve independent of the displacement of the plurality of fingers; or for operating the inlet valve to control a rate of flow of fluid from the drip chamber to the portion of the output tubing.

[0008] According to aspects illustrated herein, there is provided an infusion pump, including: a specially programmed microprocessor; a drip chamber for connection to a source of fluid and to an output tubing; a flow sensor for measuring flow; a pumping section including a plurality of fingers, an outlet valve, and a first actuator for sequentially displacing the plurality of finger to displace fluid through the output tubing; an inlet valve disposed between the pumping section and the drip chamber; and a second actuator. For detection, by the flow sensor, of flow above a predetermined level, the microprocessor is for closing the outlet valve independently of the inlet valve using the first actuator, and closing the inlet valve independently of the outlet valve using the second actuator.

[0009] According to aspects illustrated herein, there is provided an infusion pump, including: a specially programmed microprocessor; a drip chamber for connection to a source of fluid and to an output tubing; a flow sensor; a pumping section including a plurality of fingers, an outlet valve, and a first actuator for controlling operation of the plurality of fingers and the outlet valve; an inlet valve disposed between the pumping section and the drip chamber; and a second actuator for operating the inlet valve. In a gravity-feed mode the microprocessor: controls the first actuator to maintain the plurality of fingers in respective fixed positions and to at least partially open the outlet valve such that a passageway is formed in the output tubing from the drip chamber past the outlet valve; and controls the second

actuator, using data from the flow sensor including flow measured by the flow sensor, to operate the inlet valve to establish flow from the drip chamber to the output tubing at a desired flow rate. In an active pumping mode, the microprocessor: controls the second actuator to open and close the inlet valve; and controls the first actuator to operate the plurality of fingers to displace fluid through the output tubing at the desired flow rate.

[0010] According to aspects illustrated herein, there is provided an infusion pump, including: a specially programmed microprocessor; a drip chamber for connection to a source of fluid and to an output tubing; a flow sensor for measuring flow through the drip chamber from the source of fluid; an inlet valve disposed after the drip chamber; and an actuator for operating the inlet valve. In a gravity-feed mode the microprocessor: controls the actuator, using data from the flow sensor including flow measured by the flow sensor, to operate the inlet valve to establish flow from the drip chamber to the output tubing at a desired flow rate.

[0011] According to aspects illustrated herein, there is provided an infusion pump, including: a specially programmed microprocessor; a drip chamber for connection to a source of fluid and to an output tubing; a flow sensor for measuring flow through the drip chamber from the source of fluid; an element to force fluid out of the source of fluid; an inlet valve disposed after the drip chamber; and an actuator for operating the inlet valve. In a gravity-feed mode the microprocessor: controls the actuator, using data from the flow sensor including flow measured by the flow sensor, to operate the inlet valve to establish flow from the drip chamber to the output tubing at a desired flow rate.

[0012] According to aspects illustrated herein, there is provided a method for infusing a fluid using an infusion pump including a specially programmed microprocessor; a drip chamber for connection to a source of fluid and to an output tubing; a pumping section including a plurality of fingers and a first actuator; an inlet valve disposed between the drip chamber and the pumping section; and a second actuator, controllable using the microprocessor, including: controlling the first actuator, using the microprocessor, to sequentially displace the plurality of finger to compress a first portion of the output tubing to displace fluid from the drip chamber through the output tubing; and controlling the second actuator, using the microprocessor, to open or close the inlet valve independent of the displacement of the plurality of fingers, or to operate the inlet valve to control a rate of flow of fluid from the drip chamber to the first portion of the output tubing.

[0013] According to aspects illustrated herein, there is provided a method for infusing a fluid using an infusion pump including a specially programmed microprocessor; a drip chamber for connection to a source of fluid and to an output tubing; a flow sensor; a pumping section including a plurality of fingers, an outlet valve, and a first actuator; an inlet valve disposed between the drip chamber and the pumping section; and a second actuator, controllable using the microprocessor, including: measuring, using the flow sensor, flow through the drip chamber from the source of fluid; sequentially displacing, using the specially programmed microprocessor and the first actuator, the plurality of finger to displace fluid through the output tubing; and for detection, by the flow sensor, of flow above a predetermined level: closing, using the specially programmed microprocessor and the first actuator, the outlet valve independently of the inlet valve; or closing, using the specially programmed microprocessor and the second actuator, the inlet valve independently of the outlet valve.

[0014] According to aspects illustrated herein, there is provided a method for infusing a fluid using an infusion pump including a specially programmed microprocessor; a drip chamber for connection to a source of fluid and to an output tubing; a flow sensor; a pumping section including a plurality of fingers, an outlet valve, and a first actuator for controlling operation of the plurality of fingers; an inlet valve disposed upstream of the pumping section; and a second actuator for operating the inlet valve, including: measuring flow through the drip chamber from the source of fluid using the flow sensor. In a gravity-feed mode, the method includes: controlling, using the specially programmed microprocessor, the first actuator to maintain the plurality of fingers in respective fixed positions and to at least partially open the outlet valve such that a passageway is formed in the output tubing from the drip chamber past the outlet valve; and controlling, using the specially programmed microprocessor and data from the flow sensor including flow measured by the flow sensor, the second actuator to operate the inlet valve to establish flow from the drip chamber to the output tubing at a desired flow rate. In an active pumping mode the method includes: controlling, using the specially programmed microprocessor, the second actuator to open and close the inlet valve; and controlling, using the specially programmed microprocessor, the first actuator to operate the plurality of fingers to displace fluid through the output tubing at the desired flow rate.

[0015] According to aspects illustrated herein, there is provided a method for infusing a fluid using an infusion pump including a specially programmed microprocessor; a drip chamber for connection to a source of fluid and to an output tubing; a flow sensor for measuring flow; an inlet valve disposed after the drip chamber; and an actuator for operating the inlet valve. The method includes: accepting, using the microprocessor, data from the flow sensor including flow measured by the flow sensor; and in a gravity-feed mode, controlling, using the microprocessor and the data, the actuator to operate the inlet valve to establish flow from the drip chamber to the output tubing at a desired flow rate.

[0016] According to aspects illustrated herein, there is provided a method for infusing a fluid using an infusion pump including a specially programmed microprocessor; a drip chamber for connection to a source of fluid and to an output tubing; a flow sensor for measuring flow from the source of fluid; an element for forcing fluid from the source of fluid; an inlet valve disposed after the drip chamber; and an actuator for operating the inlet valve. The method includes: accepting, using the microprocessor, data from the flow sensor including flow measured by the flow sensor; and in a gravity-feed mode, controlling, the microprocessor and the data, the actuator, the flow sensor to operate the inlet valve to establish flow from the drip chamber to the output tubing at a desired flow rate.

#### BRIEF DESCRIPTION OF THE DRAWINGS

[0017] Various embodiments are disclosed, by way of example only, with reference to the accompanying schematic drawings in which corresponding reference symbols indicate corresponding parts, in which:

Figure 1 is a schematic representation of an infusion pump with independent control of inlet and outlet valves;

Figures 2A through 2G are schematic diagrams illustrating a pumping cycle for the pump shown in Figure 1;

Figure 3 is a graph showing flow pulses for the pump shown in Figure 1;

Figure 4 is a table showing example flow pulses and fluid volumes at a flow rate of 0.1 microliter/hour;

Figure 5 is a pictorial representation of a portion of the pump shown in Figure 1 showing a cam shaft bearing;

Figure 6 is a perspective view of an exemplary embodiment of an infusion pump with independent control of inlet and outlet valves and low power operation;



Figure 7 is a detail of a portion of the pump shown in Figure 6;  
Figure 8 is a schematic representation of an infusion pump for use in gravity-feed mode;  
Figure 9 is a schematic representation of a prior art peristaltic pump; and,  
Figure 10 is a schematic representation of a prior art gravity-feed infusion arrangement.

5

## DETAILED DESCRIPTION

[0018] At the outset, it should be appreciated that like drawing numbers on different drawing views identify identical, or functionally similar, structural elements of the disclosure. It is to be understood that the disclosure as claimed is not limited to the disclosed aspects.

[0019] Furthermore, it is understood that this disclosure is not limited to the particular methodology, materials and modifications described and as such may, of course, vary. It is also understood that the terminology used herein is for the purpose of describing particular aspects only, and is not intended to limit the scope of the present disclosure.

[0020] Unless defined otherwise, all technical and scientific terms used herein have the same meaning as commonly understood to one of ordinary skill in the art to which this disclosure belongs. It should be understood that any methods, devices or materials similar or equivalent to those described herein can be used in the practice or testing of the disclosure.

[0021] Figure 1 is a schematic representation of infusion pump **100** with independent control of inlet and outlet valves. Pump **100** includes specially programmed microprocessor **102**, drip chamber **104** for connection to source **106** of fluid and to output tubing **108**. The pump includes flow sensor, or flow meter, **110** for measuring flow through the drip chamber, and pumping section **112** including a plurality of fingers **114**, outlet valve, or downstream valve, **116**, and actuator **118**. The pumping section is not limited to a particular number of fingers **114**. Actuator **118** is controllable using the microprocessor, to rotate cam shaft **119** and cam lobes **120** such that the cam lobes contact the plurality of fingers to sequentially displace the plurality of finger to compress portion **121** of the output tubing against a support structure, such as supporting platen **122**, to displace fluid from the drip chamber through the output tubing and past the outlet valve. Portion **121** also can be considered the portion of the tubing between the inlet and outlet valves. Shaft **119** and cam lobes **120** can displace the fingers in any manner known in the art. Rotation of shaft **119** and cam lobes **120** also controls opening and closing of valve **116**.

[0022] The pump also includes inlet valve, or upstream valve, **124** disposed between the drip chamber and the pumping section, and actuator **126**, controllable using the

microprocessor. Actuator **126** is arranged to operate the inlet valve, for example, open or close the inlet valve, or position the inlet valve between open and closed positions, independent of the displacement of the plurality of fingers; or to operate the inlet valve, for example, to position the inlet valve between an open or closed position, to control a rate of flow of fluid from the drip chamber to the output tubing, as further described below.

[0023] Figures 2A through 2G are schematic diagrams illustrating a pumping cycle for pump **100** shown in Figure 1. The following should be viewed in light of Figures 1 through 2G. Pump **100** enables execution of extremely low continuous flow rates. For example, pump **100** is compliant with the ECRI Institute's Excellent rating for flow continuity at low flow rates, which requires that a period of no flow in an infusion regimen to be less than 20 seconds. In an example embodiment, the specially programmed microprocessor is for implementing the following example infusion scheme, which can be a low flow rate regimen. As shown in Figure 2A, at the start of a pump cycle for the infusion regimen, the microprocessor controls actuator **126** to close the inlet valve and controls actuator **118** to close the outlet valve and to move the fingers for maximum compression of the tubing by the fingers. As shown in Figure 2B, actuator **118** retracts the fingers, while the valves remain closed, to create a vacuum in portion **121** of the output tubing, that is, in the passageway formed by portion **121**.

[0024] As shown in Figure 2C, the microprocessor controls actuator **126** to displace the inlet valve to flow a specified volume of fluid, as measured by sensor **110**, from the drip chamber to portion **121** of the output tubing. By specified volume, we mean a particular volume that is inputted to the microprocessor, stored in memory **128** of the microprocessor, or calculated by the microprocessor. In general, the specified volume is associated with a desired fluid flow to achieve the desired outcome of the infusion scheme. Sensor **110** monitors flow through the drip chamber to portion **121** of the tubing. In an example embodiment, the inlet valve is continuously positionable between a fully closed position and fully open position. For example, a position of the inlet valve is not limited to a series of stepped positions, which would be the case if actuator **126** were a stepper motor. Such continuous positioning greatly increases the accuracy and range of flow rates, from the drip chamber to portion **121**, executable using the inlet valve.

[0025] As shown in Figure 2D, after the specified volume of fluid has flowed through the drip chamber to portion **121** of the tubing, for example, as measured by sensor **110**, the

microprocessor controls actuator **126** to close the inlet valve. As shown in Figure 2E, the microprocessor then controls actuator **118** to operate the outlet valve, for example, fully opening the outlet valve. As shown in Figure 2F, the microprocessor controls actuator **118** to displace the plurality of fingers to expel the specified volume of fluid past the outlet valve within a first specified time period. By specified time period, we mean a particular time period that is inputted to the microprocessor, stored in memory by the microprocessor, or calculated by the microprocessor. In general, the specified time period is associated with a desired outcome of the infusion scheme or required operation of the pump. For example, the specified time period can be associated with the ECRI Institute's Excellent rating for flow continuity at low flow rates. As is understood in the art, a time period for infusing the specified volume is usually associated with the specified volume, this time period can be the first specified time period noted above. At the end of the first specified time period, as shown in Figure 2G, the microprocessor controls actuator **118** to close the outlet valve, completing the pumping cycle.

15 [0026] As noted below, the cycle described above is typically repeated at a particular frequency to attain a desired flow rate over a longer time period.

[0027] In an example embodiment, tubing **108** is compressed between the fingers and the supporting platen so that the tubing is partially compressed, reducing the maximum amount noted above, which in turn reduce the volume of fluid entering portion **121** each time the inlet valve is opened. In an example embodiment, tubing **108** has an inner diameter of about 0.1" length L for portion **122** of the tubing (between the inlet and outlet valves) is around 1.25." This configuration results in a maximum volume of about 0.160 milliliter for portion **121**. In the example that follows, the maximum volume is reduced to about 0.080 milliliter.

25 [0028] Figure 3 is a graph showing example flow pulses for pump **100** shown in Figure 1.

[0029] Figure 4 is a table showing example flow pulses and fluid volumes at a flow rate of 0.1 microliter/hour. The following should be viewed in light of Figures 1 through 4. The unit of measurement for the x axis of the graph is second, and the unit of measure for the y axis is microliter of fluid from source **106**. The ECRI's Excellent ranking for flow continuity at low flow rate requires that the period of no flow is less than 20 seconds. For example, the time period between Figures 2A and 2F must be less than 20 seconds. The

microprocessor controls actuator **126** to displace the inlet valve to generate flow pulse **130**, that is, to flow a specified volume of fluid from the drip chamber to portion **121** of the output tubing. Flow pulses **130A** and **B** are shown in Figure 3. As an example, such pulses are generated in the portion of a pumping cycle shown in Figure 2C. In Figure 3, the pulses are sized and spaced to implement a flow of 0.1 microliter/hr. It should be understood that other flow pulses are possible, for example, as shown in Figure 4.

[0030] As shown in Figures 3 and 4, a variety of pulses **128** can be generated to implement the pumping cycle shown in Figures 2A through 2G. For example, pulse **130A** is about two second long and the subsequent expelling of fluid from portion **121** is done in about 18 seconds. As another example, pulse **130B** is about 10 seconds long and the subsequent expelling of fluid from portion **121** is done in about 10 seconds. Thus, to generate a rate of 0.1 microliter/hr with pulses **130A**, pump **100** delivers pulses **130A** (Figures 2F and 2G) about **164** times per hour, and each pulse delivers about 0.61 microliter of fluid. To generate a rate of 0.1 microliter/hr with pulses **130B**, pump **100** delivers pulses **130B** (Figures 2F and 2G) about **120** times per hour, and each pulse delivers about 0.83 microliter of fluid. It should be understood that combinations of different pulse widths, for example, combinations of pulses shown in Figure 4, can be used during an infusion regimen. Other combinations of number of pulses and flow pulses are also possible to achieve the desirable flow rate and a no-flow period of less than 20 seconds. For example, for flow rate of 0.1 milliliter/hr or 100 microliter/hr, it is possible to have 10 flow pulses per hour, each of which has 10 microliter of fluid and delivered into the section 121 in less than 20 seconds. The fluid then can be expelled in 5 minutes and 40 seconds.

[0031] To provide better flow continuity at low flow rates, the amount of fluid entering portion **121** of the tubing is made smaller than the total volume available in portion **121**. For example, when the total volume available is 0.080 milliliter, the amount of fluid entering portion **121**, for example, pulses **130**, is much less than the available volume, as shown in Figure 4. Flowing such relatively small amount of fluid can only be done if flow into portion **121** is controlled separately from the movement of the fingers in the pumping chamber, as described above and shown in Figures 2A through 2G. Shaft **119** revolves once during the pumping cycle shown in Figures 2A-2G. For example, to implement an infusion regimen of 0.1 microliter/hour, shaft **119** revolves once about every 6 minutes.

[0032] Using pulses 130A and with a maximum volume available for portion 121 equal to 0.80 milliliter, the amount of fluid entering portion 121 in each pumping cycle is no more than 0.7 percent of the maximum volume for portion 121. Using pulses 130A and with a maximum volume available for portion 121 equal to 0.80 milliliter,, the period of no flow for pulses 128A is about 2 seconds or about 10 percent of the maximum no flow period of less than 20 seconds needed for compliance with the ECRI's Excellent ranking for flow continuity at low flow rate. It should be understood that pump 100 is not limited to this ratio of fluid entering portion 121 and maximum volume of portion 121, and that other ratios are possible, for example, as shown in Figure 4

[0033] In contrast, as noted *supra*, since for a typical prior art peristaltic pump, valves and fingers are all mounted on a single cam shaft, it is not possible to control the amount of fluid entering the chamber independently from the movements of the fingers. Therefore, with a reduced volume of 0.080 milliliter for the output tubing, to generate 0.1 microliter/hr, the output tubing for the prior art pump has to be pumped out in one cycle over a period of 48 min with the attendant problems noted above.

[0034] A pumping sequence for an infusion scheme, such as shown in Figures 2A through 2G, can be implemented in a periodic sequence, for example, repeating the pumping sequence shown in Figures 2A through 2G, to control flow through the drip chamber. For example, a particular flow rate, such as 0.1 microliter/hr, can be executed by repeating the pumping sequence shown in Figures 2A through 2G.

[0035] Flow sensor 110 in conjunction with actuators 118 and 126 enable redundant shut-off of flow from the drip chamber, for example, in the event of a high flow event. In one embodiment, threshold value 132 for flow detected by sensor 110 is stored in memory element 128. This value can be fixed or can be dependent upon the flow rate for a particular infusion regimen being implemented by the pump, for example, value 132 could be a percentage of the flow rate. The microprocessor uses value 132 for determining if a high flow event is occurring and responds accordingly. For example, for detection, by the flow sensor, of flow above a predetermined level, such as value 132, the microprocessor is for using actuator 118 to close the outlet valve independently of the inlet valve and/or using actuator 126 to close the inlet valve independently of the outlet valve. Thus, even if one or the other of actuators 118 or 126 fails, flow from the drip chamber and portion 121 can be blocked. Value

132 can be received by the microprocessor as input or can be calculated by the microprocessor.

[0036] Figure 5 is a pictorial representation of pump 100 shown in Figure 1 showing cam shaft bearing 134. The following should be viewed in light of Figures 1 and 5. Cam shaft 119 is supported proximate each end by respective bearings, for example, bearing 134 at the downstream end of the shaft. The bearings hold the shaft in a position that is fixed except for rotation of the shaft. That is, the bearing fix the shaft while enabling rotation of the shaft, for example, to position cam lobes 120A and 120B to operate outlet valve 116 and fingers 114, respectively.

[0037] As noted *supra*, one possible mode of failure for a pump with a cam shaft is the failure of the bearings for the cam shaft. For example, as shown in Figure 5, if bearing 134 fails, end 136 can shift in direction D, away from the main portion of the pump. One result of the shifting of end 136 is that cam lobes 120 may be displaced far enough from the fingers and the outlet valve such that the cam lobes are no longer able to close the outlet valve or the fingers are no longer able to fully compress portion 121 of the tubing. However, since valve 124 is controlled separately from cam shaft 119 via actuator 126, valve 124 can be actuated to block the tubing regardless of the status of the cam shaft. Thus, even though failure of one or both of the bearings may render fingers 114 and valve 116 unable to control or block flow through the tubing, independently actuated valve 124 is still able to provide flow blockage to prevent a hazardous uncontrolled flow condition.

[0038] Pump 100 also provides energy savings. In an example embodiment, pump 100 is switchable between a gravity-feed mode and an active pumping mode. For example, the default mode of operation is the gravity-feed mode and pump 100 operates in this mode unless inadequate flow is detected as described below. The microprocessor operates actuator 118 to maintain the plurality of fingers in respective fixed positions and to open the outlet valve such that a passageway is formed in the output tubing between the inlet and outlet valves. For example, the fingers are displaced so as to compress the tubing to a certain specified extent (partially closing the passageway through portion 121) or are displaced such that the passageway is fully open. The actual location of the fingers and the resultant volume for the passageway can be determined according to the infusion regimen being implemented by pump 100.

[0039] The microprocessor controls actuator **126**, for example, using feed back from the flow sensor, to operate the inlet valve to establish flow from the drip chamber to the output tubing at a desired flow rate. By desire flow rate, we mean a particular flow rate that is inputted to the microprocessor, stored in memory **128** of the microprocessor, or calculated by the microprocessor. In general, the desired flow rate is associated with a desired outcome of the infusion scheme. As an example, for a particular drug being infused via the infusion scheme, a particular flow rate is needed to attain a desired therapeutic affect.

[0040] In an example embodiment, as long as gravity force is sufficient to provide the desire flow rate, the gravity-feed mode is used. For example, as long operation of the input valve is able to provide the desired flow rate, the pump operates in the gravity-feed mode. If operation in the gravity-feed mode is not able to provide the desired flow rate, the pump automatically switches to the active pumping mode. For example, if the inlet valve is fully open and the flow sensor measures flow less than a threshold related to the desired flow rate, for example, a specified percentage of the flow rate, the microprocessor switches to the active pumping mode. In general, the active pumping mode includes coordinated operation of the inlet and outlet valves and the fingers to introduce fluid into portion **121** and expel the fluid past the outlet valve. The pumping cycle shown in Figures 2A through 2G is an example, of operation in the active pumping mode. It should be understood that the active pumping mode is not limited to the pumping cycle shown in Figures 2A through 2G.

[0041] Figure 6 is a perspective view of an exemplary embodiment of infusion pump **100** with independent control of inlet and outlet valves and low power operation.

[0042] Figure 7 is a detail of a portion of pump **100** shown in Figure 6. The following should be viewed in light of Figures 6 and 7. Figures 6 and 7 depict an exemplary construction of at least portions of a pump with independent control of inlet and outlet valves and other functions described *supra*. It should be understood that a pump with independent control of inlet and outlet valves and other functions described *supra* is not limited to the configuration shown in Figures 6 and 7.

[0043] Figure 8 is a schematic representation of infusion pump **200** for use in gravity-feed mode. Pump **200** includes specially programmed microprocessor **102** and drip chamber **104** for connection to source **106** of fluid and to output tubing **108**. In one embodiment, the source of fluid is a medication bag. In one embodiment, element **107** is used to force fluid from source **106**, for example, to squeeze a medication bag, to force fluid out of source **106**

and to the drip chamber. For example, in the event that gravitational force on the fluid in source **106** is not sufficient to overcome backpressure in tubing **108**, for example, due to a patient to whom the tubing is connected, element **107** can be used to provide the extra force needed to overcome the back pressure. Any device known in the art can be used for element

5 **107**.

[0044] The pump includes flow sensor, or flow meter, **110** for measuring flow through the drip chamber, and inlet valve **124** disposed downstream of the drip chamber. Actuator **126** is controllable using the microprocessor to regulate flow through tubing **108**. Actuator **126** is arranged to operate the inlet valve, for example, open or close the inlet valve,

10 or position the inlet valve between open and closed positions, to control a rate of flow of fluid from the drip chamber to the output tubing. Thus, pump **200** is configured to operate in gravity-feed mode, for example, pump **200** does not include a pumping section, such as pumping section **112** for pump **100** in Figure 1, to actively transport fluid from source **106** through tubing **108**. In the gravity-feed mode, the flow can be via gravitation force alone or

15 can be via a combination of gravitation force and force applied by element **107**.

[0045] In gravity-feed mode, the microprocessor is arranged to control the actuator, using data from the flow sensor including flow measured by the flow sensor, to operate the inlet valve to establish flow from the drip chamber to the output tubing at a desired flow rate. That is, the microprocessor accepts data **202** from the flow sensor including flow measured

20 by the flow sensor and controls, using the data, the actuator to operate the inlet valve to establish flow from the drip chamber through the output tubing at a desired flow rate. The discussion for pump **100** regarding a desired flow rate is applicable to Figure 8 and pump **200**. Pump **200** is arranged to occlude the tubing, via valve **124**, in response to emergency or alarm conditions.

[0046] Although pumps **100** and **200** have been shown with a particular configuration of components, it should be understood that pumps **100** and **200** are not limited to the particular configuration of components shown and that other configurations of components are possible.

[0047] It will be appreciated that various of the above-disclosed and other features and functions, or alternatives thereof, may be desirably combined into many other different systems or applications. Various presently unforeseen or unanticipated alternatives,

30



modifications, variations, or improvements therein may be subsequently made by those skilled in the art which are also intended to be encompassed by the following claims.

## CLAIMS

## What We Claim Is:

- 5 1. An infusion pump, comprising:  
a specially programmed microprocessor;  
a drip chamber for connection to a source of fluid and to an output tubing;  
a pumping section including a plurality of fingers and a first actuator, controllable using the  
microprocessor, for sequentially displacing the plurality of finger to compress a first portion  
10 of the output tubing to displace fluid from the drip chamber through the output tubing;  
an inlet valve disposed between the drip chamber and the pumping section and arranged to  
compress the output tubing to restrict or block flow through the output tubing; and,  
a second actuator, controllable using the microprocessor, for:  
opening or closing the inlet valve independent of the displacement of the plurality of fingers;  
15 or,  
operating the inlet valve to control a rate of flow of fluid from the drip chamber to the portion  
of the output tubing.
2. The infusion pump of Claim 1, wherein:  
20 the pumping section includes an outlet valve;  
the output tubing includes a second portion between the inlet and outlet valves; and,  
the specially programmed microprocessor is for:  
controlling the second actuator to:  
operate the inlet valve to enable flow of a specified volume of fluid from the drip chamber to  
25 the second portion of the output tubing while controlling the first actuator to close the outlet  
valve and maintain the plurality of fingers in respective fixed positions; and,  
close the inlet valve after the specified volume of fluid has flowed to the second portion of  
the output tubing; and,  
controlling the first actuator to:  
30 fully open the outlet valve and displace the plurality of fingers to expel the specified volume  
of fluid past the outlet valve within a first specified time period; and,  
close the outlet valve at the end of the first specified time period.

3. The infusion pump of Claim 3, further comprising a flow sensor for measuring flow from the source of fluid, wherein:

the pumping section includes an outlet valve; and,

5 the microprocessor is for:

storing or calculating a desired flow rate;

receiving data from the flow sensor including measurement of flow from the source of fluid;

and,

operating the inlet valve such that the measurement of flow matches the desired flow rate.

10

4. The infusion pump of Claim 1, further comprising a flow sensor for measuring flow from the source of fluid, wherein:

the pumping section includes an outlet valve; and,

for detection, by the flow sensor, of flow above a predetermined level, the microprocessor is

15 for:

closing the outlet valve independently of the inlet valve using the first actuator; or,

closing the inlet valve independently of the outlet valve using the second actuator.

5. The infusion pump of Claim 1, further comprising a flow sensor for measuring flow from the source of fluid, wherein:

20

the pumping section includes an outlet valve;

in a gravity-feed mode the microprocessor:

controls the first actuator to maintain the plurality of fingers in respective fixed positions and

to at least partially open the outlet valve such that a passageway is formed in the output

25

tubing between the inlet and outlet valves; and,

controls the second actuator, using data from the flow sensor including flow measured by the

flow sensor, to operate the inlet valve to establish flow from the drip chamber to the output

tubing at a desired flow rate; and,

in an active pumping mode, the microprocessor:

30

controls the second actuator to open and close the inlet valve; and,

controls the first actuator to operate the plurality of fingers to displace fluid through the output tubing at the desired flow rate.

6. An infusion pump, comprising:  
a specially programmed microprocessor;  
a drip chamber for connection to a source of fluid and to an output tubing;
- 5 a flow sensor for measuring flow;  
a pumping section including a plurality of fingers, an outlet valve, and a first actuator for sequentially displacing the plurality of finger to displace fluid through the output tubing;  
an inlet valve disposed between the pumping section and the drip chamber; and,  
a second actuator, wherein for detection, by the flow sensor, of flow above a predetermined
- 10 level, the microprocessor is for:  
closing the outlet valve independently of the inlet valve using the first actuator; or,  
closing the inlet valve independently of the outlet valve using the second actuator.
7. The infusion pump of Claim 6 further comprising:
- 15 a cam shaft in a position fixed except for rotation; and,  
a cam lobe disposed on the cam shaft and engageable with the outlet valve to close the outlet valve, wherein:  
the cam shaft is rotatable by the first actuator; and,  
the flow above the predetermined level is caused by the cam shaft shifting from the position
- 20 such that the cam lobe cannot close the outlet valve.
8. An infusion pump, comprising:  
a specially programmed microprocessor;  
a drip chamber for connection to a source of fluid and to an output tubing;
- 25 a flow sensor for measuring flow;  
a pumping section including a plurality of fingers, an outlet valve, and a first actuator for controlling operation of the plurality of fingers and the outlet valve;  
an inlet valve disposed between the pumping section and the drip chamber; and,  
a second actuator for operating the inlet valve, wherein:
- 30 in a gravity-feed mode the microprocessor:

controls the first actuator to maintain the plurality of fingers in respective fixed positions and to at least partially open the outlet valve such that a passageway is formed in the output tubing from the drip chamber past the outlet valve; and,

controls the second actuator, using data from the flow sensor including flow measured by the flow sensor, to operate the inlet valve to establish flow from the drip chamber to the output tubing at a desired flow rate; and,

in an active pumping mode, the microprocessor:

controls the second actuator to open and close the inlet valve; and,

controls the first actuator to operate the plurality of fingers to displace fluid through the output tubing at the desired flow rate.

9. The infusion pump of Claim 8 wherein the second actuator is for operating the inlet valve such that the inlet valve is continuously positionable between a fully open position and a fully closed position.

10. The infusion pump of Claim 8, wherein:

when in the gravity-feed mode:

the inlet valve is fully opened or opened to within a specified portion of a fully opened position for the inlet valve; and,

the measured flow through the drip chamber from the source of fluid is less than the desired flow rate;

the microprocessor automatically switches operation of the infusion pump to the active pumping mode.

11. The infusion pump of Claim 8, wherein:

the specially programmed microprocessor includes a memory element for storing the desired flow rate; or,

the specially programmed microprocessor is for receiving input including the desired flow rate; or,

the specially programmed microprocessor is for calculating the desired flow rate.

12. A method for infusing a fluid using an infusion pump including a specially programmed microprocessor; a drip chamber for connection to a source of fluid and to an output tubing; a pumping section including a plurality of fingers and a first actuator; an inlet valve disposed between the drip chamber and the pumping section; and a second actuator, 5 controllable using the microprocessor, comprising:  
controlling the first actuator, using the microprocessor, to sequentially displace the plurality of finger to compress a first portion of the output tubing to displace fluid from the drip chamber through the output tubing; and,  
controlling the second actuator, using the microprocessor, to:  
10 open or close the inlet valve independent of the displacement of the plurality of fingers; or,  
operate the inlet valve to control a rate of flow of fluid from the drip chamber to the first portion of the output tubing.

13. The method of Claim 12, wherein the pumping section includes an outlet valve, the 15 method further comprising:  
controlling, using the specially programmed microprocessor, the second actuator to:  
operate the inlet valve to flow a specified volume of fluid from the drip chamber to a second portion of the output tubing between the inlet and outlet valves while controlling the first actuator to close the outlet valve and maintain the plurality of fingers in respective fixed 20 positions; and,  
close the inlet valve after the specified volume of fluid has flowed to the second portion of the output tubing; and,  
controlling, using the specially programmed microprocessor, the first actuator to:  
fully open the outlet valve and displace the plurality of fingers to expel the specified volume 25 of fluid past the outlet valve within a first specified time period; and,  
close the outlet valve at the end of the first specified time period.

14. The method of Claim 13 wherein:  
operating the inlet valve to flow the specified volume of fluid from the drip chamber 30 to the second portion of the output tubing includes flowing the specified volume of fluid within a second specified time period;

a passageway formed by the second portion of the output tubing has a maximum value;

the specified volume of fluid is no more than about 0.7 percent of the maximum volume;

5 the sum of the first and second specified time periods is about 20 seconds; and, the first specified time period is no more than ten percent of the sum.

15. The method of Claim 14, wherein the specially programmed microprocessor includes a memory element and the method further comprises storing, in the memory element, the first  
10 or second time periods, or storing, in the memory element, the specified volume of fluid; or,

the method further comprises receiving, using the specially programmed microprocessor, input including the first or second time periods, or the specified volume of fluid; or,

15 the method further comprises calculating, using the specially programmed microprocessor, the first or second time periods, or the specified volume of fluid.

16. The method of Claim 12, wherein:

the infusion pump includes a flow sensor for measuring flow through the drip chamber from the source of fluid; and,

20 the pumping section includes an outlet valve, the method further comprising in response to detecting, using the flow sensor, flow above a predetermined level:

closing, using the specially programmed microprocessor and the first actuator, the outlet valve independently of the inlet valve; or,

25 closing, using the specially programmed microprocessor and the second actuator, the inlet valve independently of the outlet valve.

17. The method of Claim 12, wherein:

the infusion pump includes a flow sensor for measuring flow through the drip chamber from the source of fluid; and,

30 the pumping section includes an outlet valve, the method further comprising:  
in a first mode:

controlling, using the specially programmed microprocessor, the first actuator to maintain the plurality of fingers in respective fixed positions and to at least partially open the outlet valve such that a passageway is formed in the output tubing between the inlet and outlet valves; and,

5 controlling, using the specially programmed microprocessor and data from the flow sensor including flow measured by the flow sensor, the second actuator to operate the inlet valve to establish flow from the drip chamber to the output tubing at a desired flow rate; and, in a second mode, the microprocessor:

controlling, using the specially programmed microprocessor, the second actuator to open and  
10 close the inlet valve; and,

controlling, using the specially programmed microprocessor, the first actuator to operate the plurality of fingers to displace fluid through the output tubing at the desired flow rate.

18. A method for infusing a fluid using an infusion pump including a specially  
15 programmed microprocessor; a drip chamber for connection to a source of fluid and to an output tubing; a flow sensor; a pumping section including a plurality of fingers, an outlet valve, and a first actuator; an inlet valve disposed between the drip chamber and the pumping section; and a second actuator, controllable using the microprocessor, comprising:

measuring flow using the flow sensor;

20 sequentially displacing, using the specially programmed microprocessor and the first actuator, the plurality of finger to displace fluid through the output tubing; and, for detection, by the flow sensor, of flow above a predetermined level:

closing, using the specially programmed microprocessor and the first actuator, the outlet valve independently of the inlet valve; and,

25 closing, using the specially programmed microprocessor and the second actuator, the inlet valve independently of the outlet valve.

19. The method of Claim 18, wherein:

the infusion pump includes:

30 a cam shaft in a position fixed except for rotation; and,

a cam lobe disposed on the cam shaft and engageable with the outlet valve to close the outlet valve; and,



the flow above the predetermined level is caused by the shaft shifting from the position such that the cam lobe cannot close the outlet valve.

20. A method for infusing a fluid using an infusion pump including a specially programmed microprocessor; a drip chamber for connection to a source of fluid and to an output tubing; a flow sensor; a pumping section including a plurality of fingers, an outlet valve, and a first actuator for controlling operation of the plurality of fingers; an inlet valve disposed upstream of the pumping section; and a second actuator for operating the inlet valve, comprising:
- 5 measuring flow using the flow sensor;  
in a gravity-feed mode:  
controlling, using the specially programmed microprocessor, the first actuator to maintain the plurality of fingers in respective fixed positions and to at least partially open the outlet valve such that a passageway is formed in the output tubing from the drip chamber past the outlet  
15 valve; and,  
controlling, using the specially programmed microprocessor and data from the flow sensor including flow measured by the flow sensor, the second actuator to operate the inlet valve to establish flow from the drip chamber to the output tubing at a desired flow rate; and,  
in an active pumping mode:  
20 controlling, using the specially programmed microprocessor, the second actuator to open and close the inlet valve; and,  
controlling, using the specially programmed microprocessor, the first actuator to operate the plurality of fingers to displace fluid through the output tubing at the desired flow rate.
- 25 21. The method of Claim 20, further comprising controlling, using the specially programmed microprocessor, the second actuator to operate the inlet valve such that the inlet valve is continuously positionable between a fully open position and a fully closed position.
22. The method of Claim 20, further comprising, when in the gravity-feed mode and the  
30 inlet valve is fully opened or opened to within a specified portion of a fully opened position for the inlet valve, and the measured flow through the drip chamber from the source of fluid

is less than the desired flow rate, automatically switching, using the microprocessor, the pump to the active pumping mode.

23. The method of Claim 20, wherein the specially programmed microprocessor includes  
5 a memory element and the method further comprises storing, in the memory element, the desired flow rate; or,

the method further comprises receiving, using the specially programmed microprocessor, input including the desired flow rate; or,

10 the method further comprises calculating, using the specially programmed microprocessor, the desired flow rate.

24. An infusion pump, comprising:

a specially programmed microprocessor;

a drip chamber for connection to a source of fluid and to an output tubing;

15 a flow sensor for measuring flow; an inlet valve disposed after the drip chamber; and,

an actuator for operating the inlet valve, wherein in a gravity-feed mode the microprocessor is arranged to control the actuator, using data from the flow sensor including flow measured by the flow sensor, to operate the inlet valve to establish flow from the drip chamber to the output tubing at a desired flow rate.

20

25. An infusion pump, comprising:

a specially programmed microprocessor;

a drip chamber for connection to a source of fluid and to an output tubing;

a flow sensor for measuring flow from the source of fluid;

25 an element for forcing fluid from the source of fluid;

an inlet valve disposed after the drip chamber; and,

an actuator for operating the inlet valve, wherein in a gravity-feed mode, the microprocessor is arranged to control the actuator, using data from the flow sensor including flow measured by the flow sensor, to operate the inlet valve to establish flow from the drip chamber to the

30 output tubing at a desired flow rate.

26. A method for infusing a fluid using an infusion pump including a specially programmed microprocessor; a drip chamber for connection to a source of fluid and to an output tubing; a flow sensor for measuring flow; an inlet valve disposed after the drip chamber; and an actuator for operating the inlet valve, the method including:

5 accepting, using the microprocessor, data from the flow sensor including flow measured by the flow sensor; and,

in a gravity-feed mode, controlling, using the microprocessor and the data, the actuator to operate the inlet valve to establish flow from the drip chamber to the output tubing at a desired flow rate.

10

27. A method for infusing a fluid using an infusion pump including a specially programmed microprocessor; a drip chamber for connection to a source of fluid and to an output tubing; a flow sensor for measuring flow from the source of fluid; an element for forcing fluid from the source of fluid; an inlet valve disposed after the drip chamber; and an actuator for operating the inlet valve, the method comprising:

15

accepting, using the microprocessor, data from the flow sensor including flow measured by the flow sensor; and,

in a gravity-feed mode, controlling, the microprocessor and the data, the actuator, the flow sensor to operate the inlet valve to establish flow from the drip chamber to the output tubing

20

at a desired flow rate.

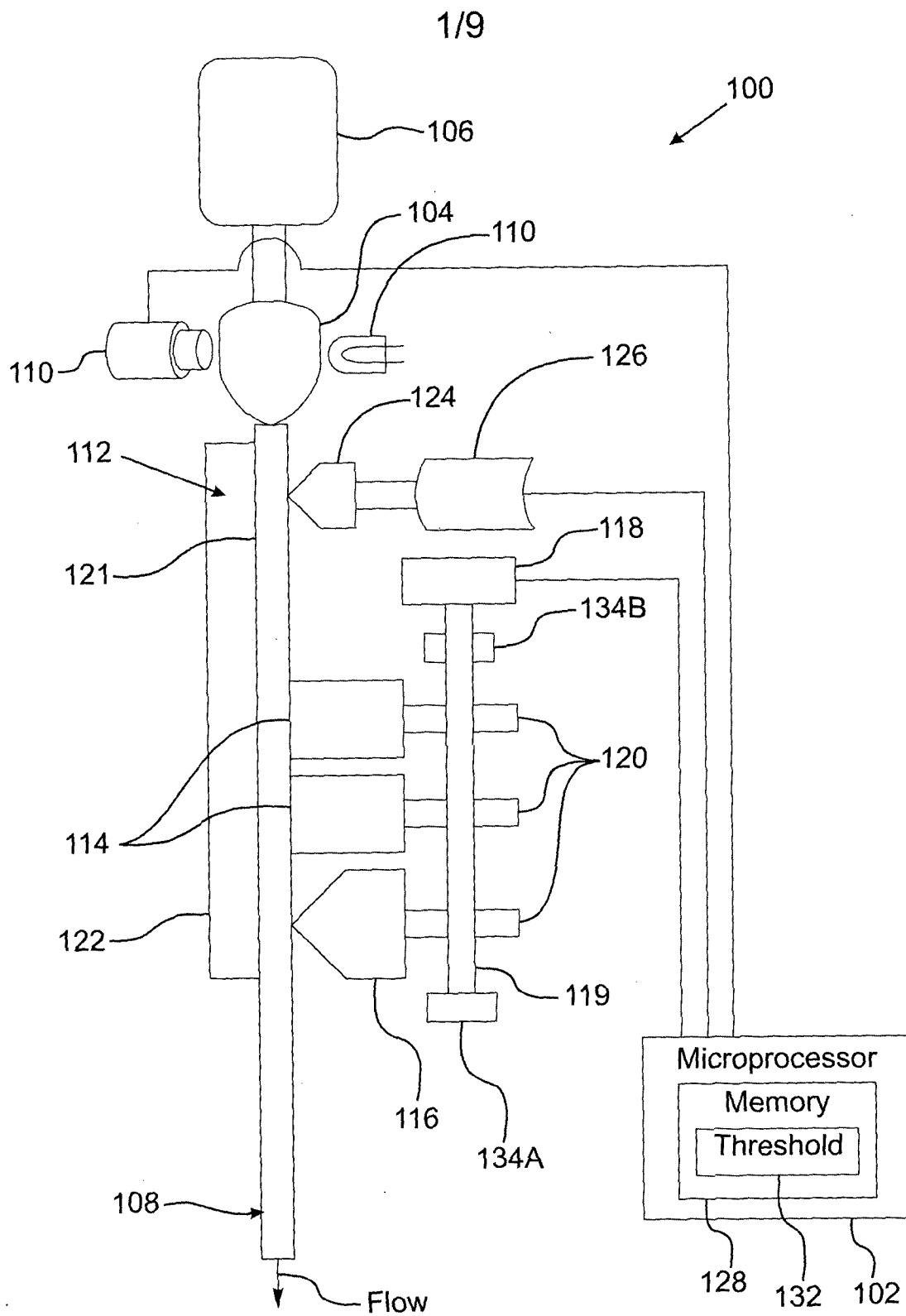


Fig. 1



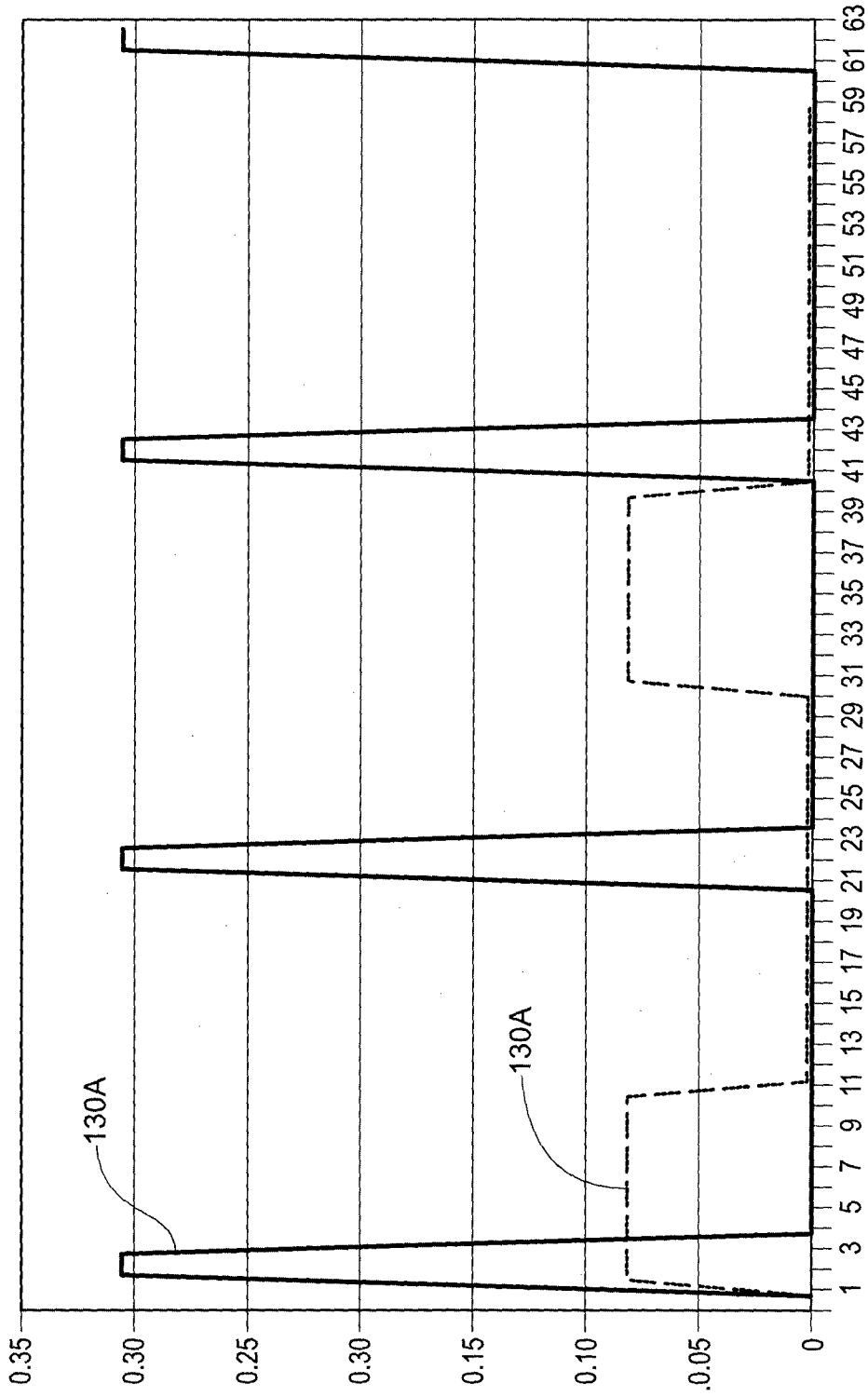


Fig. 3

4/9

Flow pulse (sec)	No. of flow pulses per hr.	Amount of fluid per flow packet micro L	Instantaneous rate micro L/hr
2	164	0.61	0.31
4	150	0.67	0.17
6	138	0.72	0.12
8	129	0.78	0.10
10	120	0.83	0.08
12	113	0.89	0.07
14	106	0.94	0.07
16	100	1.00	0.06
18	95	1.06	0.06

Fig. 4

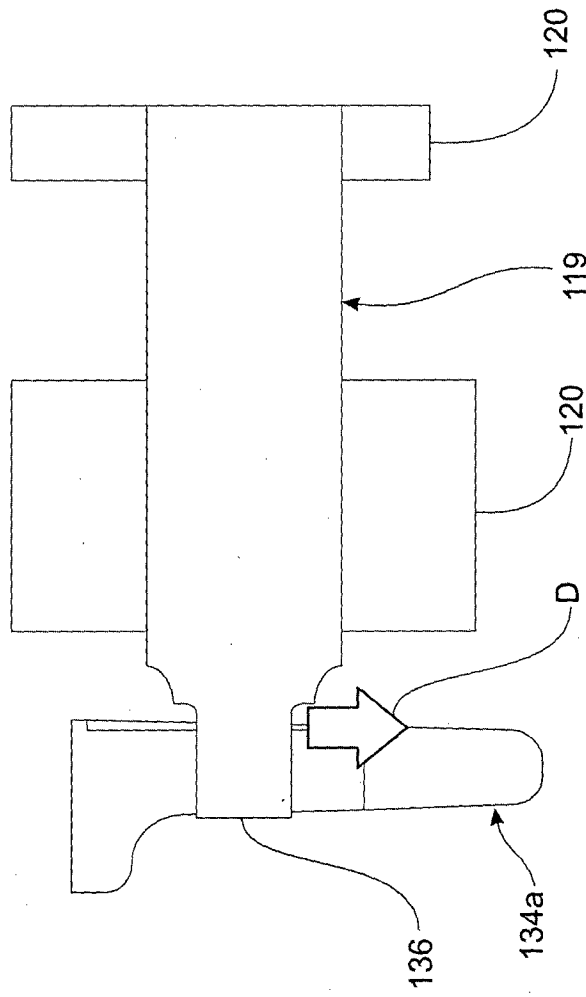
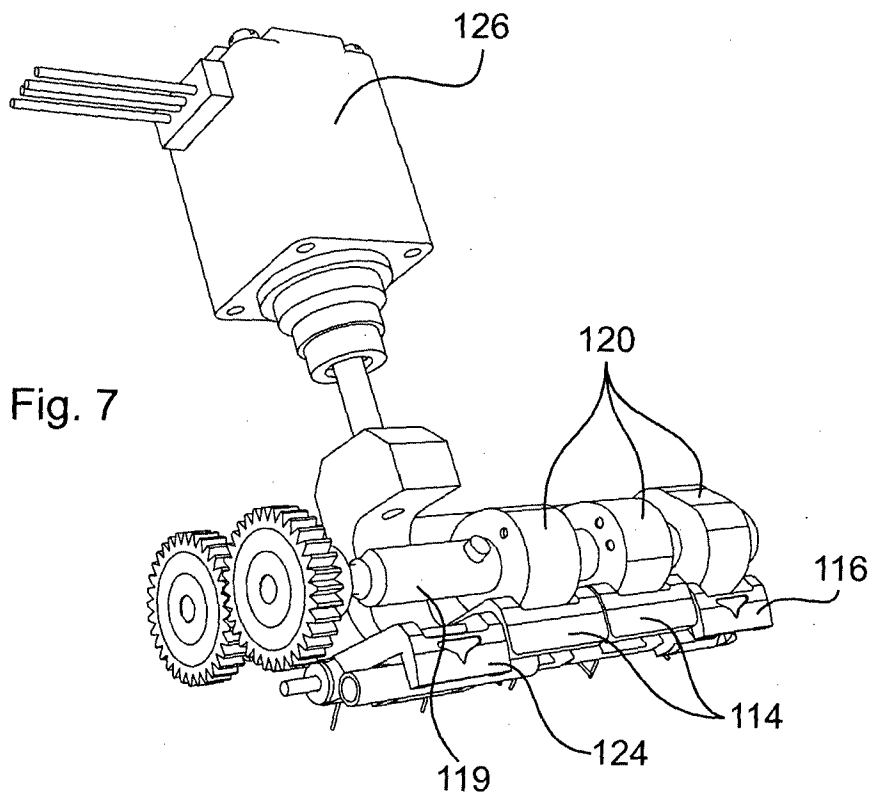
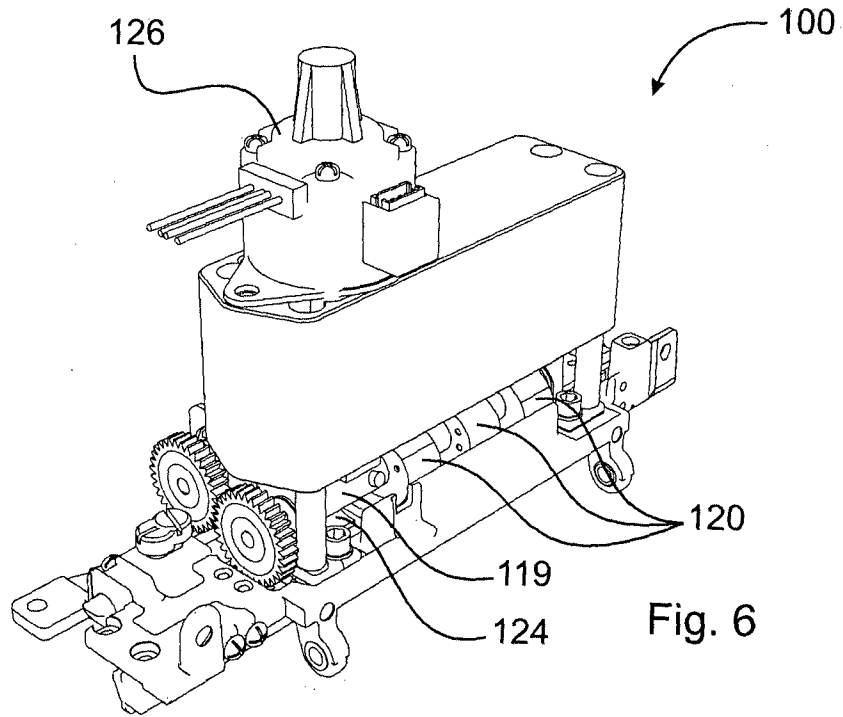


Fig. 5



6/9



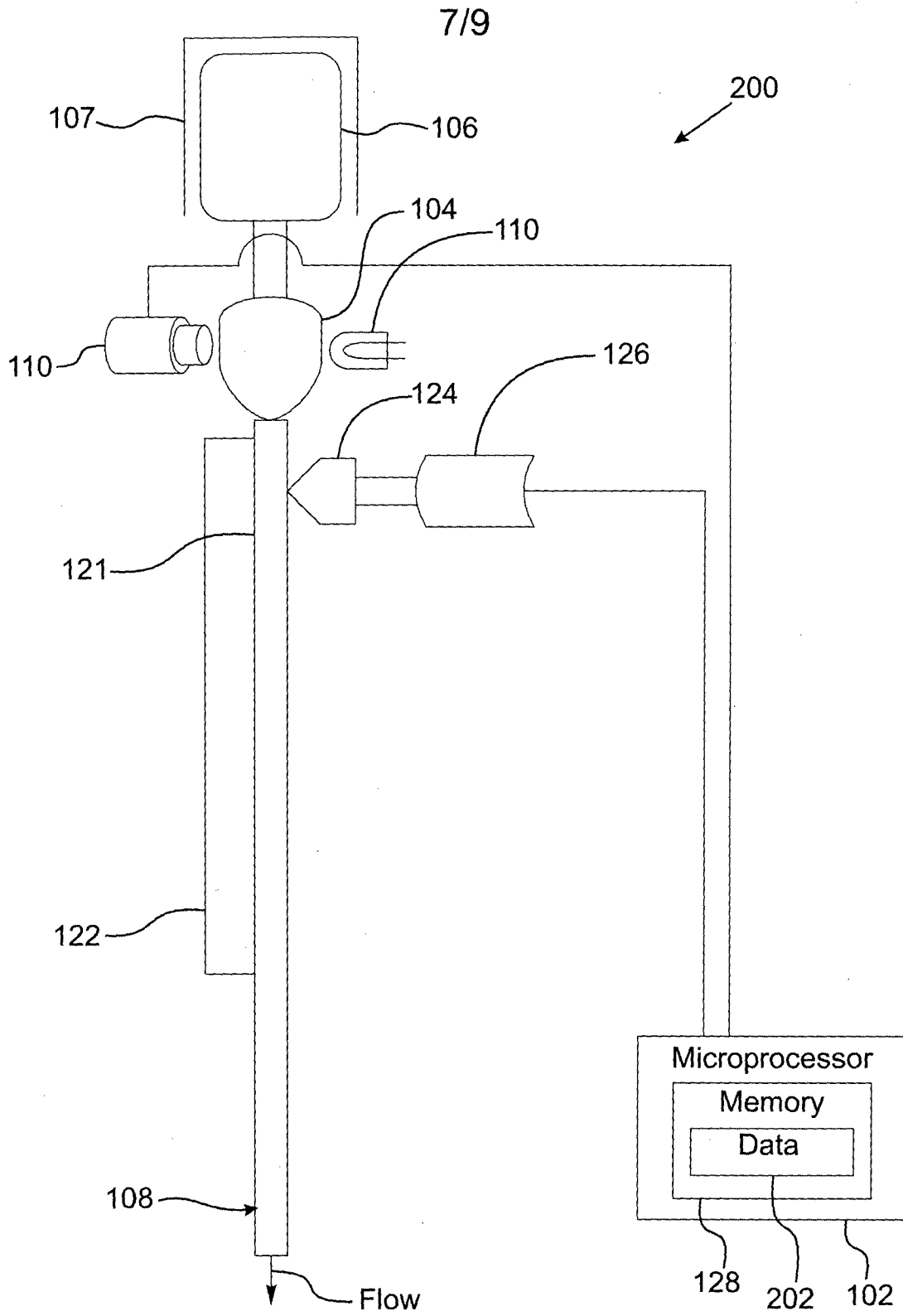


Fig. 8

8/9

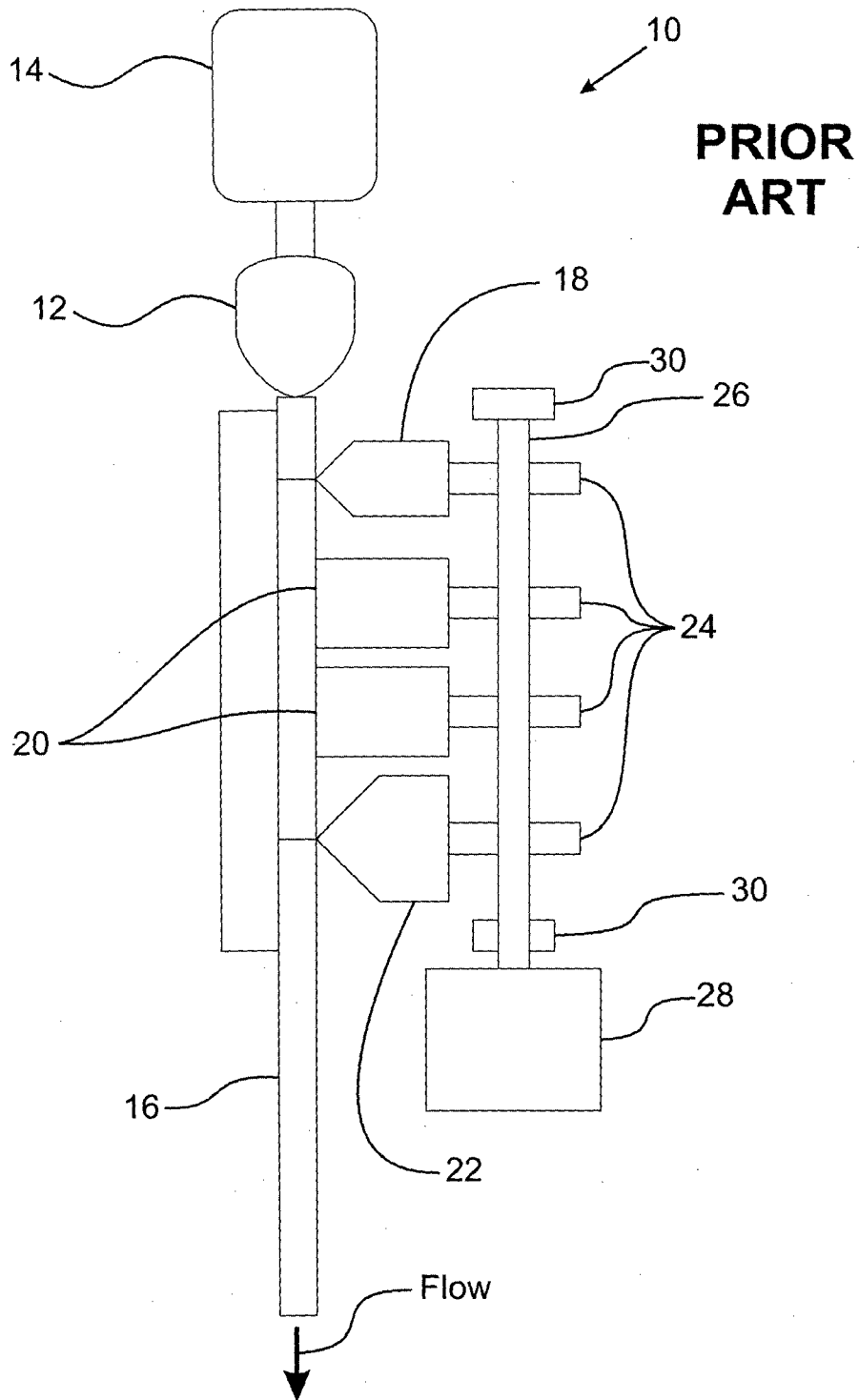


Fig. 9

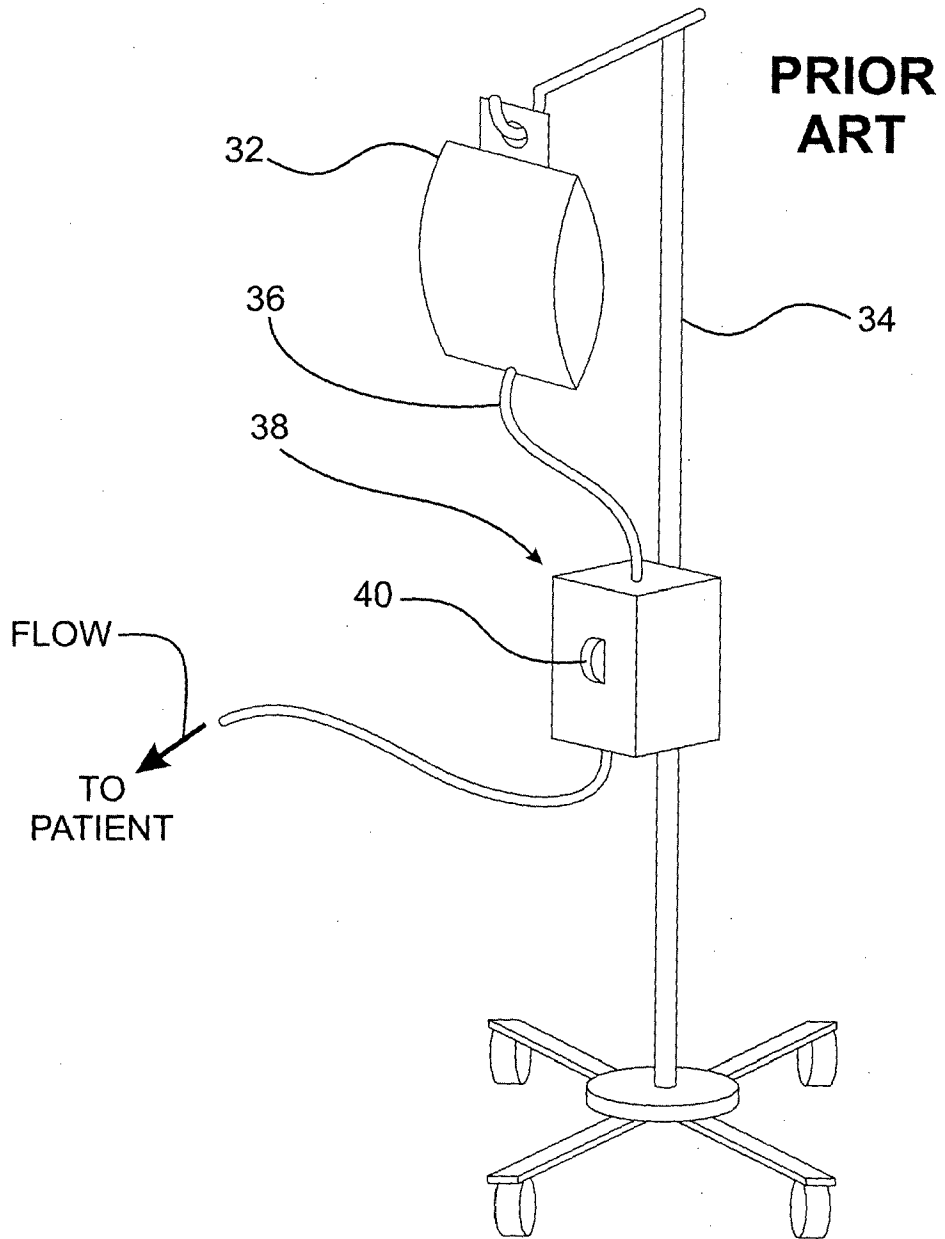


Fig. 10