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(54) **ELECTRONIC FLOW CONTROL**

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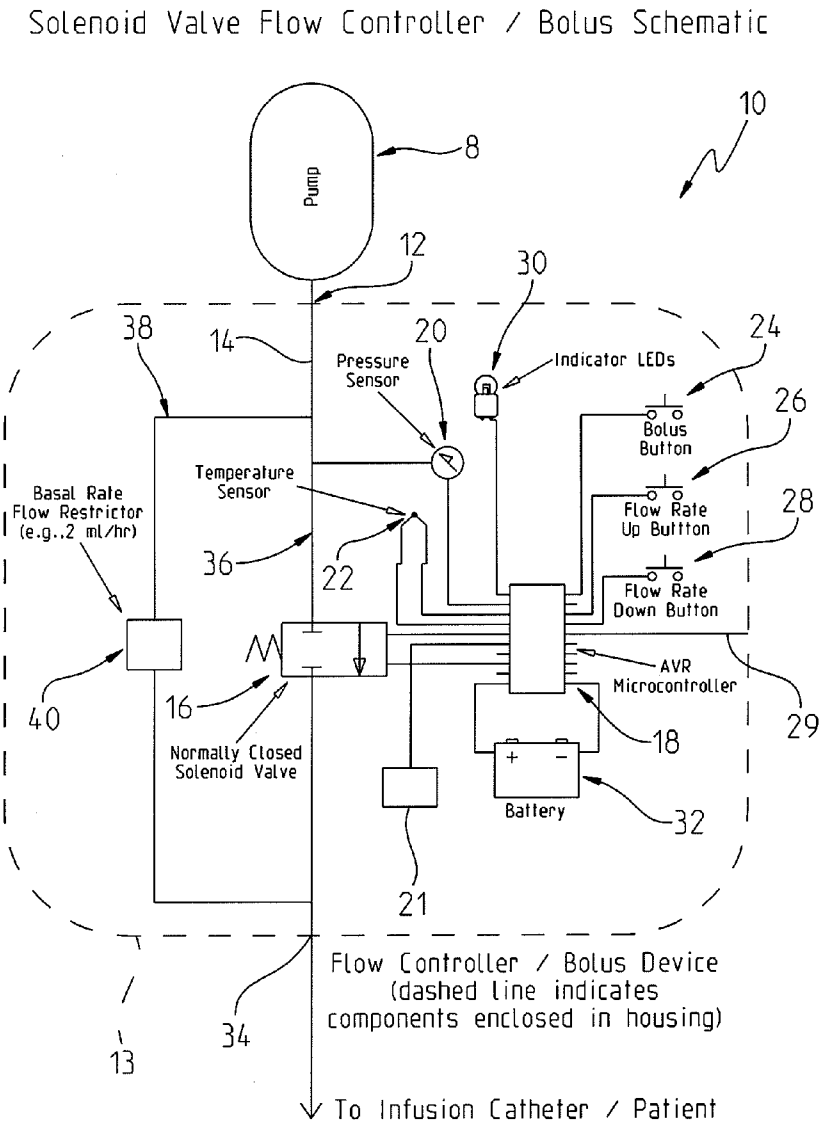
(57) **ABSTRACT**

An electronic controller is provided for controlling the evacuation of fluid from one or more fluid reservoirs. The controller includes a plurality of sensors that sense environmental factors and the controller adjusts the evacuation of fluid from the bladder(s) using information gathered by the sensors.



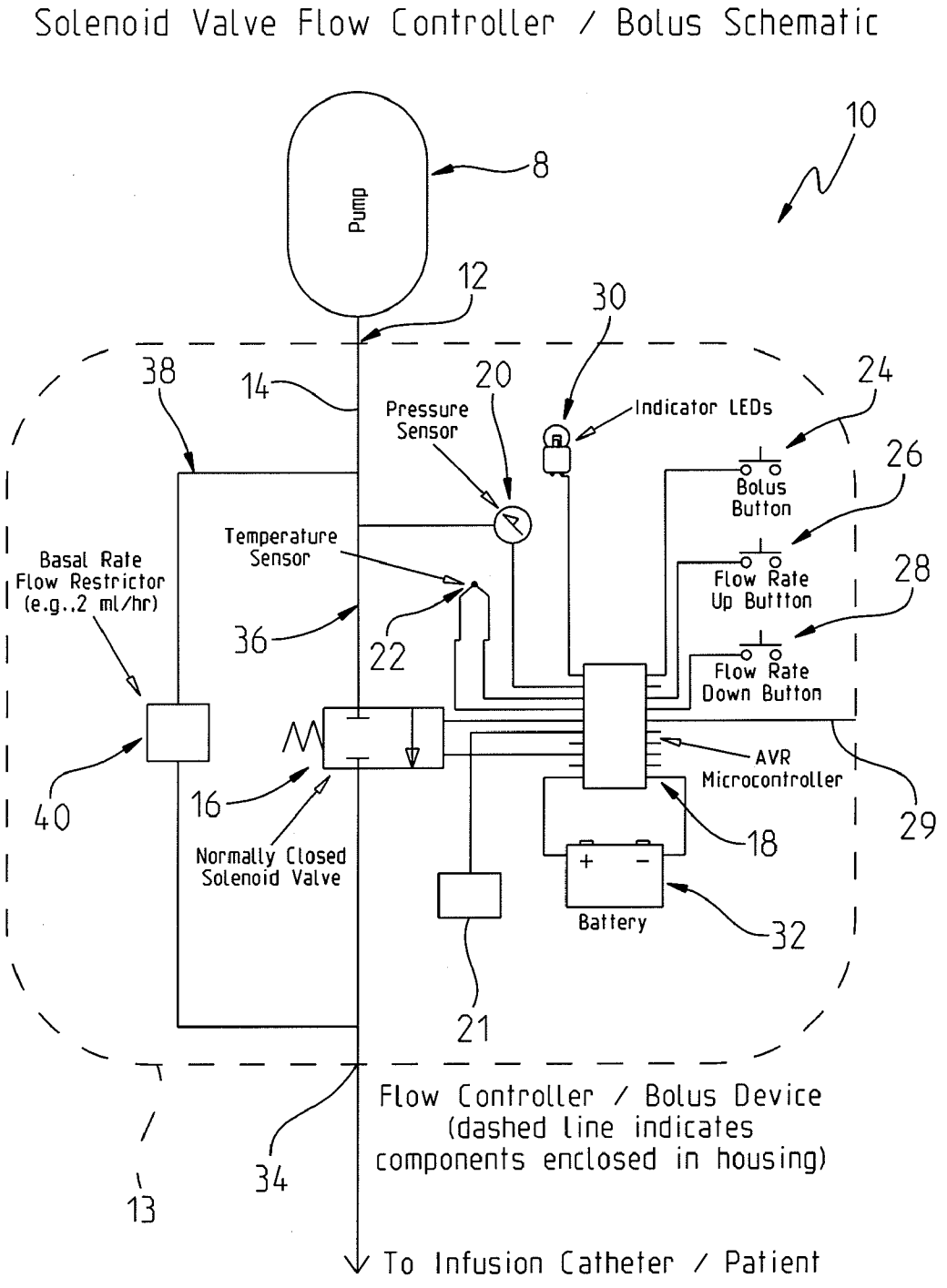

Solenoid Valve Flow Controller / Bolus Schematic
Pump
8
10
12
30
38
14
20
24
Pressure Sensor
Indicator LEDs
26
Bolus Button
Temperature Sensor
Basal Rate Flow Restrictor (e.g.,2 ml/hr)
Flow Rate Up Buttton
28
36
22
Flow Rate Down Button
AVR Microcontroller
40
16
29
18
Normally Closed Solenoid Valve
+
-
Battery
32
21
Flow Controller / Bolus Device (dashed line indicates components enclosed in housing)
34
13
To Infusion Catheter / Patient

FIG. 1

ELECTRONIC FLOW CONTROL

CLAIM FOR PRIORITY

[0001] The present application claims priority to U.S. Provisional Application 61/105,452 filed Oct. 15, 2008, and to U.S. Provisional Application 61/107,780 filed Oct. 23, 2008, the disclosures of which are incorporated herein by reference.

FIELD

[0002] The present disclosure relates generally to the administration of liquid agents to patients. More particularly, the present disclosure relates to a device and method that provides for electronic flow control from portable and disposable infusion pumps for various agents and conditions.

BACKGROUND AND SUMMARY

[0003] Drug delivery devices are used to infuse medications or other biologically active substances into human or animal subjects. For administration of selected substances, a substantially constant level of the substance is desired over an extended period. Accordingly, while a large initial bolus dose may be used in conjunction with the extended dose, the initial bolus dose is typically unsuitable for achieving an extended dose by itself. Furthermore, applications arise that require the administration of more than one substance to a particular patient or administration of one substance at multiple locations. Additionally, subsequent bolus doses and dosing regimens are sometimes needed when outside of direct contact with a healthcare provider.

[0004] Accordingly, a device and method are provided that allow the administration of one or more substances over defined periods of time and administration of the same substance at multiple locations over defined periods of time.

[0005] According to one aspect of the present disclosure, a portable kit for providing pain relief is provided comprising: a catheter for delivering an anesthetic-containing fluid adjacent a wound site in a body; tubing attached to the catheter and having a lumen in fluid communication with a lumen of the catheter; a pump adapted to deliver fluid, the pump including an outlet in fluid communication with the tubing, the pump further including an inlet port for filling a reservoir of the pump; the pump affixable to the body to permit portability; an electronic valve disposed between the catheter and the reservoir in a first flow path; a controller that generates signals to control operation of the electronic valve; and instructions on a controller interpretable medium that when interpreted by the controller cause the controller to be able to selectively place the electronic valve in each of three conditions, the first condition causing the electronic valve to periodically open and close to achieve a first output flow rate through the catheter, a second condition causing the electronic valve to open and close to achieve a second output flow rate, and the third condition causing closure of the electronic valve.

[0006] According to another aspect of the present disclosure, a portable kit for providing pain relief is provided comprising: a first pump having a first reservoir that when filled with an anesthetic provides a first pressure biased to evacuate the anesthetic from the first pump; the first pump being constructed such that the first pressure varies based upon the first reservoir experiencing environment induced pressure variations; and an electronic controller that controls the evacuation of anesthetic from the first reservoir to compensate for the variability in the first pressure to achieve a desired output flow that is independent of the environment induced pressure variations experienced by the first reservoir.

[0007] According to another aspect of the present disclosure, a portable kit for providing medication to tissue is provided comprising: a pump having a first reservoir, the first reservoir, when filled with a first fluid provides a first pressure biased to evacuate the first fluid from the first reservoir; and an electronic controller that controls the evacuation of fluid from the first reservoir, the electronic controller being able to receive input indicative of the activity of a patient, the electronic controller adjusting an output flow from the first reservoir at least partially based upon the input indicative of the activity of the patient.

[0008] According to another aspect of the present disclosure, a portable kit for providing fluid to tissue is provided comprising: a pump having a first reservoir and a second reservoir, an electronic controller that controls the evacuation of fluid from the first and second reservoirs, the electronic controller being able to receive input selected from the group including input indicative of patient status and input indicative of atmospheric status, the electronic controller adjusting output flows from the first and second reservoirs at least partially based upon the received input to achieve a output mixture of the first and second fluids, the mixture having a first ratio of the first fluid to the second fluid.

[0009] According to yet another aspect of the present disclosure, a portable kit for providing fluid to tissue is provided comprising: a pump having a first reservoir and a second reservoir, an electronic controller that controls the evacuation of fluid from the first and second reservoirs, the electronic controller being programmable to cause an output flow of the pump to vary as a function of time.

[0010] Additional features of the present disclosure will become apparent to those skilled in the art upon consideration of the following detailed description of the presently perceived best mode of carrying out the disclosure.

BRIEF DESCRIPTION OF THE DRAWINGS

[0011] The detailed description of the drawings particularly refers to the accompanying figures in which:

[0012] FIG. **1** is a schematic view of a controller and an infusion pump.

DETAILED DESCRIPTION OF THE DRAWINGS

[0013] FIG. **1** shows disposable infusion pump **8** coupled to controller **10**. Pump **8** is illustratively a GO pump that is commercially available from Symbios Medical Products. Pump **8** is an elastomeric balloon reservoir pump that is non-powered. In other words, pump **8** does not require electrical power to output fluid. Furthermore, pump **8** includes a single fluid containing reservoir. However, other pumps that are powered or that have more than one discreet reservoir therein are also envisioned. Other examples of pumps that are envisioned for use in the present disclosure are those powered by springs and vacuums.

[0014] Pump **8** includes a clasp extension (not shown) such that pump **8** may be selectively coupled to a user's belt, pocket, or the like. Elastomeric balloon reservoirs and elastomeric balloon reservoir pumps are described more completely in U.S. Patent Publication No. 2008/0097317-A1, the disclosure of which is incorporated herein by reference.

[0015] An output (not shown) from pump **8** is in fluid communication with input **12** of controller **10**. Controller **10**

includes housing **13**, fluid pathway **14**, metering solenoid **16**, microcontroller **18**, sensors **20**, **21**, **22**, buttons **24**, **26**, **28**, electrical I/O port **29**, indicators **30**, and power source **32**. Controller **10** operates to control the output of pump **8**. For embodiments having more than one discreet reservoir, controller **10** operates to control the output of both pumps independently. In yet another embodiment having more than one discreet reservoir, controller **10** controls the mixing of fluid from the reservoirs and the output of the resulting mixture. Such mixing can occur either within or outside of housing **13**.

[0016] Housing **13** is illustratively a plastic housing that at least partially encloses each of fluid pathway **14**, metering solenoid **16**, microcontroller **18**, sensors **20**, **22**, buttons **24**, **26**, **28**, indicators **30**, and power source **32**. Housing **13** is sized to be of similar or smaller size than pump **8** and to be easily transported or worn by a user.

[0017] Fluid pathway **14** provides a pathway from input **12** to output **34** of controller **10**. Pathway **14** includes metered leg **36** and constant leg **38**. Pathway **14** interfaces with sensor **20**, which is a pressure sensor. The interface of pathway **14** with sensor **20** allows the pressure being provided by pump **8** to be measured when pump **8** is coupled to and in fluid connection with input **12**. Metered leg **36** interfaces with metering solenoid **16**. Flow through metered leg **36** is determined by the state of solenoid **16**.

[0018] Constant leg **38** allows a constant connection and flow between input **12** and output **34**. Constant leg **38** includes flow restrictor **40** that is chosen to allow a desired constant flow rate. Alternatively, embodiments are envisioned without constant leg **38**. In such embodiments, any desired constant flow rate is provided via metered leg **36** through solenoid **16** as described below. Embodiments with constant leg **38** allow for the setting of a constant base rate via flow restrictor **40**. Such embodiments allow the base rate to be administered without drawing power to open solenoid **16**. Furthermore, such embodiments continue to administer fluid at times that solenoid **16** is unable to receive power.

[0019] Metering solenoid **16** is a normally closed solenoid that is disposed within metered leg **36**. A closed position of solenoid **16** prevents flow from input **12** to output **34** via metered leg **36**. Similarly, an open position of solenoid **16** allows flow from input **12** to output **34** via metered leg **36**. Solenoid **16** is electrically coupled to microcontroller **18** which delivers electrical signals to control the open/closed state of solenoid **16**. In the provided embodiment, solenoid **16** has a flow channel that is 0.3" in diameter and 1.35" long having a continuous flow rate of 30 ml/hr. The overall throughput (flow rate) of metered leg **36** is controlled and adjusted by electronic pulses received from microcontroller **18**. Exemplarily, pulses occur every 30 seconds to open solenoid **16**. The time that solenoid **16** remains open during each pulse is varied to achieve the desired flow rate. For example, if the desired flow rate were 10 ml/hr, solenoid **16** would open for 10 seconds, and then close for 20 seconds. Thus, solenoid **16** would be open ⅓ of the time and achieve ⅓ of the continuous flow rate (30 ml/hr) to get 10 ml/hr. The sizes and throughput of solenoid **16** are adjusted to achieve the desired throughput for particular applications chosen by the healthcare provider.

[0020] Microcontroller **18** is illustratively a flash programmable microcontroller with onboard memory and ram (not shown). Microcontroller **18** receives input from a plurality of sources **20**, **21**, **22**, **24**, **26**, **28**, **29**. The onboard memory stores instructions thereon the instruct microcontroller **18** how to interpret input as part of a regimen program. The program includes a regimen determined by a healthcare provider that allows the operation of solenoid **16** to vary over time according to the instructions in the program. Furthermore, the program includes instructions that allow operation of solenoid **16** that is dependent upon input received from input sources **20**, **21**, **22**, **24**, **26**, **28**, **29** to achieve the output prescribed by the program.

[0021] Sensor **20** is a pressure sensor. Some pumps, such as elastomeric balloon reservoir pumps **8** provide an output that varies dependent upon various environmental factors. Such factors include the degree of fullness and expansion of the elastomeric bladder, the ambient atmospheric pressure, ambient temperature, fluid viscosity, and gravity. Sensor **20** senses the pressure of the fluid being provided by pump **8** and supplies that information electronically to microcontroller **18**.

[0022] Similarly, sensor **22** is a temperature sensor. Sensor **22** electronically provides temperature information to microcontroller **18**. Sensor **21** is an accelerometer. Sensor **21** electronically provides information to microcontroller **18** regarding accelerations experienced thereby. Such accelerations provide indication of whether the user wearing controller **10** is engaging in physical activity or in a rest state. Additionally, sensor **21** gives indications of patient position. It should be appreciated that sensor **21** is actually a plurality of sensors in certain embodiments. Accordingly, the program of microcontroller **18** is programmed to provide dosing adjustments based upon the input from sensors **21**, **22**. Collectively, conditions such as pressure variation (regardless of the source), ambient temperature, and patient activity are able to result in environment induced pressure variations from pump **8** that are translated to solenoid **16**. By sensing such conditions, controller **10** is able to account for such environment induced pressure variations and produce a desired flow at output **34**. For embodiments having more than one discreet reservoir, controller **10** adjusts the output of each reservoir and the mix ratio based upon input from sensors **20**, **21**, **22**.

[0023] Button **24** is a bolus dose button. Pressing button **24** sends a signal to microcontroller **18** that a bolus dose is desired. The program of microcontroller **18** then controls solenoid **16** to effect the bolus dose. It should be appreciated that a caregiver can disable button **24** if desired. Furthermore, embodiments are envisioned where button **24** does not exist.

[0024] Buttons **26**, **28** are "Flow Rate Up" and "Flow Rate Down" buttons, respectively. Buttons **26**, **28** allow for the adjustment of the flow rate through metered leg **36** by the user or a healthcare provider. Again, it should be appreciated that a caregiver can disable buttons **26**, **28** if desired. Furthermore, embodiments are envisioned where buttons **26**, **28** do not exist.

[0025] Electrical I/O port **29** is illustratively a RS-232 port on the outside of housing **13**. Port **29** is capable of outputting real-time data. Such data includes a time counter value, pressure sensor reading, temperature sensor reading, flow rate setting, battery voltage, solenoid valve state, and an accumulator count for a bolus. The accumulator count is a timer that is invoked as part of the delivery of a bolus dose. The accumulator provides an indication of the progress of the bolus dose and how much of the bolus dose has been delivered and allows microcontroller **18** to determine when the desired bolus dose has been delivered. Port **29** also allows for controller **10** to be coupled to a computer or other programming device (not shown). Such programming device allows different programs and different settings to be communicated and

saved in the flash memory of microcontroller **18**. In another embodiment, microcontroller **18** is able to wirelessly transmit data for reporting and programming instead of or in addition to the transmission via port **29**.

[0026] Indicators **30** are illustratively a plurality of LED's. Embodiments are also envisioned where indicators **30** are one or more screens capable of communicating information to a user and/or health care provider. Indicators **30** are also envisioned as providing audio information. Battery **32** is coupled to microcontroller **18** and powers controller **10**. In the provided example, battery **32** is chosen to have enough energy therein to power controller **10** beyond the time it takes to release the dose of fluid provided in pump **18**.

[0027] In operation, controller **10** is programmed by a healthcare provider to provide a prescribed dosing regimen. In the provided example, the user is prevented from adjusting the dosing regimen, with the exception of allowing bolus dose additions, as will be discussed below. It should be appreciated that embodiments are envisioned where the user/patient is permitted to adjust the dosing regimen. The patient/user is prevented from adjusting the dosing by requiring a computer or other programming device with proper software thereon to be connected via port **29** to configure dosing via an adjustment mode. Alternatively, a specific button **24**, **26**, **28** combination must be pressed to enter into an adjustment mode. Once in adjustment mode, buttons **26**, **28** become active or computer access is achieved to allow an increase or decrease in a steady state flow (such as 10 ml/hr). Confirmation and indication of such increases and decreases are provided to the user via indicators **30**.

[0028] In addition to a steady state prescriptions, prescriptions that change with time can also be programmed into microcontroller **18**. Such prescriptions can decrease over time, increase and decrease along with expected periods of activity and sleep, respectively, or any other variation desired by the healthcare provider. These more detailed prescription profiles are achieved by configuring them on a computer with appropriate software thereon and then interfacing the computer with controller **10**. However, embodiments are envisioned where the more detailed prescription profiles are programmed directly on controller **10** using buttons **24**, **26**, **28**.

[0029] Part of the program includes what adjustments are to be made to the operation of solenoid **16** to regulate the dose being delivered, if any, when various input is received from sensors **20**, sensors **22**, sensors **21**. By example, if sensors **20** indicates a decreased pressure, due to being at high elevation, a manufacturing variance in pump **8**, low fill in pump **8**, or for some other reason, microcontroller **18** knows that the base rate of metering solenoid **16** is likely reduced. Accordingly, microcontroller **18** knows to adjust the open time of the duty cycle for a longer time relative to the time it is held open when sensors **20** reads a higher pressure such that controller **10** continues to achieve the desired output at output **34**. Similarly, microcontroller **18** adjusts operation of metering solenoid **16** in response to input received from sensors **22**. Also similarly, microcontroller **18** adjusts operation of metering solenoid **16** in response to input received from sensors **21**. For uses of controller **10** as a provider of post surgical treatment, activity by a patient, which would register with sensors **21**, can cause increased pain and increased swelling. Accordingly, microcontroller **18** is programmed to provide an increased dose of fluid, illustratively an anesthetic or anti-inflammatory, in response to the sensing of activity via sensors **21**.

[0030] The program within microcontroller **18** is also able to enable or disable bolus button **24**. When enabled, a patient/user presses bolus button **24** whenever a bolus dose of fluid is desired to be administered. The program can dictate how large of a bolus dose is administered in response to activation of button **24**. Additionally, the program dictates a lock out period after administration of a bolus dose in which another bolus dose can not be administered. Embodiments are envisioned where there is no lock out period. In the provided example, a bolus dose is achieved by holding metering solenoid **16** open for a period of time such that the bolus amount is allowed to pass therethrough and out of output **34**. Again, the time period to achieve the bolus amount takes into account information received from sensors **20**, **22**, **21**.

[0031] Additionally, embodiments are envisioned where the sensors **20** provides updates to microcontroller **18** every fixed segment of time, such as three seconds. Furthermore, embodiments exist where sensors **20** only takes readings and provides information to microcontroller **18** when metering solenoid **16** is in a closed position so as to provide only a static pump output pressure as opposed to a fluctuating pressure resulting from the outflowing of fluid through an open metering solenoid **16**.

[0032] The programming of microcontroller **18** also allows controller **10** to be self proving. In other words, microcontroller **18** can monitor the performance of controller **10** and confirm that it is operating as desired. Furthermore, controller **10** can provide an operation status to a user/patient or healthcare professional via indicators **30**.

[0033] While the above controller **10** has been described as a disposable controller having solenoid **16** that comes into direct contact with the fluid to be dispensed, the concepts and pieces can be utilized as part of a reusable controller as well. In such embodiments, only pumps **8**, and tubing sets that form the pathways within controller **10**, connections upstream of controller **10** between pump **8** and controller **10**, and downstream of controller **10** are disposable. Controller **10**, including, solenoid **16**, microcontroller **18**, and power source **32**, is able to be returned, checked, and reused. One embodiment of reusable controller **10** includes solenoid **16** powering a pinch valve that selectively pinches off flow through metered leg **36**. One such pinch valve is the PV256 made by Instech laboratories, Inc. Disposable tubing is placed within the pinch valve such that pinching by the pinch valve is translated to the tubing to selectively cut off flow therethrough. Accordingly, any piece that would come into contact with the fluid medication is able to be changed out between uses. One embodiment of tubing sets for use with reusable controller **10** includes one or more sensors (e.g. pressure sensor **20** and temperature sensor **22**) integrated therein with an electrical lead extending therefrom for connection to microcontroller **18** through a plug or otherwise. Furthermore, one embodiment of reusable controller **10** employs power source **32** that is a rechargeable battery. Microcontroller **18** in reusable controller **18** is programmed to monitor how many cycles controller **18** has gone through. By so monitoring, the cycle values can be reported out and can indicate when servicing should be undertaken or when reusable controller **10** should be retired.

[0034] Although the disclosure has been described in detail with reference to certain preferred embodiments, variations and modifications exist within the spirit and scope of the disclosure as described and defined in the following claims.

1. A portable kit for providing pain relief comprising:
a catheter for delivering an anesthetic-containing fluid adjacent a wound site in a body;
tubing attached to the catheter and having a lumen in fluid communication with a lumen of the catheter;
a pump adapted to deliver fluid, the pump including an outlet in fluid communication with the tubing, the pump further including an inlet port for filling a reservoir of the pump; the pump affixable to the body to permit portability;
an electronic valve disposed between the catheter and the reservoir in a first flow path;
a controller that generates signals to control operation of the electronic valve; and
instructions on a controller interpretable medium that when interpreted by the controller cause the controller to be able to selectively place the electronic valve in each of three conditions, the first condition causing the electronic valve to periodically open and close to achieve a first output flow rate through the catheter, a second condition causing the electronic valve to open and close to achieve a second output flow rate, and the third condition causing closure of the electronic valve.

2. The kit of claim **1**, wherein the pump is non-powered.

3. The kit of claim **1**, wherein the valve is in continuous fluid communication with the pump reservoir.

4. The kit of claim **1**, further including a patient accessible actuator, activation of the actuator causing the controller to generate signals instructing the electronic valve to assume the second condition.

5. The kit of claim **1**, further including a second flow path in parallel with the first flow path such that anesthetic may travel from the reservoir to the catheter without passing through the electronic valve, the second flow path including a flow restrictor therein.

6. The kit of claim **1**, wherein the second condition is achieved by causing the electronic valve to open for longer periods of time relative to the first condition.

7. The kit of claim **1**, wherein the second condition is achieved by causing the electronic valve to open more often relative to the first condition.

8. A portable kit for providing pain relief comprising:
a first pump having a first reservoir that when filled with an anesthetic provides a first pressure biased to evacuate the anesthetic from the first pump; the first pump being constructed such that the first pressure varies based upon the first reservoir experiencing environment induced pressure variations; and
an electronic controller that controls the evacuation of anesthetic from the first reservoir to compensate for the variability in the first pressure to achieve a desired output flow that is independent of the environment induced pressure variations experienced by the first reservoir.

9. The kit of claim **8**, wherein the controller further controls the evacuation to compensate for variability in at least one of anesthetic viscosity, pump pressure, patient activity, temperature, reservoir fullness, and patient position.

10. The kit of claim **8**, further including a second pump having a second reservoir, the electronic controller also controlling evacuation of fluid from the second reservoir.

11. The kit of claim **10**, wherein the output of the first pump is mixed with the output of the second pump, the electronic controller controlling the outputs of each pump to control the mixture percentage resulting from the mixing of the outputs of the first and second pumps.

12. The kit of claim **11**, wherein the controller adjusts the mixture percentage based on at least one of temperature, pressure, fluid viscosity, patient activity, and patient position experienced by at least one of the pumps.

13. A portable kit for providing medication to tissue comprising:
a pump having a first reservoir, the first reservoir, when filled with a first fluid provides a first pressure biased to evacuate the first fluid from the first reservoir; and
an electronic controller that controls the evacuation of fluid from the first reservoir, the electronic controller being able to receive input indicative of the activity of a patient, the electronic controller adjusting an output flow from the first reservoir at least partially based upon the input indicative of the activity of the patient.

14. The kit of claim **13**, wherein the electronic controller further adjusts the output flow from the first reservoir at least partially based upon an input indicative of the position of the patient.

15. The kit of claim **13**, further including a second reservoir for containing a second fluid such that the first and second fluids are mixed in first ratio for a first period of time by the electronic controller, and the first and second fluids are mixed in a second ratio for a second period of time by the electronic controller.

16. The kit of claim **15**, wherein the controller determines the first and second ratios and the first and second periods of time based upon the input indicative of the activity of the patient.

17. The kit of claim **15**, wherein the first and second ratios and the first and second periods of time are configured to effect a programmable regimen having a changing fluid delivery rate and composition.

18. A portable kit for providing fluid to tissue comprising:
a pump having a first reservoir and a second reservoir,
an electronic controller that controls the evacuation of fluid from the first and second reservoirs, the electronic controller being able to receive input selected from the group including input indicative of patient status and input indicative of atmospheric status, the electronic controller adjusting output flows from the first and second reservoirs at least partially based upon the received input to achieve a output mixture of the first and second fluids, the mixture having a first ratio of the first fluid to the second fluid.

19. The kit of claim **18**, wherein the first and second reservoirs, when filled with a fluid provide first and second pressures, respectively, biased to evacuate the fluid from the first and second reservoirs.

20. The kit of claim **18**, wherein the controller adjusts the output flows of the first and second fluids upon receiving a change in the inputs such that the mixture has a second ratio of the first fluid to the second fluid.

21. A portable kit for providing fluid to tissue comprising:
a pump having a first reservoir and a second reservoir,
an electronic controller that controls the evacuation of fluid from the first and second reservoirs, the electronic controller being programmable to cause an output flow of the pump to vary as a function of time.

22. The kit of claim **21**, wherein the controller is further able to vary both the absolute and the relative amount of fluid expelled from each of the reservoirs over time.

23. The kit of claim **21**, wherein the controller is programmed to vary the output flow based upon input received from sensors.

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